Monsanto Company and Forage Genetics International Petition (12-321-01p) for Determination of Non-regulated Status for Reduced Lignin Alfalfa KK179

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ACRONYMS AND ABBREVIATIONS

AIA	advanced informed agreement
AOSCA	American Organization of Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
BRAD	Biopesticide Registration Action Document
BRS	Biotechnology Regulatory Services (within USDA–APHIS)
Bt	*Bacillus thuringiensis* protein
CAA	Clean Air Act
CBD	Convention on Biological Diversity
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (United States)
CH_4	methane
CO	carbon monoxide
CO_2	carbon dioxide
DNA	deoxyribonucleic acid
DT	drought tolerant
EA	environmental assessment
EIS	environmental impact statement
EO	Executive Order
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act of 1973
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FFP	food, feed, or processing
FGI	Forage Genetics International
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FR	Federal Register
GDP	gross domestic product
GE	genetically engineered
GHG	greenhouse gas
GMO	genetically modified organism
IP	Identity Preservation

ACRONYMS AND ABBREVIATIONS

IPCC	Intergovernmental Panel on Climate Change
IRM	Insect Resistance Management
ISPM	International Standard for Phytosanitary Measure
IPPC	International Plant Protection Convention
LD50	lethal dose that kills 50 percent of the animals being tested
NO_2	nitrogen dioxide
N_2O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NABI	North American Biotechnology Initiative
NAPPO	North American Plant Protection Organization
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NOEL	no observable effect level
NRC	National Research Council
PPRA	Plant Pest Risk Assessment
PPA	Plant Protection Act
PRA	pest risk analysis
RNA	ribonucleic acid
TES	threatened and endangered species
TSCA	Toxic Substances Control Act
U.S.	United States
USDA	U.S. Department of Agriculture
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-FAS	U.S. Department of Agriculture-Foreign Agricultural Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service
USDA-NOP	U.S. Department of Agriculture-National Organic Program
USC	United States Code
WPS	Worker Protection Standard for Agricultural Pesticides

1 PURPOSE AND NEED

1.1 Background

Monsanto Company of St. Louis, MO and Forage Genetics International of West Salem, WI (henceforth referred to as Monsanto and FGI) submitted petition 12-321-01p to the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) in January, 2013 seeking a determination of nonregulated status for alfalfa event KK179 that has reduced levels of guaiacyl lignin. KK179 alfalfa is currently regulated under 7 CFR part 340. Interstate movements and field trials of KK179 alfalfa have been conducted under permits issued or notifications acknowledged by APHIS since 2007. These field trials were conducted in diverse growing regions within the U.S., including in California, Idaho, Illinois, Iowa, Kansas, New York, Oklahoma, Pennsylvania, Texas, Washington, and Wisconsin. Data resulting from these field trials are described in the KK179 alfalfa petition (Monsanto and FGI, 2013) and analyzed for plant pest risk in the USDA-APHIS Plant Pest Risk Assessment (PPRA)(USDA-APHIS, 2013).

The petition stated that APHIS should not regulate KK179 alfalfa because it does not present a plant pest risk. In the event of a determination of nonregulated status, the nonregulated status would include KK179 alfalfa, any progeny derived from crosses between KK179 alfalfa and conventional alfalfa, and crosses of KK179 alfalfa with other biotechnology-derived alfalfa that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

1.2 Purpose of Product

KK179 alfalfa is engineered to have reduced levels of guaiacyl lignin and so reduced overall lignin when compared to conventional alfalfa at the same stage of growth. While a certain amount of lignin is essential for healthy alfalfa plants, lignin is indigestible and slows down the digestion of cellulose in the rumen of livestock. KK179 alfalfa was produced by insertion of *CCOMT* gene segments, derived from alfalfa, assembled to form an inverted repeat DNA sequence. The inverted repeat sequence produces double-stranded RNA (dsRNA) which suppresses endogenous *CCOMT* gene expression via the RNA interference (RNAi) pathway. Suppression of the *CCOMT* gene expression leads to lower CCOMT protein expression resulting in reduced synthesis of guaiacyl lignin. The reduced lignin alfalfa increases forage quality compared to conventional forage of the same age, maximizes forage yield by delaying harvest for several days, and gives farmers more flexibility in forage harvest timing. KK179 alfalfa does not raise the maximum potential quality attainable for forage; rather, KK179 alfalfa is more likely to meet or exceed the desired quality compared to conventional alfalfa harvested at the same stage.

KK179 alfalfa is not intended to be a stand-alone commercial product, but will be combined with Roundup Ready alfalfa utilizing conventional breeding techniques. The combined traits will allow growers planting Roundup Ready × KK179 alfalfa to take advantage of the weed management benefits of the Roundup Ready weed control system as well as the flexibility to choose the production strategy that to better manages the yield-quality relationship and harvesting schedules to maximizes the profitability of alfalfa production for their farming operation.

1.3 Coordinated Framework Review and Regulatory Review

Since 1986, the United States government has regulated genetically engineered (GE) organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302; 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of "unreasonable" risk.

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

<u>USDA-APHIS</u>

APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act (PPA) or the regulations at 7 CFR 340. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

Environmental Protection Agency

The EPA is responsible for regulating the sale, distribution, and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology. The EPA regulates plant incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 et seq.) and certain biological control organisms under the Toxic Substances Control Act (TSCA) (15 U.S.C. 53 et seq.). Before planting a crop containing a PIP, a company must seek an experimental use permit from EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 registration with EPA.

Under FIFRA (7 U.S.C. 136 et seq.), EPA regulates the use of pesticides (requiring registration of a pesticide for a specific use prior to distribution or sale of the pesticide for a proposed use pattern). EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; and storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, EPA must determine through testing that the pesticide will not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions. EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide's label or labeling. The overall intent of the label is to provide clear directions for effective product performance while minimizing risks to human health and the environment. The Food Quality Protection Act (FQPA) of 1996 amended FIFRA, enabling EPA to implement periodic registration review of pesticides to ensure they are meeting current scientific and regulatory standards of safety and continue to have no unreasonable adverse effects (US-EPA, 2011).

EPA also sets tolerances for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA is required, before establishing pesticide tolerance, to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the FQPA. FDA enforces the pesticide tolerances set by EPA.

Food and Drug Administration

FDA regulates GE organisms under the authority of the FFDCA (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, in the *Federal Register* on May 29, 1992 (57 FR 22984). Under this policy, 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 bioengineered food. This voluntary consultation process provides a way for developers to receive assistance from FDA in complying with their obligations under Federal food safety laws prior to marketing.

More recently, in June 2006, FDA published recommendations in “Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use” (US-FDA, 2006) for establishing voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including bioengineered plants. Early food safety evaluations help make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with FDA, but the information may be used later in the biotechnology consultation.

1.4 Purpose and Need for APHIS Action

Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. Any party can petition APHIS to seek a determination of nonregulated status for a GE organism that is regulated under 7 CFR 340. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of GE organisms, including GE plants such as KK179 alfalfa. 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. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS must respond to a January 2013 petition from Monsanto and FGI requesting a determination of nonregulated status for KK179 alfalfa. APHIS has prepared this Environmental Assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality’s (CEQ) NEPA regulations and the USDA and APHIS NEPA implementing regulations and procedures(40 CFR parts 1500-1508, 7 CFR part 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from a determination of nonregulated status for KK179 alfalfa.

<u>Relationship to Other Environmental Documents</u>

Final Environmental Impact Statement: Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status. USDA-APHIS prepared a Final EIS (FEIS) for the deregulation of glyphosate-tolerant alfalfa events J101 and J163 (USDA-

[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).

APHIS, 2010). APHIS completed a Record of Decision (ROD) on January 27, 2011 (Federal Register Volume 76, Number 22, pages 5780-5781). This EA is tiered to that FEIS. Pertinent and current information available in the EIS has been incorporated by reference into this EA.

1.5 Public Involvement

APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. APHIS does this through a notice published in the *Federal Register*. On March 6, 2012, APHIS published a notice in the *Federal Register* advising the public that APHIS is implementing changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for GE organisms to allow for early public involvement in the process. As identified in this notice (see Appendix A for a copy of the *Federal Register* notice), APHIS will publish two separate notices in the *Federal Register* for petitions for which APHIS prepares an EA. The first notice will announce the availability of the petition, and the second notice will announce the availability of APHIS' decisionmaking documents. As part of the new process, with each of the two notices published in the *Federal Register,* there will be an opportunity for public involvement:

First Opportunity for Public Involvement. Once APHIS deems a petition complete, the petition will be made available for public comment for 60 days, providing the public an opportunity to raise issues regarding the petition itself and give input that will be considered by the Agency as it develops its EA and PPRA. APHIS will publish a notice in the *Federal Register* to inform the public that APHIS will accept written comments regarding a petition for a determination of nonregulated status for a period of 60 days from the date of the notice. This availability of the petition for public comment will be announced in a *Federal Register* notice.

Second Opportunity for Public Involvement. A notice of availability of the EA and PPRA will be published in a second *Federal Register* notice. This second notice will follow one of two approaches for public participation based on whether or not APHIS decides the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues:

- **Approach 1. For GE organisms that do not raise substantive new issues.** This approach for public participation will be used when APHIS decides, based on the review of the petition and its evaluation and analysis of comments received from the public during the 60-day comment period on the petition, that the petition involves a GE organism that raises no substantive new issues. This includes instances where APHIS decides that the petition involves gene modifications that do not raise new biological, cultural, or ecological issues due to the nature of the modification or APHIS' familiarity with the recipient organism. Under this approach, APHIS will publish a notice in the Federal Register announcing its preliminary regulatory determination and the availability of the EA, FONSI, and PPRA for a 30-day public review period.

If no substantive information is received that would warrant substantial changes to APHIS' analysis or determination, APHIS' preliminary regulatory determination will become effective upon public notification through an announcement on its website. No further Federal Register notice will be published announcing the final regulatory determination.

- **Approach 2. For GE organisms that raise substantive new issues not previously reviewed by APHIS.** A second approach for public participation will be used when APHIS determines that the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues. This could include petitions involving a recipient organism that has not previously been determined by APHIS to have nonregulated status or when APHIS determines that gene modifications raise substantive biological, cultural, or ecological issues not previously analyzed by APHIS. Substantive issues would be identified by APHIS based on its review of the petition and its evaluation and analysis of comments received from the public during the 60-day comment period on the petition.

  APHIS will solicit comments on its draft EA and draft PPRA for 30 days, as announced in a *Federal Register* notice. APHIS will review and evaluate comments and other relevant information, after which it will revise the PPRA as necessary and prepare a final EA. Following preparation of these documents, APHIS will either approve or deny the petition, announcing in the *Federal Register* the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, National Environmental Policy (NEPA) decision document, and regulatory determination.

Enhancements to stakeholder input are described in more detail in the *Federal Register* notice published on March 6, 2012 (see Appendix A).

APHIS has decided this EA will follow Approach 2. The issues discussed in this EA were developed by considering the public concerns, including public input received from the *Federal Register* notice announcing the availability of the petition (first opportunity for public involvement) (77 F.R. 13258-13260), as well as issues raised in public comments submitted for other EAs of GE organisms, concerns raised in lawsuits, as well as those issues of concern that have been raised by various stakeholders. These issues, including those regarding the agricultural production of alfalfa using various production methods and the environmental and food/feed safety of GE plants were addressed to analyze the potential environmental impacts of KK179 alfalfa.

1.6 Issues Considered

The list of resource areas considered in this draft EA were developed by APHIS through experience in considering public concerns and issues raised in public comments submitted for this petition and other EAs of GE organisms. The resource areas considered also address concerns raised in previous and unrelated lawsuits, as well as issues that have been raised by various stakeholders for this petition and in the past. The resource areas considered in this EA can be categorized as follows:

Agricultural Production Considerations:
- Acreage and Areas of Alfalfa Production
- Agronomic/Cropping Practices
- Alfalfa Seed Production
- Organic Alfalfa Production

Environmental Considerations:
- Soil Quality
- Water Resources
- Air Quality
- Climate Change
- Animal Communities
- Plant Communities
- Gene Flow and Weediness
- Microorganisms
- Biological Diversity

Human Health Considerations:
- Public Health
- Worker Safety

Livestock Health Considerations:
- Animal Feed/Livestock Health

Socioeconomic Considerations:
- Domestic Economic Environment
- Trade Economic Environment

2 AFFECTED ENVIRONMENT

The Affected Environment Section provides a discussion of the current conditions of those aspects of the human environment potentially impacted by a determination of nonregulated status of KK179 alfalfa. For the purposes of this EA, those aspects of the human environment are: alfalfa production practices, the physical environment, biological resources, public health, animal feed, and socioeconomic issues.

2.1 Agricultural Production of Alfalfa

Alfalfa (*Medicago sativa L*.) is the principal forage crop cultivated in the U.S. for animal feed. Approximately 17 to 23.5 million acres of alfalfa hay have been harvested in the U.S. over the past ten years to produce between 52 and 76 million tons of hay annually, valued between approximately $6.7 and $10.7 billion USD (USDA-NASS, 2013b). Alfalfa is the fourth largest agricultural crop in the U.S. in terms of acres harvested and fourth highest in value (USDA-NASS, 2013c; 2013a). Approximately 40 percent of U.S. alfalfa acreage is planted as pure stand, while 30 percent is planted with a cover or nurse crop and approximately 25 percent with grasses or another companion crop (USDA-APHIS, 2010).

2.1.1 Acreage and Area of Alfalfa Production

Alfalfa is cultivated in all 50 states and is also naturalized in many areas (Sullivan, 1992), but the majority of alfalfa produced in the US is grown west of the Mississippi (Figure 1). Alfalfa ranks fourth on the list of most widely grown crops by acreage, behind corn, soybean, and wheat (USDA-NASS, 2013a). In terms of value, alfalfa ranks fourth among agricultural crops (USDA-NASS, 2013c). The acreage of alfalfa hay peaked in the mid-1950s and 60s at approximately 30 million acres, and has slowly declined during the past 40 years to the present level of approximately 17 million acres (USDA-NASS, 2013b). Currently, the harvested acres of alfalfa hay represent approximately 31 percent of the harvested acres for all types of hay (USDA-NASS, 2013b).

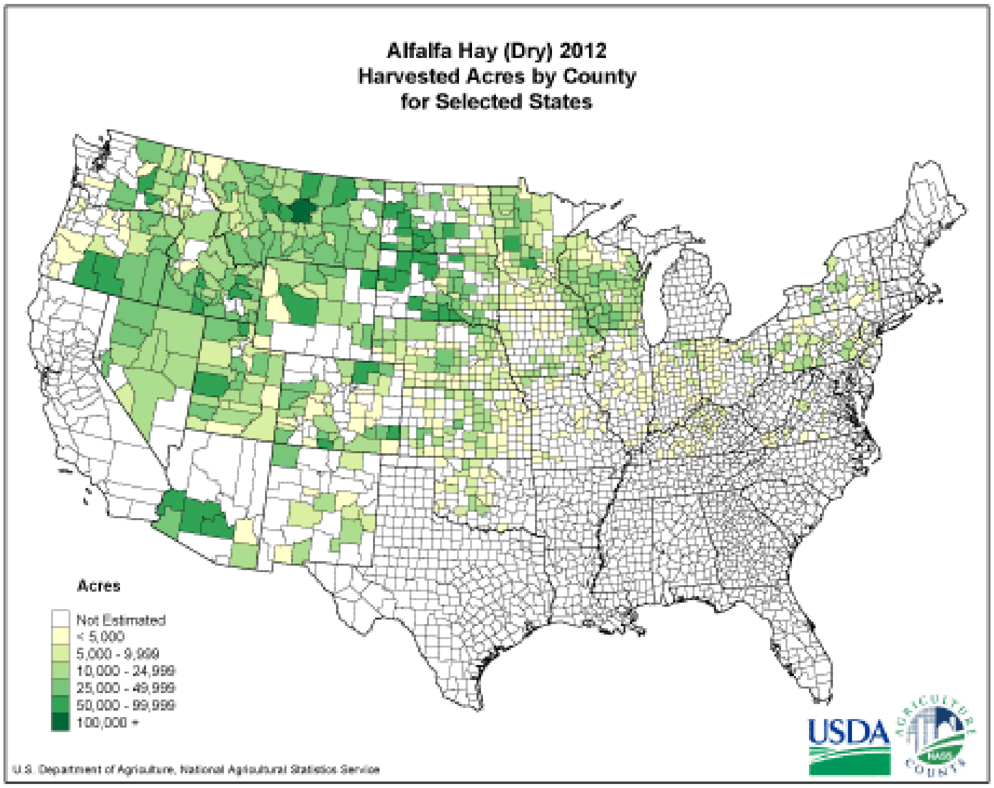

Figure 1. Geographic Distribution of Alfalfa Hay Harvested Acres in the U.S. (USDA-NASS, 2012b).

Approximately 17 to 23.5 million acres of alfalfa hay have been harvested annually over the past 10 years (Table 1). Approximately 2.3 to 3.3 million acres (13-14 percent of the harvested acres) are seeded annually for new alfalfa stands (Table 1). Annual production has ranged from 52 to 76 million tons of hay. Average annual yields have remained fairly constant at 3.19 to 3.47 tons per acre over that same period. The annual value of production has ranged from $6.7 to $10.7 billion (due to most alfalfa being fed to livestock on-farm, the value is an estimate based on multiplying average prices with production volumes and does not correspond to actual sales). Thus, alfalfa has been and continues to be an important U.S. crop.

The only biotechnology-derived alfalfa currently available in the U.S. is glyphosate-resistant alfalfa, first introduced in 2005 (USDA-APHIS, 2010) and reintroduced in 2011. USDA tracks adoption of several biotechnology-derived crops, but alfalfa is not one of them.

Table 1. Alfalfa Hay Production in the U.S. from 2000 to 2012

Year	Seeded Alfalfa Acres (000)	Harvested Acres (000)	Production (000 tons)	Yield (tons/acre)	Value of Production ($000)
2000	3,065	23,463	81,520	3.47	6,812,286
2001	3,260	23,952	80,354	3.35	7,533,401

Year	Seeded Alfalfa Acres (000)	Harvested Acres (000)	Production (000 tons)	Yield (tons/acre)	Value of Production ($000)
2002	3,282	22,923	73,014	3.19	7,137,469
2003	3,119	23,527	76,098	3.23	6,707,172
2004	2,793	21,697	75,375	3.47	6,961,519
2005	3,290	22,359	75,610	3.38	7,290,854
2006	3,184	21,138	70,548	3.34	7,519,232
2007	2,828	21,126	69,880	3.31	8,855,044
2008	2,699	21,060	70,180	3.33	10,747,161
2009	2,665	21,247	71,072	3.35	7,941,539
2010	2,545	19,966	67,971	3.40	7,728,468
2011	2,321	19,213	65,332	3.40	10,917,174
2012	2,389	17,292	52,049	3.01	10,406,769

Source: (USDA-NASS, 2013b; 2013d)

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Land use in alfalfa are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Sections III.A.2, III.C.1 (Figure 3-1), III.E.5, and III.E.6, where it was determined that land use for alfalfa forage production in 2008 was approximately 21 million acres with production occurring in all 50 states. The land use of alfalfa remains essentially unchanged from that described in the 2010 FEIS (USDA-APHIS, 2010).

2.1.2 Agronomic Practices

Due to climate and other differences, farming practices differ regionally. However, some farming characteristics are shared among growing regions. Exact alfalfa production practices vary by location, season, and farmer preference, but in general, most alfalfa is sown in the spring, except in the western United States where fall planting is more common (Hower *et al.*, 1999). Alfalfa can be sown anytime there is available moisture and a sufficient growth period for the seedling that is frost-free (about six to eight weeks).

For purposes of this land use discussion, alfalfa production (alfalfa and alfalfa mixtures) is divided into six major alfalfa growing regions: North Central region (IA, MN, ND, SD, WI), East Central region (AR, DE, IL, IN, KY, MD, MI, MO, New England states, NJ, NY, NC, OH, PA, TN, VA, WV), Plains region (KS, NE, OK, TX), Intermountain region (CO, MT, UT, WY), Pacific Northwest region (ID, NV, OR, WA), and Southwest region (AZ, CA, NM).

<u>Cultivation</u>

Alfalfa forage may be grown in pure stands or mixed with various other forage species (*e.g.*, cool-season grass mixtures, with or without other legumes, such as forage peas, birdsfoot trefoil [*Lotus corniculatus* L.], or clover [*Trifolium* L. spp.]). The use of mixed stands is widespread in the eastern and southern regions of the U.S., where pure-stand alfalfa production is challenged by climate and/or soil-type.

Variety selection is an important decision in alfalfa production that can affect crop yield, crop quality, and pest management. Alfalfa is a perennial crop; therefore, growers must stay with their choice of variety for several years. Variety selection can be challenging since there are over 250 varieties to choose from and new varieties become available each year (Undersander *et al.*, 2011). Alfalfa varieties are diverse populations of plants having multiple genotypes rather than uniform genetic strains (Putnam *et al.*, 2008a). Alfalfa is a polyploid having four complete sets of chromosomes which means that the offspring of alfalfa crosses are much more diverse than most crop species. This genetic diversity enables alfalfa varieties to be well adapted over a wide range of environments, and to resist a wide range of insects, diseases, and nematodes to a greater degree than most other crops (Putnam *et al.*, 2008a). Variety selections are based on the importance of yield potential, stand persistence, fall dormancy, winter-hardiness, disease resistance, and forage quality (Undersander *et al.*, 2011).

Fall dormant varieties of alfalfa grows from early spring until late fall or early winter. Growth begins when the average temperature reaches 50°F and continues until a freeze occurs. A fall dormant alfalfa stand requires one year after planting to become established, and may be harvested for three to five years, or longer in some areas. It may be harvested several times per season. Non-dormant alfalfa can be considered established if four or more cuttings are taken in the seeding year.

Alfalfa stands have two growing phases, establishment of seedlings (first year) and established alfalfa fields (two to eight years). Alfalfa can be established successfully in either the spring or in the late summer and fall. In the U.S., 70 percent of alfalfa acres are spring-seeded and the remaining 30 percent are planted during late summer and early fall (Hower *et al.*, 1999). Spring seeding is preferred in the northern states of the North and East Central regions, while late summer and early fall seeding is preferred in all the remaining regions of the U.S. (Undersander *et al.*, 2011). Temperature, soil moisture, and length of growing season are important factors that impact seed germination and stand establishment and ultimately determine which planting time is most successful and provide the highest alfalfa yields for a given area. Spring seeding begins as soon as the potential for damage from spring frosts is over (Undersander *et al.*, 2011). Fall seeding of alfalfa requires at least six weeks of growth after germination to survive the winter in the Central regions.

Seeding alfalfa with a companion crop (or nurse crop) such as annual ryegrass, oats, spring barley, and rye is often practiced with spring seeding to help control erosion on steep slopes, reduce seedling damage from wind erosion on sandy soils, and reduce weed competition during alfalfa establishment (Undersander *et al.*, 2011). Fall seeding of alfalfa with a companion crop is seldom practiced because of limited soil moisture and competition with alfalfa. Small-grain companion crops grown to mature grain can damage alfalfa either by competition or by lodging, which smothers the alfalfa seedlings. Direct-seeding alfalfa (seeding without a companion crop) can produce up to two extra cuttings of alfalfa and produce higher quality forage in the seeding year (Undersander *et al.*, 2011).

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Cultivation practices of alfalfa are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Sections III.A, III.E.1, and III.E.5, where it was determined that production practices vary across the alfalfa growing regions of the U.S. Most alfalfa is spring sown, except for the western U.S. where fall sowing is more common. The adaptation of alfalfa varieties to winter temperatures is based on their winter hardiness which ranges from very dormant, or more winter hardy, to extremely non-dormant, or less winter hardy. Degree of dormancy is measured by a variety's physiological changes associated with growth. Dormancy in alfalfa is thought to be brought on by shortened day length and possibly colder temperatures in autumn.

Alfalfa forage production may include the use of cover/nurse crops. However, the largest share of alfalfa is planted as a pure stand (40 percent), whereas approximately 25 percent of alfalfa is planted with grasses or other companion/nurse crops. Organic farmers may use a cover crop such as oats, which are planted with the alfalfa and harvested during the first year of stand establishment to help control weeds. Seeding alfalfa with a companion/nurse crop such as annual ryegrass, oats, spring barley, and rye is often practiced with spring seeding to help control erosion on steep slopes, reduce seedling damage from wind erosion on sandy soils, and reduce weed competition during alfalfa establishment.

The cultivation practices of alfalfa remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

Crop Rotation

Alfalfa promotes water infiltration, improves soil tilth, and provides nitrogen for subsequent crops in rotation (Orloff and Putnam, 1997; Canevari and Putnam, 2008). The extensive root system of alfalfa improves soil tilth and soil structure by creating channels that encourage water penetration and biological activity in the root zone. Considerable organic matter is added to the soil over the life of the stand which greatly benefits the growth and yield of subsequent crops, such as corn, tomato, wheat, or specialty crops. Alfalfa fixes atmospheric nitrogen through the symbiotic relationship with *Rhizobium (Sinorhizobium meliloti*) bacteria which can provide from 40 to 60 pounds of nitrogen per acre to crops that follow alfalfa (Orloff and Mueller, 2008). In turn, rotations with other crops benefit alfalfa by breaking disease and insect cycles and improving weed control and soil fertility (Orloff and Putnam, 1997; Orloff and Mueller, 2008). Alfalfa-to-alfalfa rotations are uncommon because of the potential for autotoxicity and the inefficient use of residual soil nitrogen credits.

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Crop rotation practices of alfalfa production are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Section III.E.3 and Section III.E.4 where it was determined that rotation of alfalfa with other crops is an integral part of farm management programs to maintain soil productivity/fertility, reduce soil erosion, adapt to weather changes, avoid pathogen and pest build-up, avoid alfalfa seedling autotoxicity, and increase profits. Rotating from perennial crops such as alfalfa to annual crops helps control weeds in general. Alfalfa is rotated most often with corn, wheat, oats, barley, sugar beets, and potato. The rotational crop practices associated with alfalfa production remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

Tillage

In alfalfa production, tillage may be used for seed bed preparation, for weed control, and/or stand removal. Field preparation is accomplished through a variety of tillage systems, with each system defined by the remaining plant residue on the field. Types of tillage systems include conventional, reduced, conservation (including mulch-till, strip-till, ridge-till, and no-till), and deep. Tillage practices loosen the soil, help control perennial weeds, help level the land, and break up large soil clods (Undersander *et al.*, 2011). The primary purpose of conservation tillage is to reduce soil erosion. Special attention must be given to weed management in reduced tillage systems as weed control is more difficult when there is less tillage to decrease weed populations (Undersander *et al.*, 2011). Proper field preparation before planting is critical because the alfalfa stand will be intensively managed and harvested for three to five years, or longer in some areas. Land leveling is an important step in the western irrigated regions because water must flow evenly over the ground surface in flood irrigation systems.

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Tillage practices of alfalfa production are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Sections III.E.1, Section III.E.5, and Appendix J, where it was determined that mechanical and cultural weed control methods (e.g., tillage and companion crops) are used for approximately 80 percent of the spring-seeded alfalfa and 18 percent of the fall-seeded alfalfa. In organic systems, the ground is tilled for weed management and allowed to sit for seven to ten days. Two or more passes of disking the soil may be required to control germinated weeds prior to planting seed. Alfalfa stand removal or termination is achieved through the use of deep tillage, herbicides, or both in the fall. Since normal tillage operations alone often do not provide complete termination, herbicides are used to effectively control alfalfa. The tillage practices associated with alfalfa production remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

Pesticide Use

Many insects are present in alfalfa, but fewer than 20 cause injury and fewer insects are considered serious pests (Summers *et al.*, 2008). Alfalfa weevil (*Hypera postica*) and Egyptian alfalfa weevil (*Hypera brunneipennis*) routinely cause damage annually in established alfalfa throughout the U.S. Integrated pest management programs involving chemical and cultural methods can significantly reduce insect losses in alfalfa. Insecticides and early harvest are the main control options for alfalfa weevil. Damage and yield losses are more sporadic and less frequent with other insect pests.

Pathogens that cause alfalfa diseases include fungi, bacteria, viruses, and nematodes. Diseases can kill alfalfa seedlings, reduce stand life, cause yield reduction, and reduce the feeding value of the forage (Frate and Davis, 2008). Selecting resistant varieties is one of the most effective methods to managing many of the alfalfa diseases. Other integrated strategies and techniques utilized to manage alfalfa diseases include irrigation management, planting methods, promotion of crop vigor, manipulation of cutting schedules, canopy management, and crop rotation (Frate and Davis, 2008).

Annual and perennial weeds reduce alfalfa yield and quality and cause serious economic losses in alfalfa because they compete for the same resources required for alfalfa growth and development – water, nutrients, light, and space (Canevari *et al.*, 2008). Weed competition in alfalfa occurs in two distinct time periods: seedling establishment and in established stands. Seedling alfalfa plants grow slowly and compete poorly with weeds. Forage yield losses due to the presence of weeds in new stands of alfalfa often exceed 1,000 pounds per acre (Caddel *et al.*, 2011). The feeding value or nutritional value of hay is drastically reduced by the presence of weeds. Weeds affect forage quality because most weeds are much lower in protein, higher in fiber, and are generally less palatable and less nutritious than alfalfa. Reductions in forage quality also depend on the weed species present. Annual grasses have a significant impact on quality because they have high fiber content and decrease livestock intake (Canevari *et al.*, 2008). Annual broadleaf weeds, such as curly dock, hoary alyssum, and yellow rocket are unpalatable and decrease animal intake. In addition, hay containing foxtail (*Setaria* spp.) and wild barley (*Hordeum* spp.) can cause livestock to develop serious mouth and throat ulcerations (Canevari *et al.*, 2008). Some weeds can contribute "off" flavors in milk, and other weeds contain alkaloids that are toxic to livestock (Canevari *et al.*, 2008). There are currently 16 herbicides registered for use in conventional alfalfa. According to an extensive survey conducted by the USDA from 1988 to 1992, herbicides were used on approximately 17 percent of all alfalfa acreage grown for forage during that time period (seedling establishment and established stands) (USDA-APHIS, 2010). Since 2005, glyphosate herbicide has been used, for in-crop application on glyphosate-resistant alfalfa according to labelled rates. As herbicide treatments on conventional alfalfa stands occur primarily during the year of establishment, when including glyphosate on glyphosate-resistant alfalfa since 2005, this 17 percent per year figure may not clearly depict the current level of herbicide use.

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Previously, disease and pest management and weed management practices in alfalfa production are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Section III.A.2 and Section III.E.3, where it was determined that insect pest species of economic importance vary among the growing regions of the U.S., and diseases of economic importance include pathogens that affect foliar, crown, root, vascular and seedling health. Management of weeds in alfalfa is required to maintain a healthy alfalfa stand. The presence of weeds during times of stand establishment and as the stand ages or thins can contribute to significant declines in forage yield and value. The affected environment for insect and disease management and weed management practices in alfalfa production remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

<u>Harvest</u>

To determine when to harvest, farmers balance yield and nutritional content. Deciding when to cut alfalfa forage is challenging because plant maturity affects yield and quality differently and can affect the life and vigor of the stand. Alfalfa yield and forage quality are almost always inversely related within a growth cycle. Alfalfa yield can double from the pre-bud to full-bloom stage and generally reaches maximum yield at about the 50 percent bloom stage and then levels off (Orloff and Putnam, 2008). Alfalfa harvested at an immature growth stage (short interval between cuttings) results in relatively low yield but high forage quality (Orloff and Putnam, 2008). Conversely, the cutting of alfalfa at a mature growth stage (long interval between cuttings) results in higher yield but lower quality forage. The growth stage to cut alfalfa generally reflects the intended use of the hay. The value of alfalfa forage and hay varies considerably by the level of quality, or quality grade.

In addition to the visual appearance of alfalfa hay, alfalfa hay quality is defined by a number of nutritional traits including Acid Detergent Fiber (ADF)(*i.e.*, lignin and cellulose), Neutral Detergent Fiber (NDF)(*i.e.*, lignin, cellulose and hemi-cellulose), crude protein, total digestible nutrients, and relative feed value (Putnam *et al.*, 2008b). Alfalfa hay intended for the dairy market must be cut early to late-bud stage at the latest (Orloff and Putnam, 2008). Beef cows and horses usually are fed lower quality alfalfa that can be cut later, 10 to 30 percent bloom, to maximize forage yields. Repeatedly cutting alfalfa plants at immature growth stages (pre-bud to bud) shortens stand life because it does not allow sufficient time for the alfalfa plants to replenish root reserves (Orloff and Putnam, 2008). Stand loss can lead to the invasion of weeds that compete for available resources (*e.g.*, water, nutrients, light, and space) and negatively impact forage quality. Additionally, cutting schedules influence the number of harvests possible in a year and influence seasonal yield and costs.

Harvesting hay is a four step process: 1) cutting the forage, 2) raking the partially cured hay into windrows, 3) baling the dry hay, and 4) storing the hay (Orloff and Mueller, 2008). The moisture content of alfalfa growing in the field is generally about 80 percent (Undersander *et al.*, 2011). Soluble sugars and proteins are dissolved in the forage liquid. When forage is dried to hay before being baled, water in the forage evaporates, resulting in a higher concentration of nutrients in the remaining liquid where cell growth and enzyme activity are restricted. The drying rate, mechanical handling of the forage, and the moisture content at baling all affect the quality of the hay. Rapid drying is important to minimize quality losses caused by bleaching, respiration, leaf loss, and rain damage (Orloff and Mueller, 2008). Weather conditions can make harvesting hay very challenging. Rainy weather causes delays in harvest which increases the NDF and ADF, and decreases digestibility and crude protein of the hay (Undersander *et al.*, 2011). In addition, rain on hay before baling leaches soluble nutrients (protein and carbohydrates).

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Harvest practices of alfalfa production are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Sections III.A.2, III.C.1, and III.E.1. Alfalfa harvest is determined by the farmer’s need to balance yield and nutritional content requirements for their animal feed. Yield increases as plants grow and effectively peaks at 50 percent bloom, but nutritional content is highest in young vegetative plants and decreases until full bloom. Farmers typically harvest between late-bud and full bloom. Alfalfa is typically harvested (mowed) every 22 to 40 days during the growing season, depending on growth conditions in the region, local weather patterns, and alfalfa variety. Most alfalfa production fields are cut three to four times a year, but in the Southwestern U.S. growers can cut up to 11 times per year. The harvest practices of alfalfa production remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010) .

Feral Populations

Since its introduction to the U.S., alfalfa has occasionally become feral, or naturalized, by escaping from agricultural fields or intentionally planted in non-agricultural locations then persisting by multiplying unassisted. While alfalfa does survive outside of cultivation, these scattered feral populations are not recognized as noxious or invasive weed species (USDA-APHIS, 2010). These plants can be found in sparse populations throughout the U.S., including in non-agricultural areas (USDA-APHIS, 2010; USDA-NRCS, 2012). Alfalfa has been intentionally used for numerous non-agricultural purposes including: rehabilitation of overgrazed rangelands to improve wildlife habitat and for livestock; erosion-control projects in forest interiors; improvement of compacted soils; use in seed mixes for USDA's Conservation Reserve Program (CRP); revegetation of areas damaged by wildfire; and erosion reduction in mined soils (USDA-APHIS, 2010). These uses have in some cases led to establishment of feral alfalfa populations. In situations where control of feral alfalfa is desired, it can be controlled like cultivated alfalfa using cultural or chemical methods.

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Feral alfalfa is assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Sections III.A.2 and III.A.3, where it was determined that alfalfa has occasionally become feral, or naturalized, by escaping from agricultural fields or intentionally planted in a non-agricultural location. The *Medicago sativa* subspecies (purple-flowered alfalfa used in cultivation) has naturalized population in all 50 states.

M. sativa subspecies *falcata* (yellow-flowered or Siberian alfalfa) is naturalized in the northern and western states and is being promoted as a rangeland enhancer for grazing. Like alfalfa under cultivation, feral alfalfa originated from introduced varieties. Feral alfalfa can be found in air fields, canals, cemeteries, ditch banks, fence rows, highways, irrigation ditches, pipelines, railroads, rangeland, rights-of-way, roadsides, wasteland, rangeland, preserves, parks, and recovery areas. Feral populations exist near locations used for alfalfa seed and forage production. The affected environment for feral alfalfa remains unchanged from that described in the 2010 FEIS (USDA-APHIS, 2010).

2.1.3 Alfalfa Seed Production

Seed production differs from forage production due to additional biological, technical, and quality control factors required to maintain varietal purity. Seed quality (including genetic purity, vigor, and presence of weed seed, seed-borne diseases, and inert materials, such as dirt) is a major factor in crop yields. Genetic purity in commercial seed production is generally regulated through a system of seed certification which is ensures the desired traits in that particular seed remain within purity standards (Bradford, 2006).

States have developed seed laws and certification agencies to ensure that purchasers who received certified seed can be assured that the seed meets established seed quality standards (Bradford, 2006). The U.S. Federal Seed Act of 1939 recognizes seed certification and official certifying agencies. Implementing regulations set requirements for land history, field isolation, and varietal purity standards for foundation, registered, and certified seed.

Cultivation practices used to produce certified seed commonly include recommendations for minimum isolation distances between various seed lines and planting border or barrier rows to prevent pollen movement (Sundstrom et al., 2002; Bradford, 2006). The isolation distance for alfalfa foundation, registered, and certified seeds, as dictated by the USDA's Agricultural Marketing Service (AMS) Federal Seed Act is 1,320, 300, and 165 feet, respectively (7 CFR Part 201.76). During the growing season, seed certification agencies will monitor the fields for off-types, other crops, weeds, and disease (Bradford, 2006; AOSCA, 2010). These certifying agencies also establish seed handling standards to reduce the likelihood of seed source mixing during production stages, including planting, harvesting, transporting, storage, cleaning, and ginning (Bradford, 2006; AOSCA, 2010).

In a seed certification program, classes of seed are identified to designate the seed generation from the original breeder source. Foundation seed, Registered seed, and Certified seed production is controlled by public or private seed certification programs (AOSCA, 2013b). The original seed breeder seed stock is controlled by the developer of the variety (Adam, 2005). The breeder stock is used to produce Foundation seed stock (Adam, 2005). The institution associated with the breeder controls the production of Foundation seed stock. Foundation seed stock, in turn, is used to produce Registered seed for distribution to licensees, such as seed companies (Adam, 2005). Registered seed is used by seed companies to produce large quantities of Certified seed (Adam, 2005). The Certified (or Select) seed is then sold to growers through commercial channels (Adam, 2005).

A development in the management of seed production among commercial alfalfa seed producers since 2011 has been the establishment of voluntary grower opportunity zones in many seed production areas based on best management practices established by the National Alfalfa and Forage Alliance (NAFA)(NAFA, 2011b). NAFA sponsored best management practices cover both Adventitious Presence Sensitive Alfalfa Seed Production and Roundup Ready Alfalfa Seed Production (NAFA, 2011a). The purpose of the zones and best management practices has been to facilitate local coordination of coexistence efforts by alfalfa seed growers for both conventional and GE alfalfa markets. As an additional level of assurance for Adventitious Presence Sensitive growers, AOSCA and the alfalfa seed industry have also established the Alfalfa Seed Stewardship Program which offers an optional process-based certification program that includes third party verification.

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Seed production practices in alfalfa are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Section III.C.1, where it was determined that in contrast to the broad geographic distribution for forage production, most commercial alfalfa seed production is highly concentrated in the western U.S. irrigated regions with three states (California, Idaho, and Washington) accounting for the majority of seed production. The arid climates of the western U.S. provide a warm, dry production and harvest season to maximize seed yield and quality. Over 121,000 acres of alfalfa seed were harvested in 2007 producing approximately 62 million pounds of seed with an average yield of approximately 510 pounds per acre. California is credited with 31 percent of the seed production, Washington with 17 percent, and Idaho with 15 percent. Over 60 percent of the seed production is concentrated in those three states; and if Arizona, Nevada, Oregon, Wyoming, Montana, and Utah are included in the total seed production, these nine states collectively represent over 95 percent of the seed production. The demand for alfalfa seed is driven by the demand for seed to establish new stands of alfalfa forage, with a minor amount used as field seed stock or for human consumption. Seed production practices remain largely unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

2.2 Organic Alfalfa Production

In the U.S., only products produced using specific methods and certified under the USDA-AMS National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2013). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced.

In accordance with NOP, an accredited organic certifying agent conducts an annual review of the certified operation's organic system plan and makes on-site inspections of the certified operation and its records. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards.

The NOP regulations preclude the use of excluded methods. The NOP provides the following guidance under 7 CFR Section 205.105:

> …to be sold or labeled as "100 percent organic", "organic" or "made with organic (specified ingredients or group(s))," the product must be produced and handled without the use of…
>
> (a) Synthetic substances and ingredients,…
>
> (e) Excluded methods,…

Excluded methods are then defined at 7 CFR Section 205.2 as:

> A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional

breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

Organic farming operations, as described by the NOP, are required to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods. (USDA-AMS, 2013).

Common practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields (NCAT, 2003). Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2013). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche, 2006; USDA-AMS, 2013).

USDA-NASS recently reported the organic crop production data collected in 2011 (USDA-NASS, 2012a). In that year, 231,318 acres of organic alfalfa in 30 states was harvested (Table 2) producing 747,555 tons, compared to approximately 19.2 million harvested acres of conventionally produced alfalfa (USDA-NASS, 2013a). In 2011, organic alfalfa production consisted of about 1.2 percent of total U.S. alfalfa production and was valued at approximately $69.5 million, capturing roughly 0.64 percent of the overall alfalfa crop value for that year (USDA-NASS, 2012a; 2013c).

Table 2. U.S. Certified Organic Alfalfa Harvested Acres by State, 2011[1].

State	Alfalfa (Acres)	State	Alfalfa (Acres)
California	11,826	Nevada	4,900
Colorado	6,326	New Mexico	730
Idaho	41,912	New York	8,608
Illinois	2,413	North Dakota	13,323
Indiana	3,095	Ohio	5,224
Iowa	12,251	Oregon	19,430
Kansas	985	Pennsylvania	6,659

State	Alfalfa (Acres)	State	Alfalfa (Acres)
Kentucky	178	South Dakota	7,938
Maine	212	Texas	3,893
Maryland	686	Utah	2,786
Michigan	3,664	Vermont	2,131
Minnesota	18,386	Virginia	560
Missouri	953	Washington	3,530
Montana	4,753	Wisconsin	27,126
Nebraska	7,927	Wyoming	7,998

Source: (USDA-NASS, 2012a)

1 Table does not include certain states with confidential values due to low number of farms producing organic alfalfa.

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Organic production practices in alfalfa are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Sections III.C.1 (Table 3-3) and III.C.2, where it was determined that organic alfalfa acreage represents approximately 1 percent of U.S. alfalfa acreage, with approximately 257,000 acres harvested in 2008. Organic alfalfa hay production is distributed in a similar geographic pattern to conventional hay; however, some states have a higher percentage of organic production than others. The demand for organic alfalfa derives mainly from the demand for organic dairy and beef. APHIS was unable to locate data on U.S. organic alfalfa seed or sprout production. Organic production practices remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010) .

2.3 Physical Environment

2.3.1 Water Resources

Water Use

Alfalfa is considered to be naturally drought tolerant, because of its deep taproot allowing it to use up to 70 percent of available soil water without stress or loss of production. Even though it is highly efficient at utilizing the available soil moisture, alfalfa has a high water requirement in excess of 40 inches of water during the season (Kansas State University, 1998). In the Great Plains and Western regions of the U.S., water requirements for alfalfa are greater than the annual rainfall resulting in approximately 30 percent of the total U.S. alfalfa hay acreage requiring to be irrigated in 2008 (USDA-NASS, 2010).

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Water use in alfalfa production is assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Section III.E.6 (Table 3-25), where it was determined that approximately 6.5 million acres of alfalfa production were irrigated in 2007. Water use in alfalfa production remains unchanged from that described in the 2010 FEIS (USDA-APHIS, 2010).

Water Quality

Groundwater may be impacted from alfalfa production by the movement of pesticides and nutrients vertically through soil.

Surface water may also be impacted from alfalfa production by runoff from alfalfa fields that carries soil particles and herbicides or other pesticides to streams, rivers, lakes, wetlands and other water bodies. Alfalfa fixes atmospheric nitrogen through the symbiotic relationship with *Rhizobium* bacteria (*Sinorhizobium meliloti*), such that nitrogen fertilizer applications are not needed and, therefore, runoff with nitrogen fertilizer is not an issue. As discussed below, based on existing data, the soil component of runoff is a much more important contributor to surface water impacts than is the pesticide component.

Based on the states' water quality reports to EPA, which EPA makes available through its National Assessment Database, pesticides in general and herbicides in particular are a relatively minor contributor to impairment of surface water in the U.S., compared to sedimentation/siltation (US-EPA, 2013c). Agricultural crops contribute to sedimentation and siltation in surface water through erosion of soil particles and transport through runoff to surface water bodies.

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Water quality, as an interaction of surface and ground water with alfalfa, is assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Sections III.F.1 and III.F.3, where it was determined that compared to most crops, alfalfa fields, once established, would be expected to contribute little sediment to surface water. Furthermore, use of alfalfa in non-agricultural settings provides erosion control to lower sedimentation in surface water. Alfalfa with its deep rooted characteristics interacts with the soil aiding in the percolation of water down through the soil profile into ground water. Water quality, as an interaction of surface and ground water with alfalfa, remains unchanged from that described in the 2010 FEIS (USDA-APHIS, 2010).

2.3.2 Soil Quality

Soil consists of solids (minerals and organic matter), liquid, and gases. This body of inorganic and organic matter is home to a wide variety of fungi, bacteria, and arthropods, as well as the growth medium for terrestrial plant life (USDA-NRCS, 2004). Soil is characterized by its layers that can be distinguished from the initial parent material due to additions, losses, transfers, and transformations of energy and matter (USDA-NRCS, 1999). It is further distinguished by its ability to support rooted plants in a natural environment. Soil plays a key role in determining the capacity of a site for biomass vigor and production in terms of physical support, air, water, temperature moderation, protection from toxins, and nutrient availability. Soils also determine a site's susceptibility to erosion by wind and water, and a site's flood attenuation capacity.

The practice of tillage for soil preparation and weed management can affect the quality of soils because of the varying impacts of erosion on soil nutrient composition. Field preparation is accomplished through a variety of tillage systems, with each system defined by the remaining plant residue on the field (CTIC, 2008). Soil tillage can also affect water resources and air quality.

Alfalfa is adapted to a wide range of soil types, but requires a well-drained soil for optimum production (Orloff, 2008). Alfalfa fields should have good surface drainage and have soils with good internal drainage and lack subsoil impediments (Orloff, 2008; Undersander *et al.*, 2011). Deep, medium- to coarse-textured soils with adequate water are ideal (Kansas State University, 1998). Fine-textured soils are usually difficult to manage. In deep, well-aerated soil, roots may extend 8 to 12 feet deep (Kansas State University, 1998). Alfalfa improves soil fertility and structure and helps mitigate soil erosion and because alfalfa is a legume, successive crops benefit from residual nitrogen in the soil.

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Soil quality interactions with alfalfa is assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Section III.F.1, where it was determined that alfalfa can be grown in a wide variety of soils, but grows optimally in fertile, well- drained soils with a pH at or above 6.5. Due to alfalfa's deep rooting and heavy vegetative cover characteristics, it is valued as a soil conservation crop that in turn reduces sedimentation in surface water. Because alfalfa is a legume, successive crops also benefit from residual nitrogen in the soil. Soil quality interactions with alfalfa remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

2.3.3 Air Quality

The Clean Air Act (CAA) requires the maintenance of National Ambient Air Quality Standards (NAAQS). The NAAQS, developed by the EPA to protect public health, establishes limits for six criteria pollutants: ozone (O3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO_2), lead (Pb), and Particulate Matter. The CAA requires states to achieve and maintain the NAAQS within their borders. Each state may adopt requirements stricter than those of the national standard and each is required by the EPA to develop a State Implementation Plan (SIP) that contains strategies to achieve and maintain the national standard of air quality within the state. Areas that violate air quality standards are designated as non-attainment areas for the relevant pollutants, whereas areas that comply with air quality standards are designated as attainment areas.

Agricultural air emission sources include: smoke from agricultural burning; vehicle exhaust associated with equipment used in tillage and harvest; soil particulates associated with tillage; pesticide drift from spraying; and nitrous oxide (N_20) emissions from the use of nitrogen fertilizer (USDA-NRCS, 2005; Aneja *et al.*, 2009; US-EPA, 2013a). These agricultural activities individually have the potential to cause negative impacts to air quality.

Agriculture, including land-use changes for farming, is responsible for an estimated 8 percent of all human-induced greenhouse gas emissions in the U.S. (US-EPA, 2013b). Nitrous oxide emissions from agricultural soil management are a large part of this, contributing 69 percent of all U.S. N_20 emissions (US-EPA, 2013a).

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Air quality, as an interaction with alfalfa, is assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Section III.F.2, where it was determined that alfalfa production can affect it in a number of ways. Use of tractors and other farm equipment for planting and the multiple forage harvests throughout the alfalfa stand life result in release of combustion engine emissions and dust generation that affect air quality. Air quality as an interaction with alfalfa remains unchanged from that described in the 2010 FEIS (USDA-APHIS, 2010).

2.3.4 Climate Change

Climate change represents a statistical change in climate conditions, and may be measured across both time and space. Agriculture may influence climate change through various facets of the production process. Combustion of fossil fuels in mechanized farm equipment, fertilizer application, and decomposition of agricultural waste products may all contribute greenhouse gases to the atmosphere. Greenhouse gases collectively function as retainers of solar radiation, and agriculture-related activities are recognized as both direct (e.g., exhaust from equipment) and indirect (e.g., agricultural-related soil disturbance) sources of CO_2, methane (CH_4), and N_2O.

In its annual inventory of greenhouse gas emissions, the U.S. EPA classifies different sources by sector, with the energy sector the largest contributor of greenhouse gas emissions. The agriculture sector, as defined by U.S. EPA, represented 6.9 percent of total greenhouse gas emissions for the U.S. in 2011 (US-EPA, 2013a). However, this does not include carbon dioxide (CO_2) emissions and removals from agricultural-related land use activities such as liming of agricultural soils (which are included in the land use sector); neither does it include emissions of CO_2 and nitrogen dioxide (NO_2) from diesel or gasoline-powered agricultural equipment (which are included in the energy sector). The major contributors of greenhouse gases from the agricultural sector are from agricultural soil management, including fertilizer and other cropping practices that contribute NO_2 (approximately 69 percent of emissions) and methane emissions from cattle and manure (approximately about 23 percent and 9 percent of CH_4 emissions from anthropogenic activities, respectively) (US-EPA, 2013a).

As noted by EPA, the increase of conservation tillage is contributing to soil carbon sequestration on those croplands (US-EPA, 2013a). In addition, reduced/conservation tillage can contribute to reductions in greenhouse gas emissions compared with conventional tillage, as a result of fewer trips across the field and the consequent reduction in vehicle emissions.

Climate change may also affect agricultural crop production. These potential impacts on the agro-environment and individual crops may be direct, including changing patterns in precipitation, temperature, and duration of growing season, or may cause indirect impacts influencing weed and pest pressure (US-GCRP, 2009).

GE crop varieties contribute to reduced greenhouse gas emissions, although the magnitude of those benefits for climate change is difficult to quantify – and is likely dependent on cropping systems, production practices, geographic distribution of activities, and individual grower decisions. The potential impact of climate change on agricultural output, however, has been examined in more detail. In a review of several studies on corn, rice, sorghum, soybean, wheat, common forages, cotton, some fruits, and irrigated grains, Field et al. (Field *et al.*, 2007) found that most studies projected likely climate-related yield increases of 5 to 20 percent; however, this positive impact would not be observed evenly across all regions as certain areas of the United States are expected to be negatively impacted by substantially reduced water resources. In addition, the current range of weeds and pests of agriculture is expected to change in response to climate change (US-GCRP, 2009).

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Climate change is assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Section III.F.2, where it was determined that alfalfa production similar to any crop production, can affect climate change. This is most relevant through the use of tractors and other farm equipment for planting and multiple forage harvests throughout the alfalfa stand life that result in release of emissions from combustion engines. Effects of alfalfa production on climate change remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

2.4 Biological Resources

This section provides a summary of the biological environment and includes an overview of animals, plants, gene transfer, weeds and weediness, microorganisms, and biodiversity. This summary provides the foundation to assess the potential impact to plant and animal communities and the potential for gene movement.

2.4.1 Animal Communities

Animals that might be exposed to alfalfa would be individuals of species that typically inhabit its fields and feed on alfalfa. Animal species may also be exposed to pesticide and fertilizer application and runoff (e.g., soil microbes, amphibians, and aquatic organisms) that result from alfalfa production. Wildlife (macro- and micro-fauna) abundance and composition in alfalfa fields depend on geographic location.

Alfalfa is the beginning of a food chain, and contributes valuable habitat for hundreds of species of herbivores and animals of prey (Putnam *et al.*, 2001). There is considerable below-ground biological activity in alfalfa fields, including earth worms, insects, and other organisms. Gophers and other rodents frequently make their homes under alfalfa fields (Putnam *et al.*, 2001). There is a wide range of insects, both herbivores and predators, which are present in large populations in alfalfa fields (Putnam *et al.*, 2001). Insects and rodents found in alfalfa are food sources for birds, snakes, and raptors. Raptors are frequently found soaring above alfalfa fields, or awaiting prey from nearby posts. Of all the animals that use alfalfa (not including insects or reptiles), 10 percent use it extensively for breeding and reproduction, 24 percent find it highly suitable for cover, and 57 percent use it for feeding (Putnam *et al.*, 2001).

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Animal communities in alfalfa are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Section III.B.1, where it was determined that wildlife abundance and composition in alfalfa fields depends on geographic location, surrounding habitat conditions, and alfalfa field size. Many species of insects can be found in alfalfa fields, which are preyed upon by several species of birds (e.g., songbirds, swallows, waterfowl, game species [ring-necked pheasants, quail, and wild turkey], and migratory species) and bats (Order *Chiroptera*). Species that feed directly on alfalfa include, among others, rabbits (Family *Leporidae*), deer mice (*Peromyscus maniculatus*), pocket gophers (*Thomomys* spp.), white-tailed deer (*Odocoileus virginianus*), pronghorn (*Antilocapra americana*), and elk (*Cervus canadensis*). Animal communities in alfalfa remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

2.4.2 Plants Communities

Alfalfa production in the United States encompasses a wide range of ecosystems and climate zones. The types of vegetation, including the variety of weeds, within and adjacent to alfalfa fields can vary greatly, depending on the geographic area in which the field occurs. Plant associations with alfalfa production include within-field and outside-of-field communities. Within-field communities include alfalfa as well as any weeds of alfalfa that may be found in the field. Within-field communities can also include volunteers from crops that are rotated with alfalfa and the weeds of those crops.

Out-of-field communities include plants in neighboring agricultural fields and native or naturalized species in the field margins and surrounding landscape. Some of the out-of-field plant communities can serve as sources of weeds in within-field communities.

The landscape surrounding an alfalfa field varies depending on the region. In certain areas, alfalfa fields may be bordered by other alfalfa (and other crop) fields that could be exposed to herbicides applied to the alfalfa field; or may also be surrounded by woodland, rangelands and/or pasture/grassland areas. The plant communities may be natural or managed plant habitats for the control of soil and wind erosion and serve as wildlife habitats. Any potential herbicide exposure to adjacent and surrounding plant communities is assessed and regulated by the EPA under FIFRA. Such regulation effectively manages and/or altogether prevents adverse impacts.

Weeds are classified as annuals or perennials. An annual is a plant that completes its lifecycle in one year or less and reproduces only by seed. Perennials are plants that live for more than two years. Weeds are also classified as broadleaf (dicots) or grass (monocots). Annual and perennial weeds in alfalfa fields reduce the yield, quality, and longevity of alfalfa fields because they compete for the same resources required for alfalfa growth and development – water, nutrients, light, and space (Canevari *et al.*, 2008).

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Plant communities associated with alfalfa are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Sections III.B.2 and III.B.3, where it was determined that plant species associated with alfalfa varies depending on the region. It also noted that plant communities in current alfalfa producing land, any land suitable for the production of alfalfa and adjoining terrestrial ecosystems are in the affected environment. Adjoining terrestrial ecosystems include other cultivated fields, fence rows and hedge rows, meadows, fallow fields or grasslands, woodlands, riparian habitats and other uncultivated areas. Weed infestations in alfalfa fields can reduce the yield, quality, and longevity of alfalfa fields. Examples of perennial weeds found in alfalfa fields include field bindweed (*Convolvulus arvensis*), Canada thistle (*Cirsium arvense*), curly dock (*Rumex crispus*), common dandelion (*Taraxacum officinale*), Johnsongrass (*Sorghum halepense*), hemp dogbane (*Apocynum cannabinum*), and quackgrass (*Elymus repens*). Plant communities associated with alfalfa remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

2.4.3 Gene Flow and Weediness

Gene flow is a biological process that facilitates the production of hybrid plants, introgression of novel alleles (i.e., versions of a gene) into a population, and evolution of new plant genotypes. Gene flow to and from an agro-ecosystem can occur on both spatial and temporal scales. In general, plant pollen tends to represent the major reproductive method for moving across areas, while both seed and vegetative propagation tend to promote the movement of genes across time and space.

The rate and success of gene flow is dependent on numerous external factors in addition to the donor/recipient plant. General external factors related to pollen-mediated gene flow include the presence/abundance/distance of sexually-compatible plant species; overlap of flowering phenology between populations; the method of pollination; the biology and amount of pollen produced; and weather conditions, including temperature, wind, and humidity (Zapiola *et al.*, 2008). Seed-mediated gene flow also depends on many factors, including the absence/presence/magnitude of seed dormancy; contribution and participation in various dispersal pathways; and environmental conditions and events.

Gene Flow in Commercial Alfalfa Production

Alfalfa is dependent on cross-pollination by insects, specifically bees; therefore, pollen-mediated gene flow between different alfalfa populations is possible. Many factors influence the probability of successful gene flow between alfalfa populations including: timing and degree of flowering; relative abundance of pollen sources; the presence and activity of pollinators; proximity of alfalfa populations; physical barriers between populations; the relative scale of the alfalfa populations; probability of seed maturation and germination; probability of seedling survival (Van Deynze *et al.*, 2008); starting gene frequency within the source and sink alfalfa populations, and cultural practices employed (Putnam, 2006; Van Deynze *et al.*, 2008). How these factors interact to impact the gene flow potential in alfalfa has been extensively studied and reviewed by academic researchers and the alfalfa industry with respect to potential impacts on commercial alfalfa cultivation and the environment (St. Amand *et al.*, 2000; Fitzpatrick *et al.*, 2003; Teuber *et al.*, 2005; Hammon *et al.*, 2006; Putnam, 2006; Teuber and Fitzpatrick, 2007; NAFA, 2010; Bagavathiannan *et al.*, 2011b; 2011a; Teuber *et al.*, 2011).

The development and introduction of Roundup Ready® alfalfa containing the glyphosate-resistant trait has provided a marker system to examine gene flow in alfalfa, both conventional and GE, under experimental and commercial conditions. Studies conducted under commercial seed production conditions have provided information on the realistic scenarios for gene flow (Fitzpatrick *et al.*, 2003; Teuber and Fitzpatrick, 2007; Hagler *et al.*, 2011; Teuber *et al.*, 2011). These studies along with previous studies and reviews have provided a comprehensive assessment of gene flow potential under commercial alfalfa forage and seed production conditions (Van Deynze *et al.*, 2008; USDA-APHIS, 2010). More recent studies have confirmed the previous findings that using best management practices and stewardship programs greatly decrease the potential for gene flow(Hagler *et al.*, 2011; Teuber *et al.*, 2011).

For purposes of analyzing gene flow, alfalfa populations can be categorized into three major types as sources and recipients of pollen: 1) alfalfa fields intended for hay production, 2) alfalfa fields intended for seed production, and 3) naturalized or feral alfalfa populations existing outside of managed conditions. These categories provide a comprehensive range of scenarios shown in Table 3 under which pollen flow can occur and provide a framework to evaluate pollen-mediated gene flow (Van Deynze *et al.*, 2008).

Table 3. Potential Scenarios for Pollen-mediated Gene Flow in Alfalfa (adapted from (Van Deynze *et al.*, 2008)

↓ From To→	**Hay**	**Seed**	**Feral**
Hay	Hay-to-Hay	Hay-to-Seed	Hay-to-Feral
Seed	Seed-to-Hay	Seed-to-Seed	Seed-to-Feral
Feral	Feral-to-Hay	Feral-to-Seed	Feral-to-Feral

Commercial alfalfa seed production typically requires the intentional introduction of large numbers of bee colonies in or near fields during the peak of flower production in order to achieve high rates of pollination and uniform seed ripening. Conversely, forage production does not entail the use of bees by growers at any stage. The primary pollinators used in seed production are leafcutter bees, honey bees, and to a lesser extent alkali bees. Leafcutter bees and alkali bees pollinate at rates of over 80 percent while honey bees pollinate at 22 percent (Cane, 2002; Pitts-Singer and Cane, 2011). The potential foraging range of leafcutter bees has been shown to be under 1 mile while that of honey bees can extend up to 3 miles and even further for alkali bees (Beekman and Ratnieks, 2000; Hagler *et al.*, 2011; Pitts-Singer and Cane, 2011). However, studies have shown that cross-pollination rates decrease precipitously with increasing distance from the source of pollen and that very little cross-pollination occurs at the outer recorded foraging distances (Teuber *et al.*, 2004; Teuber and Fitzpatrick, 2007).

Approximately 99.4 percent of alfalfa planted in the U.S. is cultivated exclusively for alfalfa hay (forage) production (USDA-NASS, 2009). The most commonly occurring alfalfa field interface is hay field-to-hay field. Pollen-mediated gene flow is highly improbable between adjacent hay fields (Putnam, 2006; Van Deynze *et al.*, 2008). Several factors in forage production limit potential gene flow from and into hay production fields: 1) harvest takes place at vegetative and early bloom stages when little to no pollen is produced and few flowers are present; 2) few natural pollinators of the optimal type are present; 3) biomass with flowers is removed on a regular basis that prevents seed setting; and 4) the competition and natural autotoxicity of alfalfa prevents new seedlings resulting from rare outcrossing events to successfully grow within established stands (Canevari and Putnam, 2008). Thus, forage production practices significantly lower the risk of pollen-mediated gene flow between hay production fields and outside populations (Van Deynze *et al.*, 2008).

The most important factor for avoiding seed-mediated gene flow in a hay production setting is the use of certified seed (Putnam, 2006; Teuber and Fitzpatrick, 2007). Forage growers routinely use certified seed of registered varieties for sowing alfalfa stands. High quality seed decreases the risk of seed-mediated gene flow during stand establishment and the introduction of varietal mixtures and off-types.

It is also improbable that pollen from an adjacent seed field will result in gene flow into a hay field. Forage production practices, which include multiple harvests per year of the hay field, coupled with physical isolation distance requirements of certified alfalfa seed production fields keep the potential for gene flow from seed production fields to hay production fields very low (Van Deynze *et al.*, 2008; USDA-APHIS, 2010). Under the remote possibility that an outcrossed seed in a hay field were to mature, competition from the stand and alfalfa's natural autotoxicity would reduce the probability of successful germination and survival within an existing stand.

Pollen-mediated gene flow between adjacent seed production fields (seed-to–seed) is considered a manageable and measurable occurrence for conventional cultivars of most outcrossing crops, including alfalfa. This scenario applies to a much smaller area of approximately 121,000 acres, or 0.6 percent of the total U.S. alfalfa acres, concentrated in areas optimal for alfalfa seed production (USDA-NASS, 2009; USDA-APHIS, 2010). Certified seed growers have relied for many decades on physical isolation to minimize and mitigate pollen-mediated gene flow in order to manage genetic purity of commercial varieties (Brown *et al.*, 1986; Van Deynze *et al.*, 2008; Dunkle, 2011; Kalaitzandonakes, 2011). Gene flow studies of alfalfa seed production fields have confirmed that current Association of Official Seed Certifying Agencies (AOSCA) and OECD seed isolation and production standards can be used to meet Federal Seed Act standards (Fitzpatrick *et al.*, 2003; Teuber and Fitzpatrick, 2007; AOSCA, 2013a). For special situations such as identity preserved crops where even greater purity is desired, seed producers use additional isolation or sanitation to ensure high seed purity.

In the hay-to-seed scenario, research with glyphosate-resistant alfalfa under commercial seed production conditions has shown that harvesting hay from adjacent forage production fields at stages of 20 to 50 percent bloom does not significantly raise the potential gene flow to neighboring seed production fields and risk remains very low (Teuber and Fitzpatrick, 2007; Van Deynze *et al.*, 2008). Gene flow was no more than 0.2 percent at isolation distances of 300 feet or less and did not exceed 0.05 percent at distances greater than 350 ft. (Teuber and Fitzpatrick, 2007). Agronomic factors alone make it unfavorable for alfalfa forage to be allowed to mature past the 10 percent bloom stage. In addition to increasing lignin accumulation after the 10 percent bloom stage, crude protein levels fall and ADF levels rise contributing to declines in overall forage quality (Orloff and Putnam, 2008; Putnam *et al.*, 2008b). The leaf to stem ratio also declines and further degrades quality (Putnam *et al.*, 2008b). The effective maximum yield is generally reached by 50 percent bloom, but at a marked cost in terms of quality (Orloff and Putnam, 2008; Putnam *et al.*, 2008b).

The forage production practice of harvesting a hay field at or before 10 percent bloom during the seed production pollination period is sufficient to ensure that pollen-mediated gene flow from hay production fields into seed production fields is negligible. Furthermore, this practice will continue to be a stewardship requirement for GE alfalfa hay growers, under terms of the Monsanto/FGI Technology Stewardship Agreement (MTSA) (Monsanto Company, 2013).

Additional studies under actual commercial alfalfa seed grower conditions have shown that the use of minimum isolation distances specific to pollinator species and identity-preserved production protocols successfully mitigate gene flow to levels observed for other GE crop species to produce seeds of high genetic purity (>99 percent). Inadvertent presence levels can be managed to less than 0.2 percent (Fitzpatrick, 2007; Fitzpatrick *et al.*, 2007). Levels of actual gene flow under these conditions have also been shown to be several times less than those predicted by research models developed using smaller research plots (Fitzpatrick, 2007; Fitzpatrick *et al.*, 2007).

The information from these studies has allowed the alfalfa industry in conjunction with AOSCA to develop coexistence strategies to provide additional measures for seed producers interested in further reducing the risk of pollen-mediated gene flow to their commercially-sensitive seed production crops from hay production fields. The strategies include FGI's Best Practices for Stewardship in Roundup Ready Seed Production, NAFA Best Management Practices for Roundup Ready Seed Production, and NAFA Best Management Practices for Adventitious Presence-Sensitive Alfalfa Seed Production (Fitzpatrick, 2007; NAFA, 2011a; 2012a; 2012b; 2012c), with or without identity-preserved protocols such as the AOSCA Alfalfa Seed Stewardship Program (ASSP) (AOSCA, 2013a). The protocols in these strategies require pollinator-specific isolation distances to proactively mitigate adventitious presence in conventional seed and are considered applicable to other traits in alfalfa (Van Deynze *et al.*, 2008). Other measures may include planting larger size seed production fields (greater than 5 acres) and harvesting the seed field borders as a separate lot. The AOSCA ASSP was launched in 2010 by participating state seed certification agencies to offer a voluntary identity-preserved, process-based certificate to seed producers concerned about low level presence of GE traits (AOSCA, 2013a). The establishment of formal, voluntary grower opportunity zones in many seed production areas since 2011 has facilitated local coordination of coexistence efforts by alfalfa seed growers for both conventional and GE alfalfa (NAFA, 2011b).

<u>Gene Flow with Feral Alfalfa</u>

Populations of feral alfalfa have existed in the U.S. since alfalfa's introduction due to natural dispersal from cultivated fields and from intentional introductions in non-agricultural areas for rangeland development and other purposes (USDA-APHIS, 2010). Feral alfalfa can be found in air fields, canals, cemeteries, ditch banks, fence rows, highways, irrigation ditches, pipelines, railroads, rangeland, rights-of-way, roadsides, wasteland, preserves, parks, and recovery areas. Gene flow to feral alfalfa from large-scale seed or hay production fields of conventional and GE alfalfa has been shown to occur (St. Amand *et al.*, 2000). However, typical conditions and practices for hay and seed production all but preclude the chance of gene flow into hay or seed production fields, as previously described (Van Deynze *et al.*, 2008; USDA-APHIS, 2010).

Certified alfalfa seed production requires minimum isolation from all sources of alfalfa, including feral populations (AOSCA, 2013b). Removing or mowing feral alfalfa plants near cultivated fields prevents synchronous bloom and reduces the risk of gene flow to near zero (USDA-APHIS, 2010). Seed producers are known to control these populations as there are fewer feral populations in areas of intensive alfalfa seed production compared to hay production areas (Kendrick *et al.*, 2005). This practice also lowers the potential for gene flow into as well as from feral populations (Van Deynze *et al.*, 2008). As described above, forage production practices restrict gene flow from feral populations to hay production fields to extremely low levels.

A number of factors relative to feral alfalfa itself further reduce the potential for pollen-mediated gene flow from feral alfalfa populations to extremely low levels (Van Deynze *et al.*, 2008; USDA-APHIS, 2010). First, most feral alfalfa is found in relatively small populations and at low densities. Second, the asynchronous timing of flowering and the low density of pollinators in feral areas limit the effectiveness of feral alfalfa populations as sources, sinks or bridges for gene flow. Finally, feral populations are not managed and, therefore, are more susceptible to environmental stresses. Under these conditions, pollen and seed production on feral plants are expected to be considerably less prolific compared to alfalfa plants in managed seed production fields. These same factors are also a determinant in the relatively low potential for gene flow between feral alfalfa populations (Van Deynze *et al.,* 2008; USDA-APHIS, 2010).

<u>Weediness of Alfalfa</u>

Alfalfa is a widely cultivated crop found in all parts of the continental United States, Alaska, and Hawaii and can also survive outside of cultivation. Little evidence exists to suggest that alfalfa behaves as a weed, other than as a volunteer in agricultural settings. Weed control experts from states where alfalfa is cultivated extensively have communicated that they do not consider *Medicago sativa* a weed or species with weediness potential (USDA-APHIS, 2010; Monsanto and FGI, 2013). Out of 12 weed lists available in the USDA PLANTS Database (USDA-NRCS, 2013b), *Medicago sativa* is found in only one weed identification guide by the Southern Weed Science Society (SWSS), however the author of the SWSS entry for alfalfa has clarified that alfalfa is not an invasive weed and does not displace native species but alfalfa does colonize disturbed areas (USDA-APHIS, 2010).

Seed dormancy is an important characteristic often associated with plants that are weeds (Anderson, 1996). Dormancy mechanisms, including hard seed, vary with species and are usually based on complex processes. For most crops, the number of hard seed is negligible or nonexistent. However, when alfalfa seed is produced, a portion of the seed is "hard"; that is, the seeds do not absorb water after a prescribed period of time because of an impermeable seed coat (Bass *et al.*, 1988). The percentage of hard seed in alfalfa varies widely, and depends largely on environmental conditions during and after seed maturation, harvesting and seed conditioning methods and on genetic factors (Bass *et al.*, 1988). Seed aging, weathering or mechanical scarification makes the seed coat permeable to water and allows rapid germination under favorable conditions. Apart from an impervious seed coat, alfalfa has no physiological seed dormancy mechanism to delay germination.

The viability of most alfalfa seed in soil declines over time (Bass *et al.*, 1988). A portion of the residual alfalfa seed can persist in the soil for several years, and if it remains viable may germinate as volunteers (Bass *et al.*, 1988; Mueller *et al.*, 2008). Alfalfa that has germinated and emerged unintentionally in a subsequent crop, also known as volunteer alfalfa, may compete with the succeeding rotational crop. Volunteers, including ones with herbicide- resistant traits, can be managed with pre-plant or selective post-emergent herbicide applications or by mechanical means (Monsanto and FGI, 2013). Autotoxicity limits the ability of alfalfa to compete as volunteer in previously established alfalfa stands (Caddel *et al.*, 2011).

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: The potential for gene flow and the weediness of alfalfa are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Section III.A.2, where it was determined that gene flow by pollination is dependent upon three different species of bees, with purposeful introduction of bees limited to seed production fields. Gene flow in alfalfa can also occur with secondary seedlings, but this is an unlikely avenue for effective gene flow in alfalfa fields considering the normal agronomic practice of solid-seeded alfalfa plantings and due to the autotoxic compounds alfalfa plants release into the soil that inhibit seedling germination. Despite these barriers, gene flow can naturally occur among alfalfa in hay fields, seed fields and feral alfalfa via bees and secondary seedlings. The potential for gene flow exists only between different alfalfa crop fields and feral alfalfa, due to the absence of any sexually compatible, free-living or native relatives of *Medicago* species in North America. There are potential means for unintended distribution of seed from a seed production field that may lead to gene flow, including factors associated with seed harvest, processing or storage, extreme weather phenomenon dispersing seed, and transportation by animals and birds. Gene flow in alfalfa production and feral plants remains unchanged from that described in the 2010 FEIS (USDA-APHIS, 2010).

APHIS also determined that alfalfa is a widely adapted crop that is cultivated in all 50 states; however, due to its adaptability, it is known to survive outside of cultivation. Despite its adaptability and presence outside of cultivation, there is little evidence to suggest that alfalfa is considered a weed. In correspondence with 13 weed control experts throughout alfalfa growing regions, none considered alfalfa to be a weed, other than as a volunteer in agricultural settings. Weediness in alfalfa remains unchanged from that described in the 2010 FEIS(USDA-APHIS, 2010).

2.4.4 Microorganisms

Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva *et al.*, 2004). They also suppress soil-borne plant diseases and promote plant growth (Doran *et al.*, 1996). The main factors affecting microbial population size and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva *et al.*, 2004). Plant roots, including those of alfalfa, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere. Microbial diversity in the rhizosphere may be extensive and differs from the microbial community in the bulk soil (Garbeva *et al.*, 2004).

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Microorganisms affected by alfalfa are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Section III.F.1, where it was determined that alfalfa interacts with soil microorganisms, including its symbiotic relationship with the nitrogen-fixing bacterium *Sinorhizoium meliloti*. As a result of this interaction, atmospheric nitrogen is converted to produce available nitrogen, such that alfalfa affects soil tilth, fertility and structure, making alfalfa a valued rotational crop in agriculture. Microorganisms affected by alfalfa remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

2.4.5 Biodiversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson, 1988). Biodiversity provides valuable genetic resources for crop improvement (Harlan, 1975) and also provides other functions beyond food, fiber, fuel, and income. These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 1999). The loss of biodiversity results in a need for costly management practices in order to provide these functions to the crop (Altieri, 1999).

The degree of biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management; and 4) extent of isolation of the agroecosystem from natural vegetation (Southwood and Way, 1970).

Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas. Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest result limit the diversity of plants and animals (Lovett *et al.*, 2003).

Biodiversity can be maintained or reintroduced into agroecosystems through the use of woodlots, fencerows, hedgerows, and wetlands. Agronomic practices include intercropping (the planting of two or more crops simultaneously to occupy the same field), agroforestry, crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically for the purpose of incorporating it into the soil in order to provide nutrients and organic matter), addition of organic matter (compost, green manure, animal manure, etc.), and hedgerows and windbreaks (Altieri, 1999).

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Alfalfa's effects on biodiversity are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Sections III.B.1 and III.B.2, where it was determined that alfalfa interacts with animal and plant species. The interaction on the biodiversity of these plant and animal species is based on a review of alfalfa, regarding: 1) biology, taxonomy and potential for sexually compatible relatives; 2) characterization of the transgene with respect to structure and function; 3) determination of where the new transgene and its products (if any) are produced in the plant; 4) impacts to agronomic performance, including disease and pest susceptibilities; 5) production of naturally- produced toxicants; and 6) an analysis to determine sexual compatibility with threatened and endangered species. Alfalfa's effects on biodiversity remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

2.5 Human Health

2.5.1 Consumer Health

Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Public health concerns surrounding GE alfalfa primarily involve the human consumption of GE alfalfa products (e.g., sprouts) and consumption of products derived indirectly from GE alfalfa. These include alfalfa honey and products derived from honey. Food and feed derived from GE alfalfa must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. FDA evaluates the submission and responds to the developer by letter. Monsanto and FGI indicated that they submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa to FDA in August 2012, identified under BNF No. 138 (Monsanto and FGI, 2013). The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014).

As noted by the National Research Council (NRC), unexpected and unintended compositional changes arise with all forms of genetic modification, including both conventional hybridizing and genetic engineering (NRC, 2004). The NRC also noted that at the time, no adverse health effects attributed to genetic engineering had been documented in the human population. Reviews on the nutritional quality of GE foods have generally concluded that there are no significant nutritional differences in conventional versus GE plants for food or animal feed (Faust, 2002; Flachowsky *et al.*, 2005).

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Effects of alfalfa on consumer health are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Section III.D.1, where it was determined that alfalfa has a known history of human safety through ingestion of alfalfa sprouts, teas, and dietary supplements. The safety of alfalfa products consumed as food is the focus of the U.S. FDA. Effects on consumer health from alfalfa remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

2.5.2 Worker Safety

Worker hazards in farming are common to all types of agricultural production, and include hazards of machinery and common agricultural management practices. A common agricultural practice, pesticide application, represents the primary exposure route to pesticides for farm workers. Pesticides are commonly used on alfalfa acreage in the United States (Monsanto and FGI, 2013).

As discussed in Subsection 1.3 – Coordinated Framework Review and Regulatory Review, all pesticides labeled for use on crops in the United States must first be registered by the US-EPA. Among other elements, the US-EPA pesticide registration process involves the design of use restrictions that, when followed, have been determined to be protective of worker health.

EPA's Worker Protection Standard (WPS) (40 CFR Part 170) was published in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protections to more than two and a half million agricultural workers who work with pesticides at more than 560,000 workplaces on farms, forests, nurseries, and greenhouses. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance. Worker safety precautions and use restrictions are noted clearly on pesticide registration labels. These restrictions provide instructions as to the appropriate levels of personal protection required for agricultural workers to use pesticides.

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Effects of alfalfa production on worker health are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Section III.D.2, where it was determined that worker safety is affected through agricultural operations involving machinery (forage cutting and harvest practices, including baling or green chopping) and pesticide/fertilizer applications. Effects on worker health from alfalfa remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

2.6 Animal Feed

Alfalfa is grown primarily for livestock forage. Alfalfa generally has a high yield, high protein and low fiber content, making it an ideal livestock feed (primarily dairy cattle and horse, but also used for beef cattle, sheep, and goats) (Putnam *et al.*, 2001; USDA-APHIS, 2010). The highest quality alfalfa hay (bud stage) is generally used for dairy cows. Hay that is lower in protein and higher in fiber is fed to beef cattle, horses, heifers, and non-lactating dairy cows (Ball *et al.*, 2001). Grazing alfalfa in the vegetative state is practiced sometimes for dormant-season alfalfa stubble, a substitute for early or late season cutting, and rotational grazing during the season. However, grazing can cause gastrointestinal bloating in animals, and over-grazing can result in stand maintenance problems.

Alfalfa forage contains well described classes of anti-nutrient compounds including saponins, condensed tannins, and phytoestrogens (OECD, 2005). Saponins are chief among these compounds, with soyasapogenols, zanhic acid glycosides, and medicagenic acid being quantitatively the most important (Massiot *et al.*, 1988; Massiot *et al.*, 1991; Oleszek *et al.*, 1992). Saponins can produce toxic effects, primarily by medicagenic and zanhic acids. Symptoms include irritation to mouth and digestive tract, increased membrane permeability, and, in acute cases, hemolysis (Oleszek, 1996). Saponins are also implicated as a cause of bloat due to their distinct foaming characteristics (Marston *et al.*, 2000). The presence of saponins as well as high levels of readily digestible protein and carbohydrate, the characteristics that make legumes valuable as ruminant feed, can cause accumulation of fermentation gases in the form of stable protein foam or froth in the rumen (Tanner *et al.*, 1995). A number of strategies are employed to lower risk of bloat such as pre-feeding animals prior to letting out to pasture (Cangiano *et al.*, 2008). Saponins are not known to affect growth in ruminants. There is evidence that certain saponins have beneficial properties on rumen fermentation (Wina *et al.*, 2005).

Canavanine is a secondary metabolite stored in the seeds and sprouts of most leguminous plants, including alfalfa. Canavanine in sprouts and seeds, in the form of L-canavanine, is a structural analog of L-arginine that can cause aberrant protein formation with potentially toxic effects in humans and animals (Rosenthal and Nkomo, 2000). Canavanine is suspected of being able to activate systemic lupus erythematosus (Malinow *et al.*, 1982; Akaogi *et al.*, 2006). Other evidence has highlighted benefits from canavanine in terms of potential anti-cancer activity (Thomas *et al.*, 1986; Swaffar *et al.*, 1994).

Similar to the regulatory control for direct human consumption of alfalfa under the FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from GE alfalfa must comply with all applicable legal and regulatory requirements, which in turn protects human health. To help ensure compliance, GE organisms used for feed may undergo a voluntary consultation process with FDA before release onto the market. Although a voluntary process, thus far all applicants who wish to commercialize a GE variety that will be included in the feed/food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered feed/food meets with the agency, which provides the applicant with any needed direction regarding the need for additional data or analysis, and allows for interagency discussions regarding possible issues. FDA evaluates the submission and responds to the developer by letter. Monsanto and FGI indicated that they submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa to FDA in August 2012, identified under BNF No. 138 (Monsanto and FGI, 2013). The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014).

2.7 Socioeconomics

As part of an evaluation of impacts on the human environment, NEPA requires consideration of economic and social effects (40 CFR 1508.8), whether direct, indirect, or cumulative. However, under CEQ regulations (40 CFR 1508.14), ". . . economic or social effects are not intended by themselves to require preparation of an environmental impact statement."

The following socioeconomic factors are considered in this EA: the interaction of social and economic factors that affect agricultural production and products, including farm income and employment, crop production expenses, crop value and trade. The main focus of this assessment is the socioeconomic effect on the alfalfa industry, including production and domestic and international trade, and alfalfa producers.

2.7.1 Domestic Economic Environment

Alfalfa is grown primarily for forage, with sufficient seed acreage to provide seed for establishing stands, and relatively small acreage for human consumption. Each of these commodities has its own particular market and production characteristics (USDA-APHIS, 2010).

Alfalfa acreage in the U.S. has declined from peak acreage of approximately 30 million acres in the 1950s and 1960s to the present level of approximately 17 million acres (USDA-NASS, 2013b). The production of alfalfa for hay is summarized in Table 1. As shown in that table, in 2012, about 52 million tons of alfalfa were harvested from approximately 17 million acres, with an estimated value of $10.4 billion USD (due to most alfalfa being fed to livestock on-farm, the value is an estimate based on multiplying average prices with production volumes and does not correspond to actual sales). The majority of alfalfa hay is consumed on the farm where it is produced, and dairy farms are by far the main consumer (USDA-APHIS, 2010). The quality of alfalfa hay is determined by the presence of weeds, fiber content, protein content, and other factors such as color and mold presence (USDA-APHIS, 2010).

As discussed in Section 2.1.3, over 121,000 acres of alfalfa seed were harvested in 2007 producing approximately 62 million pounds of seed. The demand for alfalfa seed is driven primarily by the demand for seed to establish new stands of alfalfa forage. Little information is available regarding production of alfalfa seed for sprouts (USDA-APHIS, 2010).

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Effects of alfalfa on the domestic economic environment are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Sections III.C.1 and III.C.4, where it was determined that alfalfa has a well-established history of economic value to U.S. agriculture. Alfalfa acreage in the U.S. has declined from peak acreage of approximately 30 million acres in the 1950s and 1960s to the present level of approximately 21 million acres in 2008. This has occurred even though the alternative forage crop used is not as environmentally sustainable, is not as nutritionally complete for livestock, and is not as profitable in the long term for many farm systems. In part, because of several social and economic reasons, risk-averse producers in much of the United States have reduced the number of acres planted to alfalfa. In contrast to several alternative feedstuff crops, alfalfa crop prices are not directly managed or insured by government programs. Very little hay is transported cross-country and almost none is imported to meet U.S. forage market shortfalls, although dairy and livestock producers require a constant supply. The crop is a perennial that peaks in yield during the second and third year. Relative to annual crops, alfalfa demand and supply are more prone to serious within-season imbalance, price volatility, and the selling price of the alfalfa crop is not known at planting time. Alfalfa growers face the risk of weather interacting with weed competition or herbicide application outcomes that can lead to unpredicted stand failure, stand depletion, and temporary or permanent loss of hay quality or stand yield potential. Effects of alfalfa on the domestic economic environment remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

2.7.2 Trade Economic Environment

The affected trade economic environment is defined as those countries with which the U.S. engages in alfalfa feed, seed and/or food trade. Therefore, the trade economic environment most likely affected by a determination of nonregulated status of KK179 alfalfa would be those countries who import crop feed, seed, and/or food from the U.S.

In 2011, the U.S. exported approximately $445 million in alfalfa hay, cubes, and meal and $106 million in alfalfa seed (USDA-FAS, 2012). Alfalfa cubes are made by drying, chopping, and pressing the alfalfa, with most of the alfalfa cube exports going to Japan. Four primary export markets (Japan, China, South Korea, and Taiwan) together accounted for two-thirds of the $401 million in alfalfa hay exports (USDA-FAS, 2012).

USDA-APHIS Glyphosate-tolerant Alfalfa FEIS: Alfalfa's effects on the trade economic environment are assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010), Section III.C.3, where it was determined that alfalfa has a limited history of trade, where trade primarily occurs from West Coast region states (California and Washington) to markets in the Asia-Pacific region. Based on the total amount of U.S. exported alfalfa, it would only require approximately 200,000 acres from these two states to grow the alfalfa forage. Effects of alfalfa on trade economic environment remain unchanged from those described in the 2010 FEIS (USDA-APHIS, 2010).

3 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of KK179 alfalfa. To respond favorably to a petition for nonregulated status, APHIS must determine that KK179 alfalfa is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2013), APHIS has concluded that KK179 alfalfa is unlikely to pose a plant pest risk. Therefore, APHIS must determine that KK179 alfalfa is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

Two alternatives are evaluated in this EA: (1) no action and (2) determination of nonregulated status of KK179 alfalfa. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section.

3.1 No Action Alternative: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. KK179 alfalfa and progeny derived from KK179 alfalfa would continue to be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of KK179 alfalfa and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of KK179 alfalfa.

This alternative is not the Preferred Alternative because APHIS has concluded through a PPRA that KK179 alfalfa is unlikely to pose a plant pest risk (USDA-APHIS, 2013). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

3.2 Preferred Alternative: Determination that KK179 Alfalfa is No Longer a Regulated Article

Under this alternative, KK179 alfalfa and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. KK179 alfalfa is unlikely to pose a plant pest risk (USDA-APHIS, 2013). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of KK179 alfalfa and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that KK179 alfalfa is unlikely to pose a plant pest risk, a determination of nonregulated status of KK179 alfalfa is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Under this alternative, growers may have future access to KK179 alfalfa and progeny derived from this event if the developer decides to commercialize KK179 alfalfa.

Monsanto and FGI have indicated its intention to develop a stacked hybrid through conventional breeding techniques (Monsanto and FGI, 2013). In this process, the low lignin trait in KK179 alfalfa would be combined with the glyphosate-resistant trait from another alfalfa variety that is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. APHIS does not have jurisdiction under the PPA and Part 340 to review such stacked hybrids developed using nonregulated articles and conventional hybridization techniques where there is no evidence of a plant pest risk. Accordingly, this EA focuses on the cultivation of KK179 alfalfa. Issues associated with potential future stacking, particularly cultivation of a stacked hybrid incorporating glyphosate-resistance from a variety assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010) and subsequently determined to be nonregulated, are presented and discussed in the cumulative effects analyses (see Section 5.0), where appropriate.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for KK179 alfalfa. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for KK179 alfalfa. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

3.3.1 Prohibit Any KK179 Alfalfa from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of KK179 alfalfa, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that KK179 alfalfa is unlikely to pose a plant pest risk (USDA-APHIS, 2013).

In enacting the Plant Protection Act, Congress found that

> [D]ecisions affecting imports, exports, and interstate movement of products regulated under [the Plant Protection Act] shall be based on sound science…§ 402(4).

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order 13563, to guide the development and implementation of policies for oversight of emerging technologies (such as genetic engineering) at the agency level. In accordance with this memorandum, agencies should adhere to Executive Order 13563 and, consistent with that Executive Order, the following principle, among others, to the extent permitted by law, when regulating emerging technologies:

> "[D]ecisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency"

Based on the Plant Pest Risk Assessment (USDA-APHIS, 2013) and the scientific data evaluated therein, APHIS concluded that KK179 alfalfa is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of KK179 alfalfa.

3.3.2 Approve the Petition in Part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that KK179 alfalfa is unlikely to pose a plant pest risk (USDA-APHIS, 2013), there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3.3.3 Isolation Distance between KK179 Alfalfa and Non-GE Alfalfa Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating KK179 alfalfa from non-GE alfalfa production. However, because APHIS has concluded that KK179 alfalfa is unlikely to pose a plant pest risk (USDA-APHIS, 2013), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of KK179 alfalfa based on the location of production of non-GE alfalfa in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' plant pest risk assessment for KK179 alfalfa, there are no geographic differences associated with any identifiable plant pest risks for KK179 alfalfa (USDA-APHIS, 2013). This alternative was rejected and not analyzed in detail because APHIS has concluded that KK179 alfalfa does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Individuals might choose on their own to geographically isolate their non-GE alfalfa production systems from KK179 alfalfa or to use isolation distances and other management practices to minimize gene movement between alfalfa fields. Information to assist growers in making informed management decisions for KK179 alfalfa is available from AOSCA (AOSCA, 2010).

3.3.4 Requirement of Testing for KK179 Alfalfa

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing for GE products in non-GE production systems. APHIS notes there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because KK179 alfalfa does not pose a plant pest risk (USDA-APHIS, 2013), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for KK179 alfalfa would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

3.4 Comparison of Alternatives

Table 4 presents a summary of the potential impacts associated with selection of either of the alternatives evaluated in this EA. The impact assessment is presented in Section 4 of this EA.

Table 4. Summary of issues of potential impacts and consequences of alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2013)
Management Practices		
Acreage and Areas of Alfalfa Production	Alfalfa acreage has declined from 30 million acres to 17 million acres in the last 40 years. USDA does not provide projections for future alfalfa acreage.	Unchanged from No Action Alternative

Table 4. Summary of issues of potential impacts and consequences of alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Agronomic Practices	General agronomic practices such as stand planting and removal, crop rotation, tillage, pest and disease management, crop nutrition, and pre- harvest and harvest practices are expected to remain the same.	KK179 alfalfa is not expected to affect agronomic practices other than greater flexibility in cutting schedules, managing harvest delays, and potentially lower production costs. To conservatively protect against gene flow, growers of KK179 alfalfa combined with glyphosate-resistant alfalfa by traditional breeding will be required by Monsanto/FGI grower agreements (MTSA) to harvest forage at or before 10 percent bloom.
Alfalfa Seed Production	Alfalfa seed production is highly concentrated in the western U.S. irrigated regions within three states California, Idaho, and Washington. Approximately 121,000 acres or 0.6 percent of the total U.S. alfalfa acres are under seed production. Certified seed producers would continue to follow federal regulations and AOSCA guidelines.	Unchanged from No Action Alternative
Organic Alfalfa Production	Specialty crop growers employ practices and standards for production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with conventional or GE crops. Organic alfalfa production consisted of about 1.2 percent of total U.S. alfalfa production capturing roughly 0.64 percent of the overall alfalfa crop value.	Unchanged from No Action Alternative
Environment		

Table 4. Summary of issues of potential impacts and consequences of alternatives.

Attribute/Measure	**Alternative A: No Action**	**Alternative B: Determination of Nonregulated Status**
Soil Quality	Agronomic practices such as crop type, tillage, and pest management can affect soil quality. Growers currently use best management practices to address their specific needs in producing alfalfa.	Unchanged from No Action Alternative
Water Resources	The primary cause of agricultural non-point source pollution is increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Agronomic practices such as crop nutrient management, pest management, and conservation buffers help protect water quality from agricultural runoff. Alfalfa is considered to naturally be drought tolerant but has a high water requirement in excess of 40 inches of water during the season.	Unchanged from No Action Alternative
Air Quality	Agricultural activities such as burning, tilling, harvesting, spraying pesticides, and fertilizing, including the emissions from farm equipment, can directly affect air quality. Aerial application of herbicides may impact air quality from drift, diffusion, and volatilization of the chemicals, as well as motor vehicle emissions from airplanes or helicopters.	In general, because agronomic practices are not expected to change, impacts to air quality are not expected to change. However, the flexibility in harvesting schedules could lead to fewer cuttings, with a corresponding reduction in emissions from equipment use. This would result in a small, localized positive impact on air quality.

Table 4. Summary of issues of potential impacts and consequences of alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Climate Change	Agriculture-related activities are recognized as both direct sources of greenhouse gases (e.g., exhaust from motorized equipment) and indirect sources (e.g., soil disturbance from tillage, fertilizer production).	In general, because agronomic practices are not expected to change, impacts to air quality are not expected to change. However, the delayed harvesting opportunity associated with KK179 alfalfa could result in reduced cuttings, which could result in a small reduction in vehicle-related greenhouse gas emissions. This could result in a small reduction in greenhouse gas emissions.
Animal Communities	Alfalfa fields may be host to many animal and insect species. Many of these animals are typically considered pests and may be controlled by the use of integrated pest management strategies.	Unchanged from No Action Alternative
Plant Communities	Alfalfa fields can be bordered by other agricultural fields, woodlands, or pasture and grasslands. The most agronomically important members of a surrounding plant community are those that behave as weeds. Alfalfa growers use production practices to manage weeds in and around fields. Alfalfa can form feral populations.	Unchanged from No Action Alternative

Table 4. Summary of issues of potential impacts and consequences of alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Gene Flow and Weediness	Alfalfa is dependent on cross pollination by insects, making pollen-mediated gene flow between different alfalfa populations possible. Gene flow to and from forage production is minimal because alfalfa is typically harvested at the vegetative or early bloom stage and pollinators are not introduced. Growers use various production practices to limit undesired cross pollination. There are no sexually compatible native relatives and alfalfa is not considered a weed.	Delaying forage cutting could have gene flow implications. However, research has shown that forage harvesting at stages of 20 to 50 percent bloom does not significantly raise the potential of gene flow to neighboring seed production fields. Growers of KK179 alfalfa (combined with glyphosate-resistant alfalfa by traditional breeding) will be required by Monsanto/FGI grower agreements (MTSA) to harvest forage at or before 10percent bloom, therefore the likelihood of gene flow from KK179 alfalfa to other alfalfa varieties is not substantially different from the No Action Alternative.
Microorganisms	Alfalfa interacts with soil microorganisms, including its symbiotic relationship with the nitrogen-fixing bacterium *Sinorhizoium meliloti*.	Unchanged from No Action Alternative
Biodiversity	The biological diversity in alfalfa fields is highly managed and may be lower than in the surrounding habitats.	Unchanged from No Action Alternative
Human and Animal Health		

Table 4. Summary of issues of potential impacts and consequences of alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Risk to Human Health	Alfalfa has a known history of human safety through ingestion of alfalfa sprouts, teas, and dietary supplements. The EPA's Worker Protection Standard (WPS); (40 CFR part 170.1, *Scope and Purpose*) requires employers to take actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.	A comprehensive assessment of KK179 alfalfa showed the integrity and stability of the inserted DNA, the safety of the expressed products, and the compositional equivalence of KK179 alfalfa to commercially available alfalfa. KK179 alfalfa would be used only for forage production and not for alfalfa products intended for direct human assumption. Impacts on consumer health are not expected to differ from those of the No Action Alternative Agricultural production with KK179 alfalfa does not require any change to the agronomic practices or chemicals currently used (i.e., pesticides) for conventional alfalfa. Therefore, worker safety issues associated with the agricultural production of KK179 alfalfa would remain the same as those under the No Action Alternative.
Risk to Animal Feed	The majority of the alfalfa cultivated in the U.S. is grown for animal feed. USDA-AMS current alfalfa hay grading system reports five quality grades: supreme, premium, good, fair and utility.	A compositional analysis concluded that forage from KK179 alfalfa is considered similar in composition to forage from conventional alfalfa. Harvested hay will continue to range from supreme to fair quality based on the USDA- AMS grading scale. Therefore this is unchanged from the No Action Alternative
Socioeconomic		

Table 4. Summary of issues of potential impacts and consequences of alternatives.

Attribute/Measure	**Alternative A: No Action**	**Alternative B: Determination of Nonregulated Status**
Domestic Economic Environment	The majority of alfalfa production is grown for animal feed. The majority of alfalfa hay is consumed on the farm where it is produced, and dairy farms are by far the main consumer. The quality of alfalfa hay is determined by the presence of weeds, fiber content, protein content, and other factors such as color and mold presence	Growers may realize economic benefits from increased flexibility in cutting time, resulting in either 1) increased quality of alfalfa forage with comparable yield to conventional alfalfa harvested at a later growth stage or 2) higher yields with quality similar to conventional alfalfa harvested at an earlier growth phase, resulting from delayed harvesting. Growers receive greater economic returns for higher quality hay, where prices can vary as much as 50 percent between supreme and fair quality (USDA-APHIS, 2010). Flexibility in forage harvest timing will allow growers to better manage the yield-quality relationship to optimize economic return based on either market prices or intended on-farm feed use.
Trade Economic Environment	In 2011, the U.S. exported approximately $445 million in alfalfa products primarily to Japan, China, South Korea, and Taiwan. U.S. alfalfa and alfalfa products will continue to play a role in global alfalfa production, and the U.S. will continue to be a supplier in the international market. East Asia is likely to continue as a major export destination for traded U.S. alfalfa products.	The trade economic impacts associated with a determination of nonregulated status of KK179 alfalfa are anticipated to be similar to the No Action alternative because Monsanto and FGI do not intend to globally launch KK179 alfalfa until the proper regulatory approvals have been obtained.
Other Regulatory Approvals		

Table 4. Summary of issues of potential impacts and consequences of alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
U.S.	Monsanto and FGI submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa to FDA in August 2012. FDA is presently evaluating the submission.	Monsanto and FGI submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa to FDA in August 2012. The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014).
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	Fully compliant

4 ENVIRONMENTAL CONSEQUENCES

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, namely taking no action and a determination by the agency that KK179 alfalfa does not pose a plant pest risk. Potential environmental impacts from the No Action Alternative and the Preferred Alternative for KK179 alfalfa are described in detail throughout this section. A cumulative effects analysis is presented for each potentially affected environmental concern. Certain aspects of this product and its cultivation would be no different between the alternatives, which is described below.

4.1 Scope of Analysis

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for KK179 alfalfa are described in detail throughout this section. An impact would be any change, positive or negative, from the existing (baseline) conditions of the affected environment (described for each resource area in Section 2.0). Impacts may be categorized as direct, indirect, or cumulative. A direct impact is an effect that results solely from a proposed action without intermediate steps or processes. Examples include soil disturbance, air emissions, and water use. An indirect impact may be an effect that is related to but removed from a proposed action by an intermediate step or process. Examples include surface water quality changes resulting from soil erosion due to increased tillage, and worker safety impacts resulting from an increase in herbicide use.

A cumulative effects analysis is also included for each environmental issue. A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. Examples include breeding KK179 alfalfa with other deregulated events. Particularly, cultivation of a stacked hybrid incorporating glyphosate-resistance from a variety assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010) and subsequently determined to be nonregulated. If there are no direct or indirect impacts identified for a resource area, then there are no cumulative impacts. Cumulative impacts are discussed in Section 5.

Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential impacts. Certain aspects of this product and its cultivation will not differ between the alternatives.

4.2 Agricultural Production of Alfalfa

Best management practices are commonly accepted, practical ways to grow alfalfa, regardless of whether the alfalfa farmer is using organic practices or conventional practices with non-GE or GE varieties. These management practices consider crop-specific planting dates, seeding rates, and harvest times, among others. Over the years, alfalfa production has resulted in well-established management practices that are available through local Cooperative Extension Service offices and their respective websites. The National Information System for the Regional Integrated Pest

Management (IPM) Centers publishes crop profiles for major crops on a state-by-state basis. These crop profiles provide production guidance for local growers, including recommended practices for specific pest control. Crop profiles for many of the alfalfa production states can be reviewed at www.ipmcenters.org/cropprofiles/index.cfm.

4.2.1 Acreage and Area of Alfalfa Production

No Action Alternative: Acreage and Area of Alfalfa Production

Under the No Action Alternative, existing trends related to area and acreage of alfalfa is expected to continue. Alfalfa is expected to continue being cultivated in all 50 states (Sullivan, 1992), with the majority of production west of the Mississippi (USDA-NASS, 2012b).

As discussed in Section 2.1.1 – Acreage and Area of Alfalfa Production, alfalfa hay acreage in the U.S. peaked in the mid-1950s and 60s at approximately 30 million acres, and has slowly declined during the past 40 years to the present level of approximately 17 million acres (USDA-NASS, 2013b). The USDA does not provide projections for future acreage for alfalfa. Alfalfa ranks fourth on the list of most widely grown crops by acreage and in terms of value (USDA-NASS, 2013a; 2013c).

Preferred Alternative: Acreage and Area of Alfalfa Production

The Preferred Alternative is not expected to extend the area of U.S. alfalfa production or cause an increase in overall alfalfa acreage, relative to the No Action Alternative. Monsanto and FGI studies have demonstrated that with the exception of the reduced lignin trait, KK179 alfalfa is phenotypically and agronomically equivalent to other commercially cultivated alfalfa (Monsanto and FGI, 2013). Because there are no changes in growth and development (with the exception of the reduced lignin) or yield, there is no expectation that the introduction of KK179 alfalfa and its use in development of alfalfa varieties will alter the acreage or geographical range of commercial alfalfa cultivation. Thus, the introduction of KK179 alfalfa is not anticipated to facilitate production of alfalfa in areas where it is not currently grown nor to impact total alfalfa production acres.

The Preferred Alternative, a determination of nonregulated status of KK179 alfalfa, is therefore not expected to increase alfalfa production, either by its availability alone or associated with other factors, or result in an increase in overall acreage of alfalfa. Potential impacts would be similar to the No Action Alternative.

4.2.2 Agronomic Practices

No Action Alternative: General Agronomic Practices

Under the No Action Alternative, KK179 alfalfa would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) alfalfa are expected to remain the same under the No Action Alternative. Agronomic practices such as stand planting and removal, crop rotation, tillage, pest and disease management, and other agronomic practices described in section 2.1.2 – Agronomic Practices, are expected to continue as practiced today, with market demand and available technology strongly influencing these practices.

<u>Preferred Alternative: General Agronomic Practices</u>

Similar to the No Action Alternative, a determination of nonregulated status of KK179 alfalfa is unlikely to substantially change current agronomic practices for alfalfa cultivation because, with the exception of the reduced lignin trait, KK179 alfalfa is phenotypically and agronomically comparable to other commercially cultivated alfalfa (Monsanto and FGI, 2013). After assessing market demand or their own farming operation's feed needs, growers will have would have the option to choose KK179 alfalfa for the additional flexibility in the timing of forage harvest already practiced to maximize forage quality and optimize economic returns based on market prices or for an intended on-farm feed use. The potential impacts to general agronomic practices associated with the Preferred Alternative would be the same as the No Action Alternative.

<u>No Action Alternative: Harvest</u>

Under the No Action Alternative, KK179 alfalfa would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) alfalfa are expected to remain the same under the No Action Alternative. Harvest practices would not change as a result of the continued regulated status of KK179 alfalfa.

<u>Preferred Alternative: Harvest</u>

In addition to lower lignin content, KK179 alfalfa will provide growers with production benefits, including: 1) greater flexibility in harvesting schedules, and 2) potentially lower production costs (Monsanto and FGI, 2013). KK179 alfalfa, allows growers the flexibility to choose one of two production strategies to improve the value of alfalfa production on their farm. Either they can: a) maximize forage quality while maintaining yield or b) potentially eliminate a cutting in a growing season, depending on plant growth stage at harvest (Monsanto and FGI, 2013).

After assessing market demand or their own farming operation's feed needs, growers deciding to maximize forage quality would have the flexibility with KK179 alfalfa to harvest forage at the same time as commercially cultivated alfalfa while producing forage with lower lignin levels and comparable annual, cumulative forage yield (Monsanto and FGI, 2013). Growers will have increased flexibility to manage the yield-quality relationship and to meet or exceed the intended quality standard targeted by the grower. Growers will also have greater flexibility to deal with unexpected harvesting delays, such as rain or competing farming priorities.

Alternatively, KK179 alfalfa can give growers the option to eliminate one forage-cutting in a growing season by delaying forage harvest while still maintaining annual, cumulative yield and obtaining lignin levels that are comparable to earlier harvest timings with commercially cultivated alfalfa (Monsanto and FGI, 2013). Growers may opt to delay harvest and still achieve the same quality hay they would expect with an earlier harvest of commercially cultivated alfalfa. With this option, the growers reduce the number of forage cuttings per year while maximizing yield at each individual harvest, thereby maintaining a comparative annual, cumulative yield. The second option may also allow growers to lower production costs by reducing the number of cuttings in a season, thereby saving in labor and equipment costs, and potentially increasing the stand life.

4.2.3 Alfalfa Seed Production

No Acton Alternative: Alfalfa Seed Production

Under the No Action Alternative, KK179 alfalfa and its progeny would continue to be regulated by APHIS under 7 CFR part 340 and the plant pest provisions of the PPA. KK179 alfalfa would not be propagated to any extent by seed producers because there would be no commercial demand for KK179 alfalfa seed. Current availability and usage of commercially cultivated (both GE and non-GE) alfalfa are expected to remain the same under the No Action Alternative. It is also expected that alfalfa seed producers would continue to implement measures to preserve the identity of their seed varieties. Alfalfa seed production practices or locations are not expected to change under the No Action Alternative.

Preferred Alternative: Alfalfa Seed Production

Field trials conducted by Monsanto and FGI have demonstrated that KK179 alfalfa, with the exception of reduced lignin, is not agronomically or phenotypically different from commercially cultivated alfalfa (Monsanto and FGI, 2013). Under the Preferred Alternative seed production would occur within production systems already developed by seed producers for foundation, registered, and certified alfalfa seed. Based on the data provided by Monsanto and FGI for KK179 alfalfa, as well as previous experience with other GE alfalfa varieties, APHIS has concluded that the availability of KK179 alfalfa under the Preferred Alternative would not alter the agronomic practices, cultivation locations, seed production practices or quality characteristics of conventional and non-GE alfalfa seed production (Monsanto and FGI, 2013).

Alfalfa seed producers can and have effectively implemented practices (e.g., isolation distances during the growing season, equipment cleaning during harvest, and post-harvest separation of harvested seed) that allow them to maintain commercially acceptable levels of varietal purity. Because KK179 alfalfa has been shown to be no different from commercial alfalfa relative to pollen morphology and viability, the cultivation of KK179 alfalfa will not impact the ability to implement production practices required for the production of foundation, registered, and certified seed. No change to seed production practices would be required if KK179 alfalfa were no longer regulated. The potential impacts to alfalfa seed production associated with the Preferred Alternative would be the same as the No-action Alternative.

4.2.4 Organic Alfalfa Production

No Action Alternative: Organic Alfalfa Production

It is important to note that the current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche, 2006; USDA-AMS, 2013). However, certain markets or contracts may have defined thresholds (Non-GMO-Project, 2010).

Under the No Action Alternative, KK179 alfalfa would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) alfalfa are expected to remain the same under the No Action Alternative. Organic production practices are expected to remain the same as described in Section 2.2 – Organic Alfalfa Production. Planting and production of GE, non-GE, and organic alfalfa will fluctuate with market demands as it has since the introduction of GE alfalfa in 2005 (USDA-APHIS, 2010).

Preferred Alternative: Organic Alfalfa Production

Approving the petition for nonregulated status of KK179 alfalfa would not change the effects of alfalfa farming on organic resources. KK179 alfalfa and GE alfalfa in general, including those currently grown commercially, are not allowed for use in organic production systems because they were developed through the use of excluded methods as defined by the NOP program standards (7 CFR part 205.2). With the exception of its reduced lignin content, KK179 alfalfa has been shown to be no different from non-GE alfalfa in its agronomic and ecological characteristics including pollen diameter, viability and morphology (Monsanto and FGI, 2013). Thus, KK179 alfalfa is expected to be no different from currently available alfalfa varieties in its ability to cross pollinate with other alfalfa and, therefore, no additional means beyond those already used to produce GE and organic alfalfa will be needed if KK179 alfalfa is grown commercially. In addition, KK179 alfalfa is not different from non-GE alfalfa in terms of seed dormancy and germination, and weediness, and would therefore be no different than non-GE alfalfa in its potential for volunteers and feral populations (Monsanto and FGI, 2013). Since the production practices do not change under the preferred alternative, when compared to the No Action Alternative, there would be no changes in the direct or indirect effects on organic alfalfa production.

4.3 Physical Environment

4.3.1 Water Resources

No Action Alternative: Water Resources

Alfalfa is considered to naturally be drought tolerant, because of its deep taproot allowing it to use up to 70 percent of available soil water without stress or loss of production. Even though it is highly efficient at utilizing the available soil moisture, alfalfa has a high water requirement in excess of 40 inches of water during the season (Kansas State University, 1998).

Under the No Action Alternative, water resources associated with alfalfa production would not be expected to change. Current availability and usage of commercially cultivated (both GE and non-GE) alfalfa are expected to remain the same under the No Action Alternative. Existing water use and water quality conditions would be expected to continue.

Preferred Alternative: Water Resources

Under the Preferred Alternative, no substantial impact to water resources is anticipated from a determination of nonregulated status of KK179 alfalfa.

As discussed in Section 4.2 – Agricultural Production of Alfalfa, KK179 alfalfa would not change cultivation practices for alfalfa production, nor would it be expected to affect the total acres and range of U.S. alfalfa production areas. KK179 alfalfa has been shown to be compositionally, agronomically and phenotypically equivalent to commercially cultivated alfalfa (Monsanto and FGI, 2013). Based on these considerations, APHIS has concluded that the potential impacts to water resources are expected to be the same under the Preferred Alternative as under the No Action Alternative.

4.3.2 Soil Quality

No Action Alternative: Soil Quality

Under the No Action Alternative, KK179 alfalfa would continue to be regulated by APHIS and current alfalfa management practices would be expected to continue. Current availability and usage of commercially cultivated (both GE and non-GE) alfalfa are expected to remain the same under the No Action Alternative. Impacts on soil quality are not expected to change.

Preferred Alternative: Soil Quality

Soil quality in U.S. alfalfa fields is unlikely to be substantially affected under the Preferred Alternative. KK179 alfalfa has been found to be compositionally, agronomically and phenotypically equivalent to commercially cultivated alfalfa (Monsanto and FGI, 2013). Therefore, microbial populations and associated biochemical processes in soil are not expected to change with the introduction of KK179 alfalfa. Field studies have shown that KK179 alfalfa is no different from commercially cultivated alfalfa in terms of response to abiotic stress (such as compaction, drought, high winds, nutritional deficiency, etc.), disease damage, arthropod-related damage and pest and beneficial arthropod abundance (Monsanto and FGI, 2013). The donor organism of the inserted CCOMT gene is alfalfa itself. Based on these data, the cultivation of KK179 alfalfa is not expected to impact microbial populations and associated biochemical processes in soil. Based on these considerations, APHIS has concluded there would be no changes in the direct or indirect effects on soil quality from the Preferred Alternative.

4.3.3 Air Quality

No Action: Air Quality

All agricultural practices have the potential to cause negative impacts to air quality. Agricultural emission sources include smoke from agricultural burning, tillage, heavy equipment emissions, pesticide drift from spraying, and indirect emissions from carbon dioxide and nitrous oxide emissions from the use of nitrogen fertilizer and degradation of organic materials (USDA-NRCS, 2006; Aneja *et al.*, 2009; US-EPA, 2013a).

Under the No Action Alternative, current agricultural practices associated with commercially cultivated alfalfa (both GE and non-GE) are expected to remain the same under the No Action Alternative. Therefore, air quality effects from agriculture, including alfalfa production, are expected to continue as described in Section 2.3.3 of this EA.

Preferred Alternative: Air Quality

Under the Preferred Alternative, a determination of nonregulated status of KK179 alfalfa is unlikely to substantially impact air quality compared to the No Action Alternative.

Agricultural practices that may affect air quality are not expected to change substantially with the introduction of KK179 alfalfa. KK179 alfalfa is similar in agronomic performance and likely requires similar cultivation practices as currently-cultivated alfalfa varieties, and is not likely to change land acreage or any cultivation practices for alfalfa production. The delayed harvesting opportunity associated with KK179 alfalfa could result in reduced cuttings (potentially one fewer cutting per year for most areas), which would result in a small, local positive effect on air quality from reduced vehicle emissions. It is expected that similar agronomic practices (with the exception of the potential for delayed harvesting) commonly utilized in commercially available alfalfa varieties would also be used by growers of KK179 alfalfa. Based on this information, APHIS concludes that the cultivation of KK179 alfalfa is not expected to adversely impact air quality.

4.3.4 Climate Change

No Action Alternative: Climate Change

Agriculture, including land-use changes associated with farming, is responsible for an estimated 6.9 percent of all human-induced GHG emissions in the United States (US-EPA, 2013a). Agriculture-related GHG emissions include CO_2, N_2O, and CH_4, produced through the combustion of fossil fuels to run farm equipment; the use of fertilizers; or the decomposition of agricultural waste products, including crop residues, animal wastes, and enteric emissions from livestock.

Under the No Action Alternative, KK179 alfalfa would continue to be regulated by APHIS. Current impacts on climate change associated with alfalfa production would not be affected. Agronomic practices associated with alfalfa production (both GE and non-GE) such as tillage, cultivation, irrigation, pesticide application, fertilizer applications and use of agriculture equipment would continue throughout the growing area. Impacts of agriculture on climate change are expected to continue.

Preferred Alternative: Climate Change

As described in Section 4.2.1, the range and area of U.S. alfalfa production is not likely to expand under the Preferred Alternative. Agricultural practices that may affect climate change are not expected to change substantially with the introduction of KK179 alfalfa. As described in the Monsanto and FGI petition (Bayer, 2011; Monsanto and FGI, 2013) the delayed harvesting opportunity associated with KK179 alfalfa could result in reduced cuttings (perhaps one fewer cutting per year for most areas), which would result in a small reduction in vehicle-related greenhouse gas emissions. Collectively, because the range, area, and agronomic practices of alfalfa are unlikely to change following a determination of nonregulated status of KK179 alfalfa, the agricultural impacts of alfalfa cultivation are also unlikely to change under the Preferred Alternative.

While agricultural activities may affect climate change, the converse is also true; climate change may affect agriculture. For example, climate change may result in shifts of herbivorous insects to higher latitudes. There is evidence that insect diversity and vegetative consumption intensity increase with increasing temperature at the same latitude in the fossil record (Bale *et al.*, 2002). How climate change will affect individual species of pest insects will depend on their physiology, feeding behavior, and overwintering strategies (Bale *et al.*, 2002). In cases where climate change favors the expansion of the range of alfalfa pests, additional alfalfa acres may be treated with insecticides. KK179 alfalfa is not any more susceptible to insect herbivory than conventional alfalfa varieties (USDA-APHIS, 2013), so change in insect pressure resulting from climate change is likely to impact KK179 alfalfa just as it would conventional alfalfa.

4.4 Biological Resources

4.4.1 Animal Communities

No Action Alternative: Animal Communities

Alfalfa production fields may be host to many animal and insect species. As described in Section 2.4.1 – Animal Communities, mammals and birds may use alfalfa fields and the surrounding vegetation for food and habitat throughout the year. Invertebrates can feed on alfalfa plants or prey upon other insects living on alfalfa plants as well as in the vegetation surrounding alfalfa fields.

Under the No Action Alternative, conventional alfalfa production would continue while KK179 alfalfa remains a regulated article. Potential impacts to animal communities associated with alfalfa cultivation are not expected to change in the No-Action Alternative.

Preferred Alternative: Animal Communities

Under the Preferred Alternative, potential impacts to animal communities are not anticipated to be substantially different compared to the No Action Alternative. Potential impacts to animal communities arise from any changes in agronomic inputs associated with the crop modification and direct exposure to the GE crop and its products.

As described in Section 4.2, Monsanto and FGI have presented the results of field trials which demonstrate that KK179 alfalfa does not require any changes to agronomic inputs when compared with conventional alfalfa (Monsanto and FGI, 2013). Land use and agricultural production of alfalfa under the Preferred Alternative is likely to continue as currently practiced. Consequently, any impact to animal communities as a result of alfalfa production practices under the Preferred Alternative is likely to be similar to the No Action Alternative.

KK179 alfalfa has been shown to be compositionally, agronomically and phenotypically equivalent to commercially cultivated alfalfa (Monsanto and FGI, 2013). The CCOMT suppression cassette encodes for dsRNA specific to a lignin biosynthetic pathway enzyme. Double stranded RNAs are composed of nucleic acids and are commonly found in eukaryotes, including plants, for endogenous gene suppression. Nucleic acids have a long history of safe consumption and are considered "Generally Recognized as Safe" (GRAS) by the U.S. FDA under its regulations at 21 CFR part 170, as there is no evidence to suggest dietary consumption of RNA is associated with mammalian toxicity or allergenicity. Additionally, compositional analysis of KK179 alfalfa has shown that forage from KK179 alfalfa is compositionally equivalent, with the exception of the intended reduction in lignin, to that of conventional alfalfa at the same stage of growth (Monsanto and FGI, 2013). Therefore, the Preferred Alternative is unlikely to differ from the No Action Alternative in its impact on animal communities.

4.4.2 Plant Communities

No Action Alternative: Plant Communities

Plant communities within agroecosystems are generally less diverse than the plant communities that border crop fields. The plant communities that inhabit crop production fields are represented by plants (including weeds) that are able to adapt and thrive in an environment that is directed specifically to the production of crops, such as alfalfa. In crop production systems, the plant community is controlled using a number of tactics to maximize the production of food, fiber, and fuel; however, herbicides are the most common and accepted tactic to manage plant communities within agroecosystems (Gianessi and Reigner, 2007).

Under the No Action Alternative, conventional alfalfa production would continue while KK179 alfalfa remains a regulated article. Potential impacts to plant communities associated with alfalfa cultivation are not expected to change in the No Action Alternative.

Preferred Alternative: Plant Communities

Under the Preferred Alternative, potential impacts to plant communities are not anticipated to be different compared to the No Action Alternative.

KK179 alfalfa has been shown to be compositionally, agronomically and phenotypically equivalent to commercially cultivated alfalfa (Monsanto and FGI, 2013). Growers are already managing alfalfa to control for competing plant life and surrounding areas that could provide pest and disease reservoirs using treatments and controls. There would be no change in herbicide use or patterns. Potential impacts related to gene flow and weediness are discussed below in Section 4.4.3.

Land use and agricultural production of alfalfa under the Preferred Alternative is likely to continue as currently practiced. Consequently, any impact to plant communities as a result of alfalfa production practices under the Preferred Alternative is the same as the No Action Alternative.

4.4.3 Gene Flow and Weediness

No Action Alternative: Gene Flow and Weediness

Under the No Action Alternative, KK179 alfalfa would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) alfalfa are expected to remain the same under the No Action Alternative.

As discussed in detail in Section 2.4.3, gene flow between seed production and other potential receptors (other seed production fields, hay fields and feral populations) is limited to negligible levels by seed production regulations and practices. Seed production regulations and practices also limit the potential for mixing of seeds.

As discussed in Section 2.4.3. – Gene Flow and Weediness, gene flow between alfalfa fields grown for forage production and other potential receptors is limited. Approximately 99.4 percent of the alfalfa planted in the U.S. is cultivated for forage production (USDA-NASS, 2009). The most common occurring forage field interface is hay field-to-hay field, however, pollen-mediated gene flow is highly improbable between adjacent hay fields (Putnam, 2006; Van Deynze *et al.*, 2008). The primary reasons for limited gene flow from a forage field are: 1) forage harvest takes place at vegetative to early bloom stages when little to no pollen is produced and few flowers are present; 2) alfalfa is strictly an insect-pollinated (certain bee species) crop, where natural pollinators [Bumble bees (*Bombus* spp.)] of the optimal type typically are not present and are solitary bees with limited foraging range (conversely, cultured bees are typically introduced in seed production fields); 3) forage biomass that may contain flowers is removed on a regular basis with each cutting, which further prevents seed setting (Sheaffer *et al.*, 1988); and 4) the competition and natural autotoxicity of alfalfa prevents new seedlings resulting from rare outcrossing events to successfully grow within established stands (Canevari and Putnam, 2008). Thus, forage production practices significantly lower the risk of pollen-mediated gene flow between hay production fields and outside populations (Van Deynze *et al.*, 2008).

As discussed in Section 2.4.3 of this EA, gene flow with other *Medicago* species is not a concern, and alfalfa (*Medicago sativa* L.), while naturalized, is not considered a weed.

Under the No Action Alternative, conventional alfalfa varieties, including GE alfalfa varieties no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act, will continue to be grown commercially while KK179 alfalfa will remain a regulated article. Alfalfa cultivation practices are expected to remain the same. Gene flow from current commercially available GE cultivars to non-GE alfalfa cultivars is expected to remain unchanged from the current conditions.

<u>Preferred Alternative: Gene Flow and Weediness</u>

Gene Flow and Weediness Potential Resulting From Plant Characteristics

Gene flow could be affected by changes in pollen or flower characteristics, or timing of flowering. The results from the phenotypic and agronomic evaluations support a conclusion that KK179 alfalfa, compared to its conventional control variety, 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 (Monsanto and FGI, 2013; USDA-APHIS, 2013). Thus, under the Preferred Alternative, the likelihood of gene flow from KK179 alfalfa to other alfalfa varieties is not substantially different than between current alfalfa varieties.

Weediness potential could be affected if seed dormancy and germination characteristics change. Monsanto and FGI have presented data from field trials showing seed dormancy and germination characterization indicating that KK179 alfalfa seed had no changes in the dormancy or germination characteristics that could be indicative of increased plant weediness or pest potential compared to the conventional alfalfa control (Monsanto and FGI, 2013). There were statistically significant differences in the germination and hard seed assessments of KK179 alfalfa non-scarified seed, with KK179 alfalfa having higher percent germinated seed and lower percent hard seed (Monsanto and FGI, 2013). When the industry-accepted standard of scarification was applied to the seed coat, KK179 alfalfa germination was higher than the control, but comparable to the range of commercially cultivated alfalfa (Monsanto and FGI, 2013). After scarification, hard seed for KK179 alfalfa was not different than the control and commercially cultivated alfalfa. Therefore, the noted differences for KK179 alfalfa are unlikely to be biologically meaningful in terms of altered weediness potential for producing volunteers and feral populations (USDA-APHIS, 2013). Collectively, these findings support the conclusion that KK179 alfalfa is no more likely to be a weed compared to conventional alfalfa (USDA-APHIS, 2013).

Except for the reduced lignin trait, KK179 alfalfa is phenotypically and agronomically equivalent to commercially cultivated alfalfa (Monsanto and FGI, 2013). KK179 alfalfa has no increased potential compared to commercially cultivated alfalfa to outcross or hybridize with cultivated alfalfa under hay production or seed production conditions, or with feral alfalfa. Monsanto and FGI are not aware of any means or mechanism by which a reduced lignin trait could confer a competitive advantage to other alfalfa populations (Monsanto and FGI, 2013). Therefore, absent an unidentified selection pressure, the KK179 trait would not be expected to confer a competitive advantage in feral alfalfa populations through outcrossing.

Potential Impacts Resulting From Delayed Harvest

With KK179 alfalfa, growers will have the flexibility to delay harvest and retain quality comparable to commercially cultivated alfalfa harvested at an earlier growth stage. In those areas of the U.S. where the 0.6 percent of seed production acreage is in sufficiently close proximity to the 99.4 percent acreage dedicated to forage production, the forage production practice of harvesting a hay field at or before 10 percent bloom during the seed production field's pollination period will be sufficiently conservative to ensure that pollen-mediated gene flow from a hay production field into a seed production field is low to near zero. This practice is already a grower's trait stewardship requirement under terms of the Monsanto/FGI technology stewardship agreement (MTSA) for forage growers purchasing glyphosate-resistant alfalfa seed (Monsanto Company, 2013). Since KK179 alfalfa will be combined with Roundup Ready alfalfa utilizing traditional breeding techniques (Monsanto and FGI, 2013) this practice will be maintained as a requirement for forage growers purchasing KK179 alfalfa. In an instance where KK179 alfalfa is allowed to develop past the 10 percent bloom stage before cutting forage, research has shown that harvesting at stages of 20 to 50 percent bloom does not significantly raise the potential gene flow to neighboring seed production fields thus the risk remains very low (Teuber and Fitzpatrick, 2007). Agronomic factors (increasing accumulation of lignin, reduction in crude protein levels and a corresponding rise in ADF levels contribute to declining forage quality and the resulting decline in leaf to stem ratio) impose heavy penalties in terms of forage quality to make it agronomically unfavorable for alfalfa forage to be allowed to mature past the 10 percent bloom stage and do not offer yield advantages past a certain point (Orloff and Putnam, 2008; Putnam *et al.*, 2008b), thus there is no expectation of changes in recommendations to harvest forage before or by 10 percent bloom.

This research and other detailed analyses of gene flow are discussed by APHIS (USDA-APHIS, 2010) in Appendix V, which is incorporated by reference into this EA. As discussed in Sections 2.1.3 – Alfalfa Seed Production and 2.4.3 – Gene Flow and Weediness, seed production, which represents about 0.6 percent of alfalfa acres, occurs in highly concentrated areas in irrigated regions in the West (USDA-NASS, 2009; USDA-APHIS, 2010). Many factors must be controlled by seed producers to meet the requirements for certified seed, including, but not limited to, isolation distances from all sources of alfalfa (Brown *et al.*, 1986; Van Deynze *et al.*, 2008; Dunkle, 2011; Kalaitzandonakes, 2011).

KK179 alfalfa would not be expected to have impacts on gene flow and weediness any different than other commercially available alfalfa. Based on these findings, APHIS has determined the Preferred Alternative, approval of a petition for nonregulated status of KK179 alfalfa, does not impact gene flow or weediness.

4.4.4 Microorganisms

No Action Alternative: Microorganisms

The soil microbial community is an integral ecosystem component that may provide and sustain critical ecological processes. Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva *et al.*, 2004). They also suppress soil-borne plant diseases and promote plant growth (Doran *et al.*, 1996).

Alfalfa interacts with soil microorganisms, including its symbiotic relationship with the nitrogen-fixing bacterium *Sinorhizoium meliloti*. As a result of this interaction, atmospheric nitrogen is converted to produce available nitrogen, such that alfalfa affects soil tilth, fertility and structure, making alfalfa a valued rotational crop in agriculture.

Under the No Action Alternative, KK179 alfalfa would continue to be regulated by APHIS. As discussed in Subsection 4.2.2 – Agronomic Practices, alfalfa cultivation practices are expected to remain as currently practiced. Growers will continue to have access to commercially cultivated (both GE and non-GE) alfalfa. Impacts to microorganisms are not likely to change under the No Action Alternative.

Preferred Alternative: Microorganisms

Under the Preferred Alternative, soil microorganisms are unlikely to be substantially affected by approval of a petition for nonregulated status of KK179 alfalfa compared to the No Action Alternative. The main factors influencing soil microbial populations include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva *et al.*, 2004).

As discussed in Section 4.2.2 – Agronomic Practices, Monsanto and FGI has presented the results of field trials which demonstrate that KK179 alfalfa does not require any changes to agronomic practices, other than providing flexibility in timing of the forage harvest, when compared with conventional alfalfa(Monsanto and FGI, 2013). No adverse effects on soil microorganisms are associated with KK179 alfalfa or its cultivation.

Because the agronomic practices of alfalfa are unlikely to change following a determination of nonregulated status of KK1479 alfalfa, the impacts of alfalfa cultivation on microorganisms are also unlikely to change under the Preferred Alternative.

4.4.5 Biodiversity

No Action Alternative: Biodiversity

Biological diversity, or the variation in species or life forms in an area, is highly managed in agricultural systems. Farmers typically plant crops that are genetically adapted to grow well in a specific area of cultivation and have been bred for a specific market. In conventional agriculture, farmers want to encourage high yields from their crop, and will intensively manage plant and animal communities through chemical and cultural controls to protect the crop from damage. Therefore, the biological diversity in agricultural systems (the agro-ecosystem) is highly managed and may be lower than in the surrounding habitats.

Under the No Action Alternative, KK179 alfalfa would continue to be a regulated article. Growers and other parties who are involved in production, handling, processing, or consumption of alfalfa would continue to have access to conventional alfalfa varieties, including GE alfalfa varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Agronomic practices associated with conventional alfalfa production such as cultivation, irrigation, pesticide application, fertilizer applications and agriculture equipment would continue unchanged. Animal and plant species that typically inhabit alfalfa fields will continue to be affected by currently utilized management plans and systems, which include the use of mechanical, cultural, and chemical control methods. The consequences of current agronomic practices associated with alfalfa production, both traditional and GE varieties, on the biodiversity of plant and animal communities is unlikely to be altered.

Impacts to biodiversity associated with agronomic practices in cultivating alfalfa are not expected to change under the No Action Alternative.

Preferred Alternative: Biodiversity

As discussed in Section 4.2 – Agricultural Production of Alfalfa, except for the reduced lignin trait, KK179 alfalfa is phenotypically and agronomically the same as commercially cultivated alfalfa. Therefore, KK179 alfalfa would not be expected to impact biodiversity any differently than other commercially available alfalfa.

As noted in Subsection 4.4.1 – Animal Communities, Monsanto and FGI have presented compositional data comparing the phenotypic, morphological and compositional characteristics of KK179 alfalfa with other varieties, including bioinformatics analysis of allergenicity, toxicity, nutrients and anti-nutrients, and amino acid homology, among others (Monsanto and FGI, 2013). KK179 alfalfa is compositionally equivalent, with the exception of the intended reduction in lignin, to that of conventional alfalfa at the same stage of growth.

Based on these findings, APHIS has determined that approval of a petition for nonregulated status of KK179 alfalfa will have the same impact on biodiversity as the No Action alternative.

4.5 Human Health

No Action Alternative: Human Health

Under the No Action Alternative, KK179 alfalfa would continue to be regulated by APHIS. Current availability and usage of commercially cultivated (both GE and non-GE) alfalfa are expected to remain the same under the No Action Alternative. Human exposure to alfalfa products does not change from the current status. This exposure includes exposure to incorporated genes and expressed proteins in different alfalfa varieties as well as exposure to herbicides used on alfalfa. These management practices, and the associated human health effects, are not likely to change under the No Action Alternative.

As discussed in Section 2.5 – Human Health, agriculture, including alfalfa farming, is a relatively high-hazard industry, with machinery-related injuries being the primary hazard. A common agricultural practice, pesticide application, represents the primary exposure route to pesticides for farm workers. Pesticides are commonly used on alfalfa acreage in the United States (Monsanto and FGI, 2013). Worker safety is taken into consideration by EPA in the pesticide registration process and reregistration process. When use is consistent with the label, pesticides present minimal risk to the worker. No changes to current worker safety are anticipated under the No Action Alternative.

Human exposure to alfalfa crops and products, and the agronomic inputs associated with their production, are not expected to change from the current condition under the No Action Alternative.

Preferred Alternative: Human Health

Under the Preferred Alternative, consumers would be exposed to food products derived only indirectly from KK179 alfalfa. As noted in the Monsanto and FGI petition, KK179 alfalfa would be used only for forage production and not for alfalfa products intended for direct human assumption (Monsanto and FGI, 2013). Consumers would be indirectly exposed to KK179 alfalfa through consumption of honey produced by bees that have foraged on KK179 alfalfa commercial seed production and forage production fields.

KK179 alfalfa was developed through *Agrobacterium*-mediated transformation of alfalfa tissue. KK179 alfalfa contains the CCOMT suppression cassette which encodes for the production of dsRNA. Double stranded RNAs are composed of nucleic acids and are commonly found in eukaryotes, including plants, for endogenous gene suppression. Nucleic acids have a long history of safe consumption and are considered “Generally Recognized as Safe” (GRAS) by the U.S. FDA under its regulations at 21 CFR part 170. There is no evidence to suggest dietary consumption of RNA is associated with mammalian toxicity or allergenicity. Therefore, based on the ubiquitous nature of the RNA-based suppression mechanism using dsRNA, demonstration of mode of action through CCOMT RNA suppression, the history of safe consumption of RNA and the apparent lack of toxicity or allergenicity of dietary RNA, the RNA-based suppression technology used in KK179 alfalfa poses no novel risks from a feed or food perspective (Monsanto and FGI, 2013; USDA-APHIS, 2013).

A comparison of KK179 alfalfa with conventional alfalfa varieties reveals compositional equivalence. Detailed compositional analyses of proximates (ash, fat, moisture, and protein), carbohydrates by calculation, ADF, NDF, ADL, minerals (Ca, Cu, Fe, Mg, Mn, P, K, Na, and Zn), amino acids (essential and non-essential), anti-nutrients (daidzein, glycitein, genistein, coumesterol, formononetin, biochanin A, and seven saponins) and secondary metabolites (canavanine, p-coumaric acid, ferulic acid, sinapic acid, total polyphenols, and free phenylalanine) in forage derived from KK179 alfalfa demonstrated that with the exception of the intended changes in lignin, KK179 alfalfa is not compositionally different from currently available alfalfa varieties (Monsanto and FGI, 2013; USDA-APHIS, 2013).

Feed derived from GE alfalfa must be in compliance with all applicable legal and regulatory requirements. GE organisms for feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Monsanto and FGI indicated that they submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa to FDA in August 2012, identified under BNF No. 138 (Monsanto and FGI, 2013). The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014).

Based on these findings, APHIS has determined that approval of a petition for nonregulated status of KK179 alfalfa will have the same impact human health as the No Action alternative.

4.6 Animal Feed

No Action Alternative: Animal Feed

The majority of the alfalfa cultivated in the U.S. is grown for animal feed. Under the No Action Alternative, alfalfa forage will still be available from currently cultivated conventional varieties (Both GE and non-GE). Exposure to existing commercially cultivated alfalfa forage used for animal feed would remain unchanged under the No Action Alternative.

Preferred Alternative: Animal Feed

APHIS' assessment of the impacts to animal feed from KK179 alfalfa is directly applicable to consumption of products derived from KK179 alfalfa and used for animal feed, since animals directly consume alfalfa forage.

Under FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from KK179 alfalfa must be in compliance with all applicable legal and regulatory requirements. GE organisms for feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Monsanto and FGI indicated that they submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa to FDA in August 2012, identified under BNF No. 138 (Monsanto and FGI, 2013). The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014).

Compositional analysis revealed no substantial differences between KK179 alfalfa and conventional alfalfa in factors important for animal feed, such as proximate and fiber components, amino acid and fatty acid content, and antinutrients and isoflavone concentrations (Monsanto and FGI, 2013). Consequently, the quality of animal feed derived from KK179 alfalfa is unlikely to be substantially different than animal feed produced from current alfalfa varieties.

In the case where growers harvest in the same time frame as used for existing commercially cultivated alfalfa to produce animal feed of higher quality due to the reduced lignin, the resulting hay would still be graded within the existing USDA- AMS feed grading system of supreme to utility quality (USDA-APHIS, 2010), but the yield of the targeted higher quality hay would potentially be greater with KK179 alfalfa. Conversely, for growers that choose to delay harvest of KK179 alfalfa, the resulting hay will be of similar feed quality to existing alfalfa varieties harvested at an earlier growth stage. Therefore, KK179 alfalfa will provide growers with flexibility in forage harvests to better manage the yield-quality relationship and harvesting schedules to meet market needs and intended on-farm uses for animal feed.

Based on these findings, approval of a petition for nonregulated status of KK179 alfalfa will have the same impact animal feed as the No Action alternative.

4.7 Socioeconomic Impacts

Alfalfa agriculture can affect socioeconomic resources such as the domestic economy, international trade economy, and the social environment. This section describes key current issues within each of these topics.

4.7.1 Domestic Economic Environment

No Action Alternative: Domestic Economic Environment

Approximately 17 to 23.5 million acres of alfalfa hay have been harvested annually over the past 10 years (USDA-NASS, 2013b; 2013d). Approximately 2.3 to 3.3 million acres (13-14 percent of the harvested acres) are seeded annually for new alfalfa stands (USDA-NASS, 2013b). In 2012, about 52 million tons of alfalfa were harvested from approximately 17 million acres, with an estimated value of $10.4 billion USD (due to most alfalfa being fed to livestock on-farm, the value is an estimate based on multiplying average prices with production volumes and does not correspond to actual sales) (USDA-NASS, 2013b; 2013d). The majority of alfalfa hay is consumed on the farm where it is produced, and dairy farms are by far the main consumer (USDA-APHIS, 2010). The quality of alfalfa hay is determined by the presence of weeds, fiber content, protein content, and other factors such as color and mold presence (USDA-APHIS, 2010).

Under the No Action Alternative, KK179 alfalfa would continue to be regulated by APHIS. Growers and other parties who are involved in production, handling, processing, or consumption of alfalfa would not have access to KK179 alfalfa and its progeny, but would continue to have access to conventional alfalfa varieties, including GE alfalfa varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Alfalfa production and use would be expected to continue much as it is currently, with the majority of the crop used on the farm where it is grown.

Impacts to the domestic economic environment associated with the cultivation of alfalfa are not expected to change under the No Action Alternative.

Preferred Alternative: Domestic Economic Environment

A determination of nonregulated status of KK179 alfalfa is not expected to adversely impact domestic commerce. The availability of KK179 alfalfa would be unlikely to influence the number of acres of alfalfa planted. Adopters of KK179 alfalfa may realize savings as a result of a delayed harvest schedule and longer harvest intervals over the life of the stand. A delayed harvest schedule likely will lead to one less forage harvest per year (i.e., in the North Central region three compared to four cuttings) (Monsanto and FGI, 2013). The elimination of one cutting could result in a reduction in overall harvesting costs. The overall KK179 alfalfa forage yield for the year or season is expected to be comparable to existing commercial alfalfa varieties, even with fewer cuttings, because of the longer harvest intervals and potentially higher forage yields with each cutting. Fewer harvests also means fewer trips across the field that result in less labor, fuel consumption and soil compaction, plus potentially less crown damage to alfalfa plants in established stands. In addition, longer harvest intervals have been shown to extend the life of the alfalfa stand because the plants have a longer period of time to replenish carbohydrate root reserves (Orloff and Putnam, 2008). Therefore, the Preferred Alternative has the potential for positive economic impacts for growers, compared to the No Action Alternative.

In 2011, organic alfalfa in was grown in 30 states and 231,318 acres were harvested producing 747,555 tons, compared to approximately 19.2 million harvested acres of conventionally produced alfalfa (USDA-NASS, 2013a). In 2011, organic alfalfa production consisted of about 1.2 percent of total U.S. alfalfa production and was valued at approximately $69.5 million, capturing roughly 0.64 percent of the overall alfalfa crop value for that year (USDA-NASS, 2012a; 2013c). KK179 alfalfa could pose comparable environmental consequences to the organic alfalfa industry as commercially available glyphosate-resistant alfalfa including additional testing, and additional production and stewardship costs to avoid unintended presence of KK179 alfalfa.

4.7.2 Trade Economic Environment

No Action Alternative: Trade Economic Environment

In 2011, the U.S. exported approximately $445 million in alfalfa hay, cubes, and meal and $106 million in alfalfa seed (USDA-FAS, 2012). Four primary export markets which include, Japan, China, South Korea, and Taiwan, together accounted for two-thirds of the $401 million in alfalfa hay exports (USDA-FAS, 2012).

Under the No Action Alternative, KK179 alfalfa would continue to be regulated by APHIS. There is unlikely to be any change to the current alfalfa market. Current availability and usage of commercially cultivated (both GE and non-GE) alfalfa are expected to remain the same under the No Action Alternative. East Asia is likely to continue as a major export destination for alfalfa products.

Preferred Alternative: Trade Economic Environment

A determination of nonregulated status of KK179 alfalfa is not expected to adversely impact international alfalfa markets. To support commercial introduction of KK179 alfalfa in the U.S., Monsanto and FGI will seek biotechnology regulatory approvals for KK179 alfalfa in all key alfalfa import countries with a functioning regulatory system to assure global compliance and support the flow of international trade (Monsanto and FGI, 2013). Monsanto and FGI will continue to monitor other countries that are key importers of alfalfa from the U.S., for the development of formal biotechnology approval processes. If new functioning regulatory processes are developed, Monsanto and FGI will make appropriate and timely regulatory submissions (Monsanto and FGI, 2013). Approval in these export countries is intended to mitigate global sensitivities to GE productions and work in accordance with international regulations. The trade economic impacts associated with a determination of nonregulated status of KK179 alfalfa are anticipated to be similar to the No Action Alternative.

5 CUMULATIVE IMPACTS

A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. For example, this may include the potential effects associated with a determination of nonregulated status for a GE crop in combination with the future production of crop seeds with multiple deregulated traits (i.e., “stacked” traits), including drought tolerance, herbicide resistance, and pest resistance, would be considered a cumulative impact.

5.1 Assumptions Used for Cumulative Impacts Analysis

Cumulative effects have been analyzed for each environmental issue assessed in Section 4, Environmental Consequences. The cumulative effects analysis is focused on the incremental impacts of the Preferred Alternative taken in consideration with related activities including past, present, and reasonably foreseeable future actions. In this analysis, if there are no direct or indirect impacts identified for a resource area, then APHIS assumes there can be no cumulative impacts. Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential cumulative impacts.

Crop varieties that contain more than one GE trait, known as a “stacked” hybrid, are currently found in agricultural production and in the marketplace. If APHIS approves the petition for nonregulated status for KK179 alfalfa, Monsanto and FGI indicated in their petition that it would likely be combined with glyphosate-resistant alfalfa varieties through traditional breeding techniques (Monsanto and FGI, 2013), including the glyphosate –resistant alfalfa assessed by APHIS in the 2010 FEIS (USDA-APHIS, 2010) and subsequently determined to be nonregulated. Stacking of nonregulated GE crop varieties using traditional breeding techniques is common practice and is not regulated by APHIS. Stacking would involve combining KK179 alfalfa with glyphosate-resistant alfalfa, which is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act when there is no evidence of a plant pest risk.

APHIS considered the potential for KK179 alfalfa to extend the range of alfalfa production and affect the conversion of land to agricultural purposes. Monsanto and FGI’s studies demonstrate that KK179 alfalfa is similar in its growth habit, agronomic properties, disease susceptibility to other commercially cultivated (both GE and non-GE) alfalfa (Monsanto and FGI, 2013). This implies that its cultural requirements would neither differ from those of other alfalfa nor change the areas in which alfalfa is currently cultivated. Land use changes associated with approving the petition for nonregulated status for KK179 alfalfa are not expected to be any different than those associated with the cultivation of other alfalfa cultivars.

Potential reasonably foreseeable cumulative effects are analyzed under the assumption that growers have used in the past and would continue to use reasonable, commonly accepted best management practices (BMPs) for their chosen system and varieties during alfalfa production. APHIS recognizes, however, that not all growers will use such BMPs.

Thus, this circumstance was also considered in the cumulative impacts analysis. APHIS assumes growers of KK179 alfalfa will adhere to the EPA-registered uses and EPA-approved labels for all pesticides applied to alfalfa.

5.2 Cumulative Impacts: Agricultural Production of Alfalfa

Neither the No Action nor the Preferred Alternative, including stacking KK179 alfalfa with non-regulated glyphosate-resistant alfalfa are expected to directly cause a measurable change in agricultural acreage or area devoted to alfalfa in the U.S. (see Subsection 4.2.1, Acreage and Area of Alfalfa Production). Because KK179 alfalfa is another alfalfa variety that is agronomically and compositionally similar to other commercially available alfalfa varieties (GE and non-GE), it is expected KK179 alfalfa will replace other similar varieties without expanding the acreage or area of alfalfa production. APHIS determined that glyphosate-resistant alfalfa would not negatively impact land use, since established seed and forage production practices in current U.S. production regions would continue to be used by growers (USDA-APHIS, 2010). There are also no anticipated changes to the availability of GE or non-GE alfalfa varieties on the market. The Preferred Alternative, therefore, would have no impacts to acreage or area of alfalfa production different than the No Action Alternative.

As described in Sections 2.2 and 4.2.4 – Organic Alfalfa Production, organic growers use common practices to maintain the organic status of their alfalfa including employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields. APHIS determined that organic production could be negatively impacted by glyphosate-resistant alfalfa to the extent that: 1) demand (sales) would decrease due to the potential adventitious presence (AP) of GE alfalfa in organic alfalfa, and 2) organic practices and GE alfalfa stewardship practices are insufficient to minimize AP in organic alfalfa. Subsequently, organic alfalfa production costs could increase and returns decrease due to avoidance costs and loss in production (USDA-APHIS, 2010). Availability of another alfalfa variety, such as KK179 alfalfa, under the Preferred Alternative, is not expected to impact the organic production of alfalfa any differently than other alfalfa varieties (GE and non-GE) currently being grown.

As described in Sections 2.1.3 and 4.2.3 – Alfalfa Seed Production, alfalfa seed growers use stewardship measures based on NAFA, AOSCA, and NOP standards to maintain the genetic purity of their alfalfa seed. These can include employing adequate isolation distances between the seed fields and hay fields of neighbors to minimize the chance that pollen will be carried between the fields. APHIS determined that seed production practices associated with glyphosate-resistant alfalfa would not affect seed purity standards established for the production of foundation, registered and certified seed; and seed production would continue to be localized in Western U.S. regions (USDA-APHIS, 2010). Furthermore, APHIS concluded that during seed production, gene-flow, between glyphosate-resistant and non-glyphosate resistant alfalfa, including organic alfalfa, has the potential to occur and that stewardship measures based on NAFA, AOSCA, and NOP standards are important safeguards to minimizing AP from GE alfalfa seed production fields (USDA-APHIS, 2010). Availability of another alfalfa variety, such as KK179 alfalfa, under the Preferred Alternative, is not expected to impact alfalfa seed production any differently than other alfalfa varieties (GE and non-GE) currently being grown.

Neither the No Action nor the Preferred Alternative, including stacking KK179 alfalfa with non-regulated glyphosate-resistant alfalfa are expected to result in changes to current alfalfa cropping practices. Studies conducted by Monsanto and FGI demonstrate that no changes to current alfalfa cropping practices such as tillage, crop rotation, or agricultural inputs associated with the adoption of KK179 alfalfa are expected (Monsanto and FGI, 2013). However, KK179 alfalfa will allow growers to alter harvest schedules. Altering harvest schedules will allow growers to either a) maximize forage quality while maintaining yield or b) potentially eliminate a cutting in a growing season, depending on plant growth stage at harvest (Monsanto and FGI, 2013). APHIS determined that general agronomic practices associated with glyphosate-resistant alfalfa would not have implications for seed and forage production practices, other than the impacts to glyphosate use for weed control and limitations in stand takeout (USDA-APHIS, 2010). Since Monsanto and FGI intend to combine KK179 alfalfa with glyphosate-resistant alfalfa utilizing traditional breeding techniques (Monsanto and FGI, 2013), similar to the No Action alternative, KK179 alfalfa growers will be required to maintain the grower's trait stewardship requirement under terms of the Monsanto/FGI technology stewardship agreement (MTSA) of harvesting a hay field at or before 10 percent bloom (Monsanto Company, 2013). Availability of another alfalfa variety, such as KK179 alfalfa, under the Preferred Alternative, is not expected to impact alfalfa cropping practices any differently than other alfalfa varieties (GE and non-GE) currently being grown.

5.3 Cumulative Impacts: Physical Environment

Neither the No Action nor the Preferred Alternative, including stacking KK179 alfalfa with non-regulated glyphosate-resistant alfalfa are expected to directly cause a measurable impact to water, soil, air quality or climate change. As discussed in Subsection 4.3, approving the petition for a determination of nonregulated status to KK179 alfalfa would have the same impacts to water, soil, air quality, and climate change as that of alfalfa varieties (GE and non-GE) 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 KK179 alfalfa is agronomically similar to other alfalfa varieties (GE and non-GE). The delayed harvesting opportunity associated with KK179 alfalfa could result in reduced cuttings (potentially one fewer cutting per year for most areas), which would result in a small, local positive effect on air quality from reduced vehicle emissions and a small reduction in vehicle-related greenhouse gas emissions. When considered with other local agricultural practices, the contributions of KK179 alfalfa to improving the quality of the physical environment are small and possibly not measurable beyond the scale of individual farms. APHIS determined that implementation of conservation tillage can lead to reduced sedimentation in surface water that flows into streams and rivers and concluded that the beneficial improvements to ground water could occur due to the herbicide profile used on glyphosate-resistant alfalfa (USDA-APHIS, 2010). Furthermore, APHIS determined that glyphosate-resistant alfalfa would not affect soil quality or soil microorganisms, including the symbiotic relationship with Sinorhizobium meliloti located in root nodules that is involved in the beneficial fixation of atmospheric nitrogen. They also concluded that the beneficial improvements to soil tilth and alfalfa's deep-rooted characteristics would continue to add value as a rotational crop and as a soil conservation crop (USDA-APHIS, 2010). APHIS determined that air quality from glyphosate herbicide application is uncertain because the level of no-till adoption will be key to determining whether there is a reduction in number of mechanical operations with the associated reduced emissions from tractor use (USDA-APHIS, 2010). Climate change associated with glyphosate-resistant alfalfa is assessed by APHIS in their 2010 FEIS (USDA-APHIS, 2010), where they indicate climate change is tied to production of greenhouse gases and that subsequently, increases in global temperatures since the mid-20th century are very likely attributed to human-caused greenhouse gas production. They also conclude that increased temperatures from this climatic change can impact forage quality which in turn can have an effect on dairy cows' productivity. As a result, APHIS determined that glyphosate-resistant alfalfa could include increased forage quality to help mitigate some of the on-going climate change (USDA-APHIS, 2010). Because of its similarity to other varieties of alfalfa (GE and non-GE), adoption of KK179 alfalfa is expected to replace other similar cultivars without changing the acreage or area of alfalfa production that could impact water, soil, air quality, and climate change. Overall, the availability of another alfalfa variety, such as KK179 alfalfa, under the Preferred Alternative, is not expected to impact water, soil, air quality and climate change any differently than other alfalfa varieties (GE and non-GE) currently being grown..

5.4 Cumulative Impacts: Biological Resources

The impacts of the Preferred Alternative, including stacking KK179 alfalfa with non-regulated glyphosate-resistant alfalfa to animal and plants communities, microorganisms, and biodiversity would be no different than that experienced under the No-action Alternative. APHIS determined that animal communities, including Threatened and Endangered species (TES), would not be affected by direct contact or consumption of glyphosate-resistant alfalfa. This assessment is based on the lack of toxicity or allergenicity from the transgenic protein (i.e., CP4 EPSPS) and due to its nutritional equivalence to other alfalfa (USDA-APHIS, 2010). Furthermore, APHIS determined that plant communities, including Threatened and Endangered species (TES), would not be affected by glyphosate-resistant alfalfa. USDA stated the following: "APHIS concludes that alfalfa does not naturally hybridize with any related wild relatives in North America. Hybrids between alfalfa and other *Medicago* species in the United States are limited to hybridization between M. sativa subspecies. There is no evidence for existence of any sexually compatible, free-living, or native relatives of *Medicago* species in the United States or North America." (USDA-APHIS, 2010). KK179 alfalfa is both agronomically and compositionally similar to other alfalfa varieties (GE and non-GE). Thus, it would not require any different agronomic practices to cultivate, and does not represent a safety or increased weediness risk that is any different from other currently available alfalfa. Cultivation of KK179 alfalfa stacked with glyphosate-resistant alfalfa is unlikely to have a cumulative effect on soil microorganisms relative to the cultivation of other alfalfa varieties (GE and non-GE). When compared to existing alfalfa production practices cultivation of KK179 alfalfa will utilize similar management conditions including the use of glyphosate and other herbicides. Because any microorganism is already extensively exposed to herbicides in current U.S. alfalfa production fields, it is unlikely that any new microorganism would be affected through production practices associated with KK179 alfalfa or its progeny. Cultivation of KK179 alfalfa and KK179 alfalfa stacked with non-regulated glyphosate-resistant alfalfa is unlikely to have toxic effects on non-target animals and microorganisms. Additionally, cultivation of KK179 alfalfa and KK179 alfalfa stacked with non-regulated glyphosate-resistant alfalfa is likely to be neutral with regard to biodiversity compared with typical GE and non-GE alfalfa production systems, due to similar management conditions for both production systems. As discussed in Subsection 4.4.5 – Biodiversity, Monsanto and FGI have presented results of field and laboratory studies indicating that KK179 alfalfa is substantially equivalent to conventional alfalfa varieties in terms of required agronomic inputs, phenotypic and morphological characteristics, and composition (Monsanto and FGI, 2013). Application of herbicides in U.S. alfalfa production will continue to be dictated by both individual farm need and EPA label use restrictions. As a consequence of its herbicide registration program, EPA has effectively determined that there is no unreasonable environmental risk if the end user adheres to the directions and restrictions on the EPA registration label when applying herbicide formulations.

There are no differences in the potential for gene flow and weediness under the Preferred Action Alternative, including stacking KK179 alfalfa with non-regulated glyphosate-resistant alfalfa than the No Action alternative. Outcrossing and weediness are addressed in the PPRA (USDA-APHIS, 2013) where it was determined that KK179 alfalfa is similar to other alfalfa varieties (GE and non-GE). With KK179 alfalfa, growers will have the flexibility to delay harvest and retain quality comparable to commercially cultivated alfalfa harvested at an earlier growth stage. In the 2010 APHIS FEIS (USDA-APHIS, 2010), APHIS determined that gene flow and weediness are manageable within the GE, non-GE and organic alfalfa production systems. This conclusion included assessments on gene flow from insect-mediated pollination, secondary seedlings from unintentional sprouting, seed purity issues related to seed production practices, and other alfalfa crops and related species. Included in these gene-flow assessments was the identification of factors that have a probability of decreasing gene flow [e.g., contracted seed growers, best management practices (BMPs) for commercial beehives to prevent unintended dispersal of pollen to a non-GE alfalfa field, following industry established isolation distances (e.g., AOSCA standards), and contracting seed production in only 11 states] and factors that would increase the probability of gene flow [e.g., feral alfalfa creating a corridor/gene reservoir, proximity of seed field increasing gene flow to another alfalfa field, presence of unharvested or volunteer alfalfa acting as a pollen source, pollinator (bee) movement resulting in unintended dispersal of pollen, glyphosate-resistant alfalfa growers not adhering to mandatory best management practices and industry accepted mitigation standards (e.g., AOSCA standards) or stewardship requirements (e.g., grower agreements)]. Since KK179 alfalfa will be combined with glyphosate-resistant alfalfa utilizing traditional breeding techniques (Monsanto and FGI, 2013), similar to the No Action alternative, KK179 alfalfa will be harvested at or before the 10 percent bloom stage as required under terms of the Monsanto/FGI technology stewardship agreement (MTSA) for forage growers purchasing glyphosate-resistant alfalfa seed (Monsanto Company, 2013).

The forage production practice of harvesting a hay field at or before 10 percent bloom during the seed production field's pollination period will be sufficiently conservative to ensure that pollen-mediated gene flow from a hay production field is low to near zero. In an instance where KK179 alfalfa is allowed to develop past the 10 percent bloom stage before cutting forage, research has shown that harvesting at stages of 20 to 50 percent bloom does not significantly raise the potential gene flow to neighboring seed production fields thus the risk remains very low (Teuber and Fitzpatrick, 2007). Agronomic factors (increasing accumulation of lignin, reduction in crude protein levels and a corresponding rise in ADF levels contribute to declining forage quality and the resulting decline in leaf to stem ratio) impose heavy penalties in terms of forage quality to make it agronomically unfavorable for alfalfa forage to be allowed to mature past the 10 percent bloom stage and do not offer yield advantages past a certain point (Orloff and Putnam, 2008; Putnam et al., 2008b), thus there is no expectation of changes in recommendations to harvest forage before or by 10 percent bloom.

KK179 alfalfa has no increased potential compared to commercially cultivated alfalfa to outcross or hybridize with cultivated alfalfa under hay production or seed production conditions, or with feral alfalfa.

5.5 Cumulative Impacts: Human Health and Animal Feed

Food and feed derived from GE alfalfa must be in compliance with all applicable legal and regulatory requirements and may undergo a voluntary consultation process with the FDA prior to release onto the market to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food. As discussed in Subsections 4.5 and 4.6, KK179 alfalfa is expected to have no toxic effect to human health or livestock (Monsanto and FGI, 2013). Monsanto and FGI submitted a safety and nutritional assessment of food and feed derived fromKK179 alfalfa to the FDA in August 2012, identified under BNF No. 138 (Monsanto and FGI, 2013). The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014). No change in food and feed safety is expected to occur under the Preferred Alternative.

In the preceding analysis, the potential impacts from approving the petition for nonregulated status to KK179 alfalfa were assessed. The compositional analysis included the major constituents (carbohydrates, protein, fat, and ash), minerals, vitamins, amino acids, fatty acids, secondary metabolites, antinutrients, phytosterols, and nutritional impact. KK179 alfalfa is agronomically and compositionally similar to other GE- and non-GE-alfalfa varieties (Monsanto and FGI, 2013; USDA-APHIS, 2013). As a result, the potential impacts under the Preferred Alternative for all the resource areas analyzed are the same as those described for the No Action Alternative.

Under the preferred alternative, KK179 alfalfa would likely be combined with glyphosate-resistant alfalfa utilizing traditional breeding techniques (Monsanto and FGI, 2013). In the 2010 APHIS FEIS (USDA-APHIS, 2010), APHIS determined that alfalfa is not a major direct food source for humans. Additionally, due to the mandatory technology stewardship agreements (e.g., grower agreement) there is very low probability that glyphosate-resistant alfalfa will be used as food. APHIS points out that consumption may occur indirectly as honey bees could bring pollen from glyphosate-resistant alfalfa fields (forage and seed) to honey-producing hives after foraging over long distances. These hives could include organic honey producers. The honey from these hives could contain trace amounts of GE alfalfa pollen that would be used for human consumption. However, based on glyphosate-resistant alfalfa's nutritional equivalence to other alfalfa and completion of a consultation with the FDA confirming its safety for human consumption, the presence of glyphosate-resistant alfalfa in honey or inadvertent consumption would not have consumer health consequences. APHIS also determined that there is no indication of allergenicity or toxicity of glyphosate-resistant alfalfa compared to other alfalfa (USDA-APHIS, 2010). Furthermore, APHIS determined based on the feed safety consultation conducted by FDA and APHIS' analysis of glyphosate-resistant alfalfa, no evidence was found to indicate glyphosate-resistant alfalfa feed would be digested and metabolized any differently than currently available alfalfa feed (USDA-APHIS, 2010). As discussed above in Subsection 4.5 and 4.6, food and feed derived from GE alfalfa must be in compliance with all applicable legal and regulatory requirements and may undergo a voluntary consultation process with the FDA prior to release onto the market. All GE traits into which the KK179 alfalfa trait would be incorporated for producing varieties of alfalfa have undergone this process to ensure their safety as food and feed products.

5.6 Cumulative Impacts: Socioeconomics

Based on the information described in Subsection 4.7.1 – Domestic Commerce, APHIS concludes that a determination of nonregulated status of KK179 alfalfa will have no foreseeable adverse cumulative effects on domestic commerce. The availability of KK179 alfalfa would be unlikely to impact alfalfa acreage or production area that may affect domestic markets.

Adopters of KK179 alfalfa may realize savings as a result of a delayed harvest schedule and longer harvest intervals over the life of the stand. A delayed harvest schedule likely will lead to one less forage harvest per year (i.e., in the North Central region three compared to four cuttings) (Monsanto and FGI, 2013). The elimination of one cutting could result in a reduction in overall harvesting costs. The overall KK179 alfalfa forage yield for the year or season is expected to be comparable to existing commercial alfalfa varieties, even with fewer cuttings, because of the longer harvest intervals and potentially higher forage yields with each cutting. Fewer harvests also means fewer trips across the field that result in less labor, fuel consumption and soil compaction, plus potentially less crown damage to alfalfa plants in established stands. In addition, longer harvest intervals have been shown to extend the life of the alfalfa stand because the plants have a longer period of time to replenish carbohydrate root reserves (Orloff and Putnam, 2008). Based on these factors, no net negative cumulative impacts on domestic economics have been identified associated with the cultivation of KK179 alfalfa.

Under the preferred alternative, KK179 alfalfa would likely be combined with glyphosate-resistant alfalfa utilizing traditional breeding techniques (Monsanto and FGI, 2013). In the 2010 APHIS FEIS (USDA-APHIS, 2010), APHIS determined that there may be a cost savings in forage production with the additional benefit of fewer weeds. The EIS also considered the possibility that organic alfalfa farmers could experience additional production costs to avoid unintended presence of glyphosate-resistant alfalfa and, if such unintended presence occurred, could potentially affect sales. The EIS also considered the possibility that glyphosate-resistant alfalfa in commercial production could require additional testing and stewardship costs by the organic industry (USDA-APHIS, 2010).

Under the Preferred Alternative, it is possible KK179 alfalfa would not be approved for import into other countries. Because the U.S. and other countries already have access to other alfalfa varieties, and KK179 alfalfa presents another option of alfalfa similar to cultivars already in the marketplace, its availability only to U.S. producers would not likely significantly impact the economic trade environment. Trade primarily occurs from West Coast region states (California and Washington) to markets in the Asia-Pacific region. Based on the total amount of U.S. exported alfalfa, it would only require approximately 200,000 acres or 1.1 percent of the alfalfa acres grown in the U.S. (USDA-APHIS, 2010). If KK179 alfalfa were not approved for import by other countries but would be approved as nonregulated in the U.S., it would not likely affect the supply of U.S. alfalfa eligible for import to other countries. Likewise, if it were approved both in the U.S. and for import by other countries, based on its similarity to other alfalfa varieties and the likelihood it would replace other such varieties without increasing the acreage or area of alfalfa production, KK179 alfalfa would still be unlikely to affect the supply of U.S. alfalfa available for export. Global export markets respond to many factors and are unlikely to change with the commercial availability of another alfalfa variety such as KK179 alfalfa.

Under the preferred alternative, KK179 alfalfa would likely be combined with glyphosate-resistant alfalfa utilizing traditional breeding techniques (Monsanto and FGI, 2013). In the 2010 APHIS FEIS (USDA-APHIS, 2010), APHIS determined that global trade/export markets may experience losses due to refusal of alfalfa products in GE-sensitive markets. However, with increased acceptance of GE products in these markets, U.S. alfalfa growers may benefit from the increased economic competitiveness of glyphosate-resistant alfalfa production (USDA-APHIS, 2010).

Based on these factors, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have a negative impact on foreign trade.

5.7 Cumulative Impacts Summary

In summary, the potential for impacts of KK179 alfalfa would not result in any changes to the resource areas when compared to the No Action Alternative. No cumulative effects are expected from approving the petition for nonregulated status for KK179 alfalfa, when taken in consideration with related activities, including past, present, and reasonably foreseeable future actions.

6 THREATENED AND ENDANGERED SPECIES

The Endangered Species Act (ESA) of 1973, as amended, is one of the most far-reaching wildlife conservation laws ever enacted by any nation. Congress passed the ESA to prevent extinctions facing many species of fish, wildlife and plants. The purpose of the ESA is to conserve endangered and threatened species and the ecosystems on which they depend as key components of America's heritage. To implement the ESA, the U.S. Fish & Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS), other Federal, State, and local agencies, Tribes, non-governmental organizations, and private citizens. Before a plant or animal species can receive the protection provided by the ESA, it must first be added to the Federal list of threatened and endangered wildlife and plants.

A species is added to the list when it is determined by the USFWS/NMFS to be endangered or threatened because of any of the following factors:

- The present or threatened destruction, modification, or curtailment of its habitat or range;
- Overutilization for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms; and
- The natural or manmade factors affecting its survival.

Once an animal or plant is added to the list, protective measures apply to the species and its habitat. These measures include protection from adverse effects of Federal activities.

Section 7 (a)(2) of the ESA requires that federal agencies, in consultation with USFWS and/or the 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 (PPA) 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 whether APHIS has any obligations under the ESA regarding analyzing the effects of herbicide use associated with all GE crops on TES. 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 herbicide use associated with GE crops currently planted because EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under FIFRA. APHIS has no statutory authority to authorize or regulate the use of glyphosate or any other herbicide, by alfalfa growers. Under APHIS' current Part 340 regulations, APHIS only has the authority to regulate KK179 alfalfa 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 herbicides or other pesticides on those organisms.

After completing a plant pest risk analysis, if APHIS determines that KK179 alfalfa seeds, plants, or parts thereof do not pose a plant pest risk, then this article would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR Part 340, and therefore, APHIS must reach a determination that this article is no longer regulated. As part of its EA analysis, APHIS is analyzing the potential effects of KK179 alfalfa on the environment including, as required by the ESA, any potential effects to threatened and endangered species and critical habitat. As part of this process, APHIS thoroughly reviews the GE product information and data related to the organism (generally a plant species, but may also be other genetically engineered organisms). For each transgene/transgenic plant, APHIS considers the following:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impacts;
- Determination of the concentrations of known plant toxicants (if any are known in the plant);
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES; and
- Any other information that may inform the potential for an organism to pose a plant pest risk.

In following this review process, APHIS, as described below, has evaluated the potential effects that a determination of nonregulated status of KK179 alfalfa may have, if any, on federally-listed TES and species proposed for listing, as well as designated critical habitat and habitat proposed for designation.

Based upon the scope of this EA and production areas identified in the Affected Environment section of this EA, APHIS obtained and reviewed the USFWS list of TES species (listed and proposed) for all 50 states where alfalfa is produced from the USFWS Environmental Conservation Online System (ECOS) (USFWS, 2014). Prior to this review, APHIS also considered the potential for KK179 alfalfa to extend the range of alfalfa production, and also the potential to extend agricultural production into previously uncultivated natural areas. APHIS has determined that agronomic characteristics and cultivation practices required for KK179 alfalfa are essentially indistinguishable from practices used to grow other alfalfa varieties (Monsanto and FGI, 2013; USDA-APHIS, 2013). Since KK179 alfalfa is expected to replace other alfalfa varieties currently cultivated, APHIS does not expect the cultivation of KK179 alfalfa to result in new alfalfa acres to be planted in areas that are not already devoted to agriculture. Accordingly, the issues discussed herein focus on the potential environmental consequences of approval of the petition for nonregulated status for KK179 alfalfa on TES and critical habitat in the areas where alfalfa is currently grown.

For its analysis on TES plants and critical habitat, APHIS focused on the agronomic differences between the regulated articles and alfalfa 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 effects on TES animals, APHIS focused on the implications of exposure to the expressed products, which are dsRNA in the plants, direct exposure to the GE crop, and the ability of the plants to serve as a host for a TES.

6.1 Potential Effects of KK179 Alfalfa on TES and Critical Habitat

<u>Threatened and Endangered Plant Species and Critical Habitat</u>

The agronomic and morphologic characteristics data provided by Monsanto and FGI were used in the APHIS analysis of the weediness potential for KK179 alfalfa, and further evaluated for the potential to impact TES and critical habitat. Agronomic studies conducted by Monsanto and FGI tested the hypothesis that the weediness potential of KK179 alfalfa is unchanged with respect to conventional alfalfa (Monsanto and FGI, 2013). No differences were detected between KK179 alfalfa and nontransgenic alfafa in growth, reproduction, or interactions with pests and diseases, other than the intended effect of reduced lignin (Monsanto and FGI, 2013; USDA-APHIS, 2013). Little evidence exists to suggest that alfalfa behaves as a weed, other than as a volunteer in agricultural settings. Weed control experts from states where alfalfa is cultivated extensively have communicated that they do not consider *Medicago sativa* a weed or species with weediness potential (USDA-APHIS, 2010; Monsanto and FGI, 2013). Alfalfa is a widely cultivated crop found in all parts of the continental United States, Alaska, and Hawaii and can also survive outside of cultivation (Subsection 2.4.3, *Gene Flow and Weediness*). The suppression of the *CCOMT* gene and resulting lower CCOMT protein expression resulting in reduced lignin synthesis in KK179 alfalfa are unlikely to appreciably improve seedling establishment or increase weediness potential (see Subsection 4.4.3). APHIS has concluded the approval of a petition of nonregulated status for KK179 alfalfa does not present a risk of weediness, and does not present an increased risk of gene flow when compared to other currently cultivated alfalfa varieties (USDA-APHIS, 2013).

APHIS evaluated the potential of KK179 alfalfa to cross with listed species. As previously discussed in the analysis of Gene Flow and Weediness, APHIS has determined that there is no risk to unrelated plant species from the cultivation of KK179 alfalfa. Alfalfa is dependent on cross-pollination by insects, specifically bees; therefore, pollen-mediated gene flow between different alfalfa populations is possible. Populations of feral alfalfa have existed in the U.S. since alfalfa's introduction due to natural dispersal from cultivated fields and from intentional introductions in non-agricultural areas for rangeland development and other purposes (USDA-APHIS, 2010). However, typical conditions and practices for hay and seed production as described in Sections 2.4.3 and 4.4.3, all but preclude the chance of gene flow into hay or seed production fields, as previously described (Van Deynze *et al.*, 2008; USDA-APHIS, 2010). After reviewing the list of threatened and endangered plant species in the U.S., APHIS determined that KK179 alfalfa would not be sexually compatible with any listed threatened or endangered plant species proposed for listing, as none of these listed plants are in the same genus nor are known to cross pollinate with species of the genus *Medicago*. The potential for gene flow exists only between different alfalfa crop fields and feral alfalfa, due to the absence of any sexually compatible, free-living or native relatives of *Medicago* species in North America.

Based on agronomic field data, literature surveyed on alfalfa weediness potential, and no sexually compatibility of TES with alfalfa, APHIS has concluded that KK179 alfalfa will have no effect on threatened or endangered plant species or critical habitat.

<u>Threatened and Endangered Animal Species</u>

For its effects analysis on TES animal species, APHIS focused on the likelihood of the species to be exposed to the gene products expressed in KK179 alfalfa, which are dsRNA that suppress *CCOMT* gene expression via the RNA interference pathway lowering CCOMT protein expression and resulting in reduced lignin synthesis.

Double stranded RNAs are composed of nucleic acids and are commonly found in eukaryotes, including plants, for endogenous gene suppression. Nucleic acids have a long history of safe consumption and are considered GRAS by the FDA under its regulations at 21 CFR part 170. There is no evidence to suggest dietary consumption of RNA is associated with mammalian toxicity or allergenicity (Monsanto and FGI, 2013; USDA-APHIS, 2013). Therefore, based on the ubiquitous nature of the RNA-based suppression mechanism using dsRNA, demonstration of mode of action through CCOMT RNA suppression, the history of safe consumption of RNA and the apparent lack of toxicity or allergenicity of dietary RNA, the RNA-based suppression technology used in KK179 alfalfa poses no novel risks to threatened or endangered animal species.

Threatened and endangered animal species that may be exposed to the gene products in KK179 alfalfa would be those TES that inhabit alfalfa fields and feed on KK179 alfalfa. To identify potential effects on threatened and endangered animal species, APHIS evaluated the risks to threatened and endangered animals from consuming KK179 alfalfa. As described in section 2.4.1 – Animal communities, alfalfa fields provide a food source and valuable habitat for hundreds of species of wildlife. Of all the animals that use alfalfa (not including insects or reptiles), 10 percent use it extensively for breeding and reproduction, 24 percent find it highly suitable for cover, and 57 percent use it for feeding (Putnam *et al.*, 2001).

KK179 alfalfa presents minimal risk to TES consuming this crop. Based on the information submitted by the applicant and reviewed by APHIS, KK179 alfalfa is agronomically, phenotypically, and biochemically comparable to conventional alfalfa (Monsanto and FGI, 2013). As discussed in Subsection 4.6 – Animal Feed, there is no difference in the composition and nutritional quality of KK179 alfalfa compared with conventional alfalfa (Monsanto and FGI, 2013); no expected hazards are associated with its consumption. Monsanto and FGI submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa to the FDA in August 2012 (Monsanto and FGI, 2013). The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014). A comparison of KK179 alfalfa with conventional alfalfa varieties reveals compositional equivalence. Detailed compositional analyses of proximates (ash, fat, moisture, and protein), carbohydrates by calculation, ADF, NDF, ADL, minerals (Ca, Cu, Fe, Mg, Mn, P, K, Na, and Zn), amino acids (essential and non-essential), anti-nutrients (daidzein, glycitein, genistein, coumesterol, formononetin, biochanin A, and seven saponins) and secondary metabolites (canavanine, p-coumaric acid, ferulic acid, sinapic acid, total polyphenols, and free phenylalanine) in forage derived from KK179 alfalfa demonstrated that with the exception of the intended changes in lignin, KK179 alfalfa is not compositionally different from currently available alfalfa varieties (Monsanto and FGI, 2013; USDA-APHIS, 2013). KK179 alfalfa does not raise the maximum potential quality attainable for forage but allows for increased farmer flexibility to better manage the yield-quality relationship and harvesting schedules to maximize the profitability of alfalfa production for their farming operation (Monsanto and FGI, 2013). Based on these analyses, APHIS concludes that consumption of KK179 alfalfa would be no different than consumption of alfalfa varieties currently grown (both GE and non-GE), and therefore would have no effect on any listed threatened or endangered animal species or animal species proposed for listing.

APHIS considered the possibility that KK179 alfalfa could serve as host plant for a threatened or endangered species. A review of the species list reveals that there are no members of the genus *Medicago* that serve as a host plant for any threatened or endangered species. Combining the above information, cultivation of KK1779 alfalfa and its progeny are expected to have no effect on threatened or endangered animals.

6.2 Summary

After reviewing the possible effects of allowing the environmental release of KK179 alfalfa, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. APHIS also considered the potential effect of a determination of nonregulated status of KK179 alfalfa on designated critical habitat and habitat proposed for designation, and could identify no differences from effects that would occur from the production of other alfalfa varieties. Alfalfa is not sexually compatible with, or serves as a host species for, any listed species or species proposed for listing. Consumption of KK179 alfalfa by any listed species or species proposed for listing will not result in a toxic or allergic reaction. Based on these factors, APHIS has concluded that a determination of nonregulated status of KK179 alfalfa, and the corresponding environmental release of this alfalfa variety will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the USFWS or NMFS is not required.

7 CONSIDERATION OF EXECUTIVE ORDERS, STANDARDS, AND TREATIES RELATING TO ENVIRONMENTAL IMPACTS

7.1 Executive Orders with Domestic Implications

The following executive orders require consideration of the potential impacts of the Federal action to various segments of the population.

- ***Executive Order (EO) 12898 (US-NARA, 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,"*** requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.

- ***EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks,"*** acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

The No-action and Preferred Alternatives were analyzed with respect to EO 12898 and EO 13045. Neither alternative is expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

Based on the information submitted by the applicant and reviewed by APHIS, KK179 alfalfa is agronomically, phenotypically, and biochemically comparable to conventional alfalfa except for the low lignin trait expressed in KK179 alfalfa. To establish that the new cultivar is nutritionally equivalent to the parent cultivar, detailed compositional analyses were conducted based on OECD guidelines for alfalfa to compare levels of key nutrients, anti-nutrients and secondary metabolites in KK179 alfalfa forage to levels in the conventional alfalfa control (Monsanto and FGI, 2013). Analysis found the differences were not biologically meaningful from a feed and food safety or nutritional perspective. Therefore, the genetic modification in KK179 alfalfa does not meaningfully impact composition, other than the intended reduction in G lignin and total lignin. As a result, the feed and food safety and nutritional quality of this product are comparable to those of conventional alfalfa, which has a history of safe use and consumption. When KK179 alfalfa is grown on a commercial scale and used as a source of feed, alfalfa products derived from KK179 alfalfa are not expected to be compositionally different from the equivalent feeds originating from conventional alfalfa (Monsanto and FGI, 2013). This compositional analysis establishes the safety of KK179 alfalfa and its products to humans, including minorities, low-income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken.

Monsanto and FGI initiated the consultation process with FDA and submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa in August 2012 (Monsanto and FGI, 2013). The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014).

Based on these factors, a determination of nonregulated status to KK179 alfalfa is not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

The following executive order addresses Federal responsibilities regarding the introduction and effects of invasive species:

> ***EO 1311 (US-NARA, 2010), "Invasive Species,"*** states that Federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause.

Alfalfa is not listed in the U.S. as a noxious weed species by the Federal government (7 CFR part 360; (USDA-NRCS, 2013a), nor is it listed as an invasive species by major invasive plant data bases. While pollen-mediated gene transfer can occur, there are no differences in the potential for gene flow and weediness. Outcrossing and weediness are addressed in the PPRA (USDA-APHIS, 2013) and KK179 alfalfa is similar to other alfalfa varieties. The risk of gene flow and weediness of KK179 alfalfa is no greater than that of other alfalfa varieties. Alfalfa is widely grown in the U.S. Based on historical experience and the data submitted by the applicant and reviewed by APHIS, KK179 alfalfa is sufficiently similar in fitness characteristics to other alfalfa varieties currently grown and is not expected to become weedy or invasive.

The following executive order requires the protection of migratory bird populations:

> ***EO 13186 (US-NARA, 2010), "Responsibilities of Federal Agencies to Protect Migratory Birds,"*** states that federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

Migratory birds may be found in alfalfa fields. A variety of birds including songbirds, swallows, waterfowl, game species, raptors, and migratory species are known to feed directly on alfalfa or the insects and small mammals that are found in and around alfalfa fields (Putnam *et al.*, 2001). Many bird species, particularly, pheasant, quail, and wild turkey nest in alfalfa fields (Putnam *et al.*, 2001). As discussed in Section 4.4.1, data submitted by the applicant has shown no difference in compositional and nutritional quality of KK179 alfalfa compared with other conventional alfalfa, apart from the reduced lignin content (Monsanto and FGI, 2013). As discussed in Section 4.6, Animal Feed, a final food consultation with the FDA for KK179 alfalfa was submitted by Monsanto and FGI in August 2012. The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014). Based on APHIS' assessment of KK179 alfalfa, it is unlikely that a determination of nonregulated status would have a negative effect on migratory bird populations.

7.2 International Implications

EO 12114 (US-NARA, 2010), "Environmental Effects Abroad of Major Federal Actions" requires federal officials to take into consideration any potential environmental effects outside the U.S., its territories, and possessions that result from actions being taken.

APHIS has given this EO careful consideration and does not expect a significant environmental impact outside the U.S. in the event of a determination of nonregulated status of KK179 alfalfa. All existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new alfalfa cultivars internationally apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340.

Any international trade of KK179 alfalfa subsequent to a determination of nonregulated status of the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC, 2010). The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC, 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (172 countries as of March 2010). In April 2004, a standard for PRA of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The *Cartagena Protocol on Biosafety* is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which include those modified through biotechnology. The Protocol came into force on September 11, 2003, and 160 countries are Parties to it as of December 2010 (CBD, 2010). Although the U.S. is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with those regulations that importing countries which are Parties to the Protocol have promulgated to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol and the required documentation.

LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (NBII, 2010). These data will be available to the Biosafety Clearinghouse.

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the Organization for Economic Cooperation and Development (OECD). NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures (RSPM) No. 14, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO, 2009).

APHIS also participates in the *North American Biotechnology Initiative (NABI)*, a forum for information exchange and cooperation on agricultural biotechnology issues for the U.S., Mexico, and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including Argentina, Brazil, Japan, China, and Korea.

7.3 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the potential changes in alfalfa production associated with a determination of nonregulated status of KK179 alfalfa (Section 4.2) and determined that the cultivation of KK179 alfalfa would not lead to the increased production or acreage of alfalfa production that could impact water resources or air quality any differently than currently cultivated alfalfa varieties. The low lignin trait conferred by the genetic modification to KK179 alfalfa is not expected to result in any changes in water usage for cultivation. As discussed in Section 4.3.1 and 4.3.3, there are no expected significant negative impacts to water resources or air quality associated with KK179 alfalfa production. Based on these analyses, APHIS concludes that a determination of nonregulated status of KK179 alfalfa would comply with the CWA and the CAA.

7.4 Impacts on Unique Characteristics of Geographic Areas

Approving the petition for a determination of nonregulated status to KK179 alfalfa is not expected to impact unique characteristics of geographic areas such as parklands, prime farmlands, wetlands, wild and scenic areas, or ecologically critical areas.

Monsanto and FGI have presented results of agronomic field trials for KK179 alfalfa. The results of these field trials demonstrate that there are no differences in agronomic practices, between KK179 alfalfa and conventional alfalfa varieties. The common agricultural practices that would be carried out in the cultivation of KK179 alfalfa are not expected to deviate from current practices, including the use of EPA-registered pesticides. The product is expected to be cultivated by growers on agricultural land currently suitable for production of alfalfa, and is not expected to increase the acreage of alfalfa production.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of KK179 alfalfa. This action would not convert land use to nonagricultural use and, therefore, would have no adverse impact on prime farmland. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to KK179 alfalfa including the use of EPA-registered pesticides. The Applicant's adherence to EPA label use restrictions for all pesticides is expected to mitigate potential impacts to the human environment.

Based on these findings, including the assumption that label use restrictions are in place to protect unique geographic areas and that those label use restrictions are adhered to, approving the petition for a determination of nonregulated status to KK179 alfalfa is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

7.5 National Historic Preservation Act (NHPA) of 1966 as Amended

The NHPA of 1966 and its implementing regulations (36 CFR 800) require Federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties and 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

APHIS' proposed action, a determination of nonregulated status of KK179 alfalfa is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

APHIS' Preferred Alternative would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of non-regulated status of KK179 alfalfa.

APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for increased noise on the use and enjoyment of a historic property during the operation of tractors and other mechanical equipment close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the alfalfa production regions. The cultivation of KK179 alfalfa is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

8 REFERENCES

Coordinated Framework for Regulation of Biotechnology 1986. Pub. L. Stat. June 26.

Statement of Policy: Foods Derived from New Plant Varieties 1992. Pub. L. Stat. May 29.

Adam, KL. "Seed production and variety development for organic systems." Butte, Montana: Appropriate Technology Transfer for Rural Areas, National Center for Appropriate Technology, 2005.

Akaogi, J; Barker, T; Kuroda, Y; Nacionales, DC; Yamasaki, Y; Stevens, BR; Reeves, WH; and Satoh, M (2006) "Role of non-protein amino acid L-canavanine in autoimmunity." *Autoimmunity Reviews.* 5 (6): p 429-35. <Go to ISI>://WOS:000240174700013.

Altieri, M (1999) "The ecological role of biodiversity in agroecosystems." *Agriculture, Ecosystems and Environment.* 74 p 19-31. http://www.sciencedirect.com/science/article/B6T3Y-3X6JG7B-3/2/af0c7abed1c5a6c972ade218e2abe75a.

Anderson, WP (1996) "Weed ecology." *Weed Science: Principles and Applications.* St. Paul, Minnesota: West Publishing Company. p 27-38.

Aneja, VP; Schlesinger, WH; and Erisman, JW (2009) "Effects of agriculture upon the air quality and climate: Research, policy, and regulations." *Environmental Science and Technology.* 43 p 4234-40.

AOSCA (2010) "General IP Protocols Standards." The Association of Official Seed Certifying Agencies. http://www.identitypreserved.com/handbook/aosca-general.htm.

AOSCA (2013a) "AOSCA Alfalfa Seed Stewardship Program (ASSP)." AOSCA. Last Accessed: December 23, 2013 http://aosca.org/page/ASSP.aspx?NT=.

AOSCA (2013b) "Seed Certification." AOSCA. http://www.aosca.org/Page/Seed_Certification.aspx?nt=96.

Bagavathiannan, MV; Gulden, RH; and Van Acker, RC (2011a) "The ability of alfalfa (*Medicago sativa*) to establish in a seminatural habitat under different seed dispersal times and disturbance." *Weed Science.* 59 (3): p 314-20. Last Accessed: 2012/10/15 http://dx.doi.org/10.1614/WS-D-10-00144.1.

Bagavathiannan, MV; Gulden, RH; and Van Acker, RC (2011b) "Occurrence of alfalfa (*Medicago sativa* L.) populations along roadsides in southern Manitoba, Canada and their potential role in intraspecific gene flow." *Transgenic Research.* 20 (2): p 397-407.

Bale, JS; Masters, GJ; Hodkinson, ID; Awmack, C; Bezemer, TM; Brown, VK; Butterfield, J; Buse, A; Coulson, JC; Farrar, J; Good, JEG; Harrington, R; Hartley, S; Jones, TH; Lindroth, RL; Press, MC; Symrnioudis, I; Watt, AD; and Whittaker, JB (2002) "Herbivory in global climate change research: direct effects of rising temperature on insect herbivores." *Global Change Biology.* 8 (1): p 1-16. http://dx.doi.org/10.1046/j.1365-2486.2002.00451.x.

Ball, DM; Collins, M; Lacefield, GD; Martin, NP; Mertens, DA; Olson, KE; Putnam, DH; Undersander, DJ; and Wolf, MW (2001) *Understanding Forage Quality*. Park Ridge, IL: American Farm Bureau Federation http://www.uky.edu/Ag/Forage/ForageQuality.pdf.

Bass, LN; Gunn, CR; Hesterman, OB; and Roos, EE (1988) "Seed physiology, seedling performance, and seed sprouting." *Alfalfa and Alfalfa Improvement*. Madison, Wisconsin: American Society of Agronomy, Inc., Crop Science Society of America, Inc., Soil Science Society of America, Inc. p 961-83. <Go to ISI>://CABI:19880713298.

Bayer (2011) "Petition for the Determination of Nonregulated Status for Event FG72." Submitted by Isabelle S. Coats, Registration Manager. Bayer Crop Science. http://www.aphis.usda.gov/biotechnology/not_reg.html.

Beekman, M and Ratnieks, FLW (2000) "Long-range foraging by the honey-bee, *Apis mellifera* L." *Functional Ecology.* 14 (4): p 490-96. http://dx.doi.org/10.1046/j.1365-2435.2000.00443.x.

Bradford, KJ. "Methods to maintain genetic purity of seed stocks." Oakland, California: University of California Agriculture and Natural Resources, 2006.

Brown, DE; Grandstaff, EL; Hanna, MR; Hanson, AA; Marble, VL; and Moutray, JB (1986) "Committee on alfalfa field isolation." *Report of the Thirtieth North American Alfalfa Improvent Conference*.

Caddel, J; Stritzke, J; Berberet, R; Bolin, P; Huhnke, R; Johnson, G; Kizer, M; Lalman, D; Mulder, P; Waldner, D; Ward, C; Zhang, H; and Cuperus, G. "Alfalfa production guide for the Southern Great Plains - Pests and pest management, Publication E-826." *Oklahoma Cooperative Extension Service*. Stillwater, Oklahoma: Oklahoma Cooperative Extension Service, 2011. http://lubbock.tamu.edu/files/2011/10/Okla-St-Alfalfa-Production-Guide_8.pdf

Cane, JH (2002) "Pollinating bees (Hymenoptera: Apiformes) of U.S. alfalfa compared for rates of pod and seed set." *Journal of Economic Entomology*. 95 (1): p 22-27. Last Accessed: 2012/10/16 http://dx.doi.org/10.1603/0022-0493-95.1.22.

Canevari, M and Putnam, DH (2008) "Managing depleted alfalfa stands: Overseeding and other options." *Irrigated Alfalfa Management for Mediterranean and Desert Zones*. Davis, California: University of California Agriculture and Natural Resources. p 227-39.

Canevari, M; Vargas, RN; and Orloff, SB (2008) "Weed management in alfalfa." *Irrigated Alfalfa Management for Mediterranean and Desert Zones*. Oakland, California: University of California Agriculture and Natural Resources. p 113-30.

Cangiano, CA; Castillo, AR; Guerrero, JN; and Putnam, DH (2008) "Alfalfa grazing management." *Irrigated Alfalfa Management for Mediterranean and Desert Zones*. Oakland, California: University of California Agriculture and Natural Resources. p 281-97.

CBD (2010) "The Cartegena Protocol on Biosafety " Convention on Biological Diversity. http://www.cbd.int/biosafety/.

CTIC (2008) "2008 Amendment to the National Crop Residue Management Survey Summary." Conservation Technology Information Center. http://www.ctic.purdue.edu/media/pdf/National%20Summary%202008%20(Amendment).pdf.

Doran, J; Sarrantonio, M; and Liebig, M (1996) "Soil health and sustainability." *Advances in Agronomy*. 56 p 1-54.

Dunkle, RL. "Maintaining seed purity in the seed trade industry." Alexandria, Virginia: American Seed Trade Association, 2011.

Faust, M (2002) "New feeds from genetically modified plants: the US approach to safety for animals and the food chain." *Livestock Production Science.* 74 (3): p 239-54.

Field, CB; Mortsch, LD; Brklacich, M; Forbes, DL; Kovacs, P; Patz, J, A.; Running, SW; and Scott, MJ (2007) "North America. Climate Change 2007: Impacts, Adaptation and Vulnerability. Contribution of Working Group II to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change." IPCC. http://www.ipcc.ch/pdf/assessment-report/ar4/wg2/ar4-wg2-chapter14.pdf.

Fitzpatrick, S (2007) "Validation of the FGI best practices for Roundup Ready® trait stewardship in alfalfa seed production." Forage Genetics International. http://www.foragegenetics.com/pdf/ValidationFGIBestPractices.pdf.

Fitzpatrick, S; Arias, J; McCaslin, M; and Reisen, P (2007) "Alfalfa gene flow research and information: Applicability to seed production systems." St. Louis, Missouri.

Fitzpatrick, S; Reisen, P; and McCaslin, M (2003) "Pollen-mediated gene flow in alfalfa: A three-year summary of field research." Virtual Meeting.

Flachowsky, G; Chesson, A; and Aulrich, K (2005) "Animal nutrition with feeds from genetically modified plants." *Archives of Animal Nutrition.* 59 (1): p 1 - 40. Last Accessed: April 20, 2011 http://www.informaworld.com/10.1080/17450390512331342368.

Frate, CA and Davis, RM (2008) "Alfalfa diseases and management." *Irrigated Alfalfa Management for Mediterranean and Desert Zones*. Oakland, California: University of California Agriculture and Natural Resources. p 155-74.

Garbeva, P; van Veen, JA; and van Elsas, JD (2004) "Microbial diversity in soil: Selection of microbial populations by plant and soil type and implications for disease suppressiveness." *Annual Review of Phytopathology.* 42 (1): p 243-70.

Gianessi, L and Reigner, N (2007) "The value of herbicides in U.S. crop production." *Weed Technology.* 21 p 559-66.

Hagler, JR; Mueller, S; Teuber, LR; Machtley, SA; and Van Deynze, A (2011) "Foraging range of honey bees, *Apis mellifera*, in alfalfa seed production fields." *Journal of Insect Science.* 11 (144): p 144. Last Accessed: 2012/08/14 http://dx.doi.org/10.1673/031.011.14401.

Hammon, B; Rinderle, C; and Franklin, M. "Pollen movement from alfalfa seed production fields." Grand Junction, Colorado: Colorado State University Cooperative Extension, 2006.

Harlan, JR (1975) "Our vanishing genetic resources." *Science.* 188 (4188): p 618-21.

Hower, AA; Harper, JK; and Harvey, RG (1999) "Alfalfa: The importance of pesticides and other pest management practices in U.S. alfalfa production."

IPPC (2010) "Official web site for the International Plant Protection Convention: International Phytosanitary Portal " International Plant Protection Convention. https://www.ippc.int/IPP/En/default.jsp.

Kalaitzandonakes, N. "Economic impacts of gene flow." Columbia, Missouri: University of Missouri, 2011.

Kansas State University. "Alfalfa production handbook." Manhattan, Kansas: Kansas State University Agricultural Experimental Station and Cooperative Extension Service, 1998.

Kendrick, D; Pester, T; Horak, M; Rogan, G; and Nickson, T (2005) "Biogeographic survey of feral alfalfa populations in the U.S. during 2001 and 2002 as a component of an ecological risk assessment of Roundup Ready Alfalfa®." American Society of Agronomy, Inc., Crop Science Society of America, Inc., Soil Science Society of America, Inc. http://a-c-s.confex.com/a-c-s/2005am/techprogram/S1292.HTM.

Lovett, S; Price, P; and Lovett, J (2003) "Managing Riparian Lands in the Cotton Industry." http://live.greeningaustralia.org.au/nativevegetation/pages/pdf/Authors%20L/18_Lovett_Price.pdf.

Malinow, MR; Bardana, EJ; Pirofsky, B; Craig, S; and McLaughlin, P (1982) "Systemic lupus erythematosus-like syndrome in monkeys fed alfalfa sprouts: Role of a nonprotein amino acid." *Science.* 216 p 415-17.

Marston, A; Wolfender, JL; and Hostettmann, K (2000) "Analysis and isolation of saponins from plant material." *Saponins in Food, Feedstuffs and Medicinal Plants*. Amsterdam, The Netherlands: Kluwer Academic Publishers. p 1-12.

Massiot, G; Lavaud, C; Besson, V; Le Men-Olivier, L; and Van Binst, G (1991) "Saponins from aerial parts of alfalfa (*Medicago sativa*)." *Journal of Agricultural and Food Chemistry.* 39 p 78-82.

Massiot, G; Lavaud, C; Guillaume, D; and Le Men-Olivier, L (1988) "Reinvestigation of the sapogenins and prosapogenins from alfalfa (*Medicago sativa*)." *Journal of Agricultural and Food Chemistry.* 36 p 902-09.

Monsanto and FGI (2013) "Petition for the Determination of Nonregulated Status for Reduced Lignin Alfalfa KK179." http://www.aphis.usda.gov/brs/aphisdocs/12_32101p.pdf.

Monsanto Company (2013) "U.S. Technology use guide." Monsanto Company. http://www.genuity.com/stewardship/Documents/TUG.pdf.

Mueller, SC; Frate, CA; and Mathews, MC (2008) "Alfalfa stand establishment." *Irrigated Alfalfa Management for Mediterranean and Desert Zones*. Oakland, California: University of California Division of Agriculture and Natural Resources. p 39-58.

NAFA (2010) "Coexistence for organic alfalfa seed & hay markets."

NAFA. "Best management practices for Roundup Ready® alfalfa seed production." St. Paul, Minnesota: National Alfalfa & Forage Alliance, 2011a.

NAFA. "Grower opportunity zones for seed production." St. Paul, Minnesota: National Alfalfa & Forage Alliance, 2011b.

NAFA. "Coexistence for alfalfa hay export markets." St. Paul, Minnesota: National Alfalfa & Forage Alliance, 2012a.

NAFA. "Coexistence for alfalfa seed export markets." St. Paul, Minnesota: National Alfalfa & Forage Alliance, 2012b.

NAFA. "Coexistence for organic alfalfa seed & hay markets." St. Paul, Minnesota: National Alfalfa & Forage Alliance, 2012c.

NAPPO (2009) "NAPPO approved standards " http://www.nappo.org/Standards/Std-e.html.

NBII (2010) "United States Regulatory Agencies Unified Biotechnology Website " http://usbiotechreg.nbii.gov/.

NCAT. "NCAT's Organic Crops Workbook: A Guide to Sustainable and Allowed Practices." National Center for Appropriate Technology, 2003. http://www.attra.org/attra-pub/PDF/cropsworkbook.pdf.

Non-GMO-Project (2010) "Non-GMO Project Working Standard." http://www.nongmoproject.org/wp-content/uploads/2009/06/NGP-Standard-v7.pdf.

NRC (2004) "Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects." National Resource Council.

OECD (2005) "Consensus document on compositional considerations for new varieties of alfalfa and other temperate forage legumes: Key feed nutrients, anti-nutrients and secondary plant metabolites."

Oleszek, W (1996) "Alfalfa saponins: Structure, biological activity, and chemotaxonomy." *Saponins Used in Food and Agriculture*. New York, New York: Plenum Press. p 155-70. <Go to ISI>://WOS:A1996BG55T00013.

Oleszek, W; Jurzysta, M; Ploszynski, M; Colquhoun, IJ; Price, KR; and Fenwick, GR (1992) "Zahnic acid tridesmoside and other dominant saponins from alfalfa (*Medicago sativa* L.) aerial parts." *Journal of Agricultural and Food Chemistry*. 40 (2): p 191-96. <Go to ISI>://BIOSIS:PREV199293106723.

Orloff, SB (2008) "Choosing appropriate sites for alfalfa production." *Irrigated Alfalfa Management for Mediterranean and Desert Zones*. Oakland, California: University of California Division of Agriculture and Natural Resources. p 19-30.

Orloff, SB and Mueller, SC (2008) "Harvesting, curing, and preservation of alfalfa." *Irrigated Alfalfa Management for Mediterranean and Desert Zones*. Oakland, California: University of California Agriculture and Natural Resources. p 209-25.

Orloff, SB and Putnam, DH (1997) "Management and replacement of depleted stands." *Intermountain Alfalfa Management*. Davis, California: University of California Agriculture and Natural Resources. p 138.

Orloff, SB and Putnam, DH (2008) "Harvest strategies for alfalfa." *Irrigated Alfalfa Management for Mediterranean and Desert Zones*. Oakland, California: University of California Agriculture and Natural Resources. p 197-207.

Pitts-Singer, TL and Cane, JH (2011) "The alfalfa leafcutting bee, *Megachile rotundata*: The world's most intensively managed solitary bee." *Annual Review of Entomology*. 56 (1): p 221-37. http://www.annualreviews.org/doi/abs/10.1146/annurev-ento-120709-144836.

Putnam, D; Russelle, M; Orloff, J; Kuhn, J; Fitzhugh, L; Godfrey, L; Kiess, A; and Long, R (2001) "Alfalfa, wildlife, and the environment, the importance and benefits of alfalfa in the 21st century." California Alfalfa and Forage Association. http://alfalfa.ucdavis.edu/-files/pdf/Alf_Wild_Env_BrochureFINAL.pdf.

Putnam, DH. "Methods to enable coexistence of diverse production systems involving genetically engineered alfalfa." Oakland, California: University of California Agriculture and Natural Resources, 2006. Vol. Publication 8193.

Putnam, DH; Orloff, SB; and Teuber, LR (2008a) "Choosing an alfalfa variety." *Irrigated Alfalfa Management for Mediterranean and Desert Zones*. Oakland, California: University of California Agriculture and Natural Resources. p 59-71.

Putnam, DH; Robinson, P; and DePeters, E (2008b) "Forage quality and testing." *Irrigated Alfalfa Management for Mediterranean and Desert Zones*. Oakland, California: University of California Agriculture and Natural Resources. p 241-64.

Ronald, P and Fouche, B (2006) "Genetic Engineering and Organic Production Systems." http://ucanr.org/freepubs/docs/8188.pdf.

Rosenthal, GA and Nkomo, P (2000) "The natural abundance of L-canavanine, an active anticancer agent, in alfalfa, *Medicago sativa* (L.)." *Pharmaceutical Biology*. 38 (1): p 1-6. <Go to ISI>://WOS:000086185700001.

Sheaffer, CC; Lacefield, GD; and Marble, VL (1988) "Cutting schedules and stands." *Alfalfa and Alfalfa Improvement*. Madison, Wisconsin: American Society of Agronomy, Inc., Crop Science Society of America, Inc., Soil Science Society of America, Inc. p 411-37.

Southwood, T and Way, M (1970) "Ecological background to pest management." *Concepts of Pest Management*. Raleigh: N.C. State University. p 7-28.

St. Amand, PC; Skinner, DZ; and Peaden, RN (2000) "Risk of alfalfa transgene dissemination and scale-dependent effects." *Theoretical and Applied Genetics.* 101 (1): p 107-14. http://dx.doi.org/10.1007/s001220051457.

Sullivan, J (1992) "*Medicago sativa*." <http://www.fs.fed.us/database/feis/plants/forb/medsat/all.html>. .

Summers, CG; Godfrey, LD; and Natwick, ET (2008) "Managing insects in alfalfa." *Irrigated Alfalfa Management for Mediterranean and Desert Zones*. Oakland, California: University of California Agriculture and Natural Resources. p 131-53.

Sundstrom, FJ; Williams, J; Deynze, AV; and Bradford, KJ (2002) *Identity preservation of agricultural commodities*. Oakland, California: University of California, Division of Agricultural and Natural Resources.

Swaffar, DS; Ang, CY; Desai, PB; and Rosenthal, GA (1994) "Inhibition of the growth of human pancreatic cancer cells by the arginine antimetabolite L-canavanine." *Cancer Research.* 54 p 6045-48.

Tanner, GJ; Moate, PJ; Davis, LH; Laby, RH; Li, Y; and Larkin, PJ (1995) "Proanthocyanidins (condensed tannin) destabilise plant protein foams in a dose dependent manner." *Australian Journal of Agricultural Research.* 46 (6): p 1101-09. <Go to ISI>://WOS:A1995RZ13300001.

Teuber, LR and Fitzpatrick, SN (2007) "Assessment of alfalfa gene flow between fields planted for hay production and adjacent fields used for seed production." *Proceedings of the California Alfalfa Seed Symposium*. http://ucce.ucdavis.edu/specialsites/alf_seed/2007/Handout.pdf.

Teuber, LR; Mueller, S; Hagler, JR; and Van Deynze, A (2011) "Gene flow in commercial alfalfa fields and implications to isolation and seed certification." p 46-48. Washington, D.C. http://www.ars.usda.gov/research/publications/publications.htm?seq_no_115=273172.

Teuber, LR; Van Deynze, A; Mueller, S; McCaslin, M; Fitzpatrick, S; and Rogan, G (2004) "Gene flow in alfalfa under honey bee (*Apis mellifera*) pollination." *Joint Conference of the 39th North American Alfalfa Improvement Conference and the 18th Trifolium Conference*.

Teuber, LR; Van Deynze, A; Mueller, S; Taggard, KL; Gibbs, LK; McCaslin, M; Fitzpatrick, S; and Rogan, G (2005) "Gene flow in alfalfa (*Medicago sativa* L.)

when honey bees (*Apis mellifera* L.) are used as pollinators." p 186. Champaign, Illinois.

Thomas, DA; Rosenthal, GA; Gold, DV; and Dickey, K (1986) "Growth inhibition of a rat colon tumor by L-canavanine." *Cancer Research.* 46 p 2898-903.

Undersander, D; Cosgrove, D; Cullen, E; Grau, C; Rice, ME; Renz, M; Sheaffer, C; Shewmaker, G; and Sulc, M (2011) *Alfalfa Management Guide*. Madison, WI: American Society of Agronomy, Inc.
Crop Science Society of America, Inc.
Soil Science Society of America, Inc.
https://www.agronomy.org/files/publications/alfalfa-management-guide.pdf.

US-EPA (2011) "Pesticides: Registration Review." U.S. Environmental Protection Agency. http://www.epa.gov/oppsrrd1/registration_review/.

US-EPA (2013a) "Inventory of U.S. greenhouse gas emissions and sinks: 1990-2011." http://www.epa.gov/climatechange/Downloads/ghgemissions/US-GHG-Inventory-2013-Main-Text.pdf.

US-EPA (2013b) "Sources of greenhouse gas emissions." Last Accessed: April 27, 2013 http://www.epa.gov/climatechange/ghgemissions/sources.html.

US-EPA "Watershed Assessment, Tracking & Environmental Results, National Summary of State Information." US-EPA. Last Accessed: December 9, 2013 http://ofmpub.epa.gov/waters10/attains_nation_cy.control#total_assessed_waters.

US-FDA (2006) "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use." U.S. Food and Drug Administration. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096156.htm.

US-FDA (2014) "Completed Consultations on Bioengineered Foods BNF No. 138." US-FDA. http://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon&id=MON%2D00179%2D5.

US-GCRP (2009) "Global Climate Change Impacts in the United States." Ed. Karl, T.R., J.M. Melillo and T.C. Peterson. Cambridge University Press. New York, NY. p 196. http://downloads.globalchange.gov/usimpacts/pdfs/climate-impacts-report.pdf.

US-NARA (2010) "Executive Orders disposition tables index." United States National Archives and Records Administration. http://www.archives.gov/federal-register/executive-orders/disposition.html.

USDA-AMS (2013) "National Organic Program." Agricultural Marketing Service United States Department of Agriculture. http://www.ams.usda.gov/AMSv1.0/nop

USDA-APHIS (2010) "Final Environmental Impact Statement: Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status
" Final Environmental Impact Statement.

USDA-APHIS (2013) "Draft Plant Pest Risk Assessment "

USDA-FAS (2012) "Analytics: Standard query, world total, alfalfa." U.S. Department of Agriculture, Foreign Agricultural Service. http://www.fas.usda.gov/GATS/ExpressQuery1.aspx.

USDA-NASS (2009) "2007 Census of Agriculture." http://www.agcensus.usda.gov/Publications/2007/Full_Report/usv1.pdf.

USDA-NASS (2010) "2007 Census of Agriculture, Farm and Ranch Irrigation Survey (2008)." http://www.agcensus.usda.gov/Publications/2007/Online_Highlights/Farm_and_Ranch_Irrigation_Survey/fris08.pdf.

USDA-NASS (2012a) "2011 Certified Organic Production Survey." USDA-NASS. http://usda01.library.cornell.edu/usda/current/OrganicProduction/OrganicProduction-10-04-2012.pdf.

USDA-NASS. "Alfalfa Hay (Dry) 2012 Harvested Acres by County for Selected States." 2012b. Choropleth map displaying alfalfa hay harvested acres by county. There are seven categories with the highest concentration of acres in the Northern Tier States. http://www.nass.usda.gov/Charts_and_Maps/Crops_County/pdf/AL-HA12-RGBChor.pdf.

USDA-NASS (2013a) "Crop production: 2012 Summary, January 2013." http://usda01.library.cornell.edu/usda/current/CropProdSu/CropProdSu-01-11-2013.pdf.

USDA-NASS (2013b) "Crop production: Historical track records, April 2013." http://usda01.library.cornell.edu/usda/current/htrcp/htrcp-04-12-2013.pdf.

USDA-NASS (2013c) "Crop values: 2012 Summary, February 2013." http://usda01.library.cornell.edu/usda/current/CropValuSu/CropValuSu-02-15-2013.pdf.

USDA-NASS "Quick Stats." http://quickstats.nass.usda.gov/#866ACB4D-9926-36FE-835C-384F84F66917.

USDA-NRCS (1999) "Conservation Tillage Systems and Wildlife." U.S. Department of Agriculture–Natural Resources Conservation Service. http://www.nrcs.usda.gov/Internet/FSE_DOCUMENTS/nrcs143_022212.pdf.

USDA-NRCS (2004) "Soil Biology and Land Management." U.S. Department of Agriculture–Natural Resources Conservation Service. http://soils.usda.gov/sqi/publications/publications.html#atn.

USDA-NRCS (2005) "Residue and tillage management, no till/strip till/direct seed."

USDA-NRCS. "Conservation Resource Brief: Air Quality, Number 0605." National Resources Conservation Service, 2006. Vol. 2010.

USDA-NRCS (2012) "PLANTS profile: *Medicago sativa* L. alfalfa." Last Accessed: May 1, 2012 http://plants.usda.gov/java/profile?symbol=MESA.

USDA-NRCS "Federal Noxious Weeds." Last Accessed: December 3, 2013 http://plants.usda.gov/java/noxious?rptType=Federal.

USDA-NRCS (2013b) "Introduced, Invasive, and Noxious Plants." USDA Natural Resource Conservation Service. Last Accessed: December 19, 2013 http://plants.usda.gov/java/invasiveOne.

USFWS "Environmental Conservation System Online." United States Fish and Wildlife Services. Last Accessed: February 25, 2014 http://ecos.fws.gov/tess_public/pub/adHocSpeciesForm.jsp.

Van Deynze, AE; Fitzpatrick, S; Hammon, B; McCaslin, MH; Putnam, DH; Teuber, LR; and Undersander, DJ. "Gene flow in alfalfa: Biology, mitigation, and potential impact on production." Ames, Iowa: Council for Agricultural Science and Technology, 2008.

Wilson, E (1988) *Biodiversity*. Washington DC: National Academy Press.

Wina, E; Muetzel, S; and Becker, K (2005) "The impact of saponins or saponin-containing plant materials on ruminant production - A review." *Journal of Agricultural and Food Chemistry.* 53 p 8093-105.

Zapiola, ML; Campbell, CK; Butler, MD; and Mallory-Smith, CA (2008) "Escape and establishment of transgenic glyphosate-resistant creeping bentgrass Agrostis stolonifera in Oregon, USA: a 4-year study." *Journal of Applied Ecology.* 45 (2): p 486-94. http://dx.doi.org/10.1111/j.1365-2664.2007.01430.x.