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

Final Environmental Impact Statement—December 2010

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Executive Summary

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

Purpose and Need

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

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

Background

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

APHIS assessed the plant pest risks posed by the use of GT alfalfa lines J101 and J163 and prepared an Environmental Assessment (EA). The EA was prepared to identify and evaluate any environmental impacts on the human environment that could result from the approval of the petition. In a notice published in the *Federal Register* (*FR*) on June 27, 2005 (70 *FR* 36917–36919, Docket No. 04-085-3), APHIS advised the public of its determination, effective June 14, 2005, that the Monsanto and FGI GT alfalfa lines J101

and J163 did not pose a plant pest risk and were therefore no longer considered regulated articles under 7 CFR part 340.

Approximately 9 months later, a group of organic alfalfa growers and several other associations filed a lawsuit in the United States (U.S.) District Court for the Northern District of California that challenged the APHIS decision to grant nonregulated status to J101 and J163. On February 13, 2007, the Court ruled that the APHIS EA failed to consider certain environmental and economic impacts adequately, as required by the National Environmental Policy Act (NEPA). The Court vacated the APHIS decision to grant nonregulated status to J101 and J163. The Court also ordered APHIS to prepare a NEPA-compliant Environmental Impact Statement (EIS) before deciding whether to grant nonregulated status to J101 and J163. In addition, as of March 12, 2007 all sales of GT alfalfa sales were halted, and as of March 30, 2007, any further planting of GT alfalfa was prohibited. On March 23, 2007, APHIS published a notice in the *Federal Register* (72 *FR* 13735-13736 APHIS Docket No. 04-085-1) announcing the Court's decision that Monsanto and FGI GT alfalfa lines J101 and J163 were once again regulated articles under 7 CFR part 340.

The Court decided that growers who had already planted GT alfalfa during the two years that the product had been deregulated would not have to remove the plants. Those plants were permitted to be harvested, used and sold. In the two growing seasons that GT alfalfa was on the market (2005 and 2006), approximately 200,000 total acres were planted in 1,552 counties in 48 states (no plantings occurred in Alaska and Hawaii). These GT alfalfa fields may still be harvested, but the fields are subject to court-ordered stewardship practices to minimize the potential that GT alfalfa will be present in harvests of non-GT alfalfa. APHIS prepared this EIS in connection with the order by the United States District Court for the Northern District of California that vacated the determination of deregulated status of J101 and J163 alfalfa.

In December 2009, APHIS made the draft EIS (DEIS) available for public comment. The DEIS was available for an extended 75-day comment period, which closed on March 3, 2010. APHIS also held four public meetings across the United States during the open comment period. Approximately 133 people attended these public meetings. Approximately 244,000 comments were received. Substantive comments and recommended study reports were considered for incorporation into and revisions of the final EIS (FEIS) were made as appropriate.

Purpose and Need for Agency Action

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

APHIS is required by 7 CFR § 340.6 to make a determination on petitions submitted to the agency under this part. The agency may grant the petition in whole or in part, or it may deny the petition. The determination is based on the data required in 7 CFR § 340.6(c), which are provided by the applicant and supported by the best available science.

The purpose of this action is to determine if the use of GT alfalfa in the U.S. agricultural environment presents a greater plant pest risk than varieties of non-GE, commercially available alfalfa. The agency's need is to make a decision on the petition that is consistent with the regulatory requirements in 7 CFR part 340.

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

Alternatives

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

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

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

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

Affected Environment

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

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

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

Environmental Consequences

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

Biology of Alfalfa

- Movement of genes between alfalfa plants depends on weather, timing of flowering, availability of pollinators, successful pollination, distance between plants, and time needed for seed maturity. Although the probability is low, GT

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

Weeds in Alfalfa

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

Impacts of GT Alfalfa on Plants and Animals

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

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

the introduction and establishment of a reproductively compatible, non-native species growing near GT alfalfa.

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

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

- Because of the high toxicity of glyphosate to plants, adoption of GT alfalfa could adversely affect individual plants near GT alfalfa fields if they are exposed to glyphosate. Glyphosate exposure could occur through aerial drift, runoff of surface waters containing glyphosate, or leaching of glyphosate into drainage systems. Plants exposed to glyphosate via aerial drift might experience impaired germination or growth characteristics. To mitigate potential adverse effects due to glyphosate drift, the U.S. Environmental Protection Agency (EPA) has imposed specific label use restrictions for glyphosate use when applied with aerial equipment, including "the product should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g., when wind is blowing away from the sensitive areas)." The potential for glyphosate transport from terrestrial to aquatic environments is limited, and glyphosate is not expected to reach groundwater due to sorption and degradation in the soil.
- Glyphosate has low toxicity to mammals, birds, and fish, but is slightly toxic to amphibians. However, amphibians exhibited greater sensitivity to Roundup® formulations than to glyphosate tested as an acid or isopropylamine (IPA) salt, likely due to the surfactant, polyethoxylated tallowamine (POEA), which has been used for a long time in agricultural formulations. POEA has been found to be more toxic to amphibians and other aquatic animals than the herbicide itself. Adoption of GT alfalfa, however, is unlikely to adversely affect amphibians, because none of the glyphosate formulations that contain surfactants are approved for use over or near surface waters.
- APHIS has no authority under the Plant Protection Act to regulate herbicide use associated with GT plants that are granted nonregulated status. The use of glyphosate is regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under FIFRA, EPA registers pesticides and prescribes the conditions for use of the pesticide. Applying pesticides in a way that is inconsistent with the label is illegal. On the label, EPA includes instructions on how glyphosate herbicides should be applied. Directions include application restrictions that minimize impacts on nearby environments. EPA has determined that there is no unreasonable environmental risk if the user adheres to the labeled directions. Therefore, APHIS has determined that the use of EPA-registered glyphosate for GT alfalfa production will not adversely impact federally listed

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

Herbicide Use

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

Socioeconomic Impacts

- There is some evidence that GT alfalfa can offer alfalfa hay farmers high quality alfalfa hay at relatively lower costs.
- To the extent that GT alfalfa is adopted by alfalfa hay farmers, the overall supply curve for high quality alfalfa could shift, increasing the quantity of high quality alfalfa hay and decreasing its price.
- There is evidence of consumer preference for nongenetically modified foods in the United States. This preference is likely more prevalent among consumers of organic products. However, the extent to which this preference translates to decreased demand (sales) for conventional and organic products under the potential low-level presence of GE content in feed used for dairy and meat cattle in the production chain of organic foods is unclear. The impact of GT alfalfa deregulation on domestic demand might best be analyzed by imagining a small GT-sensitive market within the domestic conventional and organic alfalfa markets.

- Among U.S. main export markets for alfalfa hay and seed, there is evidence of some sensitivity to GE products. As in the case of the domestic organic markets, the GT alfalfa sensitive segment is likely to be only a portion of the existing export market.
- The extent to which GE sensitive domestic and foreign markets are affected by GT alfalfa deregulation depends on the extent to which gene flow can be controlled through stewardship programs. These programs might or might not increase the costs of seed production for sensitive markets. To the extent that they do, the impact on overall demand is likely to be low, given the low sensitivity of the demand for alfalfa seeds to changes in its price.
- There is no evidence that the domestic or export market for organic dairy and meat derived from alfalfa-fed cattle would be lost to domestic alfalfa producers with GT alfalfa deregulation, nor that the credibility of the National Organic Program would be compromised, although testing for GE content in alfalfa seed might be increasingly required for access to GT-sensitive markets.

Human Health and Safety

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

Land Use and Physical Environment

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

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I. Purpose and Need

A. Introduction

1. APHIS Mission

"Protecting American agriculture" is the basic charge of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). APHIS provides leadership in ensuring the health and care of plants and animals. In doing so, the agency improves agricultural productivity and competitiveness and contributes to the national economy and public health.

The APHIS Biotechnology Regulatory Service's (BRS) mission is to protect America's agriculture and environment using a dynamic and science-based regulatory framework that provides for the safe development and use of genetically engineered (GE) organisms. Genetic engineering refers to the process by which genes or other genetic elements from one or more organisms are inserted into the genetic material of a second organism using molecular biology methods. Moving a new gene or genes in this way enables researchers to introduce useful new traits into an organism from individuals of the same species or from unrelated species.

GE organisms are subject to APHIS oversight if they are regulated articles as defined in 7 Code of Federal Regulations (CFR) § 340.0. Importation, interstate movement, or release into the environment of GE organisms requires authorization from APHIS. APHIS regulations also contain provisions that, after appropriate analysis, APHIS may determine that a GE organism is unlikely to pose a plant pest risk and grant that GE organism nonregulated status. APHIS regulation of GE organisms is discussed in more detail below.

B. Regulatory Authority

1. USDA

APHIS regulations at 7 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 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 the donor, recipient, or vector organism is considered a plant pest, or its plant pest status is unknown. A GE organism is also regulated under 7 CFR part 340 when APHIS has supporting information that the GE organism might be a plant pest or APHIS has determined that the GE organism is a plant pest.

Glyphosate-tolerant (GT) alfalfa, a GE organism, is a regulated article because some of the donor organisms and some of the vector DNA sequences were derived from organisms listed in 7 CFR § 340.2 and are considered to be plant pests.

A person may petition the agency to evaluate submitted data and determine that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, should no longer be regulated, under 7 CFR § 340.6 "Petition for Determination of Nonregulated Status." The petitioner must provide information (§ 340.6(c)(4)) related to plant pest risk that the agency uses to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. An organism is no longer subject to the regulatory requirements of 7 CFR part 340 if APHIS grants a petition for nonregulated status.

2. FDA

The Food and Drug Administration (FDA) regulates under the authority of the Federal Food Drug and Cosmetic Act (FFDCA). FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those developed through genetic engineering such as GT alfalfa. All foods and feeds, whether imported or domestic and whether derived from plants modified by conventional breeding techniques or by genetic engineering techniques, must meet the same rigorous safety standards. Under the FFDCA, food and feed manufacturers are responsible for ensuring that the products they market are safe and properly labeled. In addition, FDA must approve the use of any food additives, including those introduced into food or feed through plant breeding, before marketing. To help developers of foods and feeds derived from GE plants to comply with their obligations, under the FFDCA FDA encourages them to participate in its voluntary consultation process. In that process, developers submit to FDA a summary of data and information that provide the basis for a conclusion that a GE food is as safe as comparable non-GE food in the food supply. The goal of the consultation process is to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food. Monsanto Company of St. Louis, Missouri (Monsanto) and Forage Genetics International (FGI) of West Salem, Wisconsin completed the FDA voluntary consultation process for both lines of GT alfalfa. The FDA letter to Monsanto and FGI, and the FDA's summary of the consultation on regarding two lines of GT alfalfa (J101 and J163) (see section I.B.3), can be found at http://www.fda.gov/bioconinventory and appendix P of this EIS.

3. EPA

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the U.S Environmental Protection Agency (EPA) regulates the herbicides that are applied to GE herbicide-tolerant crops, such as GT alfalfa. Before a pesticide can be used on an herbicide-tolerant crop, the pesticide manufacturer must seek a label change for that pesticide. The label

describes how the herbicide can be applied to the herbicide-resistant crop and any restrictions on the use of the herbicide. Growers of the herbicide-resistant crop must follow the EPA label when applying the registered herbicide to the crop.

Several products containing glyphosate are labeled for use on GT alfalfa: Honcho®, Honcho Plus®, Roundup Original MAX®, Roundup WeatherMAX®, and Roundup Ultra MAX II®. These labels can be viewed at: http://www.monsanto.com/products/Pages/msds-labels.aspx

C. History

On April 16, 2004, APHIS received a petition from Monsanto and FGI requesting a determination of nonregulated status under 7 CFR part 340 for two alfalfa (*Medicago sativa* L.) lines designated as J101 and J163, which have been genetically engineered for tolerance to the herbicide glyphosate. The Monsanto and FGI petition stated that the two GT alfalfa lines should not be regulated by APHIS because they do not present a plant pest risk.

Alfalfa plants, like all plants, produce an enzyme called 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS). EPSPS is necessary for the production of certain amino acids essential for plant growth. Monsanto and FGI have incorporated the gene sequence from a native soil microorganism, *Agrobacterium*, into the alfalfa genome in order to make alfalfa tolerant to glyphosate, the active ingredient in Roundup®, an herbicide Monsanto produces, and in other formulations produced by other companies. As discussed in the technical report, *Glyphosate-tolerant Alfalfa Presence in Human Food and Animal Feed* (see appendix Q), the expressed gene product in GT alfalfa is a protein, EPSPS, derived from the CP4 strain of *Agrobacterium*, thus called CP4 EPSPS. This gene, along with its regulatory sequences, was introduced into these alfalfa plants via the well-characterized *Agrobacterium*-mediated transformation method. The protein is a single polypeptide that is 455 amino acids long and is structurally and functionally similar to the native plant EPSPS enzymes. The herbicide glyphosate inhibits an essential step in aromatic amine synthesis in plants by blocking the action of the natural EPSPS enzymes. However, the CP4 EPSPS protein is not inhibited by the herbicide glyphosate; thus any plant expressing adequate levels of this protein is resistant to glyphosate application. In other words, it is the insertion of this gene sequence and the production of the CP4 EPSPS protein that make GE alfalfa events J101 and J163 tolerant to glyphosate and glyphosate herbicide formulations.

Glyphosate kills plants by inhibiting the activity of EPSPS. As a "non-selective" herbicide, glyphosate kills almost all plant species when enough of it is applied because nearly all plants require normal EPSPS activity for

growth. Alfalfa plants that are genetically engineered to produce CP4 EPSPS are glyphosate tolerant because glyphosate does not inhibit the activity of CP4 EPSPS. If alfalfa plants producing CP4 EPSPS are growing in a field with weeds, applying glyphosate to the field will kill the weeds but not the alfalfa plants.

As stated in the petition, the petitioner's purpose of developing Roundup-Ready® alfalfa is to (1) offer producers a wide-spectrum weed-control option that will enhance the effectiveness of stand establishment and increase alfalfa forage and seed purity through better control of most of the weeds that impact forage and seed production; (2) increase the flexibility of treating weeds on an as-needed basis; (3) enable alfalfa production on marginal lands with severe weed infestations; and (4) provide growers with a weed-control system that has a reduced risk profile for the environment.

APHIS assessed the plant pest risks posed by the nonregulated use of lines J101 and J163 and prepared an Environmental Assessment (EA) to identify and evaluate any impacts on the human environment that could result from the approval of the petition. In a notice published in the *FR* on June 27, 2005 (70 *FR* 36917–36919, Docket No. 04-085-3), APHIS advised the public of its determination, effective June 14, 2005, that the Monsanto and FGI GT alfalfa lines J101 and J163 were no longer considered regulated articles under 7 CFR part 340. Concurrently, APHIS published its finding of no significant impact (FONSI) on the human environment based on the EA.

1. Litigation Overview

Approximately 9 months later, a group of organic alfalfa growers and several other associations filed a lawsuit in the United States District Court for the Northern District of California that challenged the APHIS decision to grant nonregulated status to J101 and J163. On February 13, 2007, the Court ruled that the APHIS EA failed to consider certain environmental and economic impacts adequately, as required by the National Environmental Policy Act (NEPA). The Court vacated the APHIS decision to grant nonregulated status to J101 and J163. The Court also ordered APHIS to prepare a NEPA-compliant Environmental Impact Statement (EIS) before deciding whether to grant nonregulated status to J101 and J163. In addition, as of March 12, 2007 all sales of GT alfalfa sales were halted, and as of March 30, 2007, any further planting of GT alfalfa was prohibited. On March 23, 2007, APHIS published a notice in the *FR* (72 *FR* 13735-13736 APHIS Docket No. 04-085-1) announcing the Court's decision that Monsanto and FGI GT alfalfa lines J101 and J163 were once again regulated articles under 7 CFR part 340.

The Court decided that growers who had already planted GT alfalfa during the two years that the product had been deregulated would not have to remove the plants. Those plants were permitted to be harvested, used and

sold. In the two growing seasons that GT alfalfa was on the market (2005 and 2006), approximately 200,000 total acres were planted in 1,552 counties in 48 states (no plantings occurred in Alaska and Hawaii). These GT alfalfa fields may still be harvested, but the fields are subject to court-ordered stewardship practices to minimize the potential that GT alfalfa will be present in harvests of non-GT alfalfa. This EIS was prepared to comply with the order from the U.S. District Court for the Northern District of California to identify and analyze any environmental impacts associated with the APHIS determination on the petition to grant nonregulated status to GE alfalfa lines J101 and J163.

D. Scoping for the EIS

The granting of nonregulated status to GT alfalfa lines raises several issues that are addressed in this EIS. APHIS identified these issues through a scoping process. Public scoping is required under NEPA, as amended, Council on Environmental Quality (CEQ) regulations for implementing NEPA, the USDA regulations implementing NEPA, and the APHIS National Environmental Policy Act (APHIS NEPA) of 1969 Implementing Procedures. Scoping for this EIS began on January 7, 2008, when APHIS gave notice in the *FR* (73 *FR* 1198–1200) of its intent to prepare a draft EIS (DEIS). The notice listed several questions that are discussed in this EIS:

1. What are the particular management practices for organic alfalfa, conventional alfalfa, and GT alfalfa? What are the procedures and associated costs of establishing, growing, harvesting, and marketing (includes selling prices and premiums for various quality standards) for each of the three types of alfalfa? What crop rotation regimes are used with each type of alfalfa?
2. What are the production levels of organic and conventional alfalfa seed and hay by region, state, and county? Which regions of the country may be affected more than others with the deregulation of GT alfalfa? What is the acreage of cultivated, volunteer, or feral alfalfa? What are the potential impacts on adjacent, nonagricultural lands such as natural areas, forested lands, or along transportation routes that may occur with the use of GT alfalfa?
3. What is the expected effect of GT alfalfa release on animal production systems?
4. What are the potential impacts of GT alfalfa release on food and feed? How does glyphosate tolerance affect food or feed value or nutritional quality? Should the adventitious presence of GT alfalfa occur in situations where it is unwanted, unintended, or unexpected, what impact would this have on the ability of producers to market affected organic or conventional

alfalfa or livestock fed this material? What are the negative impacts, if any, on food or feed value or quality from the use of glyphosate?

5. What differences are there in weediness traits of conventional alfalfa versus GT alfalfa under managed crop production systems as well as in unmanaged ecosystems?
6. What is the occurrence of common and serious weeds found in organic alfalfa systems, in conventional alfalfa systems, and in GT alfalfa systems? What are the current impacts of weeds, herbicide-tolerant weeds, weed-management practices, and unmet weed management needs for organic and conventional alfalfa cultivation? How may the weed impacts change with the use of GT alfalfa?
7. What are the particular management practices for controlling weeds in organic alfalfa systems, in conventional alfalfa systems, and in GT alfalfa systems? What are the potential changes in crop rotation practices and weed management practices for control of volunteer alfalfa or herbicide-tolerant weeds in rotational crops that may occur with the use of GT alfalfa? What are the potential effects on alfalfa stand termination and renovation practices that may occur with the use of GT alfalfa? What is the potential weediness of GT alfalfa?
8. What is the potential cumulative impact of glyphosate-resistant weeds, especially with the increase in acreage of GT crops? Are there glyphosate-resistant weeds and what is their prevalence in crops and in noncrop ecosystems? Will the release of GT alfalfa cause an increase in glyphosate-resistant weeds in alfalfa and in other crops? Which weeds are the most likely to gain glyphosate resistance with the use of GT alfalfa? What are the alternatives for management of GT or other herbicide-tolerant weeds in GT alfalfa stands or in subsequent crops? What are the potential changes that may occur in GT alfalfa as to susceptibility or tolerance to other herbicides?
9. What are current or prospective herbicide-tolerant weed mitigation options, including those addressed by the EPA-approved label for glyphosate herbicides?
10. What is the potential for gene flow in all combinations between seed fields, hay fields, and feral plants? To what extent will deregulation of GT alfalfa impact hybridization between cultivated and feral alfalfa, alfalfa's introgression or establishment outside of cultivated lands, and alfalfa's persistence in situations where it is unwanted, unintended, or unexpected? What are the risks associated with feral GT alfalfa plants? How will the removal of GT alfalfa in situations where it is unwanted, unintended, or unexpected result in adverse impacts? In such situations, how will GT alfalfa be controlled or managed differently from other unwanted, unintended, or unexpected alfalfa? To what extent can organic or conventional alfalfa farmers prevent their crops from being commingled with unwanted, unintended, or unexpected GT alfalfa?

11. What are the potential economic and social impacts of GT alfalfa release on organic and conventional alfalfa farmers? What are the potential impacts of the presence of GT alfalfa caused by pollen movement or seed admixtures? What are the economic issues associated with using alfalfa seed or hay commingled with GT alfalfa? What are the particular economics of growing seed or hay of organic alfalfa, conventional alfalfa, or GT alfalfa? What are the potential changes in the economics of growing and marketing organic and conventional alfalfa that may occur with the use of GT alfalfa? What are the potential changes in production levels of other crops that may occur with the use of GT alfalfa (i.e., will the release of GT alfalfa result in more or fewer acres of corn, wheat, other forage crops, etc.)? What are the potential changes in growing practices, management practices, and crop rotational practices in the production of alfalfa hay or seed for planting or sprouting purposes that may occur with the use of GT alfalfa? What are the potential changes in the choice of seeds available for organic and conventional alfalfa farmers that may occur with the use of GT alfalfa?
12. What are the potential impacts of the deregulation of GT alfalfa on U.S. trade? If the presence of GT alfalfa should occur in organic or conventional alfalfa where it is unwanted, unintended, or unexpected, what are the expected impacts on trade with countries that normally import alfalfa seed or hay? What are the expected impacts on trade with countries that do not normally import alfalfa? Is there an expected impact on trade in other commodities?
13. What is the potential cumulative impact of increased glyphosate usage with the release of GT crops? Have changes in glyphosate usage impacted soil quality, water quality, air quality, weed populations, crop rotations, soil microorganisms, diseases, insects, soil fertility, food or feed quality, crop acreages, and crop yields? Does the level of glyphosate tolerance within GT alfalfa plants have a major impact on the amount of glyphosate applied on the GT alfalfa crop on a routine basis?
14. What are the potential impacts of the release of GT alfalfa on threatened or endangered species and designated critical habitat? What are the potential effects of GT alfalfa use on listed threatened or endangered species, species proposed for listing, designated critical habitat, or habitat proposed for designation? What are the potential effects of glyphosate use on listed threatened or endangered species, species proposed for listing, designated critical habitat, or habitat proposed for designation; including glyphosate used on GT alfalfa?
15. What are the potential health and safety risks to field workers or other workers that would come into contact with GT alfalfa?
16. Can any of the potential negative environmental impacts resulting from the deregulation of GT alfalfa be reasonably mitigated, and what is the likelihood that mitigation measures will be successfully implemented?

The EIS will consider the stewardship measures outlined in the addendum to section VIII of the petition, as well as any other mitigation measures APHIS considers applicable and viable. Such measures, some of which may be outside the jurisdiction of APHIS, are designed to reduce inadvertent gene flow of GT alfalfa to negligible levels, as well as to monitor and minimize the potential development of GT weeds.

17. What are the impacts of the mitigation measures on coexistence with organic and conventional alfalfa production and export markets?
18. Are there any other potential direct, indirect, or cumulative impacts from the release of GT alfalfa other than those mentioned above?

The notice solicited public involvement in the form of written comments regarding the above issues and alternatives for regulatory action. Written comments were accepted from the public during a comment period, which lasted until February 6, 2008 (See appendix F).

1. Scoping Analysis and Documentation

All comments and proposed alternatives received were evaluated on the basis of whether they addressed the issues in question, were based on valid science, and were reasonable and practicable. A summary of the public comments is provided in appendix F to this EIS. The results of the scoping process helped APHIS to formulate the alternatives that were analyzed in the DEIS. Relevant issues raised through the scoping process were incorporated into the formulation of the regulatory alternatives as described in chapter 2 and issues discussed in chapters 3 and 4.

2. How the DEIS was Developed

On January 7, 2008, APHIS published in the *FR* a Notice of Intent (NOI) (73 *FR* 1198–1200) to prepare a DEIS, in compliance with NEPA and the APHIS NEPA implementation rules. The purpose of the DEIS is to identify and analyze any environmental impacts that could result from the granting of nonregulated status to two lines of genetically engineered, GT alfalfa, designated J101 and J163. As described above, the NOI posed several questions in broad categories related to issues of potential concern. The 30-day comment period closed on February 6, 2008. APHIS received and reviewed approximately 240 public comments. These and all other comments were analyzed, and APHIS identified any new issues not originally provided in the NOI.

APHIS considered all comments received in response to the *FR* notice to ensure that all pertinent issues were addressed, and that the EIS examined any environmental impacts that could result from a decision to grant or not grant nonregulated status to GT alfalfa lines J101 and J163. The results of the scoping process and NOI are summarized in appendix F.

3. How the Final Environmental Impact Statement was Developed

In December 2009, APHIS made the DEIS available for public comment. The DEIS was available for an extended 75-day comment period, which closed on March 3, 2010. APHIS also held four public meetings across the United States during the open comment period. Approximately 133 people attended these public meetings. APHIS received and reviewed approximately 244,000 public comments on the DEIS. Substantive comments and recommended studies were considered for incorporation and revision for the final EIS (FEIS). Responses to all substantive comments are included in chapter 5 of the FEIS.

E. Purpose and Need for Agency Action

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

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

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

F. Requirements for Further Environmental Analysis

APHIS is issuing this FEIS which addresses public comments received on the DEIS, in accordance with NEPA regulations. Supplements to the FEIS could be necessary as new information is brought to the agency's attention, as changes occur in the program or its administration, or as the scope of the document is expanded (40 CFR § 1502.9).

II. Alternatives

A. Introduction

The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for regulating the introduction (importation, interstate movement, and environmental release) of genetically engineered (GE) organisms that are known to, or could, pose a plant pest risk. GE organisms are considered to be regulated articles if the donor organism, recipient organism, vector, or vector agent used in their creation is a member of a taxonomic group listed in the regulations at 7 CFR part 340 and is known to be a plant pest or the plant pest status of that organism is not known or there is a reason to believe that one of these organisms may be a plant pest.

A person may petition the agency to evaluate submitted data and assess whether a particular regulated article is unlikely to pose a plant pest risk, and, therefore, should no longer be subject to the regulations in 7 CFR 340. This petition process is described in 7 CFR § 340.6 "Petition for Determination of Nonregulated Status." The petitioner is required to provide information (§ 340.6(c)(4)) related to plant pest risk that the agency uses to assess whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. If, based on this information, the agency concludes that the article is unlikely to pose a plant pest risk, the agency may make a determination to approve the petition and confer nonregulated status on the regulated article Thereafter, APHIS would no longer require permits or notification for the introduction of this GE organism.

As discussed in chapter 1, the mission of the agency is to protect American agriculture from the introduction and dissemination of plant pests (in general), and in the case of GE organisms, to do so by implementing the regulations established in 7 CFR 340. In response to a petition under those regulations, for two lines of glyphosate tolerant alfalfa, APHIS conducted a plant pest risk assessment (Appendix W). This assessment indicates that both GT alfalfa lines J101 and J163[1] are no more likely to pose a plant pest risk than other alfalfa varieties. Therefore, APHIS is considering whether to grant nonregulated status to the varieties. This Environmental Impact Statement will inform the APHIS Administrator of potential impacts on the human environment of GT alfalfa's use in American agriculture if APHIS were to grant the varieties non-regulated status.

[1] Throughout this document "GT alfalfa" refers to glyphosate-tolerant alfalfa lines J101 and J163

This analysis also considers the impacts of a management program that could be implemented with the commercial use of GT alfalfa.

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

B. Description of Alternatives

This EIS analyzes the potential environmental consequences of a proposal to grant nonregulated status to glyphosate-tolerant (GT) alfalfa. APHIS considered the impacts to the human environment of three alternative actions, each of which are described in more detail below:

These alternatives include:

1. Deny the petition (no action alternative).
2. Grant the petition in full (preferred alternative).
3. Allow the commercialization of GT alfalfa using a combination of restrictions on hay and seed production designed to promote coexistence. It includes a combination of best management practices, isolation distances, and geographic restrictions (preferred alternative).

These alternatives represent a full range of reasonable alternatives in reference to the petition for nonregulated status of GT alfalfa and are framed to highlight the issues associated with the cultivation of GT alfalfa if it is allowed to have nonregulated status. These alternatives vary in their feasibility based on regulatory and economic considerations. An additional alternative is analyzed in detail in this final EIS. The inclusion of this alternative in the detailed analysis is based on public comments on the DEIS. Several commenters believed that an alternative that considered isolation distances and geographic restrictions was reasonable and should not have been dismissed from detailed consideration as it was in the DEIS.

APHIS is therefore analyzing the additional alternative in detail. This third alternative combines very specific isolation distances and geographic restrictions. Additional alternatives rejected from further consideration are discussed in Section C below.

1. No Action

Under the No Action Alternative, APHIS would deny the petition to grant nonregulated status to glyphosate-tolerant (GT) alfalfa lines J101 and J163, The lines would continue to be subject to the regulations in 7 CFR part 340. Permits would continue to be required to introduce viable GT alfalfa plant material[2]. Permit conditions would be specified by APHIS. These conditions would be designed to confine GT alfalfa. The size of planting would be limited to help maintain confinement. In addition, the number of permits granted would be limited by agency resources, both in terms of the number of permits which could be reviewed by APHIS, and in APHIS' ability to inspect the fields and enforce compliance with regulations. Therefore, the number of acres planted and the amount of seed and hay transported between states would likely be far less than the current commercial production of conventionally-bred alfalfa for seed and hay in the U.S. In time it is expected that the number of acres of GT alfalfa would decrease because the alfalfa that was planted while GT alfalfa had nonregulated status would be replaced by conventional varieties.

2. Grant Nonregulated Status to Both Lines (Deregulation Alternative)

Under the Deregulation alternative, GT alfalfa would be granted non-regulated status and would no longer be subject to the regulations at 7 CFR part 340. Permits or notifications issued by APHIS would no longer be required for introductions of GT alfalfa derived from these events. Under this alternative, growers could freely move and plant GT alfalfa seed without further oversight from APHIS. Although APHIS would no longer have any regulatory control over the planting, distribution, or other actions related to GT alfalfa, APHIS does assume that growers would continue to be subject to contract restrictions imposed by Monsanto's technology use agreement.[3] These non-regulatory restrictions include managing hay to prevent seed production, harvesting at or before ten percent bloom in areas where seed is produced, and prohibitions on use in wildlife feed plots. Similarly, growers who raise alfalfa for seed are assumed to be directly contracted by the licensee, Forage Genetics, and are required to follow Forage Genetics Best Practices. These management practices include pollinator management, specific isolation distances, stand termination documentation, and product segregation (FGI, 2007). The developer, Forage Genetics International, predicts that approximately 50 percent of the alfalfa acres would be planted to GT alfalfa. There is a

[2] Introduce is defined in 7CFR 340.1 as: To move into or through the United States, to release into the environment, to move interstate, or any attempt thereat.

[3] http://www.monsanto.com/SiteCollectionDocuments/Technology-Use-Guide.pdf

prediction that the majority of these acres would be located in the Western U.S. Because glyphosate is not labeled for use on seed in all states, only in those states where it is labeled for use on seed will likely have any GT alfalfa seed production.

3. Combined Isolation Distances and Geographic Restrictions on the Production of GT Alfalfa

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

The following is a description of the very specific management practices that would be included in the requirements described above for GT alfalfa.

GT Alfalfa Production

- GT alfalfa forage fields may not be harvested for seed. The only GT alfalfa seed fields would be in the geographically restricted areas, described below, that are designated for GT alfalfa seed.
- GT alfalfa seed bag labeling and seed identification (e.g., a unique seed colorant) would be required. These product identity mechanisms would be designed to notify all GT alfalfa forage growers of the presence of the GT alfalfa trait and the geographic limitations for product use.
- An annual report would be submitted to the USDA summarizing activities in education and training, monitoring, and compliance with the conditions of this license agreement. The USDA or a designated third party could audit the petitioner's records to determine compliance with the conditions of this license or otherwise investigate potential noncompliance with these conditions.

- Develop an education program and provide training to ensure that all growers, distributers and handlers of GT alfalfa are aware of the management practices, geographic restrictions and the isolation distance set forth in this licensing.

GT Alfalfa Forage

- In Tier I states there are no restrictions on planting GT alfalfa for forage production. Tier I states are those states in which commercial alfalfa seed is not produced. The 2007 Census of Agriculture identifies these states as: Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New Jersey, Pennsylvania, Maryland, Delaware, West Virginia, Virginia, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, Arkansas, Tennessee, Kentucky, Indiana, Illinois, Wisconsin, Alaska, and Hawaii.
- Tier II states are those states that produce some seed, but seed production is limited to less than one percent of the total U.S. seed production. States in Tier II are: Colorado, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, New Mexico, New York, North Dakota, Ohio, Oklahoma, South Dakota, and Texas.
- In Tier II states, GT alfalfa planted within 165 ft of a seed field must be harvested at or before ten percent bloom.
- Tier III states produce more than 1 percent of the U.S. alfalfa seed. These states are: Arizona, California, Idaho, Montana, Nevada, Oregon, Utah, Washington, and Wyoming.
- In Tier III states GT alfalfa for forage cannot be planted in counties where seed is grown (based on the 2007 Census of Agriculture). If a GT alfalfa forage field is located within 165 ft of a conventional alfalfa seed field (which may occur on the border of a county), the GT alfalfa grower must harvest forage at or before ten percent bloom. All GT alfalfa forage growers are required to report GPS coordinates of all GT alfalfa forage field locations. GPS field location information will be made available to the supervising program and seed certifying agencies for monitoring and for enforcing the planting restrictions applicable to GT alfalfa forage fields.

GT alfalfa seed production

- GT alfalfa seed production will be limited to the geographic areas in Tiers II and III where the grower can maintain isolation distances of 5 miles between GT alfalfa and conventional alfalfa.
- Field locations will be identified by GPS and will be included in the annual report to USDA. Location data will be made available to official seed certifying agencies upon request.

- Equipment will be used only for GT alfalfa seed production or cleaned by an appropriate protocol to remove GT alfalfa from the equipment before use on other (not GT alfalfa) crops.
- GT alfalfa seed will be handled and stored in a way to prevent comingling with other agricultural products.

C. Alternatives Rejected from Further Consideration

1. Impose Testing Requirement

During the comment periods for other petitions for granting nonregulated status, and during the scoping period for this EIS, some comments have requested that USDA require and provide testing for GE products in non-GE production systems. APHIS has rejected this alternative from further consideration first because it is outside of the scope of the decision being made through this NEPA process. The action that is being considered under this NEPA analysis is whether or not to grant a petition in whole or in part to GT alfalfa. An alternative with testing for GE products in non-GE production systems would be a regulatory program and not a full deregulation (non-regulatory) alternative. Moreover, requiring testing of non-GT alfalfa would burden growers of alfalfa who are not currently (or have ever been) subject to the regulations in 7 CFR 340. Such a regulatory imposition may increase the likelihood that growers of non-GE crops would be held responsible to demonstrate that their crops contain no (or below a certain threshold of) GE varieties. It has no bearing on APHIS' need to protect U.S. agriculture from the introduction and dissemination of plant pests, and it is inconsistent with an equitable coexistence policy. Therefore, this alternative does not meet the purpose and need described in Chapter 1 of this EIS.

2. Ban Planting of GT Alfalfa

Several comments suggested that APHIS consider an alternative where GT alfalfa would no longer be grown for seed or hay in the United States even under regulatory permits. Current planting of GT alfalfa would need to be removed from fields where it is planted. Current seed stores would need to be destroyed or shipped to countries that permit the use of this product. Non-GT alfalfa varieties would be available to growers who wish to grow alfalfa. Research and development of glyphosate tolerant alfalfa varieties would not be permitted.

APHIS has rejected this alternative from further analysis because it does not meet the purpose and need described in Chapter 1. APHIS currently regulates GT alfalfa under 7 CFR part 340. APHIS would not be able to authorize their introduction even with permits and notifications, which is currently done under the regulations. APHIS has issued many of these regulatory authorizations in the past and has not identified any plant pest-related justification to discontinue issuing permits or acknowledge notifications for GT alfalfa. To prohibit all planting and growth of GE

alfalfa plants even plantings under confined conditions would be inconsistent with BRS' mission to allow the safe development of GE organisms. Further, an outright complete ban on any permitted planting and growing of GT alfalfa would be inconsistent with the Department's need to support the coexistence of GE and non-GE production systems.

Adopting this alternative would prohibit growers from choosing to grow GT alfalfa.

3. Grant Nonregulated Status to Only One Variety of GT Alfalfa

APHIS has removed from consideration the concept of approving only one of the genetically-engineered GT alfalfa lines (either J101 or J163) and not both lines. APHIS conducted a risk assessment of the plant pest risks posed by GT alfalfa lines J101 and J163 (USDA-APHIS, 2009). The risk assessment of GT alfalfa J101 and J163 suggests that neither J101 nor J163 pose a greater plant pest risk than other alfalfa varieties: 1) neither of the two lines show any evidence of increased weediness compared to the other alfalfa varieties; 2) neither line exhibits increased insect or disease susceptibility when compared to other alfalfa varieties in similar environments; 3) the genetic sequences from plant pests inserted into either one of the two alfalfa lines do not pose a plant pest risk; and 4) neither line exhibits increased plant pest risk characteristics. There are also no significant biological differences between the two lines in terms of transgene protein expression and composition (chapter 3). Additionally, none of the comments received during the public comment period of the original EA in 2005 (USDA, 2005) and during the public comment period of the NOI or the Draft EIS cited concerns regarding a difference in or occurrence of any plant pest risks in GT alfalfa lines J101 and J163. Since there are no biological differences between GT alfalfa lines J101 and J163 (and the public comments did not raise or claim any perceived differences in GT alfalfa lines J101 and J163), APHIS has no scientific basis for distinguishing the two GT alfalfa lines. APHIS will only issue a decision in conjunction with both GT alfalfa lines and will not consider granting nonregulated status to only one of the GT alfalfa lines.

D. Comparison of Impacts by Alternative Matrix

Table 2-1 below summarizes the environmental impacts of the proposed action and alternatives by resource area.

Table 2-1. Summary of Impacts of Each Alternative

	No Action Alternative	**Deregulation Alternative – Grant Nonregulated Status to Both Lines**	**Isolation/Geographic Restriction Alternative**
Biological resources	• Gene flow from GT alfalfa would remain the same for the GT alfalfa currently planted. In time, conventional alfalfa would be expected to replace most GT alfalfa. However some GT alfalfa may still be planted under permit. • GT Weed shifts and GR weeds may occur in alfalfa. However due to the low acreage it is not likely to occur over the larger landscape. • No adverse impacts on plants and animals from conventional alfalfa or the GT alfalfa gene product. • In the short-term, impacts on plants and animals from exposure to glyphosate would remain the same. In time, as GT alfalfa is replaced, greater impacts on plants and animals may occur if use of herbicides with higher EIQs is used on conventional alfalfa.	• AP of GT alfalfa genes could be found in conventional alfalfa at low levels. • New GR weed biotypes would likely be slow to develop in GT alfalfa stands. • GR and GT weed shifts may occur. • GT alfalfa gene product is not expected to adversely affect plants and animals. • Increased glyphosate use could affect non-target plants, but is not expected to adversely affect animals.	• AP of GT alfalfa genes could be found in conventional alfalfa at low levels. Likelihood of finding GT alfalfa genes in non-GT alfalfa lower than deregulation alternative. • New GR weed biotypes – similar to Deregulation Alternative. • Weed shifts- similar to Deregulation Alternative. • Gene product – similar to Deregulation Alternative. • Glyphosate use – similar to No Action Alternative in areas where GT alfalfa would be prohibited, and similar to Deregulation Alternative in areas where GT alfalfa is cultivated.

	No Action Alternative	Deregulation Alternative – Grant Nonregulated Status to Both Lines	Isolation/Geographic Restriction Alternative
Socioeconomics	• Loss of opportunity for improved quality and/or reduced costs of alfalfa hay. • Loss of opportunity for marketing and business efforts conducted over GT alfalfa planted during the time in which it was deregulated. • No adverse effect on organic farmers regarding potential increased production costs or decreased demand. • However, organic farmers would not have the opportunity to gain market of GT-sensitive consumers.	• GT alfalfa could offer alfalfa hay farmers high quality alfalfa hay at relatively lower costs. • The extent to which the preference for non-GE modified food translates to decreased demand (sales) for conventional and organic products under the potential AP of GE content in feed used for dairy and meet cattle in the production chain of organic foods is unclear. • The extent to which GT sensitive domestic and foreign markets are affected depends on the extent to which gene flow can be controlled through stewardship programs. These programs might or might not increase the costs of seed production for sensitive markets. To the extent that they do, the impact on overall demand is likely to be low, given the low sensitivity of the demand for alfalfa seeds to changes in price. • There is no evidence that the domestic or export market for organic dairy and meat derived from alfalfa-fed cattle would be lost to domestic alfalfa producers, or that the credibility of the NOP would be compromised.	• Tier I states – similar to Deregulation Alternative. • Tier II states – hay growers would have similar costs to those for the Deregulation Alternative; growers of seed who are selling to markets that are not sensitive to AP of GT alfalfa seed would not incur any additional costs. Growers of seed for sensitive markets may need to provide additional isolation from GT alfalfa hay fields. • Tier III states – GT alfalfa hay production would be prohibited in designated counties; therefore any profit that could be obtained through the sale of GT hay would be lost. . Growers of seed for GT alfalfa-sensitive markets would not incur the additional costs of maintaining segregated plantings and buffers as under the Deregulation Alternative. • Hay growers in Tier III counties designated for hay production would be able to grow GT alfalfa hay with some restrictions. • Growers of GT alfalfa seed likely to become concentrated by region to maintain isolation distances from conventional seed growers.

	No Action Alternative	Deregulation Alternative – Grant Nonregulated Status to Both Lines	Isolation/Geographic Restriction Alternative
Human Health & Safety	• For the GT alfalfa currently in production, the gene product would have no adverse effects on livestock or humans. • For future plantings, risks to human health and safety from the gene product fertilization of livestock feed would not change from current conditions. • No change in the current exposure to glyphosate residues or to the current exposure to the other herbicides currently used in alfalfa production. • For workers, exposure to glyphosate or other herbicide residues would remain the same as current exposure.	• No adverse impacts are expected.	• Same as Deregulation Alternative.

	No Action Alternative	Deregulation Alternative – Grant Nonregulated Status to Both Lines	Isolation/Geographic Restriction Alternative
Land Use & Physical Environment	• Farmers would be limited to the cultivation options and production practices associated with conventional varieties of alfalfa. • Organic farmers would no longer need to use adopted management practices to ensure GT-free alfalfa. • Little or no impact on soils in the acres of GT alfalfa currently under production. • Possibility of increased soil erosion and disturbances to soil microorganisms due to preclusion of an increase in the amount of acres managed with conservation tillage and no-tillage systems. • Little potential for the conversion of conventional agricultural systems to commercial GT alfalfa fields.	• No adverse impacts on soils, climate, air quality, water, or water use are expected. • Land devoted to alfalfa cultivation would be affected largely by the price of alfalfa hay and not by the availability of GT technology.	• Tier I and Tier II states – similar to Deregulation Alternative. • Tier III states – growers may chose to plant GT alfalfa to serve local markets. Because some growers in neighboring counties would not be allowed to plant GT alfalfa, certain growers in permitted counties may chose to plant additional acres of GT alfalfa to sell in the restricted counties if there is local demand for the product. Seed production of GT alfalfa and non-GT alfalfa would be segregated. In areas where GT alfalfa seed is grown, the concentration of alfalfa seed fields may increase. Growers in these areas may convert land from other uses to alfalfa seed production.
Herbicide Use	• In the short term, rates and volumes of glyphosate and other (non-glyphosate) herbicide applications would remain unchanged in the context of application to alfalfa fields. In	• Glyphosate use would increase. • Other (non-glyphosate) herbicide use could increase, decrease, or remain the same. • The net effect will likely be	• Similar to Deregulation Alternative.

	No Action Alternative	Deregulation Alternative – Grant Nonregulated Status to Both Lines	Isolation/Geographic Restriction Alternative
	the long term, volumes of herbicides with higher EIQs compared to glyphosate may increase or remain unchanged as conventional alfalfa replaces GT alfalfa.	increased use of glyphosate with a decreased, an unchanged, or an increased use of herbicides with higher EIQs compared to glyphosate.	

Notes: GT = glyphosate tolerant; GR = glyphosate resistant GE = genetically engineered; T&E = threatened and endangered; NOP = National Organic Program; EIQ = environmental impact quotient

III. Affected Environment

A. Overview of Alfalfa

Alfalfa (*Medicago sativa* L.) is among the most important forage crops in the United States, with more than 20 million acres in cultivation. It is recognized as the oldest plant grown solely for forage. Conventional alfalfa (alfalfa that is not a genetically engineered (GE) variety and is not grown using organic practices) has been used by farmers as livestock feed for decades because of its high protein and low fiber content. Alfalfa ranks fourth on the list of most widely grown crops by acreage, behind corn, soybeans, and wheat, and is ranked third among agricultural crops in terms of value. Because it is widespread and is typically grown as a perennial crop, alfalfa also provides habitat for wildlife (Putnam et al., 2001; Kuhn et al., 1996).

Dairy farmers would be the most likely users of glyphosate-tolerant (GT) alfalfa because they often depend on pure alfalfa stands that are free of weeds and grasses, whereas beef cattle producers and horse owners typically feed their animals a mix of alfalfa-grass hay (Putnam, 2005). About 40 percent of U.S. alfalfa acreage is planted as pure stands, 30 percent is planted with a cover or nurse crop, and about 25 percent is planted with grasses or another companion crop (Rogan and Fitzpatrick, 2004).

The following discussion is in part taken from the technical report, *Effects of Glyphosate-Resistant Weeds in Agricultural Systems* (appendix G to this Environmental Impact Statement [EIS]).

1. Uses of Alfalfa

Seed

Based on testimony provided to Food and Drug Administration (FDA) in 1998 by sprout industry expert Dr. Earl Hauserman, an estimated 2.5 percent or less of seeds is used for human consumption (DHHS FDA, 1998). Humans consume alfalfa in the form of sprouts, dietary supplements, and herbal teas, with sprouts representing the vast majority (more than 95 percent by weight) of this consumption in the United States. The seed grown for sprouts is subject to more stringent restrictions for chemical applications during growing because the chemicals must be evaluated as food residues. Furthermore, epidemiological (disease-related) investigations have suggested that alfalfa seeds may be the source of sprout-associated illness outbreaks. Thus, preventive controls are used to reduce the risk of raw sprouts serving as a vehicle for foodborne illness. For example, sprout seed and hay seed used for forage are usually grown separately (FDA 1999).

Some GT alfalfa was planted without restrictions during the 2005 and 2006 growing seasons because of Animal and Plant Health Inspection Service's (APHIS) initial deregulation determination that occurred in 2005. Prior to this, Monsanto and Forage Genetics International completed a consultation with FDA regarding the foods and feeds derived from GT alfalfa events J101 and J163. As part of that consultation, Monsanto and FGI concluded that the feeds and foods derived from GT alfalfa events J101 and J163 are not materially different in safety, composition, or any other relevant parameter from alfalfa now grown, marketed, and consumed. FDA had no questions about Monsanto and FGI's conclusion (U.S. FDA 2004a, b—see appendix P). However, Monsanto does not allow GT alfalfa to be planted for sprouts (Monsanto 2008), a restriction that is enforced through signed agreements between Monsanto/FGI and purchasers of GT alfalfa seeds.

Forage

Alfalfa is considered the "Queen of Forages" because of its high nutritional content for ruminants and horses (Putnam et al., 2001). As alfalfa grows, yield increases until alfalfa yield peaks at full bloom. Nutritional content, however, is highest in young vegetative alfalfa plants and decreases as plants approach full flower. 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 (too young to milk), and non-lactating dairy cows (Ball et al., 2001). Alfalfa for livestock feed is stored in a variety of forms such as hay (dry baled at 18 to 20 percent moisture); haylage (round bale silage, baled at 50 to 60 percent moisture and wrapped in plastic); and silage (chopped and blown into a silo or a truck).

Grazing

Grazing is sometimes used as an alternative to harvesting alfalfa. Grazing alfalfa in a vegetative state has the potential to provide high nutritional gains per animal, but the risks include animal losses due to gastrointestinal bloating and difficulties in alfalfa stand maintenance if continuous grazing is allowed. Farmers might choose grazing for dormant-season alfalfa stubble, a substitute for early or late season cutting, and rotational grazing during the growing season (Orloff et al., 1997). Alfalfa for grazing can be planted with companion perennial grasses to reduce bloat (Sullivan, 1992).

Other

Alfalfa and clover are common nectar sources for supporting the hives of honey bees. Although alfalfa is not specifically grown for bees, hives of both managed and wild bees are often associated with alfalfa fields (Hammon et al., 2007). Alfalfa plants are also used for a variety of non-

agricultural purposes. These uses include rehabilitation of overgrazed rangelands, erosion-control projects in interior forests, treatment of compacted soils, revegetation of areas damaged by wildfire, and erosion reduction in mined soils (Sullivan, 1992). In addition, seed mixes that include alfalfa are used for the United States Department of Agriculture's (USDA) Conservation Reserve Program (CRP) (USDA 2007; FAPRI, 2007). Alfalfa is often grown with a companion crop, such as small grains, to control weeds, increase forage yields for the first cutting of the seeding year, and protect alfalfa seedlings from wind or frost (Orloff et al., 1997).

Area of Adaptation

2. Biology of Conventional Alfalfa

Alfalfa is recognized as a widely adapted crop, growing in all continental States, and in Alaska and Hawaii. Alfalfa grows best in fertile, well-drained soils; however, because of its adaptability, it also survives outside of cultivation. Feral alfalfa populations, although sparse, occur throughout the United States (appendix H, Bagavathiannan and Van Acker, 2009, USDA NRCS 2010).

Little evidence exists to suggest that alfalfa is considered a weed (see appendices G and H), other than as a volunteer in agricultural settings. In correspondence with 13 weed control experts in Arizona, California, Idaho, Oregon, Pennsylvania, South Dakota, Washington, and Wisconsin, Monsanto found that none considered alfalfa a weed. In South Dakota and Wisconsin, it is encouraged to grow along roadsides (Rogan and Fitzpatrick, 2004). Alfalfa is not native to North America and is considered "naturalized" (Rogan and Fitzpatrick, 2004).

Growth and Reproduction

Alfalfa is a deep-rooted and short-lived perennial. During establishment, alfalfa initially grows from seed, but after each harvest or winter, it regrows from buds arising from the perennial root structure (the crown). Conventional alfalfa forage is grown in pure and mixed-species forage systems, or to a lesser extent, grazed in pasture or rangeland. The vegetative growth interval (i.e., harvest schedule) during most of the year is 22 to 40 days, and the crop is typically harvested for forage three to eight times per year, depending on location and seasonal climate (Van Deynze et al., 2008). Fields grown for hay production are typically maintained for three to six years or longer in some areas, with an average of five to six years (Rogan and Fitzpatrick, 2004). Most alfalfa in the United States is managed to limit growth to the juvenile (vegetative) state so that forage production (yield) and nutritional quality of the hay are optimized. Hay with open flowers or seed (late maturity) is lower quality for feed and has lower market value than the premium and supreme hay that is harvested before bloom or in early bloom. In seed fields, flowering

and seed production are promoted. In most fields, flower buds begin to form on stems approximately four to six weeks after field mowing during long-day photoperiods and warm weather. Flowering is not triggered under short days or cool weather (i.e., late summer through mid spring). Once flowering ensues, alfalfa flowers indeterminately, and its duration depends on moisture, temperature, and other factors (Rogan and Fitzpatrick, 2004).

Alfalfa is predominantly cross-pollinated and the flowers depend entirely on bees for cross-pollination. Wind cross-pollination in alfalfa does not occur (Viands et al., 1988). Alfalfa requires bees to physically "trip" flowers to release pollen for egg fertilization and seed production. In the United States, alfalfa seed production fields are pollinated primarily with leafcutter bees (*Megachile rotundata* F.) in the Pacific Northwest and honey bees *(Apis mellifera)* in California. Some growers in niche areas of southern Washington use alkali bees (*Nomia melanderi* C.), and certain seed producers use a blend of cultured species for pollination. Native bees, including *Bombus* spp., *Osmia* spp., *Agapostomen* spp., and *Megachile* spp. can be found visiting alfalfa in varying numbers. Other insect pollinators have not been shown to be effective for alfalfa (Rogan and Fitzpatrick, 2004).

Plant Genetics and Gene Flow

Gene flow is a measure of the exchange of genes between populations, and it occurs naturally between alfalfa populations. Gene flow between alfalfa populations could occur via transfer of pollen, most commonly by insect pollinators, or by dispersal or accidental mixing of seeds. Alfalfa does not naturally hybridize with any wild relatives in North America (appendix I). For more information on plant genetics and gene flow see section IV.B and appendix I.

Gene Flow Due to Pollen Transfer and Pollination

Alfalfa is pollinated by several different pollinators but agricultural farmers typically utilize three different bee species: leafcutter bees, alkali bees, and honey bees. Selection of pollinators is not based on the type of alfalfa grown (e.g., GT, conventional, or organic) and isolation distances are typically employed to reduce the likelihood of gene flow between alfalfa populations. Although many wild bee species are efficient alfalfa pollinators (Brunet and Stewart, 2010), most regions that cultivated alfalfa set seed do not have naturally occurring populations of these insects (Rogan and Fitzpatrick, 2004). Alfalfa farmers purposely stock bees only in seed farming, as they do not want or need pollination of hay fields. In general, alfalfa seed production is pollinated with leafcutter and alkali bees as they are more effective pollinators than honey bees (Mueller, 2008).

Bee habits vary by species and also by range and climate. In general, bees will forage where they need to in order to collect pollen and nectar. If there is an abundant source of both close to the nest, then their average foraging distances will be lower than if the bees must forage farther to find adequate pollen and nectar (Pasquet et al., 2008). In terms of foraging distances, leafcutter bees will forage for up to a mile from the nest (Pitts-singer, 2008), honey bees typically forage within 1.86 miles of the nest (Beekman and Ratnieks, 2000), and alkali bees will forage up to 4 to 5 miles away, but pollination typically occurs are within a 2 mile radius (USGS, 2008). Passive transfer of pollen, which could also result in gene flow, is also possible due to physical contact between bees (Mueller, 2005). However, it is unlikely that gene flow would result from passive pollen transfer among cohabitating bees due to very little accumulation of viable pollen on the surface of bees that make repeated foraging trips to an alfalfa field or feral grouping of plants. For more information on pollination see IV.B.2 and appendix I.

Gene Flow Due to Secondary Seedlings

Secondary seedlings (seedlings that are not planted directly by the farmer but rather sprout unintentionally) are an unlikely avenue for effective gene flow into existing solid-seeded alfalfa plantings as alfalfa plants and alfalfa debris produce compounds that elicit an autotoxic reaction to germinating alfalfa seeds. Cultivated fields do not successfully self-seed. Attempts to thicken existing alfalfa stands by deliberately inter-planting new seed into them typically fail, which is why most agronomists do not recommend the practice (Canevari et al., 2000).

There are several possible pathways for the unintentional distribution of alfalfa seeds that may lead to gene flow due to secondary seedlings. These include:

- Factors associated with the harvest, processing, or storage of alfalfa seeds. Secondary seedlings may occur if alfalfa harvests for seed production result in high rates of seed shattering in fields. Improper cleaning of shared harvesting and processing equipment could result in secondary seed dispersal (Mallory-Smith and Zapiola, 2008). Finally, spillage during transportation (failure to tarp, insecure gates, etc.) could contribute to dispersal.
- Factors associated with weather. Extreme weather phenomenon could contribute to the dispersal of seeds and result in secondary seedlings. Natural dispersal due to extreme weather events cannot be prevented (Mallory-Smith and Zapiola, 2008).
- Factors associated with animals. Seed predation of ripe seeds both on standing plants and shattered seeds left in harvested fields could be transported by birds or other animals. Natural dispersal of seeds due to

wildlife can contribute to gene flow and cannot be prevented (Mallory-Smith and Zapiola, 2008).

For more information on gene flow due to secondary seedlings, see chapter IV.B and appendix V (4.5).

Seed Purity

Seed farmers are concerned with the purity of their seed stock, and follow State and Federal-mandated standards in order to produce seed of certified purity. Isolation distances between fields and threshold amounts of other varieties that are allowable in a crop vary by State, but in general, seed stock must be 99 percent of the variety or varieties stated on the label.

If a seed stock is 99 percent the variety or varieties stated on the label, then up to one percent of the seed is not the stated variety and is called 'off-type.' Assuming that off-type has the same germination (the process of a seed beginning to sprout) and fitness (a measure of survival and reproduction) as the certified variety, one can calculate the number of plants in an acre that would be off-type.[4] A thriving alfalfa hay field can have 15 plants per square foot (Orloff et al., 1997), which equals 653,400 plants in an acre (0.5 percent of 653,400 is 3,267). If the variety present in low levels is mixed evenly in the seed batch, then there might be an off-type plant every 13.3 square feet. In older stands where plant density may be closer to five plants per square foot, there might be an off-type plant every 40 square feet. For more information on seed purity see chapter IV.B.2.

Gene Flow to Other Alfalfa Crops and Wild Relatives

Gene flow occurs naturally among alfalfa in hay fields, seed fields, and feral and other alfalfa populations via bees and secondary seedlings.

Hybrids between alfalfa and other *Medicago* species in the United States are limited to hybridization between *M. sativa* subspecies. As discussed in appendix I and V. 5.5, 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.

The potential for gene flow exists only between different alfalfa crop fields and between crop and feral alfalfa. The three alfalfa populations discussed are defined as follows (based partly on Bagavathiannan and Van Acker 2008, 2009):

[4] Only 60 percent of the seeds germinate and emerge and only 40 percent of emerged seedlings survive the first year (Orloff et al., 1997).

- *Hay field population*: agricultural field that is intentionally planted with alfalfa and is harvested for hay (may also include some grazing).
- *Seed field population*: agricultural field that is intentionally planted with alfalfa and is harvested as seed stock.
- *Feral and other alfalfa:*

– *Feral* — alfalfa growing on any nonagricultural land (including roadsides, fences, waste lots) that reproduces without intentional human inputs, including reseeding. This is considered the "naturalized" population in the United States because alfalfa was introduced to the continent at least 200 years ago (Putnam et al., 2001).

– *Habitat/rehabilitation/erosion control* — alfalfa that is intentionally sown (most likely in a seed mix), but is not managed after planting.

– *Rangeland* — seed may be sporadically sown for grazing, but land is not mowed for regular hay harvest, populations are mostly self sustaining.

– *Volunteer* — alfalfa growing unintentionally, out of rotation in an agricultural field with another crop (e.g., corn).

– *Escaped volunteer* — alfalfa from seed that escaped from an agricultural field (this is the first generation of a feral population). Escaped and isolated plants could represent a founder event for new feral populations. Escaped volunteers may not persist, depending on conditions.

There are several factors that influence the probability of gene flow between these fields. The following is a list of factors adapted from Putnam (2006):

- Probability of synchronous flowering (e.g., the percentage of days where several plants flower simultaneously).
- Availability of pollen (e.g., the percentage of bloom during each day of synchronous flowering).
- Pollinator activity on days of synchronous flowering and placement of beehives (e.g., influenced by timed bee release and weather).
- Distance between fields (alfalfa populations).
- Size of fields (alfalfa populations).
- Probability of seed maturation.
- Probability of seed germination.

For more information on gene flow to other alfalfa crops and wild relatives see IV.B and appendixes I and V.

Related Species

Alfalfa, of the genus *Medicago,* is in the tribe Trifolieae, which includes *Trifolium* (true clovers), *Melilotus* (sweetclover), and *Trigonella* (fenugreek). *Medicago* species do not hybridize (interbreed to form hybrid offspring) with these (or other) genera. The *M. sativa* complex has been successfully hybridized with 12 other perennial *Medicago* species (McCoy and Bingham, 1988). Many of these interspecific hybrids have been successful, however, only by using embryo culture of the hybrid in the greenhouse or laboratory (McCoy et al., 1986), making them highly unlikely to occur in nature. No perennial *Medicago* species are present naturally in the Americas, Australia, New Zealand, or South Africa, as it is native to the Middle East and Central Asia (Xu et al., 2004).

Susceptibility to Glyphosate and Other Herbicides

According to Crop Data Management System's (CDMS) Agricultural Product Label Service database, the herbicides 2,4-D, clopyralid, dicamba, glufosinate, glyphosate, and primsulfuron-methyl were labeled for control (removal) of alfalfa. Independent research has demonstrated that dicamba, 2,4-D, tank mixtures of dicamba and 2,4-D, and clopyralid were often more effective than glyphosate for terminating alfalfa stands (Endres, 1999; Mayerle, 2002; Manitoba Agriculture and Food, 2002). Additional data demonstrated that early post-emergence applications of herbicides (applied during the stage between the emergence of a seedling and the maturity of the plant) used to control weeds in corn (Harness XTRA (acetochlor + atrazine), Degree (acetochlor), and Degree XTRA (acetochlor + atrazine) applied in tank mixtures with broadleaf herbicides Banvel (dicamba), 2,4-D, Marksman (atrazine + dicamba), and Hornet (clopyralid + flumetsulam) effectively controlled GT alfalfa in a GT corn crop. As expected, GT alfalfa events J101 and J163 were susceptible to herbicides typically used to control alfalfa Rogan and Fitzpatrick 2004). Other plant traits were no different from non-GT alfalfa (see appendix U).

Susceptibility to Insect Damage and Disease

The major alfalfa diseases of economic importance in the United States are caused by those pathogens that impact the foliar, crown, root, vascular, and seedling health of the alfalfa plants. Alfalfa diseases are primarily caused by fungi; however, nematodes, bacteria, viruses, and other microbes also cause economic losses in alfalfa production (Leath et al., 1988). Diseases that occurred in the GT alfalfa test locations included, but were not limited to, seedling damping-off (caused by fungi such as such as *Pythium, Phytophthora,* and *Aphanomyces*); foliar diseases (caused by fungi such as *Leptosphaerulina, Colletotrichum, Peronospora, Phoma, Stemphylium, Cercospora*, and stem nematodes like *Ditylenchus*); and root rots, vascular wilts, and crown diseases (caused by fungi such as

Phytophthora, Verticillium, Fusarium, Phoma, and bacterial wilt caused by *Clavibacter*) (Rogan and Fitzpatrick, 2004).

Insect pest species that are economically important in alfalfa vary widely among regions in the United States. The broad geographic distribution of the GT alfalfa test sites in the United States, and even broader exposure since deregulation in 2005, has exposed GT alfalfa to a wide range of naturally occurring insect pests. Insects that have an economic effect on the growing of GT and non-GT alfalfa included, but were not limited to potato leafhoppers (*Empoasca fabae*), pea aphids (*Acyrthosiphon pisum*), blue (*A. kondoi*) and spotted alfalfa aphids (*Therioaphis maculate*)], alfalfa weevil (*Hypera postica*), lygus bugs (*Lygus species*), other plant bug species (family *Miridae*), and alfalfa caterpillars (various lepidopteron species) (Rogan and Fitzpatrick, 2004).

3. Feral Alfalfa

Since its introduction to the United States, alfalfa has occasionally become feral, or naturalized, by escaping from agricultural fields or intentionally planted in non-agricultural locations then persisting by multiplying unassisted. Settings where feral alfalfa can be found include air fields, canals, cemeteries, ditch banks, fence rows, highways, irrigation ditches, pipelines, railroads, rangeland, rights-of-way, roadsides, wasteland (Rogan and Fitzpatrick, 2004), rangeland, preserves, parks, and fire recovery areas. Alfalfa plants that are not crops generally have no regular external inputs like irrigation, herbicides, insecticides, and fertilizers; alfalfa was found to survive and increase on rangeland in Utah for more than ten years and can reseed on sites with as few as 11 inches (28 cm) of precipitation per year (Sullivan, 1992). *Falcata* has persisted without inputs for over 80 years in rangeland (Smith, 1997; Bliss, 2003).

Alfalfa that exists outside of cultivation is typically not targeted for control by herbicide. In some instances on lands where unmanaged or feral alfalfa now occurs, the planting was intentional (e.g., feral plants exist in relegated sown pastures, abandoned alfalfa fields, or on roadsides once sown with alfalfa seed, [Rogan and Fitzpatrick, 2004]). All feral alfalfa in the United States, like alfalfa under cultivation, originated from introduced varieties. Rogan and Fitzpatrick (2004) summarize the extent of feral populations in six major alfalfa-producing States, confirming that minor feral populations do exist in areas where alfalfa seed or forage is produced. In situations where control of feral alfalfa is desired, it can be controlled or discouraged just like cultivated alfalfa using cultural[5] or chemical methods (Rogan and Fitzpatrick, 2004). Appendix H includes the (USDA) maps for naturalized alfalfa by state and county.

[5] Cultural weed control methods include adding companion crops to the chief crop to smother or suppress weeds, applying a combination of mulches, or crop rotation.

Sullivan (1992) reviewed alfalfa use for rehabilitation and disturbed sites. Seed mixes, including alfalfa, are used for the USDA's CRP (USDA 2007). Some uses of alfalfa that can lead to feral alfalfa populations are:

- rehabilitation of overgrazed rangelands for improving wildlife habitat and livestock;
- erosion-control projects in interior forests;
- improvements of compacted soils (alfalfa has deep roots that grow vigorously in compacted soils);
- seed mixes used for USDA's CRP (FAPRI, 2007);
- revegetation of areas damaged by wildfire (Oregon DFW, 2008); and
- erosion reduction in mined soils (Sullivan, 1992; Withers, 2002).

Survival without management inputs requires feral plants to have certain traits. Bagavathiannan and Van Acker (2008, 2009) list the following traits that are common among the most successful feral species:

- variety of pollinators,
- continuous seed production,
- considerable seed output,
- seeds produced in several habitats,
- seed dispersal over short and long distances,
- seed dormancy (ability to form a seedbank),
- broad germination requirements,
- discontinuous germination,
- rapid vegetative growth,
- ability to withstand competition,
- tolerance to unfavorable biotic and abiotic conditions, and
- rapid flowering.

Alfalfa has many of the above attributes and competes well with other native and introduced plants in many different weedy environments. Although feral alfalfa can be found in competition with many other plant species and in different soils, several environmental factors can limit establishment of seedlings. As summarized by Bagavathiannan and Van Acker (2009), these factors include low or excessive water conditions, low light intensity, soil temperatures beyond 10 to 37 °C, and low pH soils.

The *M. sativa* subspecies (purple-flowered alfalfa used in cultivation) has naturalized populations in all 50 States, while *M. sativa* subsp. *falcata* (yellow-flowered or Siberian alfalfa) is naturalized in the northern and western States and is being promoted as a rangeland enhancer for grazing, as reported in the USDA, Natural Resources Conservation Service (NRCS), National Plant Data Center, PLANTS Database (USDA NRCS 2010).

B. Biological Environment at Risk

1. Animals

Animals that might be exposed to the gene product in GT alfalfa and changes in alfalfa production practices from using GT alfalfa (i.e., a potential increase in glyphosate application) would be individuals of species that typically inhabit alfalfa fields and feed on GT alfalfa, and species that could be exposed to glyphosate application and runoff (e.g., soil microbes, amphibians, and aquatic organisms). Wildlife abundance and composition in alfalfa fields depends on geographic location, surrounding habitat conditions, and alfalfa field size. In California, for example, a survey of 675 wild animals and birds that occur regularly in the State revealed that 27 percent use alfalfa fields for feeding, cover, and/or reproduction (Putnam et al., 2001). 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) (Putnam et al., 2001). 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*) (Putnam et al., 2001). Alfalfa also is used by farmers to feed horses and livestock.

The Endangered Species Act (ESA) of 1973, as amended, protects federally listed threatened and endangered (T&E) species. As part of APHIS's environmental review process for GE crops, APHIS thoroughly reviews GE product information and data to inform the Endangered Species Act effects analysis. For each transgene(s)/transgenic plant, the following information, data, and questions are considered by APHIS:

- 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 impact.
- 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 T&E plant species or a host of any T&E species.

Those T&E animal species that may be exposed to the gene product in GT alfalfa or exposed to the application of glyphosate would be those T&E species that inhabit alfalfa fields and feed on GT alfalfa, and those T&E species that could be exposed to glyphosate application and runoff (e.g., amphibians and aquatic organisms). The federally threatened California red-legged frog (*Rana aurora draytonii*) is an example of a T&E species that could be exposed to glyphosate application and runoff.

The Migratory Bird Treaty Act of 1918, as amended (16 U.S.C. 703 et seq.), protects migratory birds by prohibiting actions such as hunting, capturing, or killing listed species or their nests and eggs. Furthermore, Executive Order (EO) 13186, *Responsibilities of Federal Agencies to Protect Migratory Birds*, addresses the responsibilities of Federal agencies to protect migratory birds under the Act. The Order has resulted in Memorandums of Understanding (MOUs) between Federal agencies and the U.S. Fish and Wildlife Service (USFWS) which memorialize actions that each party will take to fulfill their respective responsibilities under the Act. APHIS is currently developing an MOU to identify actions APHIS would take to prevent adverse impacts on migratory birds.

2. Plants

Plant species that might be exposed to the gene product in GT alfalfa and changes in alfalfa production practices from using GT alfalfa (i.e., a potential increase in glyphosate application) would be those species that are sexually compatible with alfalfa and non-target and weed species that could be exposed to glyphosate applications. The landscape surrounding an alfalfa field varies depending on the region. In certain areas, alfalfa fields can be bordered by other alfalfa fields (or fields of another crop). Alfalfa fields also can be surrounded by woodland and/or pasture/grassland areas. Therefore, the types of weeds in and around an alfalfa field depend on the immediate area in which the alfalfa is planted. Weed species present will also vary depending on the geographic region where the alfalfa is planted. Weeds compete with crops for water, nutrients, light, and other growth factors. 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*) (Medlin and Siegelin, 2001).

Weeds can develop resistance to herbicides for the following reasons: frequent exposure to a particular herbicide, the spread of naturally resistant weed seeds, and the outcrossing of herbicide-tolerant genes from plants—either GE plants or plants that naturally have herbicide tolerance genes—to weedy relatives. Currently, glyphosate-resistant weeds inhabit two million acres of farmland in the United States (Hubbard, 2008). Some of the glyphosate-resistant weeds may also produce copious amounts of seeds, which may lay dormant in the soil and germinate many years later, further compounding the problem of glyphosate-resistant weeds and complicating the containment efforts by farmers relying only on glyphosate for weed control. The most problematic glyphosate-resistant weeds in the United States include pigweed (*Amaranthus palmeri*), horseweed (*Conyza canadensis*), common ragweed (*Ambrosia artemisiifolia*), giant ragweed (*Ambrosia trifida*), and ryegrass (*Lolium* spp.) (Hubbard, 2008).

Commercially cultivated alfalfa properly belongs to the *M. sativa* complex, a group of closely related subspecies that are reproductively compatible. The most commonly cultivated alfalfa in the world is *M. sativa* subsp. *sativa*, but subspecies *falcata* is also cultivated on a limited basis, primarily under rangeland conditions and in colder regions (e.g., Canada and Siberia). Other subspecies in the complex include subsp. *glutinosa*, subsp. *coerulea*, subsp. x *tunetana*, subsp. x *varia*, subsp. x *polychroa*, and subsp. x *hemicycla* (Quiros and Bauchan, 1988). Two other closely related species, *M. prostrata* and *M. glomerata*, can be considered capable of limited natural hybridization with alfalfa (Quiros and Bauchan, 1988). However, they do not occur naturally in North America.

Current native populations of members in the *M. sativa* complex to which cultivated alfalfa would hybridize, as well as other perennial *Medicago* species, exist particularly in Europe, Asia, the Middle East, and North Africa (Sinskaya, 1961; Lesins and Lesins, 1979; Ivanov, 1988). Based on a search for *Medicago* populations in the United States, twelve matches were found (see table 3-1). All of the twelve matches were to plants non-native to North America and were either conspecific (belonging to the same species) to *Medicago sativa* (two) or naturally sexually incompatible with *M. sativa* complex (ten).

Evolutionarily, *M. sativa* is very distantly related to the annual members of *Medicago*. However, *Medicago lupulina* (black medic), an annual (possibly a sometimes short-lived perennial) self-pollinating species, is known to occur throughout the United States and is the species that might be of most concern for hybridization. *M. lupulina* is considered a weed in

lawns and waste places, as well as in forages because its seeds frequently contaminate forage legume seed crops. Successful hybridizations between *M. sativa* and *M. lupulina* have been reported

Table 3-1. Members of the Genus Medicago Found in North America as Listed by NatureServe Explorer.

***Medicago* sp. in North America**	**Evidence for Natural Hybridization to *Medicago sativa* Complex**	**Range of Occurrence**
M. arabica Spotted Medicago	No	**CAN**: BC, NB **USA**: AL, AR, CA, CT, DC, FL, GA, IL, LA, MA, ME, MO, MS, NC, NJ, OK, OR, PA, RI, SC, TX, VA, VT, WA
M laciniata Cut-leaf Medicago	No	**CAN**: ON **USA**: MA, ME
M. littoralis Water Medicago	No	**USA**: NJ
M. lupulina Black Medicago	No. Reports of hand-cross hybrids are disputed and discounted as false hybrids by numerous experts.	**CAN**: AB, BC, MB, NB, NF, NS, ON, PE, QC, SK **USA**: AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY
M. minima Small Medicago –grass	No	**USA**: AL, AR, AZ, CA, CT, FL, HI, KS, LA, MA, MD, MI, MO, NC, NJ, NY, OK, OR, TN, TX, VA, WA
M. monspeliaca Hairy Medicago	No	**USA**: AL, ME, MD, NY
M. orbicularis Button Medicago	No	**CAN:** BC, ON **USA:** AL, CA, FL, GA, IL, LA, MD, MS, NC, NJ, OK, TN, TX
M. polymorpha Toothed Medicago	No	**CAN:** BC, NB, ON, QC, SK **USA:** AK, AL, AR, AZ, CA, CT, FL, GA, HI, ID, LA, MA, ME, MI, MO, MS, MT, NC, NE, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, TN, TX, UT, VA, VT, WA, WY
M. praecox Mediterranean Medicago	No	**USA**: CA, MA
M. rugosa Wrinkled Medicago	No. A single hybrid plant was produced via hand-pollination and embryo rescue; no viable progeny produced.	**USA**: HI
M. sativa Alfalfa	Yes, Conspecific	**CAN**: AB, BC, MB, NB, NF, NS, ON, PE, QC, SK, YT **USA**: AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY
M. sativa ssp.	Yes, Conspecific	**CAN**: AB, BC, MB, NS, ON, PE, QC,

Table 3-1. Members of the Genus Medicago Found in North America as Listed by NatureServe Explorer.

Medicago sp. in North America	Evidence for Natural Hybridization to *Medicago sativa* Complex	Range of Occurrence
falcate Yellow Alfalfa		SK **USA**: AK, DE, IA, IL, KS, MA, MD, MI, MN, MS, MT, ND, NE, NJ, NV, PA, SD, UT, VA, WA, WY

Source: All data presented in NatureServe Explorer at http://www.natureserve.org/explorer were updated to be current with NatureServe's central databases as of October 6, 2007. This report was printed on November 11, 2007.

(Southworth, 1928; Fryer, 1930; Schrock, 1943), but the validity of these past crosses has been disputed. According to Quiros and Bauchan (1988) and McCoy and Bingham (1988), no annual species are known to naturally hybridize with *M. sativa.*

Gene flow between alfalfa populations is a natural occurrence and bee-mediated cross-pollination among plants within a cultivar is necessary for commercial seed production. Alfalfa seed producers use spatial isolation to separate cultivars and manage bee and pollen flow between fields of different cultivars. The minimum isolation standard for foundation and certified seed fields more than five acres in size is 600 and 50 feet, and for fields five acres or less, the standard is 900 and 165 feet, respectively (Association of Official Seed Certifying Agencies [AOSCA], 2003). State seed certifying organizations that are members of AOSCA may adopt the same or more stringent local standards for certified alfalfa seeds. For example, Idaho Crop Improvement Association (2007) requires a greater isolation distance (900 feet) than AOSCA between certified seed fields when one field is conventional and the other is of a genetically modified type (e.g., GT). The AOSCA Alfalfa Seed Stewardship Program (ASSP)-2010 standard is designed to provide seed that has no detectable GT transgene. It recommends isolation distances of five miles between GT and non-GT seed fields and two miles between GT hay and non-GT seed fields. In addition to field isolation, certified seed production applies standards for field history, known genetic origin of the stock seed, and in-crop volunteer control to maintain a variety true to type.

Alfalfa plants and alfalfa debris produce compounds that elicit an autotoxic reaction to a germinating alfalfa seed. This autotoxic reaction and inter-plant competition severely limits germination and seedling vigor of alfalfa sown or dropped into existing or newly terminated alfalfa stands (Xuan et al., 2005).

Those T&E plant species that may be exposed to the gene product in GT alfalfa would be those T&E species that are sexually compatible with GT alfalfa. As discussed above and shown in table 3-1, 12 *Medicago*

populations are known to occur in North America, none of which are threatened or endangered. Therefore, APHIS has determined that GT alfalfa would not be sexually compatible with any listed T&E plant species or species proposed for listing, or a host of any T&E species, because there are no listed species or species proposed for listing in the genus *Medicago* or that would use *Medicago* species as a host.

In accordance with EO 13112, *Invasive Species*, invasive species are alien species whose introduction does or is likely to cause economic or environmental harm to human health. A species is regarded as invasive if it (1) has been introduced by human action to a location where it did not previously occur naturally; (2) becomes capable of establishing a breeding population in the new location without further intervention by humans; and (3) spreads widely throughout the new location. The Order requests that actions taken by Federal agencies that affect the status of invasive species use relevant programs to prevent introducing invasive species and provide means through which to restore native species and habitat conditions to their original state. Although alfalfa has been documented to survive, to a small extent, outside of cultivation (Rogan and Fitzpatrick, 2004), alfalfa is not considered an invasive species (USDA NRCS, 2010; USDA ARS, 2003).

3. Affected Environment for Animals and Plants

The affected environment for plants and animals includes any land that is currently producing alfalfa, any land that is suitable for GT alfalfa cultivation (regardless of current use), and any area that potentially could receive glyphosate runoff due to production of GT alfalfa. The terrestrial ecosystems potentially at risk from glyphosate application associated with GT alfalfa include the treated area and areas immediately adjacent to the treated area that might receive glyphosate drift or runoff, and might include other cultivated fields, fence rows and hedgerows, meadows, fallow fields or grasslands, woodlands, riparian habitats, or other uncultivated areas. The use of glyphosate is regulated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) restrictions administered by the U.S. Environmental Protection Agency (EPA), which mandates registration and regulates use of all pesticides. APHIS has no regulatory authority over the use of glyphosate for any GT crop.

EPA includes instructions and restrictions on how glyphosate herbicides can be applied, and has determined that there is no unreasonable environmental risk if the user adheres to the directions when applying glyphosate herbicide formulations. Directions include application restrictions that minimize impacts on nearby environments. Violators of the regulations are liable for all negative consequences of their actions. Therefore, farmers who use glyphosate are very likely to follow its label restrictions, and adverse impacts from the predicted increased glyphosate use would be minimized.

Aquatic ecosystems potentially at risk from glyphosate include water bodies adjacent to, or downstream from, the treated field, and might include impounded bodies such as ponds, lakes and reservoirs, or flowing waterways such as streams or rivers (this discussion is based on the concept that even in the context of FIFRA regulations and label restrictions that are legally required to be followed, there is a chance that glyphosate use might, nonetheless, result in environmental impacts). The proposed use sites may be located either near freshwater or saltwater habitats. For uses in coastal areas, an aquatic habitat also includes marine ecosystems with estuaries.

C. Socioeconomics

This section addresses the topics of: (1) the economics of conventional (non-GE and non-organically produced) alfalfa production and use; (2) the economics of organic alfalfa production and use; (3) the international trade in alfalfa seeds and hay; and (4) the social environment of alfalfa farming and public perceptions regarding organic and genetically modified ingredients in food.

The following discussion is based in part from the following technical reports, *Changes in the Economics of Alfalfa Farming with Deregulation of Glyphosate-Tolerant Alfalfa* (appendix K)*; Impacts on United States Trade of Deregulation of Glyphosate-Tolerant Alfalfa* (appendix R); *Economic and Social Impacts on Conventional and Organic Farmers of Deregulation of Glyphosate-Tolerant Alfalfa* (appendix S)*;* and *Downstream Effects to Organic Production and Marketing of Deregulation of Glyphosate-Tolerant Alfalfa* (appendix T).

1. Domestic Economic Environment at Risk – Conventional Alfalfa

The economics of conventional alfalfa are presented below, divided into discussions of: (a) the production and demand for alfalfa hay; (b) alfalfa seed, and (c) alfalfa for human consumption. Each of these commodities has its own particular market and production characteristics.

Conventional Alfalfa Farming for Forage

Production of Alfalfa for Forage

The harvested acreage of alfalfa hay (dry) was approximately 21 million acres in 2008, generating some 70.2 million tons of hay (including hay mixtures) at an average yield of 3.33 tons per acre (see table 3-3). This yield corresponds to almost half the production of all hay that year (approximately 145.6 million tons). Statistics for acreage of alfalfa used as haylage (alfalfa baled at a higher moisture content than dry hay) for all States is only captured in the Agricultural Census; based on the most recent 2007 census and more recent USDA–National Agricultural Statistics Service (NASS) data available on 18 States, haylage acreage

likely accounts for an additional 10 to 15 percent of alfalfa acreage grown for forage. Alfalfa is the fourth most common crop by acreage in the United States (USDA-NASS 2008).

The alfalfa share of total hay production has been falling in recent years, as has absolute production of alfalfa hay (see table 3-3). In 2007, alfalfa production was at its lowest level (69.9 million tons) compared to a high of 84.4 million tons in 1999. Although it is a highly sustainable practice, alfalfa's use in crop rotation is declining in the United States because it demands different management, equipment, market channels, and labor schedules not common to other mainstream cropping systems (USDA-ERS 2002). In certain locations, livestock to consume the hay is no longer located in the vicinity, and transportation of the hay could be prohibitively expensive.

Alfalfa is grown for forage in almost all of the States (see figure 3-1), with farming conditions varying considerably depending on climate, rainfall, soil fertility, weed and disease prevalence, whether it is seeded in fall or in spring, or for dairy or other uses among other factors. Hower et al., (1999) differentiated between four distinct regions in alfalfa farming: north-central, west, northeast, and south. The north-central region represented the highest acreage of alfalfa followed by the west. Together these two regions had 90 percent of the alfalfa acreage in the country. The west, however, had the highest yields, relatively high prices, the most seeding done in fall and relatively high rates of insecticide and herbicide use (50 percent of alfalfa hay acreage), while the north-central region had the lowest yields, lowest prices, most seeding done in spring, and the lowest rates of insecticide and herbicide use (8.1 percent of alfalfa hay acreage). A study conducted by Rogan and Fitzpatrick (2004) also found that western regions tend to have significantly higher yields than the larger overall acreage of the north-central area.

Hay Production Cost Studies

There have been a number of cost studies prepared by university cooperative extension services on the production of alfalfa hay and alfalfa haylage. These studies show regional differences in the costs of inputs, including chemical use which varied from 9 to 22 percent of total operating costs in the cost studies (Myer et al. 1997, The Ohio State University Extension 2003). The cost studies showed the cost of inputs for alfalfa hay production to be a less significant determinant of returns than yield and quality.

The Integrated Pest and Crop Management Portal of the University of Wisconsin Plant Sciences outreach programs posts a "Roundup Ready® Alfalfa Calculator" (http://ipcm.wisc.edu/WCMNews/tabid/53/EntryID/208/Default.aspx). Table 3-2 shows the

results of this calculator for costs of conventional hay in Wisconsin, which includes both establishment and production costs, as presented on the Website. APHIS extended this analysis to include herbicide costs and the price of alfalfa hay (as discussed in technical report, *Changes in the Economics of Alfalfa Farming with Deregulation of Glyphosate-Tolerant Alfalfa* (appendix K)) and found that while a 40 percent increase in seed costs and herbicide costs have a less than proportional impact on profit, a 40 percent increase in alfalfa hay prices will more than triple the profit per acre. This implies that reductions in the costs of herbicides and seeds are less important to producers' operational decisions than the possibility of obtaining higher quality alfalfa hay. As percentage changes in yield also seem to have a high impact on returns, it could be argued that farmers of conventional alfalfa face a trade-off between pursuing higher yields of alfalfa of lower quality, by harvesting a shared alfalfa-weed mix, or pursuing higher prices of alfalfa with lesser weed content.

Table 3-2. Establishment and Production Cost of Conventional Alfalfa Units Per Acre**.**

he	$200.00
Pounds of seed per acre	12
Technology fee per bag ($/bag)	$0.00
Yield in seeding year (t/a DM)	3.50
Herbicide cost ($/acre/application)	$20.00
Herbicide application cost ($/acre)	$10.00
Number of herbicide applications	1
Value of ease of roundup use ($/acre)	$0.00
Yield depression from pursuit/raptor (t/a DM)	0.30
Expected stand life (yrs including seeding year)	3
Value of hay (per ton DM)	$100.00
Fixed costs per acre per year	$180.00
Harvesting costs per acre per harvest	$35.00
Number of harvests	2
Seeding Year Production Costs/Results	
Seed cost (prorated + tech fee) per acre*	$16.00
Total seed and herbicide cost per ton of hay	$14.38
Total Cost Per Ton of Hay Seeding Year	**$85.80**
Profit per acre - seeding year	**$49.69**

Source: Integrated Pest Crop Management, University of Wisconsin

Table 3-3. Total U.S. Alfalfa Hay Acres and Value by Method of Production Practice (2002-2008).

Practice	Factor	2002	2003	2004	2005	2006	2007	2008	Mean
Conventional									
All alfalfa dry hay, acres (1)		22,923,000	23,527,000	21,697,000	22,359,000	21,138,000	21,126,000	21,060,000	21,975,714
Change in acres per year		--	2.63%	-7.78%	3.05%	-5.46%	-0.06%	-0.31%	-1.13%
Total production, tons (1)		73,014,000	76,098,000	75,375,000	75,610,000	70,548,000	69,880,000	70,180,000	72,957,857
Value of production ($) (1)		7,137,466,000	6,707,172,000	6,961,519,000	7,290,845,000	7,519,232,000	8,855,044,000	10,747,161,000	7,888,348,857
Average production, tons per acre		3.19	3.23	3.47	3.38	3.34	3.31	3.33	3.32
Value ($) per ton, average		97.75	88.14	92.36	96.43	106.58	126.72	153.14	108.7
Value ($) per acre, average		311.37	285.08	320.85	326.08	355.72	419.15	510.31	361.22
Organic									
Organic alfalfa hay, acres (2)		155437	135,717	175,260	204,380	188,911	223,234	256,554	191,356
Change in acres per year		-	-12.69%	29.14%	16.62%	-7.57%	18.17%	14.93%	8.37%
Organic (%) of total alfalfa acres		0.68%	0.58%	0.81%	0.91%	0.89%	1.06%	1.22%	0.88%
Average production, tons per acre (3)	0.875	2.79	2.83	3.04	2.96	2.92	2.89	2.92	2.91
Total production, tons		433,209	384,104	532,744	604,746	551,679	646,106	748,069	557,237
Value ($) per ton, average (4)	1.18	115.35	104.00	108.98	113.78	125.77	149.53	180.70	128.30
Value of production ($)		49,970,909	39,948,199	58,060,021	68,810,378	69,383,611	96,610,393	135,177,447	73,994,423
Value ($) per acre, average		321.49	294.35	331.28	336.68	367.28	432.78	526.90	372.96
Value-added per ton		17.60	15.86	16.62	17.36	19.18	22.81	27.56	19.57
Value-added per acre		10.12	9.27	10.43	10.60	11.56	13.62	16.59	11.74
Value-added as percent of conventional, per acre		3.25%	3.25%	3.25%	3.25%	3.25%	3.25%	3.25%	3.25%
Export									
Export alfalfa dry hay, tons (5)		989,734	1,024,188	1,038,165	947,128	1,125,363	891,513	825,086	977,311
Total production (%) of U.S. dry hay total		1.36%	1.35%	1.38%	1.25%	1.60%	1.28%	1.18%	1.34%
Value ($) of export (5)		153,569,000	158,348,000	171,533,000	165,087,000	165,192,000	171,249,000	215,181,000	171,451,286
Value ($) per ton, average		155.16	154.61	165.23	174.30	146.79	192.09	260.80	178.43

Sources: (1) USDA-NASS Statistics by Subject, Crops and Plants; (2) USDA-ERS, Data Sets, Organic Production; (3) Long et al (2007) estimated 12.5% reduction in yield for organic alfalfa production; (4) assuming 18% price premium for organic alfalfa; (5) USDA-FAS, Gats Online, metric tons transformed to short tons. Other cells calculated from data shown.

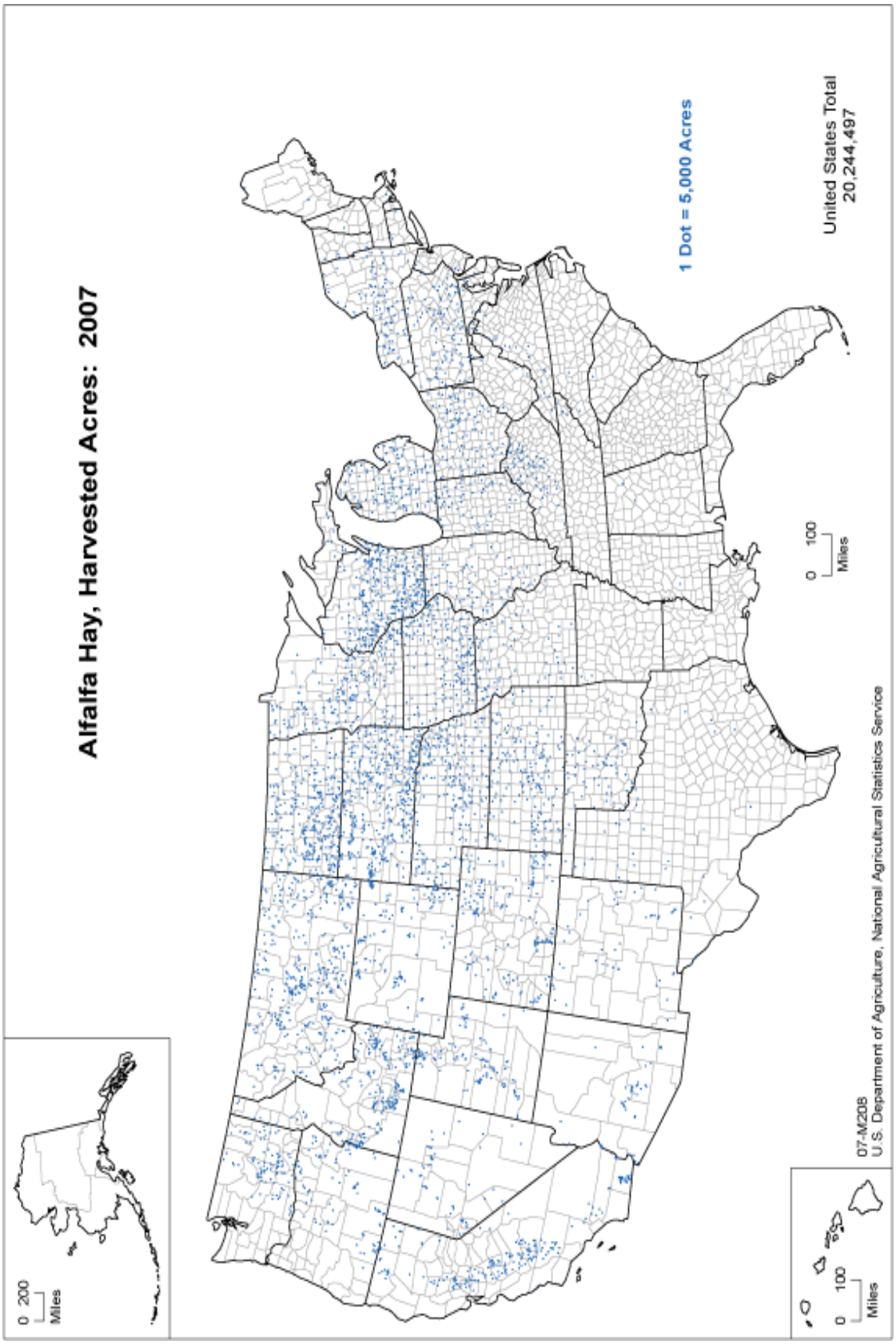

Figure 3-1. Geographic distribution of alfalfa forage acres, 2007 (USDA, 2007).

Demand for Alfalfa Forage

APHIS was unable to locate complete and systematic data on alfalfa forage consumption in the United States (Klonsky et al., 2007); however, an approximate aggregate value of the demand for alfalfa hay can be obtained through production and trade statistics (assuming the accumulation of stored alfalfa hay over time is zero.). USDA–NASS estimates the value of alfalfa hay production in the United States was approximately $8 billion in 2009. This number was obtained by multiplying average prices with volumes produced and does not correspond to actual sales. Actual sales were likely much less as, according to Klonsky et al. (2007), the majority of the alfalfa hay produced in the United States is not sold but consumed on the farm where it is produced. This estimate is provided, therefore, for illustrative purposes only.

Discounting for this rough figure of $8 billion, the $354 million in alfalfa hay exports (see below for more information on alfalfa exports), and adding $4 million in imports of alfalfa that occurred that year, the domestic market for alfalfa hay would be approximately $7.6 billion in 2009. The same reasoning would lead to a domestic market of $10.5 billion in 2008 and $8.8 billion in 2007 (see table 3-4).

Table 3-4. Domestic Alfalfa Hay Market (1,000s of Dollars).

Item	2009	2008	2007
Production	7,997,221	10,747,161	8,855,044
Exports	354,074	215,181	171,249
Imports*	3,848	16,079	6,800
Consumption	7,646,995	10,548,059	8,844,595

Sources: Production data from USDA NASS (20010). Trade data from USDA Foreign Agricultural Service (FAS). Consumption calculated as production – exports + imports, and assuming change in alfalfa inventories is zero.
* Imports reported as alfalfa bales, not alfalfa hay.

APHIS was unable to find data on the national distribution of the consumption of alfalfa hay among its various uses. Putnam (2005) states that the three main domestic markets for alfalfa are dairy farms, beef farms and horse farms, with minor uses of alfalfa hay "for small ruminants (sheep, goats), alfalfa meal for processed feeds, and alfalfa pellets for pets and rabbits." Of these, dairy farms are "by far" the main consumer. Klonsky et al. (2007) estimates dairy farms absorb between 75 to 85 percent of alfalfa hay in California, with another 10 to 15 percent consumed by horses and 5 to 10 percent used in the production of beef.

One indication of the role of dairy farms on alfalfa hay consumption can be found by multiplying the number of dairy cows in the United States by

an estimate of alfalfa hay intake. Using alfalfa consumption estimates provided in Hoyt (2001) of an intake of 15 pounds of alfalfa hay per day per dairy cow, another seven pounds a day for milk replacement heifers and another three pounds a day for dairy heifers under 500 pounds, and assuming the proportion between milk cows, milk replacement heifers and heifers under 500 pounds is roughly 4:2:1, APHIS estimates consumption of alfalfa hay for dairy to be approximately 177 million pounds per day, or 32.8 million tons a year.[6] This corresponds to roughly 46 percent of the domestic market estimated to be at 71.8 million tons in 2007 (72.6 million tons produced, minus exports, plus imports).[7]

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 (Klonsky et al., 2007). USDA's Agricultural Marketing Service uses the grades of supreme, premium, good, fair, and utility to regularly report average prices in various States. They describe each grade as follows:

- Supreme: Very early maturity, pre bloom, soft fine stemmed, extra leafy. Factors indicative of very high nutritive content. Hay is excellent color and free of damage.
- Premium: Early maturity, that is, pre-bloom in legumes and pre-head in grass hays, extra leafy and fine stemmed-factors indicative of a high nutritive content. Hay is green and free of damage.
- Good: Early to average maturity, that is, early to mid-bloom in legumes and early head in grass hays, leafy, fine to medium stemmed, and free of damage other than slight discoloration.
- Fair: Late maturity, that is, mid to late-bloom in legumes, head-in grass hays, moderate or below leaf content, and generally coarse stemmed. Hay may show light damage.
- Utility: Hay in very late maturity, such as mature seed pods in legumes or mature head in grass hays, coarse stemmed. This category could include hay discounted due to excessive damage and heavy weed content or mold. Defects will be identified in market reports when using this category (USDA-AMS, 2008).

Other sources note that alfalfa hay quality grades differ to some degree from State to State (McWilliams et al., 2005), or speak of high quality alfalfa as being "dairy-quality" (Klonsky et al., 2007). According to

[6] 9.2 million milk cows in 2007 (USDA ERS, 2008) x 15 lbs = 138 million lbs
4.6 million replacement heifers x 7 lbs = 32.2 million lbs
3.2 million heifers under 500 pounds x 3 lbs = 9.6 million lbs.
[7] Production data from USDA ERS, 2007. Trade data from USDA FAS (online searchable database). Trade data is available in metric tons, transformed to short tons by multiplying by 1.10231.

Klonsky et al. (2007), there is no clear cut classification for alfalfa hay quality.

Dairy cattle and horses both tend to have high forage quality requirements (Van Deynze et al., 2004). Most weeds are lower in forage quality or palatability (ability to appeal to animals as food) than alfalfa, and forage with high weed content can adversely affect milk production, as well as animal growth and health (Van Deynze et al., 2004). Forage quality requirements for sheep and goats are less rigorous. Beef producers in particular, facing relatively low margins, are apparently a market for lower quality (and cheaper) alfalfa (Klonsky et al., 2007).

Some States provide data on prices of different hay qualities. Table 3-5 below shows some of the historic price differences for different hay qualities in areas of California. The table also illustrates differences in prices depending upon location. As shown, prices can vary by more than 50 percent depending on quality and location. Distinctive regional alfalfa markets likely

Table 3-5. Price Differences of Hay Qualities ($/Ton), 10-Year Average, 1997-2006.

				Hay Quality Category	
	Region	**Supreme**	**Premium**	**Good**	**Fair**
Southern California					
	Imperial Valley	121	115.24	100.29	86.35
	Blythe/Parker	120.14	114.52	99.38	82.56
	Chino/LA	148.37	140.34	125.65	110.74
	Mojave Desert	129.11	123.01	111.86	93.52
San Joaquin Valley					
	Kern County	139.45	128.07	110.01	92.57
	Tulare/ Visalia/ Hanford	163.54	149.42	129.83	109.13
	Hanford/ Corcoran/ Tulare	146.25	132.62	113.75	94.08
	Fresno/ Madera Counties	145.24	129.77	108.48	92.27
	Los Banos/ Dos Palos	147.24	136.66	116.92	96.98
	Escalon/ Modesto/ Turlock	161.69	148.94	130.23	109.20

Source: Klonsky et al. (2007)

reflect the importance of transportation costs in limiting the trucking of relatively high volume, low value alfalfa hay across longer distances.

Alfalfa Forage as an Input to Human Food Production

This section briefly describes alfalfa feed as an economic input to its primary industries of use (dairy farms, beef cattle, and horses, with much smaller amounts being used for goat, sheep and small animal feed, and other processed feeds).

Dairy Production

USDA estimated production costs for dairy farms in the United States based on the 2005 Agricultural Resources Management Survey (ARMS). According to this data, feed corresponds to 30 to 60 percent of total costs per hundredweight (100 pounds) sold, which includes one-time costs for establishment. The weight of feed on total costs is lower for smaller farms given the relatively larger overhead. Looking at the share of operational costs (a subset of total costs) feed costs represent, roughly 70 to 80 percent, suggests the price of feed is a major determinant of the cost of dairy production for dairy farms (see table 3-6, below).

Alfalfa is likely a considerable share of feed costs. Short (2004) reports hay and straw, presumably mostly alfalfa, represents roughly a third of feed costs. Alfalfa can also be used in cubes or pellets. In some regions (Wisconsin, Minnesota) haylage is also a significant share of feed.

Table 3-6. Weight of Feed Costs in Dairy Farms.

Farm Type	Feed Costs/ Operational Costs	Feed Costs/ Total Costs
Conventional United States	73.3%	44.1%
Conventional California	79.7%	57.8%
Conventional Wisconsin	72.0%	40.4%
Conventional < 50 cows	73.4%	30.0%
Conventional 1000 cows or more	76.7%	55.0%
Organic United States	77.8%	41.9%
Organic < 50 cows	76.9%	33.7%
Organic 200 cows or more	79.6%	52.7%

Source: USDA-ERS 2005a

Beef Production

USDA-Economic Research Service (ERS) produces cost estimates annually for a variety of farm products. According to the latest estimates

available (2005–06), feed corresponds to an average of 56.8 percent of operational costs and 28.8 percent of total costs of cow-calf production (USDA-ERS, 2008a). Harvested forages correspond to almost half of feed costs (46.9 percent). Other sources report a somewhat lower figure of 35 percent of operational costs and 20.8 percent of operational and ownership costs, with only between 10 to 20 percent of feed costs corresponding to purchased harvested forages (Short, 2001).

Alfalfa is likely a lower share of feed costs in cow-calf production than it is in dairy production since the main source for cow-calf production feed is grazing (Short, 2001). As cattle move on to feedlots (sometime through stocker operators), feed becomes mostly grain based ration.

Other Livestock, Pet food, and Honey Production

Of the remaining potential sources of demand for alfalfa hay, the most important is horses. Putnam (2005) estimates that horses can consume between 5 to 15 percent of alfalfa hay in California. He also, however, describes the horse market for alfalfa hay as idiosyncratic, subjective, and supplemented by alternative hay such as timothy and grass.

The honey industry utilizes alfalfa fields for honey production. Alfalfa produces a large amount of nectar from which honey bees produce excellent crops of high quality honey (McGregor, 1976). Honey producers typically do not pay to use alfalfa fields but rather get paid to provide pollination services to alfalfa seed fields. This suggests the honey industry works more as a service provider to alfalfa seed production than as a downstream market.

Conventional Alfalfa Farming for Seed

Production of Alfalfa for Seed

Unlike alfalfa hay production, alfalfa seed production is largely concentrated both geographically and in the number of producers (see table 3-7). The latest complete information on alfalfa seed production comes from the 2007 Census of Agriculture, when 121,467 acres of alfalfa seed were harvested producing approximately 62 million tons of seeds at an average productivity of

Table 3-7. State Production of Alfalfa Seed.

State	Farms	Seed Acres Harvested	Pounds of Seed Harvested
California	114	36,625	19,083,458
Washington	82	17,127	10,860,608
Idaho	92	12,788	9,346,709

Wyoming	62	10,548	5,915,816
Nevada	19	6,498	4,237,101
Montana	80	10,338	3,729,635
Oregon	32	4,959	3,183,375
Utah	54	3,803	2,077,813
Arizona	53	5,206	1,902,669
South Dakota	47	6,014	428,447
Oklahoma	29	2,004	281,121
Texas	24	546	79,885
Minnesota	17	611	63,461
Missouri	19	399	40,540
North Dakota	6	(D)	34,784
New Mexico	15	310	29,907
Kansas	5	342	22,430
Nebraska	29	545	21,216
Michigan	10	(D)	15,610
New York	3	27	6,180
Iowa	5	(D)	(D)
Ohio	1	(D)	(D)
Colorado	8	1,815	(D)

(D): Data withheld to avoid disclosing data for individual farms.

Source: USDA 2007 Census of Agriculture

approximately 510 lbs per acre. California was responsible for 31 percent of this production, Washington 17 percent, and Idaho 15 percent, with over 60 percent of production concentrated in those three States and the remaining also highly concentrated in Western States (Nevada, Oregon, Wyoming, Montana, and Utah). Mueller (1995) suggests California's share of production has fallen in recent years and a larger share is coming from the Northwestern States. In 2007, production came from 806 farms. This means that farming conditions for alfalfa seed production are likely more homogeneous than alfalfa hay farming. U.S. alfalfa seed growers also compete with their conventional seed producing counterparts in Canada, Australia, and elsewhere where comparative production costs are significantly lower (e.g., USDA Docket 04-085-1; public comment by M. Wagoner [December 12, 2004; comment P5]).

Alfalfa seed acreage and production increased between 2002 and 2007, reversing the trend of decreases in alfalfa seed production over the preceding years. Similar economic, social, and competitive challenges face both U.S. alfalfa seed and forage growers. Mueller (2008) attributes recent reductions in alfalfa seed acreage in California to "changes in economics, environmental constraints, and regulatory issues." Mueller (1995) lists among difficulties of alfalfa seed farming in California scarcity of water for crop irrigation and lack of development of new chemicals for insect control due to high registration costs. However,

between 2002 and 2007, California gained almost 10,000 acres of alfalfa seed production.

Some farmers allow existing alfalfa hay stands to go to seed at the end of the stand life or when there is little water. According to Mueller (2005), this is the case for most of the seed produced in the Imperial Valley (California), about half of the non-certified seed produced in Utah, and much of the dryland seed produced in Montana. This seed would typically not receive certification.

Despite the mixed purpose of many alfalfa fields that generate seeds, there are clear differences in best practices for managing forage alfalfa and seed alfalfa. Dense stands produce higher forage yields but lesser seed yields than thinner stands, as when alfalfa is planted in rows as opposed to solid planting, and certain chemicals used in seed production limit field use for forage (Mueller, 2008). Alfalfa seed farmers also have some costs that are not present in alfalfa hay farming; some insects are only important for alfalfa seed production (Mueller, 1995), and costs associated with contracting with bee keepers for pollination services are considerable.

The presence of weeds could have a greater impact on costs in alfalfa seed production compared to alfalfa forage production. The separation of weed seeds from alfalfa seeds after harvesting is costly, so control of weeds in the fields is a more desirable method of seed quality control than post-harvest screening and separation (Mueller, Undated). No primary or secondary noxious weeds[8] are allowed for certified seed, with the removal of dodder seed of particular importance (Mueller, 2008) (see section below on Weeds in Alfalfa for more information on dodder and other alfalfa weeds).

As discussed in the technical report, *Changes in the Economics of Alfalfa Farming with Deregulation of Glyphosate-Tolerant Alfalfa* (appendix K), another important difference between alfalfa hay and alfalfa seed production is that the quality of seeds (germination, yield, dormancy, and other varietal properties) are not readily observable at the moment of purchase. To ensure quality, mechanisms come into place to offer clients (and breeding companies) assurance that seeds sold as one variety or another will perform as expected. State Crop Improvement Associations—or sometimes Seed Grower Associations (all of these are members of the AOSCA)—provide certifications that seed production followed minimum standards, such as isolation between different alfalfa varieties, absence of prohibited noxious weeds in the field, inspection of conditioning (separation) facilities, maintaining traceability of seed lots, and seed testing.

[8] Primary noxious weeds cause harm wherever they grow and are an economic issue, while secondary weeds are designated at a local level for additional control.

Finally, an important cost in seed production is the seed itself. The development of crop varieties became a predominantly private activity in the past 30 years (Fernandez-Cornejo and Schimmelphenning, 2004) and the Plant Protection Variety Act of the early 1970s simulated cultivar development in alfalfa (Bouton, 1998). Today almost all new alfalfa varieties are owned and patented.

Seed Production Cost Studies

There have been a number of cost studies related to the cost of producing of alfalfa seed. The cost studies reviewed for this EIS deal with the economics of alfalfa seed production in three Western States—California, Nevada, and Idaho—due to the geography of seed production. A 1985 cost study found land rental to be the highest cost component (Sheesley, 1985). Recent cost studies show, however, that pollination services (bees) account for the most significant cost component of alfalfa seed production, ranging from 18 to 30 percent of annual production costs. The second most significant cost component found in the recent cost studies was insect control, accounting for between 10 and 17 percent of total annual production costs (Kettle et al., 1999a; Kettle et al., 1999b; Meister, 2004; Rimbey et al., 2005). Similar results were found in a 2005 cost study from the University of Idaho (Rimbey et al., 2005). The study assumes a farm with 150 acres of alfalfa seed over a three year period (the life of the stand) and found that pollination accounted for 25.1 percent of the operating costs, followed by insecticides at 16.6 percent. Irrigation and herbicides are each just below ten percent of total operating costs. Table 3-8 below shows the main cost items reported, with the last column showing the percentage total that each line item represents of the total costs.

Table 3-8. Alfalfa Seed Production Costs.

Item	$ Per Acre	Percent of Total Costs
Irrigation	61.08	9.58%
Insect Control	105.65	16.58%
Weed Control	59.36	9.31%
Pollination	160.00	25.10%
TOTAL OPERATING COSTS/ACRE	**637,36**	**100.00%**

Source: Rimbey et al 2005

Demand for Alfalfa Seed

The demand for alfalfa seed derives from the demand for establishing new stands of alfalfa hay, and to a much lesser extent from the demand for alfalfa products destined for human consumption. As in the case of alfalfa

hay, the domestic alfalfa seed market can only be estimated using available data for production, exports and imports. The last year for which complete data is available is 2007, the year of the last Census of Agriculture.

The estimation presented in table 3-9 suggests the domestic demand for alfalfa seeds in 2007 was approximately $63 million, up from $52 million in 1997. Imports represented some 64 percent of domestic demand, although it is possible that some of these imports were re-exported.

Table 3-9. Domestic Alfalfa Seed Market (1,000s of Dollars).

	2007	2002	1997
Production	93,173	66,724	104,492
Exports	66,094	25,963	50,372
Imports	36,363	10,864	14,521
Consumption	63,442	51,625	68,641

Sources: Production data from USDA Census of Agriculture (2007, 2002, 1997); Trade data from USDA Foreign Agricultural Service (FAS); Consumption calculated as production – exports + imports, and assuming change in alfalfa inventories is zero.

Conventional Alfalfa Farming for Human Use

Some alfalfa seed is used to produce sprouts for human consumption. Seed for sprouting is produced throughout the world, but the major suppliers are in the United States, Canada, and Australia. Approximately 80 million pounds of alfalfa seed are produced each year in the United States. More than 85 percent of that is produced in six Western States—California, Washington, Idaho, Wyoming, Nevada, and Montana. The balance is from Oregon, Arizona, Utah, and other States. The primary market for that seed is planting stock to produce forage to support the livestock industry in the United States and throughout the world. Only a small fraction of the seed produced is used for sprouting (Mueller, Undated).

APHIS was unable to locate any publicly available sales data for alfalfa sprouts. In testimony given in a public meeting convened by the U.S. Department of Health and Human Services' (DHHS) Food and Drug Administration (1998), sprout industry expert Dr. Earl Hauserman noted that as of 1998 there were about 350 sprouters in the United States. He noted that green sprouts (alfalfa, broccoli, clover, mustard, onion, radish, sunflower, and other sprouts) amounted to about $80 million a year in sales. Mr. Hauserman also stated that alfalfa sprouts account for about 75 to 80 percent of the green sprout market, or $60 to $64 million in annual sales. Hauserman stated that U.S. sprouters utilized approximately 125,000 to 150,000 pounds of alfalfa seed a month to produce about 5 to 6 million 4-ounce packages a month. On an annualized basis, Hauserman's testimony would imply that in 1998 alfalfa sprouters purchased 1.5 to 1.8 million pounds of alfalfa seeds, and produced 15 to 18 million pounds of alfalfa sprouts.

Dehydrated alfalfa leaf is commercially available as a dietary supplement in several forms, such as tablets, powders and tea. Alfalfa is also believed by some to be useful as an herbal or homeopathic medicine (Foster and Johnson, 2006). APHIS was unable to locate any publicly available sales data for alfalfa produced for dietary supplements, herbal remedies, or homeopathic medicines. Nelson (2008) reports an estimate that the total U.S. alfalfa supplement market could be satisfied with ten tons of alfalfa hay production, which could be produced on one to two acres.

2. Domestic Economic Environment at Risk

The economics of organic alfalfa are presented below, broken into discussions of: (a) the production and demand for alfalfa hay; (b) alfalfa seed, and (c) alfalfa for human consumption. Each of these has its own particular market and production characteristics.

Organic Alfalfa Farming for Forage

Production of Organic Alfalfa for Forage

Between 2000 and 2005, the number of acres in certified organic alfalfa hay production fluctuated slightly, but overall showed an increasing trend. The percentage of total alfalfa hay acres certified as organic per year was between 0.51 to 0.92 percent nationally during this time period (see table 3-10). During 2005 (the most recent year for which certified organic alfalfa acres are reported), there were 204,380 acres in certified organic production, which was approximately 0.92 percent of the U.S. alfalfa dry hay total. Although the organic dairy and

Table 3-10. Organic Alfalfa Hay Harvested Acreage.

Acreage	2000	2001	2002	2003	2004	2005
Total	113,157	116,608	155,437	135,717	175,260	204,380
Share of Total U.S. Acreage	0.51%	0.49%	0.67%	0.58%	0.81%	0.92%

Source: USDA-ERS 2005b, USDA-NASS 2007a.

livestock industries are growing very rapidly, organic hay alfalfa acres could be growing at a slightly slower rate because many of the organic dairy and livestock producers are allowing more access to non-alfalfa (e.g., grass) organic pastures to avoid the high bloat incidence associated with grazing pure alfalfa. In contrast to conventional hay marketed mainly on forage quality grade, the main selling criterion for organic hay is often its organic status (USDA-AMS-LGMR, 2007).

Organic alfalfa hay production is distributed in similar geographical pattern to conventional hay; however, production of organic alfalfa hay is a more significant proportion of total alfalfa hay production in some States. In 2005, for example, more than 4 percent of all alfalfa hay acreage in Idaho was organic, compared to just 0.92 percent nationally. Organic alfalfa also seems to be grown in pockets, with 72 percent of

organic acreage located in just six States—Idaho, Wisconsin, Minnesota, North Dakota, South Dakota, and California (see table 3-11). These six States only account for about 41 percent of total U.S. alfalfa acreage.

The increased price per ton of hay received by organic growers is partially offset by a reduction in forage quality (due to increased weeds in the hay) and an approximately 12.5 percent reduction of alfalfa yield per acre (Long et al., 2007).[9] The 2005 national average yield per acre for alfalfa was 3.39 tons. Based on differences in organic and conventional alfalfa yield from Long et al. (2007), the total estimated U.S. organic hay production in 2005 was about 606,242 tons; the total U.S. production of alfalfa hay in 2005 was approximately 76,149,000 tons. This estimate is approximate, however, and is only presented here for illustrative purposes. Table 3-3 contains a comparison of total estimated U.S. organic and conventional alfalfa yields for 2002 to 2005.

Demand for Organic Alfalfa for Forage

As in the case of non-organic alfalfa for forage, the demand for organic alfalfa derives mainly from the demand for organic dairy and beef (Butler, 2002). To be sold as organic in the United States, alfalfa hay must meet standards established by the Organic Foods Production Act of 1990 and the National Organic Program (NOP) that became effective in 2001. These standards require that organic dairy and meat products come from dairy cows and livestock fed with 100 percent organic feed, with exceptions for vitamin and mineral supplements (USDA-NOP, 2008). As shown in table 3-3, organic alfalfa hay represented 0.92 percent of total alfalfa hay acres harvested in 2005, up from 0.51 percent in 2000.

[9] Estimates of 10 to 20 percent (or more) yield reductions were estimated by D. Putnam and D. Undersander, State Forage Extension Specialists from California and Wisconsin, respectively (Pers. Comm. No date).

Table 3-11. U.S. Alfalfa Hay (Dry) Acreage, Ranked by Number of Certified Organic Acres by State, 2005.

State	Total NASS 2005 Reported Alfalfa Hay (Acres)	Certified Organic ERS 2005 Reported (Acres)	Calculated Standard Practice (NASS - ERS) (Acres)	% Standard Practice (Acres)	% Certified Organic Acres	Organic Practice State's National Rank by $Val. (Rank)	NASS 2005 Production Yield (Tons/acre)	NASS 2005 Production Yield/State (1,000 Tons)	NASS 2005 Unit Price ($/Ton)	Val. -- Total Production ($1)	Estimated ** Econ. Val.-added -- Certified Organic Hay Based on 18% Price Premium ($)	Estimated 2005 Econ. Incremental Val.-added - Organic Hay (% of State Total)
U.S. Total	**22,439,000**	**204,380**	**22,234,620**	**99.09%**	**0.91%**		**2.45**	**76,149**	**104**	**7,342,000,000**	**12,037,080**	**0.16%**
Idaho	1,140,000	49,497	1,090,503	95.66%	4.34%	2	4.2	4,788	112	536,256,000	4,191,044	0.78%
Wisconsin	1,550,000	29,389	1,520,611	98.10%	1.90%	3	2.4	3,720	112	416,640,000	1,421,967	0.34%
Minnesota	1,350,000	21,339	1,328,661	98.42%	1.58%	5	3.5	4,725	73	344,925,000	981,382	0.28%
North Dakota	1,650,000	20,614	1,629,386	98.75%	1.25%	18	2	3,300	55	181,500,000	408,153	0.22%
South Dakota	2,400,000	13,930	2,386,070	99.42%	0.58%	6	2.15	5,160	65	335,400,000	350,418	0.10%
California	1,040,000	13,246	1,026,754	98.73%	1.27%	1	6.9	7,176	136	975,936,000	2,237,341	0.23%
Iowa	1,250,000	9,193	1,240,807	99.26%	0.74%	4	4.1	5,125	80.5	412,563,000	546,132	0.13%
Colorado	800,000	8,943	791,057	98.88%	1.12%	7	3.7	2,960	101	298,960,000	601,563	0.20%
Nebraska	1,250,000	8,192	1,241,809	99.34%	0.66%	14	3.7	4,625	50	231,250,000	272,777	0.12%
Oregon	400,000	6,592	393,408	98.35%	1.65%	16	4.4	1,760	118	207,680,000	616,062	0.30%
Montana	1,750,000	5,318	1,744,682	99.70%	0.30%	8	2.2	3,850	71	273,350,000	149,529	0.05%
Nevada	260,000	3,000	257,000	98.85%	1.15%	20	4.8	1,248	120	149,760,000	311,040	0.21%
Illinois	400,000	2,488	397,512	99.38%	0.62%	22	3.5	1,400	99	138,600,000	155,159	0.11%
Wyoming	600,000	1,726	598,274	99.71%	0.29%	25	2.6	1,560	75	117,000,000	60,597	0.05%
Pennsylvania	510,000	1,217	508,783	99.76%	0.24%	17	2.6	1,326	153	202,878,000	87,128	0.04%
Missouri	450,000	1,180	448,820	99.74%	0.26%	23	2.7	1,215	102	123,930,000	58,485	0.05%
Washington	450,000	1,140	448,860	99.75%	0.25%	10	5.2	2,340	112	262,080,000	119,508	0.05%
Texas	150,000	1,115	148,885	99.26%	0.74%	27	5.4	810	127	102,870,000	137,640	0.13%
Ohio	510,000	1,030	508,970	99.80%	0.20%	13	3.6	1,836	130	238,680,000	86,784	0.04%
Utah	540,000	925	539,075	99.83%	0.17%	15	4.2	2,268	96	217,728,000	67,133	0.03%
Michigan	900,000	714	899,286	99.92%	0.08%	11	3.1	2,790	92	256,680,000	36,674	0.01%
New Mexico	240,000	670	239,330	99.72%	0.28%	19	5.1	1,224	128	156,672,000	78,728	0.05%
Kansas	850,000	661	849,339	99.92%	0.08%	12	4	3,400	74.5	253,300,000	35,477	0.01%
Indiana	340,000	597	339,404	99.82%	0.18%	21	3.8	1,292	112	144,704,000	45,697	0.03%
Arizona	260,000	487	259,513	99.81%	0.19%	9	8.4	2,184	124	270,816,000	91,307	0.03%
Maine	11,000	345	10,655	96.86%	3.14%	37	2.7	30	167	5,010,000	28,284	0.56%
New York	450,000	321	449,679	99.93%	0.07%	24	2.1	945	131	123,795,000	15,910	0.01%
Virginia	110,000	276	109,724	99.75%	0.25%	29	3.6	396	124	49,104,000	22,177	0.05%
Connecticut	8,000	102	7,898	98.73%	1.27%	38	2.4	19	194	3,686,000	8,450	0.23%
Oklahoma	320,000	90	319,910	99.97%	0.03%	26	3.7	1,184	97	114,848,000	5,814	0.01%
Maryland	40,000	28	39,973	99.93%	0.07%	30	3.9	156	169	26,364,000	3,263	0.01%
Kentucky	260,000	13	259,987	100.00%	0.00%	28	3.2	832	118	98,176,000	884	0.00%
Massachusetts	14,000	2	13,998	99.99%	0.01%	36	2.2	31	183	5,673,000	131	0.00%
Alabama	-	-	-	-	-	n/a	-	-	-	-	-	-
Alaska	-	-	-	-	-	n/a	-	-	-	-	-	-
Arkansas	20,000	-	20,000	100.00%	0.00%	35	2.3	46	147	6,762,000	-	-
Delaware	5,000	-	5,000	100.00%	0.00%	41	3.6	18	169	3,042,000	-	-

State	Total NASS 2005 Reported Alfalfa Hay (Acres)	Certified Organic ERS 2005 Reported (Acres)	Calculated Standard Practice (NASS - ERS) (Acres)	% Standard Practice (Acres)	% Certified Organic Acres	Organic Practice State's National Rank by $Val. (Rank)	NASS 2005 Production Yield (Tons/acre)	NASS 2005 Production Yield/State (1,000 Tons)	NASS 2005 Unit Price ($/Ton)	Val. -- Total Production ($1)	Estimated** Econ. Val.-added -- Certified Organic Hay Based on 18% Price Premium ($)	Estimated 2005 Econ. Incremental Val.-added - Organic Hay (% of State Total)
Florida	-	-	-	-	-	n/a	-	-	-	-	-	-
Georgia	-	-	-	-	-	n/a	-	-	-	-	-	-
Hawaii	-	-	-	-	-	n/a	-	-	-	-	-	-
Louisiana	-	-	-	-	-	n/a	-	-	-	-	-	-
Mississippi	-	-	-	-	-	n/a	-	-	-	-	-	-
New Hampshire	8,000	-	8,000	100.00%	0.00%	40	2.1	17	197	3,349,000	-	-
New Jersey	25,000	-	25,000	100.00%	0.00%	34	2.7	68	150	10,200,000	-	-
North Carolina	11,000	-	11,000	100.00%	0.00%	39	2.5	28	130	3,640,000	-	-
Rhode Island	2,000	-	2,000	100.00%	0.00%	42	3	6	188	1,128,000	-	-
South Carolina	-	-	-	-	-	n/a	-	-	-	-	-	-
Tennessee	35,000	-	35,000	100.00%	0.00%	31	3.2	112	120	13,440,000	-	-
Vermont	45,000	-	45,000	100.00%	0.00%	32	1.8	81	161	13,041,000	-	-
West Virginia	35,000	-	35,000	100.00%	0.00%	33	2.8	98	108	10,584,000	-	-

Sources: Organic acres—USDA, Economic Research Service, based on information from USDA-accredited State and private organic certifiers; standard practice data from NASS. Most recent year (2005) for which both certified organic and U.S. total alfalfa hay acre data are available for direct comparison.

** Estimate assumes equivalent yield per acre and equivalent forage quality grade for organic and standard practice hays. 18% price premium estimate based on median hay selling price for organic vs non-organic hays of the same quality group within the same geography of sale (USDA Livestock, Hay & Grain News, 2005 California Annual Hay Report.)

Table 3-11, continued

Prices and quality requirements are significantly different between organic and non-organic alfalfa hay. USDA-NASS reports the average conventional hay crop value in dollars per ton. USDA-ERS reports the organic hay acreage but does not, however, report the value of organic hay, and therefore, it must be estimated. It is commonplace for certified organic feedstuffs to sell for a 10 to 30 percent price premium, depending upon demand and local supplies (Long et al., 2005; USDA-AMS-LGMN, 2006). The value-added price per ton for certified organic alfalfa hay is, on average, 18 percent greater than conventional hay. This price premium was calculated by comparing the mean sale prices of conventional and certified organic hay occurring within each sale location, within each forage quality grade and within each USDA hay market sale reporting period during 2006 (raw data were from USDA-AMS-LGMN, 2006). This price premium is generally supported by the University of California's 2007 Organic Alfalfa Hay report, which found that prices for organic alfalfa hay vary depending on season, market, and quality, but will be approximately 20 percent greater than prices for conventional hay, and 2007 USDA-AMS data for three counties in California, which found a slightly greater than 20 percent premium for organic alfalfa. The higher prices of organic hay would generally deter conventional livestock producers from using organic alfalfa when not necessary. Table 3-3 shows the value per ton, value per acre, and value added for organic alfalfa hay from 2002 through 2005 using this estimated 18 percent price premium.

Organic Alfalfa Farming for Seed

Production of Organic Alfalfa for Seed

APHIS was unable to locate data on U.S. organic alfalfa seed production. U.S. organic hay production in 2005 was roughly 0.92 percent of total alfalfa hay production. APHIS expects that stand establishment demand for organic alfalfa seed (expressed as a percentage of total alfalfa seed demand) would likely be in roughly the same proportion. Because the NOP-permitted use of non-organically produced seeds and foreign seed imports, the production of organic seed could be somewhat less than this percentage of the total. In the Fourth National Organic Farmers' Survey, 138 organic farmers reported producing a total of 15,169 acres of organic hay, one percent of which was then sold as seed or propagation stock (OFRF, 2004).

Demand for Organic Alfalfa Seeds

Demand for organic alfalfa seeds derives from the demand for organic alfalfa hay, as NOP requires the use of organic seeds to establish organic alfalfa stands (CFR Title 7, §205.204). As previously stated, an exception

is made to this requirement in cases where such seed is unavailable.[10] In these cases, untreated conventional seeds from non-organically managed fields or conventional seeds treated with substances included in the national list of synthetic substances allowed for use in organic crop production are typically allowed.

APHIS was unable to estimate the demand for organic alfalfa seed, due to the lack of data on production of organic alfalfa seed, as well as on the organic seed trade. Some demand likely does exist and could be supplied by either domestic or imported production (imported seeds were approximately 21 percent of total domestic consumption in 2002[11]). The Organic Materials Review Institute (OMRI), a nonprofit organization managed by the organic industry, reports three suppliers of organic alfalfa seed for forage in its seed database (http://seeds.omri.org/index.php?dosearch=1&terms=alfalfa&submit=Go). Some of this seed is imported from Canada. It is also possible that because non-organic seeds are permitted for use in the production of organic alfalfa hay, demand for organic alfalfa seed could remain low.

The main reason reported by organic certifiers to accept farmers' claims that organic seeds were not available was that organic seeds are not "equivalent" to non-organic available seeds in quality. However, equivalency is not well-defined and has been subject to dispute (Baker, 2008).[12] This could be an indication of an unfulfilled demand that, given the growth rates in organic alfalfa seed production, could stimulate the development of "equivalent" organic varieties that are now not available.

Organic Alfalfa Farming for Human Use

Some alfalfa seed is used to produce sprouts for human consumption and dehydrated alfalfa leaf is used as a dietary supplement. APHIS was unable to locate any publicly available data on the share of this market that makes use of organic alfalfa. Estimates of the market for alfalfa for human use, organic or not, are provided in 1.c above.

3. Trade Economics of Conventional and Organic Alfalfa

Certain official statistics for the tonnage of exported alfalfa hay data are highly mixed with and confounded by export statistics for other species crop hays (e.g., USDA-AMS-LGMR, 2007; Woodward, 2006; Putnam, 2005). USDA-FAS (2006) reports estimates for all alfalfa exports, which includes dry hay, cubes, pellets, and meal. These hay data are reported by volume (tons), not by acres. Approximately 1.6 percent of the U.S. dry hay crop is exported (table 3-3). Most of this exported hay is grown in Washington and California, where average yield is 4.9 and 6.9 tons per

[10] This exception is not made for production of organic edible sprouts.
[11] Production data for U.S. domestic seed production comes from USDA Census of Agriculture (2002, 1997); Trade data for seed exports comes from USDA Foreign Agricultural Service.
[12] When asked what crop was most often claimed to not have available organic seeds, certifiers identified alfalfa.

acre, respectively, and relative to the national average, hay value per ton is high. Using the mean hay yield for these two States (5.9 tons per acre), the exported hay represents the equivalent production of approximately 204 thousand acres. It should be noted that an acre producing for the export market during one or more cutting periods likely produces hay for the domestic market at other times of the year (Putnam, 2005) (i.e., fields of alfalfa are not dedicated to the export market per se as they are in organic production). The number of acres from which exported hay is harvested annually is not known (Putnam, 2005).

On average, the Foreign Agriculture Service (FAS)-reported selling price of exported hay is approximately $160 per ton, which is similar to the price for domestically sold hay in the region of production (Pacific Northwest and California). Using USDA-AMS-LGMN data, in 2006, within grade, within location, and within month, the calculated price paid for export alfalfa hay was approximately zero to six percent lower per ton on average than the price for domestic cattle-use hay of the same grade (calculated from head-to-head comparison of selling prices reported by USDA-AMS-LGMN, 2006). Therefore, in general, export market hay has a similar selling price per ton as other locally available hay; it is not considered a value-added market per se although there is significant value in the ability to contract for a large volume of sales to a few importing customers ahead of harvest time. According to Shewmaker et al. (2006), "The export market helps support and stabilize[s] domestic forage prices in the [Pacific Northwest]." According to a National Alfalfa and Forage Alliance (NAFA) document addressing coexistence in the alfalfa export markets (NAFA, 2007), the export hay market is of key importance to certain producers in Washington, Oregon, and California, and coexistence strategies for minimizing comingling between GT and non-GT alfalfa could be effective (see table 3-12).

Table 3-12. Alfalfa and Other Hay Exports from California, Oregon and Washington Ports (Tons), 2006.

	Destination			
Port	Japan	Other Countries	Total	%
California Ports	694,516	241,333	935,849	35%
Oregon-Washington Ports	1,246,055	486,495	1,732,550	65%
Total	1,940,571	727,828	2,668,399	100%

Source: United States Department of Commerce.

Annually, the export hay market is valued at approximately $192 million (USDA-FAS, 2006) (table 3-3). In general, hay sold into the export market channel is of "good," "good/premium," or "premium grade." In 2006, no or few "supreme" grade hay lots were exported (USDA-AMS-LGMN, 2007). The highest quality grade hays always are in high demand domestically and locally. The export quality specifications, although

affected by objective forage quality grade, can be more sensitive to highly subjective hay attributes (e.g., green color, dirt-free, animal/insect-free) (Putnam, 2005). Approximately three-fourths of U.S. alfalfa hay exports go to Japan each year; other key alfalfa hay export markets include the Republic of Korea (13 to 16

Table 3-13. U.S. Forage Export Markets (1000s of Metric Tons).

Forage Importing Country	2001	2002	2003	2004	2005	2006	6-year Ave. Market Share (%)
Japan	524,090	786,409	869,648	865,317	750,907	680,769	73.9%
Korea REP	122,475	133,935	127,657	109,634	100,796	128,331	11.9%
Taiwan	35,779	72,756	55,574	58,876	62,426	68,662	5.8%
Canada	41,251	47,517	64,683	65,113	62,114	39,447	5.3%
UAE	9,004	10,034	4,552	13,197	15,810	19,864	1.2%
Mexico	3,149	5,669	12,497	12,967	23,388	8,987	1.1%
Hong Kong	0	450	923	1,065	1,070	1,087	0.1%
China	982	880	611	127	251	420	0.1%
UK	4,310	2,175	1,602	418	776	407	0.2%
Singapore	0	0	85	55	327	314	0.0%
Other	2,127	6,996	5,396	9,820	2,839	2,309	0.5%
Total	743,167	1,066,821	1,143,228	1,136,589	1,020,704	950,597	100.0%

Source: Department of Commerce, U.S. Census Bureau, Foreign Trade Statistics.

percent) and Taiwan and Canada (5 to 7 percent) (table 3-13, hay exports; Woodward, 2006). More than 85 percent of alfalfa forage exports are hay/compressed bales, with approximately 13 and 1 percent exported as cubes or meal products, respectively (USDA-FAS, 2006).

4. Social Environment at Risk

Alfalfa Seed and Forage Farming

The following discussion is taken largely from a Monsanto report, *Impacts of Roundup Ready® Alfalfa on Production Practices and Marketing of Alfalfa Seed and Hay* (appendix V).

Along with its primary value as a high quality livestock feed, alfalfa is a valued rotational crop in U.S. agriculture because it improves soil fertility and structure. It helps mitigate soil erosion and because alfalfa is a legume, successive crops benefit from residual nitrogen in the soil. Although it is a highly sustainable practice, alfalfa's use in crop rotation is declining in the United States because it demands different management, equipment, market channels, and labor schedules not common to other mainstream cropping systems (USDA-ERS, 2002). In addition, livestock to consume the hay could no longer be located in the vicinity. Alfalfa

forage-cutting schedules, yield, quality, and persistence are challenged by weather and pests.

In general, alfalfa requires somewhat more complex management and more labor to produce per ton of bulk forage than alternative annual row crops, such as corn silage. 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.

In parallel and for several of the same reasons, the numbers of alfalfa seed growers and seed acres have declined in the United States. Most alfalfa seed is grown on highly valued irrigated land in the West where there is much competition for the limited number of skilled growers and suitable acres for alfalfa seed growing. U.S. alfalfa seed growers compete with their conventional seed producing counterparts in Canada, Australia, and elsewhere, where comparative production costs are significantly lower (e.g., USDA Docket 04-085-1; public comment by M. Wagoner [December 12, 2004; comment P5]).

Alfalfa seed yield is highly influenced by grower inputs (such as fertilizer, pesticides, herbicides, and/or irrigation), weeds and insect pests and seasonal weather fluctuations. The cost and availability of required cultured pollinator bees is highly variable (many cultured bees are imported from Western Canada). Similar economic, social, and competitive challenges face both U.S. alfalfa seed and forage growers. Weeds, for example, increase the costs for all alfalfa producers.

Consumer Demand and Preferences

The Organic Segment of the Food Industry

The organic sector is rapidly growing both in the European Union (EU) and the United States (Dimitri and Oberholtzer, 2005). Together,

consumer purchases in these two regions made up 95 percent of the $25 billion in estimated world retail sales of organic food products in 2003 (Willer and Geier, 2005). In reporting the results of their annual manufacturer survey, the Organic Trade Association (2007) reports that U.S. organic food sales were estimated to be $16.67 billion in 2006, up 22 percent from 2005 (see table 3-14).

The Organic Trade Association (2007) notes that organic foods have shown consistent annual growth rates of 15 to 21 percent since 1997, when fairly comprehensive data were first available. Moreover, they report growth rate data based on historical surveys and interviews with long-time participants in the organic foods business in a similar range of nearly 20 percent annually since 1990. Organic food sales are projected to continue growing at a similar pace through 2010 (table 3-14).

Table 3-14. U.S. Organic Food Sales and Sales Growth Forecasts.

	Sales (Millions of $)			Annual Sales Growth Rates (%)		
Category of Food	2004	2005	2006	2004-2005	2005-2006	Forecasted Annual 2007-2010
Organic Dairy	1,731	2,140	2,668	24	25	20
Organic Meat	195	256	334	31	30	27
All Organic	12,460	13,831	16,673	11	22	18

Source: For 2005-2006, Organic Trade Association Manufacturers Survey (2007); For 2004, Organic Trade Association Manufacturers Survey (2006). Data rounded to the nearest integer value.

Of the total amount of 2006 organic food sales reported by the Organic Trade Association (2007), 16 percent were made up of organic dairy products, while another 2 percent came from organic meat. Moreover, organic dairy product sales in 2006 were reported to represent an increase of 25 percent over 2005 levels. Table 3-14 also provides recent trend sales data for organic meat, indicating an even faster growth rate than organic dairy products, though from a much lower base sales level. The Organic Trade Association (2007) notes that overall consumer purchases of organic foods in 2006 represented only 2.79 percent of total U.S. food sales, though this figure is up from 0.81 percent in 1997. The Organic Trade Association (2008) reports that while organic dairy sales in the United States represented 0.79 percent of all dairy sales in 1997, by 2006 that figure had increased to 4 percent of all dairy sales.

Organic production could be somewhat lagging behind the growth in demand; the Organic Trade Association (2006) indicated that 52 percent of respondent firms reported that a lack of dependable supply of organic raw materials has restricted their company from generating more sales of organic products. Willer et al. (2008) report that agricultural land under organic production systems represented 0.5 percent of all agricultural land in the United States in 2006, somewhat below the worldwide average.

There is evidence that consumer perceptions of organic food safety could be an important driver for consumer substitution of organic for conventionally produced food. In particular, Dimitri and Oberholtzer (2005) argue that changes in organic and conventional food demand are driven in part by "food scares." They note, for example, that mad cow disease (bovine spongiform encephalopathy (BSE)) considerably influenced the European organic livestock and dairy industry. Dimitri and Oberholtzer (2005) report that in response to news reports on BSE, many consumers substituted organic dairy and meat products (which consumers perceived as safer) for conventionally raised dairy and meat products. Dimitri and Oberholtzer (2005) report that other food scares that caused European consumers to substitute organic for conventionally produced food include episodes of contaminated chicken feed in Belgium in 1999, feed contaminated by dioxin in 2004, and more recently, carcinogenic food dyes in TV dinners in Ireland in 2005. Dimitri and Oberholtzer (2005) do not find evidence that U.S. consumers are as strongly affected by food scares.

Consumer Sensitivity to GE Content in Food

Demand for GE foods or for foods free of GE content is very difficult to estimate. In the case of European countries this is because most European major food retailers do not carry GE foods in response to consumer demand (Noussair et al., 2004). In the case of the United States, the absence of mandatory GE food identity labeling makes demand estimation difficult. Most U.S. consumers are unaware of the prevalence of GE content in the U.S. food supply (Anderson et al., 2006; Hallman and Hebden, 2005; Thomson and Dininni, 2005). Hallman and Aquino (2003) found that only one-fourth of U.S. residents believed that they had ever consumed food containing GE ingredients. There seems to be no estimate available of consumer demand for GE-free food products (Noussair et al., 2004).

In the last decade, there have been a considerable number of attempts to identify consumer preferences regarding GE foods, in and outside the United States, most of them based on consumer surveys done under various conditions asking consumers to express their preferences under hypothetical situations. The results overwhelmingly show lack of information regarding GE foods and some resistance toward their consumption (Hallman and Aquino, 2003).

A number of studies have implemented experiments in which consumers actually get to choose among products and benefit from their choices. Lusk et al. (2004) developed a meta-analysis of 25 studies including 57 valuations of GE foods. Over half of the studies analyzed are from the United States, with a third from Europe, and the remainder from Asia, Canada, and Australia. Seventeen of the studies are based on consumer

surveys while eight are based on experiments. These studies report that the willingness to pay for GE-free foods was positive, implying that consumers were willing to pay more for these foods. This willingness decreased if the genetically engineered food provided some tangible benefits to consumers, such as increased nutrition value.

A number of other studies have investigated whether the resistance to GE foods and the lack of information regarding biotechnology are correlated. Chern and Rickertsen (2002) conducted a student survey in four countries (United States, Japan, Norway, and Taiwan) and a national phone survey in the United States and Norway. Willingness to consume GE foods increased when it was explained that GE foods could include benefits such as the reduced use of pesticides. Bertolini at al. (2003) compared attitudes toward GE foods in the United States, Japan, and Italy in random surveys of food shoppers. They also found a positive impact of familiarity with GE technology on acceptance. On the other hand, Hallman and Aquino (2003) conducted a survey of a random sample of U.S. households and found out that improved information on GE food did not necessarily mean increased approval. Those most knowledgeable of genetic engineering tended to have more extreme opinions, in favor or against, than those less knowledgeable. Noussair et al. (2004) also found that prior beliefs regarding GE food had a stronger influence on consumer choice than information.

Studies also exist investigating how consumers value varying levels of GE content in their foods. In an experiment in France, where consumer surveys reveal very strong resistance to GE products, Noussair et al. (2004) found that 89 percent of consumers were willing to purchase a product with up to 1 percent GE content and 96 percent with up to 0.1 percent GE content. They also found that consumers differentiated between GE-free and 0.1 percent of GE-content. On the other hand, a nationwide study in the United Kingdom found that consumers did not distinguish between 0 and 0.5 percent GE levels in food and did not place a value in having products with 0 percent GE content as opposed to 0.5 percent (Rigby et al., 2004).

Over 40 countries have adopted some type of labeling regulations specifically for identifying GE food products (Guère et al., 2007).[13] In Europe, the main impact of GE identity labeling requirements has been the virtual disappearance of many GE food products, given that the cost differentials in production are small (since often GE ingredients are a minor share of total ingredients in products) and the risk of loss of market share is high given the perceived consumer resistance (Guère et al., 2007). In addition, to the extent that GE identity labeling requirements require segregation of GE and non-GE food products throughout the production

[13] Some of these regulations have not yet been implemented or only partially so.

process, this type of labeling could imply considerable costs (Noussair et al., 2004).

United States

There is relatively little literature specifically assessing purchase motivations associated with GE foods in the United States. In their summary of 25 valuation studies relating to GE food, Lusk and Rozan (2005) found that U.S. consumers are more receptive to GE foods than their European counterparts, although a preference for non-GE foods remains, suggested by various estimates of willingness to pay for GE-free foods.

Lusk and Rozan (2005) attribute differences in GE product receptivity by consumers in France and the United States, partially to differences in information about GE foods and partially to different levels of trust in the sources providing information. While the United States showed greater knowledge of GE foods, there was also greater trust in the institutions delivering the information (food regulatory agencies, universities, and agribusiness).

There is some evidence that consumers support genetic engineering for use in crops to a greater extent than in animals from which dairy, meat, and other food products derive (Ganiere et al., 2006). Hallman et al. (2003) reported that one-half of U.S. residents surveyed approved of plant-based genetic engineering, while only one-quarter approved of it for use in animal agriculture. In fact, the survey by Lusk et al. (2003) found that consumers in the United States were more averse to hormone use than use of GE animal feed.

Several studies have argued that even with the negative opinions Americans express about biotechnology in surveys, there has been little apparent effect on sales of food items that contain or are raised on GE ingredients or feeds (Fernandez-Cornejo and Caswell, 2006; Putnam, 2005). What these studies reveal is that, despite a consumer preference for foods free of genetically engineered content, this preference does not necessarily translate into decreased sales of products potentially produced with genetically engineered ingredients.

Some suggest that the demand for food free of genetically engineered content can be found in the growth of the organic market. One of the unique attributes of organic foods, and one possible reason consumer demand for organic foods is increasing, is the intended absence of GE ingredients in the process of producing them (Anderson et al., 2006; Dhar and Foltz, 2005; Larue et al., 2004). However, the organic standard is broader than the absence of genetically engineered content, involving the prohibition of many substances commonly used in conventional

agriculture and specific processes and procedures. Simultaneously, it is narrower than a GE-free concept, in the sense that is does not guarantee the absence of adventitious presence of genetically engineered content when such presence is unintentional.

An indication that at least a segment of the organic market (sales) is sensitive to the presence of the genetically engineered content in organic products, even if unintended, is the recent development of a private certification standard with third-party verification and labeling for products free of genetically engineered content (Non-GMO Project, 2010a). Although this standard is also process based, it does require testing for a list of ingredients potentially carrying genetically modified content at specific points in the production chain, in contrast with NOP standards and allows for 0.9% Genetically Modified Organism (GMO) content (Non-GMO Project, 2010b).

Environmental Justice

EO 12898 (*Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*, February 11, 1994) directs Federal agencies to identify and address "disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations." In implementing EO 12898 in the context of National Environmental Policy Act (NEPA), a lead agency must determine whether a proposed action would have any disproportionately high or adverse human health or environmental effects on low-income or minority populations as compared to impacts on the general population.

The Council on Environmental Quality (CEQ) guidance for implementation of EO 12898 in the context of NEPA (*Environmental Justice. Guidance Under the National Environmental Policy Act*, December 10, 1997) identifies a minority population as an affected area where over 50% of the population belongs to a minority group or where the percentage presence of minority groups is meaningfully greater than in the general population. Geographically disperse groups with common conditions of environmental exposure may also be considered as a community subject to analysis for percentage presence of minority groups (e.g., agricultural workers).

Although alfalfa is grown in all of continental United States, about 85 percent of conventional alfalfa hay acreage is located in 18 States—South Dakota, North Dakota, Montana, Wisconsin, Minnesota, Iowa, Idaho, Nebraska, California, Colorado, Michigan, Kansas, Pennsylvania, Utah, Wyoming, Ohio, Oregon, and Washington (see Appendix S). Over 70 percent of organic acreage is located in six states—Idaho, Wisconsin, Minnesota, North Dakota, South Dakota, and California (see section

III.C.2). Seed production is highly concentrated in California, Washington, Idaho, Nevada, Oregon, Wyoming, Montana, and Utah (see section III.C.1). Although the origin of alfalfa for exports is less clear, almost all is originated in Western states and strong exporters include California, Washington, Oregon, Idaho, Nevada, and Utah (see Appendix R).

Table 3-15 shows the minority presence as a share of total population in the United States and in the above mentioned states, sorted by total minority presence, from highest to lowest. Two states have total minority presence higher than that of the United States as a whole: California and Nevada. Washington has relative high presence of Asians and of people of two or more races. South Dakota, Montana and North Dakota have a particularly high presence of Native Americans. Over a fifth of the population in California, Nevada, and Colorado is Hispanic.

To the extent that impacts of GT alfalfa deregulation affect primarily farm households, table 3-16 shows the presence of minorities among farm operators (those who run the farm: owners or other) in the 19 states analyzed, sorted by white race, from lowest to highest share. The total minority share (total population minus non-hispanic whites) is not available. If all Hispanics were white, the highest possible share of total minorities among farm operators would be in California, where total minorities would reach 11.17% + (100% - 92.56%) = 18.6% of farm operators, a share considerably below that of minorities in the population as a whole.

A large percentage of agricultural workers in the United States are born in Mexico – 75 percent in the 2001/2 fiscal year (USDOL 2005). A relatively small share - 14 percent - of all crop workers had a field crop as their primary crop in 2001/2, with most agricultural workers being employed in fruit, vegetable, and horticultural crops (USDOL 2005). However, any impacts on agricultural workers would likely affect a considerably larger share of Hispanics than the share of Hispanics in the total population.

The CEQ guidance for implementation of EO 12898 in the context of NEPA (*Environmental Justice. Guidance Under the National Environmental Policy Act*, December 10, 1997) suggests using U.S. Census Bureau Current Population Reports, Series P-60 on Income and Poverty for identification of low-income populations. This data is based on the American Community Survey done annually through a representative household sample. Table 3-17 below shows the share of population in poverty in the 19 states analyzed, sorted by poverty rate, from highest to lowest. The share of the population in poverty is slightly higher in Michigan, Ohio, Montana, and Idaho than the share of the population in poverty in the country as a whole. In other states, the share of the population in poverty is lower.

Table 3-15. Minority Presence, 2009

Geography	Total Population	Percent of Total Population								
		White	Black or African American	Alaska Native or American Indian	Asian	Native Hawaiian and Other Pacific Islander	Some other race alone	Two or more races	Hispanic or Latino[a]	Total Minority Population[b]
United States	*307,006,556*	*74.84%*	*12.41%*	*0.80%*	*4.49%*	*0.15%*	*4.87%*	*2.44%*	*15.75%*	*35.07%*
California	36,961,664	62.65%	6.08%	0.80%	12.50%	0.37%	13.79%	3.81%	37.02%	58.54%
Nevada	2,643,085	76.17%	7.67%	1.17%	6.61%	0.53%	4.52%	3.33%	26.50%	44.37%
Colorado	5,024,748	84.60%	3.88%	0.98%	2.59%	0.11%	4.61%	3.23%	20.26%	29.54%
Washington	6,664,195	80.17%	3.44%	1.32%	6.62%	0.45%	3.75%	4.25%	10.31%	25.59%
Michigan	9,969,727	79.91%	13.93%	0.50%	2.43%	0.03%	1.23%	1.98%	4.24%	22.73%
Oregon	3,825,657	85.61%	1.78%	1.27%	3.60%	0.36%	3.90%	3.48%	11.20%	20.57%
Kansas	2,818,747	86.32%	5.58%	0.83%	2.19%	0.06%	2.12%	2.91%	9.30%	20.18%
Pennsylvania	12,604,767	83.51%	10.51%	0.13%	2.47%	0.02%	1.82%	1.53%	5.13%	19.25%
Utah	2,784,572	89.35%	1.16%	1.12%	2.04%	0.81%	3.34%	2.19%	12.32%	18.94%
Ohio	11,542,645	83.99%	11.81%	0.17%	1.56%	0.02%	0.68%	1.77%	2.80%	17.90%
Nebraska	1,796,622	88.15%	4.27%	0.93%	1.66%	0.05%	2.83%	2.09%	8.34%	16.71%
Idaho	1,545,801	92.35%	0.66%	1.47%	1.12%	0.08%	1.79%	2.53%	10.69%	15.56%
Wisconsin	5,654,774	88.38%	6.00%	0.86%	2.12%	0.02%	1.05%	1.56%	5.29%	15.48%
Minnesota	5,266,215	87.38%	4.43%	1.05%	3.72%	0.06%	1.39%	1.98%	4.25%	15.27%
South Dakota	812,383	86.33%	1.05%	8.58%	1.01%	0.01%	0.95%	2.07%	2.48%	14.91%
Wyoming	544,270	91.33%	0.95%	2.58%	0.67%	0.07%	1.85%	2.56%	8.08%	13.90%
Montana	974,989	89.41%	0.30%	6.74%	0.54%	0.03%	0.75%	2.23%	2.86%	12.40%
North Dakota	646,844	90.17%	1.08%	5.73%	0.78%	0.03%	0.61%	1.60%	1.95%	10.94%
Iowa	3,007,857	92.26%	2.54%	0.37%	1.52%	0.01%	1.50%	1.80%	4.34%	10.10%

Source: U.S. Census Bureau, American Community Survey 2009

[a] Individuals who identify themselves as Hispanic, Latino, or Spanish might be of any race; the sum of the other percentages under the "Percent of Total Population" columns plus the "Hispanic or Latino" column therefore does not equal 100 percent.

[b] The total minority population, for the purposes of this analysis, is the total population minus the non-Latino/Spanish/Hispanic white population.

Table 3-16. Minority Farm Operators, 2007

		Share of Total Operators						
	Total Operators	White	Black or African American	American Indian or Alaska Native	Asian	Native Hawaiian or Other Pacific Islander	Multi-Race	Spanish, Hispanic or Latino Origin
Nevada	4,969	88.95%	0.08%	9.82%	0.28%	0.10%	0.76%	5.23%
California	127,127	92.56%	0.34%	1.45%	4.55%	0.24%	0.86%	11.17%
Montana	45,925	94.57%	0.03%	4.38%	0.17%	0.03%	0.81%	0.75%
Utah	25,726	94.73%	0.02%	4.53%	0.33%	0.09%	0.31%	1.84%
Washington	62,367	96.12%	0.13%	1.46%	1.07%	0.15%	1.07%	4.18%
Oregon	63,110	96.77%	0.08%	1.34%	0.72%	0.12%	0.97%	2.11%
South Dakota	45,864	97.04%	0.02%	2.51%	0.07%	0.02%	0.34%	0.43%
Colorado	59,479	97.52%	0.12%	1.04%	0.33%	0.10%	0.89%	4.39%
Wyoming	18,105	97.54%	0.04%	1.79%	0.14%	0.06%	0.43%	1.41%
Michigan	83,938	97.91%	0.39%	0.73%	0.15%	0.04%	0.78%	1.12%
Idaho	39,530	98.16%	0.03%	0.89%	0.35%	0.07%	0.51%	2.35%
North Dakota	44,622	98.58%	0.01%	1.13%	0.04%	0.00%	0.24%	0.32%
Minnesota	117,552	98.81%	0.03%	0.35%	0.22%	0.02%	0.57%	0.43%
Kansas	95,818	98.84%	0.21%	0.53%	0.06%	0.01%	0.35%	0.81%
Pennsylvania	92,790	99.23%	0.11%	0.29%	0.11%	0.02%	0.24%	0.57%
Ohio	111,917	99.36%	0.21%	0.14%	0.12%	0.01%	0.16%	0.42%
Wisconsin	120,934	99.39%	0.06%	0.13%	0.29%	0.01%	0.11%	0.34%
Iowa	133,996	99.63%	0.03%	0.11%	0.13%	0.01%	0.09%	0.41%
Nebraska	70,690	99.73%	0.02%	0.09%	0.03%	0.01%	0.12%	0.41%

Source: Census of Agriculture 2007 – State Data

Table 3-17. Low-Income Presence, 2009

	Total[a]	Low-Income	Share
United States	299,026,555	42,868,163	14.34%
Michigan	9,735,741	1,576,704	16.20%
Ohio	11,225,133	1,709,971	15.23%
Montana	946,333	143,028	15.11%
Idaho	1,511,950	216,115	14.29%
Oregon	3,748,545	534,594	14.26%
South Dakota	782,725	111,305	14.22%
California	36,202,780	5,128,708	14.17%
Kansas	2,732,685	365,033	13.36%
Colorado	4,917,061	634,387	12.90%
Pennsylvania	12,165,877	1,516,705	12.47%
Wisconsin	5,495,845	683,408	12.43%
Nevada	2,606,479	321,940	12.35%
Nebraska	1,739,311	214,765	12.35%
Washington	6,530,664	804,237	12.31%
Iowa	2,905,436	342,934	11.80%
North Dakota	620,821	72,342	11.65%
Utah	2,741,756	316,217	11.53%
Minnesota	5,133,038	563,006	10.97%
Wyoming	529,982	52,144	9.84%

ource: U.S. Census Bureau, American Community Survey 2009.

[u]niverse is population for whom poverty status is determined

With respect to farm households, in 2003, 11 percent of the U.S. population was below the U.S. Census Bureau poverty line, while 14 percent of farm households were poor. Offutt and Gundersen (2005) argue that the U.S. Census Bureau poverty line might not adequately capture poverty in farm households, given that it does not capture the volatility of farm income and the greater asset holdings of farm households. Under the USDA alternative concept of Limited Resource Farmer, 11 percent of farm households would fall under that category in 2003, while under the USDA Low Income/Low Wealth concept, only 5 percent of farm households would be classified as such in that same year.

D. Human Health and Safety

The affected environment in terms of human health and safety related to GT alfalfa includes all aspects of direct and indirect human contact with alfalfa. People directly ingest alfalfa in the form of alfalfa sprouts, teas, and dietary supplements; they come in direct skin (dermal) contact on farms and elsewhere, including via skin care products; and they inhale alfalfa pollen and dust, usually on or near farms. People indirectly come into contact with alfalfa via consumption of meat, dairy, and other products derived from livestock that are fed alfalfa, and people ingest alfalfa honey and products derived from honey. Additionally, insecticides and herbicides are used on some alfalfa stands, which in turn can result in exposure to these substances. Within the context of GT alfalfa and genetically engineered crops more broadly, people in the United States have been eating and otherwise coming into contact with genetically engineered crops since 1996, when GT soybeans and other crops first became commercially available (Fernandez-Cornejo and Schimmelphenning, 2004).

This section on the affected environment within the context of human health and safety is organized by (1) public health and safety and (2) worker health and safety. It is based in large part on the following appendices: *Health and Safety Risks from Increased Glyphosate and Other Chemical Use on Humans (Exclusive of Field Workers)* (appendix L), *Health and Safety Risks for Field Workers* (appendix M), *FDA Submission* (appendix P), and *Presence of Glyphosate-Tolerant Alfalfa in Human Food and Animal Feed* (appendix Q).

1. Public Health and Safety

Section I.B of this EIS briefly describes the framework within which agricultural products, including biotechnology products such as GT alfalfa, are regulated to ensure they are safe for human consumption and other contact. Issues affecting the public health environment are addressed by three Federal agencies—APHIS, the FDA, and the EPA—using a variety of means. While APHIS is responsible for the importation, interstate movement, and release into the environment of GE organisms, FDA and EPA have more specific public health goals, including ensuring the safety and proper labeling of all plant-derived foods and feeds (FDA), and regulating the sale, distribution, and use of pesticides to protect human health and the environment (EPA).

More specifically, FDA enforces laws regarding food additives, including those introduced into food or feed by way of plant breeding. These additives must receive FDA approval before marketing. Note that the term "food additive" only refers to substances introduced into food that are not pesticides and are not generally recognized as safe (GRAS) by qualified scientific experts. In general, substances intentionally added to or modified in food via biotechnology have been proteins and fats that are, with respect to safety, similar to other proteins and fats that are commonly and safely consumed in the diet and, thus, are presumptively GRAS (Brackett, 2005). More broadly, alfalfa itself (as an extract, herb, or seed) is considered GRAS within the category of spices and other natural seasonings and flavorings (21 CFR 182.10 and 182.20).

The affected environment with regard to public health also is the focus of a voluntary consultation process that developers of genetically modified crops may undergo with FDA to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food. This voluntary consultation also facilitates inter-agency communication. A key component of the FDA consultation is a focus on whether the gene product has either allergenic or toxic properties, whether to humans directly (e.g., ingestion of sprouts) or indirectly (e.g., ingestion of milk from cows fed alfalfa). These properties are generally assessed by examining the molecular similarity between the gene product and known allergens and toxins (FDA, 2006). For example, many thousands of allergens in our environment have been identified from many sources: animal hair, pollen, insect bites, dust mites, plants, pharmaceuticals, and food. Characteristics of the molecular structure of many of these allergens have been entered into databases that can be searched for matches to gene product (Metcalfe et al., 1996, 2003). While no specific allergens have been identified from alfalfa, pollen has been implicated as a minor to moderate contributor to some respiratory allergic diseases such as asthma (Steinman, 2009; Lipkowitz and Navarra, 2001). Long-term ingestion of alfalfa seeds and sprouts has been correlated with a lupus-like autoimmune disease due to the amino acid L-canavanine (Lipkowitz and

Navarra, 2001; Malinow et al., 1982). Alfalfa sprouts also have been the source of several foodborne outbreaks due to bacterial contamination (FDA, 1999). Epidemiological investigations suggest that seeds are the likely source in most, if not all, sprout-associated illness outbreaks.

The affected environment in terms of alfalfa and public health also includes the pesticides (insecticides, herbicides, and fungicides), including the “inerts” (adjuvants, surfactants, preservatives, solvents, diluents, thickeners, and stabilizers), that are used. People are exposed to pesticides in general via inhalation, oral, and dermal routes if they live near farms that use them. They can ingest the crops that are sprayed directly, or products derived from crops, including animals fed the crops and the products from these animals (e.g., milk). Consumption of adjacent crops affected by spray drift is also a possible route of exposure, as is inhalation and dermal exposure from spray drift to residents nearby spraying operations.

EPA evaluates these pesticides before they can be marketed and used in the United States, to ensure that they will meet Federal safety standards to protect human health and the environment. EPA undertakes this analysis under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). Pesticides that meet the requirements are granted a license or "registration" that permits their distribution, sale, and use according to specific use directions and requirements identified on the label. EPA sets a tolerance, or maximum residue limit, which is the amount of pesticide residue allowed to remain in or on each treated food commodity. The tolerance is the residue level that triggers enforcement actions. That is, if residues are found above that level, the commodity will be subject to seizure by the government. In setting the tolerance, EPA must make a safety finding that the pesticide can be used with "reasonable certainty of no harm" from aggregate exposure to the pesticide chemical residue. To make this finding, EPA considers:

- the toxicity of the pesticide and its break-down products;
- the cumulative effects from exposure to different pesticides that produce similar effects in the human body;
- whether there is increased susceptibility to infants and children or other sensitive subpopulations from exposure to the pesticide;
- whether the pesticide produces an effect in humans similar to that produced by a naturally occurring estrogen or produces other endocrine-disruption effects;
- how much of the pesticide is applied and how often; the aggregate, nonoccupational exposure from the pesticide (exposure through diet, including from milk and other livestock products; from pesticide use in and around the home; and from drinking water); and

- how much of the pesticide (i.e., the residue) remains in or on food by the time it is marketed and prepared.

On average, about 25 percent of the U.S. alfalfa acreage annually receives at least one insecticide application, with almost 50 percent being applied by aircraft (Hower, 1999). About 17 percent of the alfalfa hay acreage and almost 80 percent of the alfalfa seed acreage are treated with herbicides, with only about 7 percent of the applications being conducted by aircraft. Because the subject of this EIS is an herbicide-tolerant crop, GT alfalfa, some additional detail is warranted on the herbicides that are used on alfalfa (See appendix J, *Effects of Changes in Farming Practices on Water, Soil, and Air Due to Use of Glyphosate-Tolerant Alfalfa*, for additional detail on herbicide use). Herbicides are used at three different phases in conventional alfalfa farming—stand establishment (to prepare ground), established stands (to control weeds), and during stand removal (to kill alfalfa). For stand establishment and weed control, 16 herbicides have been used. After three to eight years, alfalfa stands are usually thinning and vulnerable to weeds, so the stand is removed by killing the alfalfa by either plowing, herbicide application, or both (Rogan and Fitzpatrick, 2004). A largely separate, but smaller, set of herbicides are used for stand removal or to control volunteer alfalfa (Dillehay and Curran, 2006; Miller et al., 2006; Renz, 2007; Rogan and Fitzpatrick, 2004).

Another key component of the affected environment is the nutritional composition of alfalfa in terms of both its direct human consumption and its indirect consumption by human due to its use as feed for livestock. As noted above, direct human ingestion of alfalfa occurs via supplements, teas, and sprouts, with the latter likely occupying the largest fraction in terms of intake. In 1988, sprout production represented about seven percent of the total alfalfa seed produced in the United States (Bass et al., 1988). Alfalfa extracts also are used as additives in most major food categories, including alcoholic and non-alcoholic beverages, frozen desserts, candy, baked goods, gelatins and puddings, and meat and meat products (Khan and Abourashed, 2010). Total use of these extracts in the United States has been estimated at 233 pounds, with an approximate average ingestion of 14 micrograms per person per day (Burdock and Fenaroli, 2005).

As discussed more in appendix Q, alfalfa generally has a high protein and low fiber content, making it an ideal livestock feed, which is its largest use (primarily dairy cattle and horse, but also used for beef cattle, sheep, and goats). Reviews on the nutritional quality of GE foods not intended to modify the nutritional quality of the food have generally concluded that there is no significant nutritional difference in conventional versus GE plants for food or animal feed (Flachowsky et al., 2005; Faust, 2002).

While several aspects of the affected environment highlight the potential for adverse human health effects from the introduction of genetically engineered crops such as GT alfalfa, the National Research Council (NRC) and others thus far have indicated that no adverse health effects attributed to genetic engineering had been documented in the human population (ASSAF, 2010; Lemaux, 2009; NRC, 2004). Nevertheless, unexpected and unintended compositional changes arise with all forms of genetic modification, including both conventional breeding and genetic engineering. Whether such changes actually result in health effects depends on the nature of the modification (e.g., the gene products being changed) and the biological consequences of any resulting changes.

2. Worker Health and Safety

Field workers are in close contact with alfalfa and are uniquely exposed to peak short term as well as lower and longer term levels of plant material and applied pesticides, with subsequent potential for allergenicity, pathogenicity, and toxicity. The affected environment for field workers thus centers on exposure during application of fertilizer and pesticides, during seed harvest, and during cutting and baling or green chopping for haylage.

As discussed above for public health and safety, there are no reported allergenic or toxic proteins found in conventional alfalfa, and thus in this context alfalfa is generally considered to be a safe product for close contact by workers.

In all of these operations most of the work is accomplished while on tractors or specialized vehicles (Lee et al., 2003). Pesticides thus are mostly applied with equipment that has enclosed cabs, thus minimizing exposure to applicators. With the possible exception of baling, workers would be having relatively little direct contact with the alfalfa. If the alfalfa is dry and dusty this dust could be wind borne. While this might pose allergen risks, preharvest intervals have been designed to provide protection from pesticide residues. If the alfalfa is wet when it is stored and there is a buildup of fungi and other microbial contaminants, acute respiratory illness (e.g., “silo unloader’s disease,” organic dust toxicity) and/or chronic respiratory diseases (e.g., “farmer’s lung”) can result (Stellman, 1998). Fire risks also are a concern with inappropriately stored hay. Plant material (hay and straw) continues to respire (produce oxygen) for a short time after it is stored, which creates heat. Too much heat generated causes combustion.

Two basic types of worker pesticide exposure scenarios exist for alfalfa. The first is the general worker scenario in which workers have periodic long-term dermal exposure to pesticides via one of three typical pesticide application methods: directed foliar, broadcast foliar, or aerial. Directed foliar application is applied by backpack, which is not a typical application

method for alfalfa production. Broadcast and aerial, however, are common, and both present dermal and inhalation exposure potential.

The second type of exposure scenario is the accident scenario. This scenario includes spills on arms and spills on legs. Depending on the pesticide's chemical characteristics, these spills can result in significant uptake into the bloodstream or damage directly to the skin.

Another hazard is traumatic injury risk from the harvesting and baling equipment and bedding choppers, which are designed to chop, cut, and mangle the hay. Approximately 64 percent of the 1,300 agriculture-related fatalities are attributed to either tractors (50 percent) or other machinery (14 percent) (Margentino, 1992). Of the machinery fatalities, approximately 22 percent occur during silage handling or hay baling.

A second category of workers besides those on the farm itself includes those processing the alfalfa into supplements, extracts, teas, etc. These workers would likely be exposed primarily during transport and initial processing of the alfalfa. Exposures to equipment hazards and to extracting solvents are some of the risks faced by these workers.

E. Land Use and Production Practices

Alfalfa is grown for forage, grazing, seed production (forage and sprouts), and human consumption. While alfalfa is not specifically grown for honey, hives of both managed and wild bees are often associated with alfalfa fields (Hammon et al., 2007). The most acreage is for dry hay forage, as discussed in section III.C.1. In the 2 years that GT alfalfa was on the market, ~200,000 acres were planted in 1,552 counties and 48 states with the exception of Alaska and Hawaii. In March of 2007 USDA published a notice in the *Federal Register* that GT alfalfa is a regulated article and GT alfalfa was once again a regulated article, but existing fields could stay in production. The affected environment includes the choices alfalfa growers have when cultivating alfalfa for forage or seed or when using alfalfa in non-agricultural settings, such as trap crops for insect management, rangeland for erosion control, and on Conservation Reserve Program[14] lands. The characteristics of the seed variety influence what farming practices a farmer selects.

The following discussion comes in part from technical reports, *Effects of Glyphosate-Resistant Weeds in Agricultural Systems*, appendix G; *Effects of Changes in Farming Practices on Water, Soil and Air Due to Use of*

[14]The Conservation Reserve Program (CRP) is a voluntary program for agricultural landowners. Through CRP, landowners can receive annual rental payments and cost-share assistance to establish long-term, resource conserving covers on eligible farmland. http://www.apfo.usda.gov/FSA/webapp?area=home&subject=copr&topic=crp

Glyphosate-Tolerant Alfalfa, appendix J; and *Gene Flow within Alfalfa and Mitigation Strategies*, appendix V.

1. Alfalfa Production Practices

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). Weeds are the most damaging pest during early stand establishment, especially for spring-sown alfalfa.

Based on an extensive survey[15] performed from 1988 to 1992, herbicides are used much more often with seed fields (78.3 percent of acreage) than with hay fields (16.7 percent of acreage) (Hower et al., 1999). According to NASS (1999), in 1998 growers applied herbicides to 7 percent of their alfalfa hay acres across the U.S. Mechanical and cultural methods for weed control (e.g., tillage and companion crops) were used for ~80 percent of the spring planted alfalfa and 18 percent of the fall planted alfalfa (Hower et al., 1999).

Seed

The following discussion comes in part from technical reports, *Effects of Glyphosate-Tolerant Weeds in Agricultural Systems*, appendix G; *Effects of Changes in Farming Practices on Water, Soil and Air Due to Use of Glyphosate-Tolerant Alfalfa*, appendix J; and *Gene Flow within Alfalfa and Mitigation Strategies*, appendix V.

Nearly all alfalfa seed is used for the establishment of hay fields, with a minor amount used as seed field stock seed (variety increase) or for sprouting purposes. Alfalfa seed is not consumed as a grain and, therefore, not used directly as a food or feed product. Essentially all alfalfa planting seed produced in the United States is grown using insecticides and/or herbicides, the use of which precludes the seeds' use for food or sprouting purposes. Additionally, alfalfa seeds for planting purposes are commonly coated with seed treatments (Brick, 2002) and therefore should not be used for sprouting purposes (DeWaal, 1998; Oregon State University, 2004). The use of biologically contaminated canal waters, waste waters, or livestock manures to fertilize alfalfa sprout seed fields are also prohibited by food safety regulations. Bass et al. (1988) estimated that 7 percent of U.S. alfalfa seed is used for sprouting, but this has not been confirmed. In 1998, sprout industry expert Dr. Earl Hauserman gave testimony estimating that 2.5 percent or less of alfalfa seeds are used for human consumption (DHHS FDA, 1998). An FDA

[15] Data collected in the herbicide survey represented 90.1% of the 25.6 million acres produced annually from 1988-1992 as reported by the NASS.

survey conducted in 1999 found that approximately 83 percent of the sprout producers surveyed stocked seed sacks that were traceable to the source and 51 percent of the bags originated from the United States (FDA, 1999). Acreage or production of sprout-destined seed is not reported and field locations for such production are not recorded, therefore, they are not known officially.

Alfalfa seed production occurs almost exclusively in niche areas of the Western United States on approximately 100 to 120 thousand acres under intensive management and irrigated field conditions (see table 3-7). Alfalfa seed production requires a long growing season with a very warm temperature, very low humidity during seed ripening, and specialized equipment. Most professional seed producers use cultured bees and specialized equipment associated with bee culture.

As seen in table 3-7, seed production is mainly concentrated in a few western states. In the most recent USDA-NASS Census of Agriculture (2007a), during 2002 and 2007, 1,234 and 806 farmers grew alfalfa seed on 110.6 and 120 thousand acres, respectively. This is a small number of growers in comparison to those growing alfalfa for forage (i.e., 344,000 and 290,000 alfalfa hay growers in 2002 and 2007, respectively). During 2007, 90 percent of the U.S. seed crop tonnage was grown by 304 seed growers operating farms with at least 100 acres of alfalfa seed (USDA-NASS, 2009). Therefore, most of the alfalfa seed production is managed by a relatively small number of large professional seed producers. Nearly all large growers have at least one proprietary seed production contract with one of the four national alfalfa seed production companies.

Cultural practices used to produce seed are distinct from those used to produce forage. Professional seed growers usually grow seed under terms of a two or three year term seed company contract, by variety name. The contracting seed company supplies the stock seed (e.g., foundation seed) to the seed producer and the genetic source variety of the seed is documented. In contrast, seed companies purchasing or growing "common seed" or "catch crop" seed typically use lower management and inputs, the genetic identity of the stock seed is often unspecified /unknown and the resultant product quality is highly variable and cannot be certified as to cultivar or variety identity.

Typically, seed fields are planted in the fall and clipped back in late spring so that bloom within the field is uniform, synchronous, and optimally timed for the warm dry season and optimal pollinator activity. Weed and in-crop volunteer controls (herbicides and cultivation) are applied mainly prior to the start of pollination or after seed harvest. Flowering begins in approximately mid June. Insecticides (primarily for *Lygus* control) and other pesticides are applied prior to bee release to avoid insecticide damage to the bees. At approximately 50 percent flower (early to mid-

July), cultured bees are gradually moved into the seed field for pollination with their domicile or hive for local shelter. The field is actively pollinated for approximately one month, allowed to ripen seed for approximately 4 weeks more, and then chemically desiccated or swathed several days prior to combining the seed. At the end of the pollination period and just prior to desiccation, the pollinating generation of bees is either at the end of their lifecycle (e.g., leafcutter or alkali bees), or are transported by the honeybee keeper to a different location to forage on fall-flowering plant species. Seed is harvested in mid August to late September depending on geography. In long-growing season regions, the cool-season alfalfa forage growth between seed crops is sometimes mechanically harvested or grazed.

Usually, stands of alfalfa grown for seed production only are maintained for an average of three production seasons. Seed production contracts and AOSCA variety certification standards generally predetermine the length of the seed stand. Because most seed production is planted in widely spaced rows and are not cut monthly, relative to forage stands, weeds in seed fields have more time and open area to proliferate and compete with the alfalfa. Therefore, weeds, insects, and pests are intensively managed in seed production systems. Weed seeds and weed debris in grower seed lots directly reduce the purity and yield of alfalfa seed and drive up growers' costs to remove them.

Forage

Due to climate and other differences, farming practices differ regionally. However, some farming characteristics are shared among growing regions. Alfalfa stands have two growing phases, establishment of seedlings (first year) and established alfalfa fields (two to eight years). Weed management differs for each phase (Orloff et al., 1997). Well-established alfalfa that is not thinning has fewer weeds because established alfalfa is a good competitor. Alfalfa is typically harvested (mowed) every 22 to 40 days depending on growth conditions in the region, local weather patterns, and alfalfa variety. In most of the growing regions, alfalfa is only cut three to four times a year, but in the Southwestern United States, growers can cut up to 11 times per year (Putnam et al., 2001).

To determine when to harvest, farmers balance yield and nutritional content. Yield increases as plants grow and peaks at 100 percent bloom, but nutritional content is highest in young vegetative plants and decreases until full flower. There is no optimal harvest schedule, because farmers make different decisions based on changing market demand. Farmers typically harvest between late bud stage and full bloom. The highest quality hay (bud stage) is generally used for active dairy cows, whereas, hay that is lower in protein and higher in fiber is fed to beef cattle, horses, heifers (too young to milk), and non-lactating dairy cows (Ball et al.,

2001). Alfalfa for livestock feed can be stored in a variety of forms (Ball et al., 2001):

- hay—dry baled at 18-20 percent moisture;
- haylage—round bale silage, baled at 50-60 percent moisture, wrapped in plastic; and
- silage—chopped and blown into a silo or a truck.

Another factor influencing maturity at harvest is the desire for robust root reserves for overwintering and increased stand longevity. Alfalfa devotes more resources to root reserves as it matures. Root reserves are more important in colder climates. Farmers in colder climates may let their hay fields mature more for the last fall cutting (Shroyer et al., 1984; Hesterman and Durling, 1991; Howley and Wright,1991; Baldridge et al., 1985; Meyer and Helm, 1994; Bosworh et al., undated).

Alfalfa grown for hay is sometimes grown with a companion crop to act as weed control and to prevent soil erosion. These crops, such as oats, spring wheat, or peas tend to grow much quicker than alfalfa, and out-compete any weeds while alfalfa is becoming established. Once the companion crop begins to compete with the alfalfa for nutrients, water, and space, the companion crop can be harvested, and serves as extra profit for the farmer (Smith et al., 1998). At this point, the alfalfa is established enough to compete against any weeds on its own. Oats are the most popular companion crop to alfalfa because they are the least competitive, with alternatives such as peas also in wide use, but exact companion crop habits depend on farmer preference and region (McCordick et al., 2008; Smith et al., 1998). Studies have found that companion cropping in alfalfa can suppress weed growth more than herbicide treatments, but that the crop then competes with the alfalfa, reducing alfalfa yield (McCordick et al., 2008).

Companion crops are different from nurse crops in that nurse crops are a specific type of companion crop. Nurse crops (such as small grains, primarily oat or a small grain-pea mixture) do not compete with alfalfa for nutrients, but rather are removed or killed with herbicide early in development. This can result in both effective weed control and little impact on alfalfa yield (McCordick et al., 2008). Nurse crops can also help reduce wind, water, and soil erosion and provide early groundcover like other companion crops (Hall, 2004). Other types of companion cropping include using a cover crop, used during dormant seasons to protect the soil, or a barrier crop, used as pest management strategy by serving as a refuge and distraction for pests.

2. Alfalfa Farming Practices

Alfalfa farming practices are broken into three categories: organic, conventional, and GT alfalfa.

Organic Farming

Organic production includes only those cropping systems that fall under the USDA-NOP definition of organic farming and are certified organic production systems. In organic systems, the use of synthetic pesticides, fertilizers, and genetically engineered crops is limited. A list of NOP approved substances for organic farming inputs can be found on the USDA Web site (http://www.ams.usda.gov/AMSv1.0/). Neither glyphosate nor GT alfalfa is permitted in organic systems.

In organic systems, where only NOP approved herbicides may be used, the area to be seeded with alfalfa is tilled for weed management and allowed to sit for seven to ten days. Two or more passes to turn the soil with discs may be necessary if weed germination is observed. It is recommended that the field be treated with nutrients, such as compost and boron, and left for a week to check for further weed germination. Further, composted manure fertilizer can be used to kill weed seeds (Canevari et al., 2007a). Planting may occur once weed growth potential is minimized (Guerena and Sullivan, 2003).

According to USDA-NOP standards, the following [synthetic] inputs can be used as herbicides or weed barriers, as applicable, to control weeds[16]: 1) soap-based herbicides for use in farmstead maintenance (roadways, ditches, rights-of-ways, building perimeters) and ornamental crops; 2) mulches- newspaper or other recycled paper, without glossy or colored inks; plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)) (http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5068682&acct=nopgeninfo).

Organic farmers also use cover crops such as oats, which are harvested during the first year of stand establishment, to allow alfalfa to be better able to compete with weeds the following spring. Alfalfa can be used as a "clean-up" crop in crop rotations to resolve weed issues (Poole, 2001).

[16] Insecticides and substances to control plant diseases are also included on the NOP list, but are not listed here because they are beyond the scope of this Report.

Conventional Farming

Conventional farming includes any farming system where synthetic (manufactured) pesticides or fertilizers are used in accordance with manufacturer labels, but not following any restrictions contained in the USDA-NOP. The definition of conventional farming can include the use of GE crops, but for this report, genetically engineered GT alfalfa is considered separately from conventional farming (Harker et al., 2005). Conventional farming covers a broad scope of farming practices, ranging from farmers who only occasionally use synthetic pesticides and fertilizers to those farmers whose harvest depends on regular pesticide and fertilizer inputs.

Herbicides are used on approximately 17 percent of alfalfa acreage and is described briefly below (the technical report *Effects of Changes in Farming Practices on Water, Soil, and Air Due to Use of Glyphosate-Tolerant Alfalfa*, appendix J, discusses this use in more detail). Herbicides are used at three different phases in conventional alfalfa farming: stand establishment, established stands (to control weeds), and during stand removal to kill alfalfa. The 16 herbicides that can be used for weed control in conventional alfalfa farming are summarized in table 3-18 (based on Canevari et al., 2007a: Loux et al., 2007; OMAFRA, 2008; Rogan and Fitzpatrick, 2004). Based on an extensive survey[17] performed from 1988 to 1992, herbicides are used much more often with seed fields (78.3 percent of acreage) than with hay fields (16.7 percent of acreage) (Hower et al., 1999). Mechanical and cultural methods for weed control (e.g., tillage and companion crops) were used for ~80 percent of the spring-planted alfalfa and 18 percent of the fall planted alfalfa (Hower et al., 1999).

Table 3-18. Herbicides Used to Control Weeds in Conventional Alfalfa

Herbicide (Brand)	Stand Stage	Notes
2,4-DB (Butyrac, Butoxone)	1-4 trifoliolate or established stands	No harvesting or grazing allowed for 60 days following treatment
Benefin (Balan)	Before seeding	Not for use on soils high in organic matter
Bromoxynil Buctril)	2-4 trifoliolate	Often tank mixed with other herbicides
Clethodim (Prism, Select)	2-4 trifoliolate or established stands	Well established perennials require multiple applications Allow 15 days between application and grazing, feeding, or harvesting of alfalfa

[17] Data collected in the herbicide survey represented 90.1% of the 25.6 million acres produced annually from 1988-1992 as reported by the NASS.

Table 3-18. Herbicides Used to Control Weeds in Conventional Alfalfa

Herbicide (Brand)	Stand Stage	Notes
Diuron (Karmex, Direx)	Established stands	Persists in soil for one year, so cannot be used in last year of stand
EPTC (Eptam)	Established stands	Applied before germination Controls for 30 to 45 days so repeated applications might be necessary
Hexazinone Velpar)	6 inches of root growth in new stands or established stands	Many crops cannot be planted for 18 months without yield damage
Imazamox (Raptor)	2-4 trifoliolate or established stands	Preharvest interval is 20 days
Imazethapyr (Pursuit)	2-4 trifoliolate or established stands	Follow-up planting restrictions range from 4 to 40 months
Metribuzin (Sencor)	Established stands	No grazing or harvesting allowed for 28 days following application
Norfluzaon (Solicam)	Established stands	Cannot be applied within 28 days of harvest Does not control emerged weeds 24 month rotation interval
Paraquat (Gramoxone Inteon)	3, 6, or 9 trifoliolate; established stands	Rescue treatment when weeds form a canopy over alfalfa No harvest or grazing until 60 days after application Often used in the last year of the stand
Pronamide (Kerb)	First trifoliate leaf stage	No grazing or harvesting allowed for 120 days following application
Sethoxydim (Poast)	2-4 trifoliolate or established stands	Well established perennials require multiple applications
Terbacil (Sinbar)	Established stands	Cannot plant any other crop for 2 years after Sinbar application
Trifluralin (Treflan/TR-10)	Established stands	Applied before germination Rainfall or sprinkler irrigation is required within 3 days after irrigation to incorporate the herbicide Controls dodder before germination

The exact use of herbicide on alfalfa crops typically depends on region, weed spectrum, and farmer preference, among other factors. One herbicide rarely takes care of all weed control issues in a crop, and farmers usually have sequential combinations of herbicides to take care of summer and winter weeds. In California, research has shown that with the proper sequence and application rates, farmers can achieve weed-free alfalfa hay (Gianessi et al., 2002). In field experiments in southwestern Michigan, researchers found no net economic benefit to herbicide use in alfalfa establishment (Brothers and Hesterman, 1991).

One important herbicide, especially for purposes of this EIS, is glyphosate. Glyphosate was first introduced as an herbicide under the trade name of Roundup® by Monsanto in 1974. Glyphosate is a systemic,

post-emergence herbicide widely used on both agricultural commodities (food uses) and nonagriculture sites (Cerdeira and Duke, 2006). Glyphosate is a substituted glycine, the simplest amino acid. The glyphosate molecule has a methylphosphono group bonded to the nitrogen atom of the amino group of glycine, as denoted in figure 3-2 below.

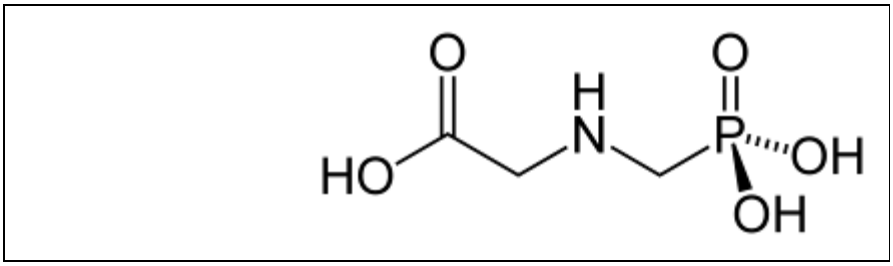

Figure 3-2. Molecular structure of glyphosate.

At normal temperatures, glyphosate is a white crystalline substance that is not volatile (is not likely to vaporize at normal pressure) and is highly soluble in water. Glyphosate salts serve as the source of the active ingredient *N*-(phosphonomethyl) glycine. To improve handling, performance, and concentration, the glyphosate acid is formulated as a salt compound. Several salts of glyphosate are currently marketed. The term acid equivalent (a.e.) refers to the weight of the glyphosate acid, which is herbicidally active, while the term active ingredient (a.i.) is the weight of the glyphosate acid plus the salt.[18] While GT alfalfa could tolerate other herbicides formulated with glyphosate, there are five glyphosate herbicides recommended for use on GT alfalfa. These end use products (EUPs) are presented in table 3-19.

[18] The *active ingredient* is the chemical or substance component of a pesticide/herbicide product that can kill, repel, attract, mitigate or control a pest or that acts as a plant growth regulator, desiccant, or nitrogen stabilizer. The remainder of a formulated product consists of one or more "inert ingredients" (such as water, solvents, emulsifiers, surfactants, clay and propellants), which are there for reasons other than pesticidal activity." The *acid equivalent* is a correction that adjusts for active ingredients that are formulated as salts (active ingredient combined with potassium or isopropylamine salts) in a concentrated form to provide an accurate percentage of the active ingredient (as the acid) per volume of the product. The acid equivalent represents the amount of acid (active ingredient) in the final mixed product that came from a certain amount of salt (active ingredient combined with a salt). The acid equivalent can be defined as the part of the formulation that will be converted back to an acid when the concentrated product is diluted in water, if the formulation's active ingredient is a derivative of the original acid. This matters for herbicides such as glyphosate, as the initial acid molecule is converted to a salt in the concentrated herbicide formulation (so the salt is the derivative of the acid). This is done to facilitate more convenient packaging (i.e., smaller containers) and better product performance, such as a more complete mixing with water. Active ingredient and acid equivalent can sometimes be used interchangeably in the case of an herbicide where the active ingredient of a formulation is an acid (Monsanto, 2009).

Table 3-19. Monsanto End Use Products Approved for Use on Glyphosate-tolerant Alfalfa.

Product Name	% Salt	Glyphosate salt CAS No.	U.S. EPA PC Code	Surfactant	Year
Honcho®	41	Isopropylamine CAS: 38641-94-0	103601	Alkyl Tallow Ethoxylated Amines CAS 61791-26-2	2007b
Honcho Plus®	41	Isopropylamine CAS: 38641-94-0	103601	Trade Secret	2007d
Roundup Original MAX®	48.7	Potassium CAS: 70901-12-1	103613	Trade Secret	2007e
Roundup WeatherMAX ®	48.8	Potassium CAS: 70901-12-1	103613	Trade Secret	2007f
Roundup Ultra MAX II®	48.8	Potassium CAS: 70901-12-1	103613	Trade Secret	2004

Glyphosate is a very effective non-selective herbicide (Cerdeira and Duke, 2006). Herbicide formulations in liquid form are generally considered trade secrets. One formulation of glyphosate, Honcho®, has a tallow amine surfactant (Monsanto, 2007a). This and other surfactants (surface action agents that are soluble in organic solvents and water), such as polyethoxylated tallowamine (POEA), are added to the herbicide formulations to increase leaf penetration (Monsanto, 2007a).

The Roundup Original MAX®, Roundup WeatherMAX®, and Roundup Ultra MAX II® products contain 48.8 percent of the potassium salt of glyphosate, equivalent to 4.5 lbs of glyphosate equivalents per gallon (540 g glyphosate per L). The product is to be applied over-the-top (e.g., spot treatment, broadcast ground application) for pre-plant, pre-emergence, and post-emergence uses.

Typical single application rates of products containing glyphosate range from less than 1.5 pounds of glyphosate a.e. per acre up to 3.75 pounds of glyphosate a.e. per acre. Application rates were determined using specific product labels for each end use product recommended for use on GT alfalfa (Monsanto, 2007a, 2007e, 2007c, 2007d, 2005a, 2005b, 2004), and are calculated to minimize impact on nearby environments. Application rates of the five end use products recommended for use on GT alfalfa are presented in table 3-20. The maximum use rate (ground or aerial application) for a single application of glyphosate on GT alfalfa is 1.55 pounds of glyphosate a.e. per acre.

Table 3-20. Maximum Single Application Rates of EUPs Recommended for Use on Glyphosate-tolerant Alfalfa.

Product	Single Use Application Rate	Reference
Honcho®	2.0 lbs a.i./acre	Monsanto, 2007a; 2007b
Honcho Plus®	2.0 lbs a.i./acre	Monsanto, 2007c; 2007d
Roundup Original MAX®	1.9 lbs a.i./acre	Monsanto, 2007e
Roundup WeatherMAX®	1.9 lbs a.i./acre	Monsanto, 2007f; 2005a
Roundup Ultra MAX II®	1.9 lbs a.i./acre	Monsanto 2005b; 2004; 2003

GT Farming

GT alfalfa can be integrated into conventional farming practices. Farming GT alfalfa is mostly the same as farming conventional alfalfa, with a few important exceptions:

- Weeds can be controlled by the application of glyphosate directly on top of growing alfalfa, the limits of which are discussed in section III.E.3 below.
- When alfalfa stands reach the end of their life cycle, typically after 3 to 8 years depending on growing region, glyphosate cannot be used to kill the stand to prepare for another rotation (Miller et al., 2006).
- Because several of the recommended GT alfalfa stand removal herbicides result in restrictions regarding what crops can be planted next, careful crop rotation plans are necessary when using GT alfalfa.
- Glyphosate can be used to prepare a field for alfalfa in the stand establishment year and also to mitigate areas of GT alfalfa fields that fail to establish following seeding, preventing the buildup of mature weed populations within field.
- For producers using companion crops, non-GT crops cannot be used as companion crops for GT alfalfa.

In GT alfalfa, herbicides other than glyphosate combined with tillage are required to obtain 100 percent removal. Several of the recommended GT alfalfa stand removal herbicides result in restrictions regarding what crops can be planted next, so careful crop rotation plans are necessary when using GT alfalfa (Miller et al., 2006).

Another important difference is that non-GT crops cannot be used as companion crops for GT alfalfa. This difference is important for farmers that traditionally interseed companion crops like small grains (e.g., oats) with alfalfa; it does not affect farmers that plant pure alfalfa stands. Companion crops may possibly benefit stand establishment by weed control, increased forage yield during the seedling year, and wind and

frost protection for young alfalfa seedlings (Orloff et al., 1997). However, it is important to carefully monitor the seeding rates to avoid excessive competition of companion crops with the alfalfa. Companion crops can increase overall forage yield (which includes alfalfa, the companion crop and any weeds), but may decrease hay quality (McCordick et al., 2008).

3. Weeds in Alfalfa

The following discussion is based in part on the technical report, *Effects of Glyphosate-Resistant Weeds in Agricultural Systems* (appendix G).

Healthy, productive stands of alfalfa require attention to manage pests (including weeds), fertilizer inputs, irrigation (if applicable), and harvest timing. Weeds can be a problem in alfalfa, but once alfalfa is established, it acts as a suppressor of weeds and is commonly used in rotations for weed reduction. For example, prior rotation in alfalfa can reduce weed densities in sunflower to the same level as herbicide treatment. Alfalfa in corn rotations has also been observed to benefit corn yield and suppress weeds (Clay and Aguilar, 1998).

Several years after sowing when plants weaken and stands become thin, weeds become more competitive with alfalfa and can contribute to a significant decline in alfalfa yield and forage value. Well-established alfalfa fields or fields undergoing stand renovation are sometimes used for the disposal of livestock manures. Weed seeds present in livestock manure can contribute to an accumulation of weed seeds in the soil and weed problems in alfalfa production systems. Certain weed species found in alfalfa stands are particularly difficult to control (Hower et al., 1999), are poisonous to livestock, negatively affect palatably or livestock performance, impart off flavors to milk products, and may be noxious regulated species (e.g., dodder).

Farmers are concerned about glyphosate-resistant weeds (Johnson and Gibson, 2006). One hundred and twenty-nine weeds are known to infest alfalfa, some of which have already shown glyphosate resistance or tolerance. Since 1998, nine new GT weeds have been found in the United States. Eleven out of the 19 new GT weeds known globally are also known to be weeds in alfalfa stands. At least 21 weeds that have natural tolerance to glyphosate exist. Ten of these naturally glyphosate-tolerant weeds are known to be a problem in alfalfa. See *Effects of Glyphosate-Resistant Weeds in Agricultural Systems* (appendix G; table G-7) for a list of weeds that are known to be glyphosate resistant or tolerant.

Weeds are controlled in conventional alfalfa with chemicals (herbicides), cultural methods (rotation, mowing, companion crops, monitoring), and mechanical methods (tillage). Many of these cultural and mechanical methods are permitted for organic farmers. In contrast to organic systems, GT systems allow for the use of GT alfalfa varieties and the herbicide glyphosate (see section III.E.3 above and appendix G).

New Glyphosate-Resistant Weeds

Glyphosate-resistant biotypes have recently been identified for the following eleven weeds that are also common in alfalfa: common ragweed, horseweed, Italian ryegrass, Johnsongrass, Palmer Amaranth, buckhorn plantain, goosegrass, junglerice, perennial ryegrass, tall waterhemp, and kochia (*Effects of Glyphosate-Resistant Weeds in Agricultural Systems* [appendix G; section 4.1.1] briefly discusses each).

Glyphosate-Tolerant Weeds

Ten weeds that are common in alfalfa and are glyphosate tolerant include bermudagrass, burning nettle, cheeseweed, common lambsquarters, field bindweed, filaree, large crabgrass, morningglory, nutsedge, and purslane (*Effects of Glyphosate-Resistant Weeds in Agricultural Systems* [appendix G; section 4.1.2] briefly discusses each).

Weed Management Options

Weed management strategies in organic alfalfa systems, conventional alfalfa systems, and glyphosate-tolerant alfalfa systems differ. Management options for conventional systems include (Nandula et al., 2005; Guerena and Sullivan, 2003):

- Chemical (See table G-1)
  - Alternating herbicides with different modes of action
  - Tank mixing herbicides
  - Sequences of herbicides
  - Application timing (e.g., apply at a more sensitive lifestage)
- Cultural
  - Rotation between GT cultivars and non-GT cultivars
  - Rotation to nonalfalfa crops (e.g., grains)
  - Rotation to crops having tolerance to a different mode of herbicide action
  - Spot burning
  - Flood irrigation
  - Winter crops in rotation
  - Companion crops/co-cultivation/interseeding/nurse crop)
  - Cover crops (smother crops) (prior to planting alfalfa)
  - Field scouting for early detection
  - Monitor for weed species and population shifts
  - Mowing (harvesting)
  - Hand weeding
- Mechanical
- Tillage cultivation

Cutting intervals affect weed infestation. For example, if alfalfa is cut too frequently (20 to 25 days), there is not enough time for roots to build up a sufficient storage of carbohydrates so growth after cutting is not vigorous enough and weeds have a competitive advantage. However, sometimes early harvest can rescue a heavily weed-infested new stand if the weeds are beyond the stage of successful herbicide treatment (Canevari et al., 2007a). Alternating long and short intervals between cuttings enables alfalfa to maintain root reserves so plants can recover from defoliation quickly and more vigorously compete with weeds (Canevari et al., 2007a).

Crop rotations can help maintain soil fertility, reduce soil erosion, avoid pathogen and pest buildup, adapt to weather changes, avoid alfalfa seedling autotoxicity, and increase profits (Peel, 1998). Alfalfa is also used in crop rotation because it provides nitrogen to the soil, which decreases fertilizer inputs in other rotations. It can be economically advantageous to include alfalfa in rotations (Mends and Dobbs, 1991). Perennials and annuals promote and restrict different weeds, so rotating perennials with annuals helps control weeds in general. Monsanto recommends that alfalfa can be rotated to grass crops (corn and cereal crops) or broadleaf crops (Monsanto, 2008). This limits some options for farmers, as GT corn and GT soybean are both popular rotation crops for alfalfa. Typical rotation crops include wheat, oats, barley, potato (*Solanum tuberosum L.*), sugar beet (*Beta vulgaris L.*), and corn. Appropriate weed management practices reduce the probability of weeds developing glyphosate resistance (Rogan and Fitzpatrick, 2004).

Distribution of Glyphosate-Resistant Weeds

Table 3-21 shows that currently 19 U.S. states are affected by glyphosate-resistant weeds. The majority of new glyphosate-resistant weeds are located in the Southeast and Midwest. The overlap with the major alfalfa producing states in the Intermountain regions seems to be minimal at this point (see also table 3-23).

Table 3-21. Glyphosate-Resistant Weed Infestations by State.

State	Weed species	~ Number of Sites in State Infested	~ Number of Acres in State Infested	Situation	Year Reported
Arkansas	***Conyza canadensis*** Horseweed	6-10 increasing	1,001-10,000 increasing	Cotton	2003
	Ambrosia artemisiifolia Common Ragweed	1	11-50	Soybean	2004
	Ambrosia trifida Giant Ragweed	6-10 increasing	101-500 increasing	Soybean	2005
	Amaranthus palmeri Palmer Amaranth	1,001-10,000 increasing	100,001-1,000,000	Soybean	2006

Table 3-21. Glyphosate-Resistant Weed Infestations by State.

State	Weed species	~ Number of Sites in State Infested	~ Number of Acres in State Infested	Situation	Year Reported
	Sorghum halepense Johnsongrass	1	unknown	Soybean	2007
California	***Lolium rigidum*** Rigid Ryegrass	11-50 increasing	1,001-10,000 increasing	Almonds	1998
	Conyza Canadensis Horseweed	1	unknown	Roadside	2005
	Conyza bonariensis Hairy Fleabane	2-5	unknown	Roadside	2007
Delaware	***Conyza canadensis*** Horseweed	101-500	10,001-100,000	Soybean	2000
Georgia	***Amaranthus palmeri*** Palmer Amaranth	101-500 increasing	100,001-1,000,000 increasing	Cotton Soybean	2005
Illinois	***Conyza canadensis*** Horseweed	1,001-10,000 increasing	10,0001-1,000,000 increasing	Soybean	2005
	Amaranthus rudis Common Waterhemp***	1 increasing	51-100 increasing	Corn Soybean	2006
Indiana	***Conyza canadensis*** Horseweed	2-5 increasing	101-500 increasing	Soybean	2002
	Ambrosia trifida Giant Ragweed	1 increasing	11-50 increasing	Soybean	2005
Kansas	***Conyza canadensis*** Horseweed	51-100 increasing	10,001-100,000 increasing	Cotton Soybean	2005
	Ambrosia trifida Giant Ragweed	2-5 increasing	501-1,000 increasing	Soybean	2006
	Amaranthus rudis Common Waterhemp	2-5 increasing	101-500 increasing	Soybean	2006
	Kochia scoparia Kochia	2-5	51-100	Corn Soybean	2007
	Ambrosia artemisiifolia Common Ragweed	1 increasing	11-50 increasing	Soybean	2007
Kentucky	***Conyza canadensis*** Horseweed	2-5 increasing	51-100 increasing	Soybean	2001
Maryland	***Conyza canadensis*** Horseweed	6-10 increasing	501-1,000 increasing	Soybean	2002
Michigan	***Conyza canadensis*** Horseweed	1 increasing	51-100 increasing	Nursery	2007
Minnesota	***Ambrosia trifida*** Giant Ragweed	2-5 increasing	101-500 increasing	Soybean	2006

Table 3-21. Glyphosate-Resistant Weed Infestations by State.

State	Weed species	~ Number of Sites in State Infested	~ Number of Acres in State Infested	Situation	Year Reported
	Amaranthus rudis Common Waterhemp	2-5 increasing	51-100 increasing	Soybean	2007
Mississippi	***Conyza canadensis*** Horseweed	101-500 increasing	1,001-10,000 increasing	corn, cotton, rice, and soybean	2003
	Lolium multiflorum Italian Ryegrass	Unknown	1,001-10,000 increasing	Cotton Soybean	2005
Missouri	***Conyza canadensis*** Horseweed	101-500 increasing	10,001-100,000 increasing	Cotton	2002
	Ambrosia artemisiifolia Common Ragweed	2-5	51-100	Soybean	2004
	Amaranthus rudis Common Waterhemp**	101-500 increasing	100,001-1,000,000 increasing	Corn Soybean	2005
New Jersey	***Conyza canadensis*** Horseweed	6-10 increasing	101-500 increasing	Soybean	2002
North Carolina	***Conyza canadensis*** Horseweed	2-5 increasing	6-10 increasing	Cotton	2003
Ohio	***Conyza canadensis*** Horseweed	101-500 increasing	1,001-10,000 increasing	Soybean	2002
	Conyza canadensis Horseweed*	2-5 increasing	101-500 increasing	Soybean	2003
	Ambrosia trifida Giant Ragweed	2-5 increasing	101-500 increasing	Soybean	2004
Oregon	***Lolium multiflorum*** Italian Ryegrass	1 stable	1-5 stable	Orchards	2004
Pennsylvania	***Conyza canadensis*** Horseweed	2-5 increasing	101-500 increasing	Soybean	2003
Tennessee	***Conyza canadensis*** Horseweed	501-1,000 increasing	>2,000,000 increasing	Cotton Soybean	2001
	Amaranthus palmeri Palmer Amaranth	2-5 increasing	101-500 increasing	Cotton	2006
	Ambrosia trifida Giant Ragweed	101-500 increasing	1,001-10,000 increasing	Cotton Soybean	2007

* Resistant to chlorimuron-ethyl, cloransulam-methyl, and glyphosate.
** Resistant to acifluorfen-Na, cloransulam-methyl, fomesafen, glyphosate, imazamox, imazethapyr, and lactofen.
*** Resistant to chlorimuron-ethyl, glyphosate, and imazethapyr
Source: Heap et al., 2010.

4. Crop Rotation in Alfalfa

For weed, insect, and disease management, it is recommended that alfalfa be used in rotation with other crops. It is also advised to rotate alfalfa because mature alfalfa produces compounds that are autotoxic to seedling alfalfa. Autotoxicity is the primary problem for alfalfa seeded after alfalfa (Rogan and Fitzpatrick, 2004).

Table 3-22 presents rotation recommendations for control of several common alfalfa pests.

The major regional differences for growing alfalfa forage are due to different climatic regions and the adaptation of different varieties to these climatic regions. The major factors involved in variety adaptation are winter temperatures and rainfall. The areas of alfalfa adaptation for the United States are shown in figure 3-3. These regions are recognized by the USDA–Plant Variety Protection Office and the National Alfalfa and Miscellaneous Legume Variety Review Board (Rogan and Fitzpatrick, 2004).

Table 3-22. Recommended Rotations for Pest Reduction.

Pest	Recommended Rotation
Root knot nematode	1 year rotation with cotton
Stem nematode	3-4 year rotation with small grains, beans, cotton, corn, sorghum, lettuce, carrots, tomatoes, or forage grasses.*
Disease Bacterial wilt Anthracnose Spring blackstem Common leafspot Stagonospora	3-4 year rotation with small grains, beans, corn, sorghum, forage grasses.*
Winter weeds	A minimum of 1 year (preferably longer) in crops such as small grains, wheat, oats, winter forage grasses that allow the use of selective herbicides that are not registered in alfalfa.
Summer weeds	A minimum of 1 year (preferably longer) in crops such as small grains, beans, cotton, corn, sorghum, summer forage grasses that allow the use of selective herbicides that are not registered in alfalfa.
Dodder	At least 2 years with cotton or other nonhost crops such as small grains, beans, corn, sorghum, or forage grasses. Avoid rotations with crops such as tomatoes, onions, and carrots that also serve as a host for this weed.
Nutsedge	Two year rotation with corn or sorghum rotation that includes application of herbicide to control nutsedge.

* Three to four-year rotations give satisfactory results. A rotation for fewer years will provide minimal suppression.
Source: Goodell, 2006

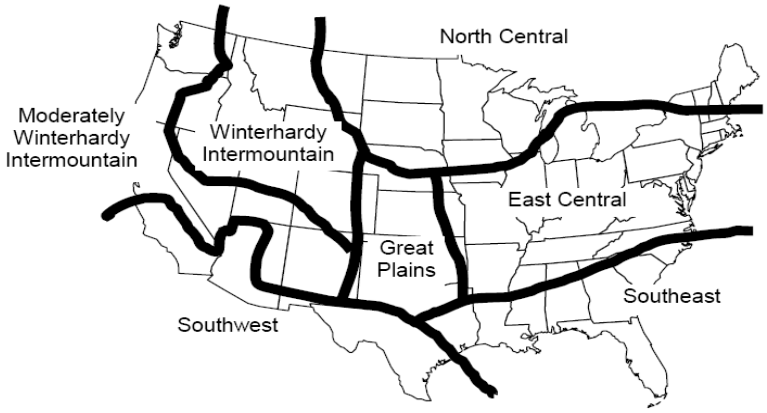

Figure 3-3. Areas of alfalfa adaptation in the United States (Rogan and Fitzpatrick, 2004).

5. Regional Differences in Production Practices

The adaptation of alfalfa varieties to winter temperatures is based on their winter hardiness, which ranges from very dormant and more winter hardy to extremely nondormant and less winter hardy (Teuber et al., 1998; Rogan and Fitzpatrick, 2004). Dormancy is a condition where physiological activities associated with growth temporarily cease. For alfalfa, dormancy is thought to be brought on by shorter day length and possibly colder temperatures in the autumn. The alfalfa plants reverse this process in the spring with the onset of warmer temperatures and longer day lengths. The more dormant varieties require numerically more and warmer days along with longer day lengths for vigorous growth to begin again. In regions where winter temperatures are less severe and the length of the growing season increases, the need for winter hardiness decreases and results in more harvests per year and increased yields per acre per year (Rogan and Fitzpatrick, 2004).

Rainfall influences soil moisture, soil pH, and humidity, which in turn, affects the prevalence of disease, weed, nematode, and insect problems. Therefore, throughout the 1900's, many alfalfa varieties were first developed with varying levels of winter hardiness, and then later for resistance levels to various diseases, insects, and nematodes (Melton et al., 1988).

Seed Production

Most of the high quality alfalfa seed is grown under irrigation in the western states as noted in tables 3-11 and 3-23 with California, Washington, and Idaho being the top three seed production states. Small acreage seed growers located mainly in the Plains primarily produce uncertified seeds (e.g., for the past several years, South Dakota Crop

Improvement has not certified any alfalfa seed production although much alfalfa seed is produced). Overall, approximately 8 and 58 percent of the dormant and non-dormant seed crops are exported, respectively (table 3-21). The states that export the most non-dormant and dormant alfalfa variety seeds are California and Idaho (table 3-23).

Forage Production

The north-central region has the most acres devoted to alfalfa forage production, followed by the east-central region and the intermountain region. The least amount of forage production occurs in the southeast region (USDA-NASS, 2009). Less than 1 percent of alfalfa hay produced is exported. Nearly 100 percent of exported alfalfa hay is produced in the Pacific Northwest and Southwest regions (Niebergs et al., 2008).

As a percentage of acres produced, the north-central, east-central, and southeast regions use most of the hay on the same farm on which it is grown. For the southwest and Pacific Northwest, most of the forage sold is used for dairy farms (USDA-NASS, 2002) (see tables 3-23, 3-24, and 3-25 for more details on forage production).

Table 3-23. Alfalfa Forage and Seed Production by State.

2006 National Agricultural Statistics Service Data											2007 FAS Report
	State	Acres by State (1000s)		Hay and Haylage Harvested							2002-06 Mean
		Dry Hay 2006	Hay and Haylage 2006	Average Yield T/A	Forage Tons Harvested	Seed Production Acres	Average Yield (lbs/A)	Seed Lbs Harvested	Seed Dormant	Harvested ND/SD	Seed Export
Southwest	AZ	250	250	8.3	2,075	4	500	2,000,000	0	2,000,000	1,000,000
	CA	1,050	1,070	6.9	7,426	38	550	20,900,000	209,000	20,691,000	12,885,713
	NM	220	234	51	1,184	2	400	800,000	0	800,000	0
	Total	**1,520**	**1,554**		**10,685**	**44**		**23,700,000**	**209,000**	**23,491,000**	**13,885,713**
PNW	ID	1,180	1,230	4.5	5,523	28	700	19,600,000	18,302,000	1,568,000	2,500,000
	NV	270	270	5.1	1,377	5	600	3,000,000	3,000,000	0	0
	OR	430	430	4.4	1,892	5	650	3,250,000	3,250,000	0	150,000
	WA	440	455	4.9	2,239	15	750	11,250,000	10,125,000	1,125,000	2,847,247
	Total	**2,320**	**2,385**		**11,031**	**53**		**37,100,000**	**34,677,000**	**2,693,000**	**5,497,247**
Inter-Mountain	CO	780	780	3.8	2,964	0.6	200	390,000	390,000	0	0
	MT	1,550	1,550	2.1	3,255	5.5	200	3,025,000	3,025,000	0	500,000
	UT	560	560	4	2,240	2.2	200	1,320,000	1,320,000	0	100,000
	WY	500	500	2.8	1,400	7.5	400	4,125,000	4,125,000	0	1,094,738
	Total	**3,390**	**3,390**		**9,859**	**15.8**		**8,860,000**	**8,860,000**	**0**	**1,694,738**
Plains	KS	950	965	3.8	3,677	0.5	200	100,000	100,000		0
	NE	1,250	1,265	3.3	4,212	0.4	200	80,000	80,000		0
	OK	380	380	2.1	798	0.4	200	80,000	80,000		0
	TX	150	160	4.4	707	1	400	400,000	40,000	360,000	0
	Total	**2,730**	**2,770**		**9,394**	**2.3**		**660,000**	**300,000**	**360,000**	**0**
North Central	IA	1,180	1,230	4	4,908	0	0	-		0	0
	MN	1,350	1,500	3.6	5,460	0	0	-		0	0
	ND	1,450	1,450	1/.2	1,740	0	0	-		0	0
	WI	1,650	2,400	3.9	9,336	0	0	-		0	0
	SD	1,800	1,820	1.6	2,930	7	250	1,750,000	1,750,000	0	0
	Total	**7,430**	**8,400**		**24,374**	**7**		**1,750,000**	**1,750,000**	**0**	**0**

Table 3-23, continued

2006 National Agricultural Statistics Service Data											2007 FAS Report
	State	Acres by State (1000s)		Hay and Haylage Harvested							2002-06 Mean
		Dry Hay 2006	Hay and Haylage 2006	Average Yield T/A	Forage Tons Harvested	Seed Production Acres	Average Yield (lbs/A)	Seed Lbs Harvested	Seed Dormant	Harvested ND/SD	Seed Export
East Central	CT	7	7	2.1	15						0
	DE	5	5	3.9	20						0
	IL	440	460	4.2	1,918						0
	IN	360	360	4.1	1,476						0
	ME	10	10	1.9	19						0
	MD	40	40	3.9	156						0
	MA	13	13	2.3	30						0
	MI	830	980	4	3,940						0
	MO	390	400	3	1,184						0
	NH	8	8	2.4	19						0
	NJ	25	25	2.5	63						0
	NY	370	610	3.3	2,019						0
	OH	470	550	4	2,195						0
	PA	500	660	3.8	2,515						0
	RI	1	1	3	3						0
	VT	45	90	3.6	322						0
	Total	**3,514**	**4,219**		**15,894**	**0**		**0**	**0**	**0**	**0**

Weediness and Weed Control

Weeds and their control have a major impact on the management practices in alfalfa seed and forage production. Weed control measures vary by farm within a region as much as among regions. The plant species that are considered weeds in alfalfa production are also affected by the different climates in which alfalfa is grown; thus, different weeds can be expected to vary in their importance in the different alfalfa growing regions. Since each herbicide has a fairly finite array of weeds that it can control without causing major damage to the alfalfa, the use of the different herbicides varies among the regions. Several decision criteria are used in determining herbicide use, including:

- the weeds that are causing the most concern on the farm;
- the stage of growth of alfalfa and weeds;
- the potential damage to the crop;
- the intended use of the crop (i.e. forage or seed production);
- the potential carry-over for injuring the following crop in the farm's crop rotation; and
- the price-value relationship of each herbicide (Orloff et al., 1997).

Because alfalfa seedlings grow slowly, they are susceptible to weed competition, especially in the establishment year (Peters and Linscott, 1988; Hower et al., 1999). Extension weed specialists and forage specialists indicate that the best weed control in an established stand of alfalfa is achieved by establishing and maintaining a dense healthy stand of alfalfa. Important factors in establishing a dense healthy stand include proper soil fertility and pH, seedbed preparation, varietal selection, appropriate cutting schedules, insect control, and good weed control in the seeding year (Undersander et al., 2004). Stringent weed control during the first 60 days after alfalfa emergence is critical for high quality forage from first harvest, and to prevent stand loss due to early weed competition (Leep et al., 2003). The use of companion crops, such as oats, depends on the relative competitiveness/tolerance to competition of the companion crop plants, alfalfa seedlings, and the weeds. These attributes of competitiveness and tolerance to competition are greatly affected by the appropriate soil fertility, seed bed preparation, moisture availability, and timing of clippings/harvests.

Tillage practices during cultivation of crops impact the soil and water, and can influence such factors as weed control, crop rotations, and yields. Tillage is most often used between crops in order to remove the traces of the previous crop and as weed control in preparation for the next crop. Excessive tillage causes soil erosion, but reducing tillage through use of

herbicide improves soil nutrients, increases moisture content, benefits soil microbes, decreases runoff, and reduces atmospheric pollutants (Fawcett and Towery, 2002).

Perennial weed species in forage crops become an increasing problem without tillage (Peters and Linscott, 1988). Dandelions, plantain, cinquefoils, docks, and thistle species are among the perennials infesting alfalfa (Peters and Linscott, 1988). Other perennial weed problems in alfalfa are quackgrass, nutsedges, white cockle, yellow rocket, Johnsongrass, and bermudagrass.

The cultural methods used to control weeds in the seedling year are clipping, companion crop, flash grazing (where fields are briefly and heavily stocked with grazing animals), and early harvest for spring seeding. Early harvest is not recommended for fall seeding because the alfalfa needs to mature more to build root reserves to survive the winter (Hower et al., 1999). Mowing or cutting is performed frequently (2-7 cuttings per year) in alfalfa as a natural part of the harvesting process. Multiple cuttings for hay harvest each year, for several consecutive years, will impact the weed population and species present in alfalfa. Mowing is beneficial in preventing weed seed production and further infestations, such as annual broadleaf weeds in new alfalfa stands or weeds such as Canada thistle and Johnsongrass in established stands of alfalfa (Peters and Linscott, 1988). Annual grasses cannot be controlled effectively by mowing because growth is regenerated from crown buds near the soil surface below the point of mowing, and mowing is not effective for controlling quackgrass because of its growth patterns.

For organic alfalfa hay growers, these cultural methods are still the only means of controlling or reducing weeds in alfalfa hay fields. For organic alfalfa seed growers, synthetic insecticides, fungicides, and herbicides cannot be used.

Seeding and Harvesting

Good establishment is required for a long-lived productive stand of alfalfa (Undersander et al., 2004). Seeding failures can be the result of poor seedbed preparation, seeding too deep, low moisture availability, freezing, diseases, insects, excess competition for light and nutrients from other alfalfa seedlings, companion crop or weeds, damage from herbicides or insecticides, and excess straw from the companion crop. For seeding, slight differences may be in the equipment used (some farmers may use drills, while others may broadcast the seed and some may even aerial broadcast). Seeding time during the year varies from region to region (the far northern areas will generally seed in the spring to avoid major freezing damage of young seedling plants whereas other areas will seed in the fall), but recommended seeding times are based as much on the previous crop

and soil water availability throughout the year as on time of year. The recommended soil preparations are very similar in all regions unless no-till planting is used. No-till planting can be used in all regions (Undersander et al., 2004). For fertilizing, any differences that occur are in the composition of the fertilizer used because of the different soil types in the different regions, but all of the regions generally recommend good availability of phosphorus and potassium. Nitrogen fertilizer is generally not recommended unless considerable refuse from the previous crop exists.

Alfalfa grown for forage can be used for grazing or harvested as silage or hay. Different equipment is used for each type of harvesting. The only major difference for harvests among regions is the total number of harvests per year, with the far northern regions having up to two to three harvests per year due to a shorter growing season than the southern regions, which can have six or more harvests per year (Undersander et al., 2004). The major differences are in the adaptation of different varieties to the different climates in the United States, and differing levels of various pests (weeds, diseases, and insects), which have effects on the pesticides that might be used.

6. Distribution of Acreage (by State and County)

The number and location of alfalfa forage acres are closely associated with livestock operations, especially dairy. In the United States in 2008, approximately 21 million acres were grown for forage production (figure 3-2). The alfalfa acreage in the United States has declined gradually over the past 40 years from a high of approximately 30 million acres (Rogan and Fitzpatrick, 2004).

Table 3-23 summarizes 2006 total hay (and seed) acreage as the sum of "alfalfa dry hay" and "alfalfa hay and haylage" categories, and presents acreage and yield per acre summaries by region and state. Multi-year national statistics for conventional, organic, and exported alfalfa dry hay acres and values are presented in table 3-3 for the 4-year period from 2002 to 2005.[19] During the period 2002 to 2006, the number of conventional acres grown for alfalfa forage was relatively stable, with an average of 3.33 tons dry hay per acre.

Alfalfa seeds of each variety type are grown in their respective area of adaptation: dormant varieties in the north and, non-and semi-dormant varieties in the southwest, especially California (tables 3-7, 3-11, and 3-23). According to USDA-NASS statistics for 2006, 122 thousand acres were harvested for alfalfa seed, total production was 72 million pounds

[19] 2005 is the most recent year for which organic alfalfa acreage data are available from USDA. Therefore, 2005 is used as the year of comparison for the relative size of organic, export and domestic markets. Dry hay values are used in table 3-21 because exported hay is dried before sale or processing.

and the average yield was approximately 590 lbs per acre (weighted average) (table 3-23).

Table 3-24 presents the U.S. states in order of percentage of alfalfa harvest (in 2005). For each state, the growing region, the percentage of the total national harvest of all alfalfa are presented for 2002, 2005, and 2007; and the percentage of the national organic certified harvest are presented for 2002 and 2005. In 2005, the most recent USDA organic harvest report, 22,439,000 acres of dry hay alfalfa were harvested and 204,380 (0.9 percent) of those acres were certified organic. The number of acres harvested in a state does not indicate the quantity of the harvest. For example, as shown in table 3-25, because of the growing season length, California ranks top in production (in 2007, ~11 percent of the national harvest and ~7 million pounds) and South Dakota ranks second (in 2007, ~6.8 percent of the national harvest and ~4 million pounds) even though South Dakota has ~2 million acres and California has less than 1 million acres of alfalfa. In addition, even though the northeastern states rank low in the percentage of acres and quantity of harvest, alfalfa is the number one crop for several of those states (NAFA, 2007).

Table 3-24. Alfalfa Growing Regions and Percentage of Dry Hay Harvest by State.

State	Growing Region	Percent of harvest acres			Percent of organic harvest	
		2002	2005	2007	2002	2005
South Dakota	North Central	10.57	10.70	9.86	8.58	6.82
Montana	Winter Hardy Intermountain	6.76	7.80	9.23	3.66	2.60
North Dakota	North Central	6.13	7.35	7.20	11.22	10.09
Wisconsin	North Central	7.32	6.91	7.50	16.34	14.38
Minnesota	North Central	5.59	6.02	4.67	6.40	10.44
Iowa	North Central	5.16	5.57	4.10	6.11	4.50
Nebraska	North Central	5.92	5.57	5.36	2.71	4.01
Idaho	PNW-Intermountain	4.57	5.08	5.12	24.69	24.22
California	Moderate Winter Hardy Intermountain/ Southwest	5.19	4.63	4.88	2.92	6.48
Michigan	East Central	3.56	4.01	3.45	2.07	0.35
Kansas	Great Plains	4.14	3.79	3.92	1.40	0.32
Colorado	Winter Hardy Intermountain	3.40	3.57	4.25	3.45	4.38
Wyoming	Winter Hardy Intermountain	2.16	2.67	3.33	0.19	0.84
Utah	Moderate Winter Hardy Intermountain	2.48	2.41	2.71	0.60	0.45

Table 3-24. Alfalfa Growing Regions and Percentage of Dry Hay Harvest by State.

State	Growing Region	Percent of harvest acres			Percent of organic harvest	
		2002	2005	2007	2002	2005
Ohio	East Central	2.71	2.27	2.16	1.89	0.50
Pennsylvania	East Central	2.96	2.27	2.35	0.96	0.60
Missouri	East Central	1.77	2.01	1.46	0.23	0.58
New York	East Central	2.90	2.01	2.22	1.34	0.16
Washington	PNW-Intermountain	2.37	2.01	2.22	1.19	0.56
Illinois	East Central	1.84	1.78	1.59	0.80	1.22
Oregon	PNW-Intermountain	2.15	1.78	2.12	0.42	3.23
Indiana	East Central	1.41	1.52	1.19	0.03	0.29
Oklahoma	Great Plains	1.54	1.43	1.65	0.00	0.04
Kentucky	East Central	1.37	1.16	1.33	0.00	0.01
Nevada	Moderate Winter Hardy Intermountain	1.34	1.16	1.35	1.25	1.47
Arizona	Moderate Winter Hardy Intermountain/ Southwest	1.03	1.16	1.27	0.91	0.24
New Mexico	Moderate Winter Hardy Intermountain	0.83	1.07	1.17	0.14	0.33
Texas	Great Plains/ Southwest/ Southeast	0.72	0.67	0.76	0.18	0.55
Virginia	East Central	0.62	0.49	0.44	0.31	0.14
Vermont	East Central	0.20	0.20	0.16	0.00	0.00
Maryland	East Central	0.25	0.18	0.20	0.00	0.01
Tennessee	East Central	0.13	0.16	0.10	0.00	0.00
West Virginia	East Central	0.23	0.16	0.14	0.00	0.00
New Jersey	East Central	0.12	0.11	0.10	0.00	0.00
Arkansas	East Central	0.07	0.09	0.06	0.00	0.00
Massachusetts	East Central	0.07	0.06	0.05	0.00	0.00
Maine	North Central	0.06	0.05	0.05	0.00	0.17
North Carolina	Southeast	0.10	0.05	0.05	0.00	0.00
Connecticut	East Central	0.04	0.04	0.04	0.00	0.05
New Hampshire	East Central	0.04	0.04	0.03	0.00	0.00
Delaware	East Central	ND	0.02	0.02	0.00	0.00
Rhode Island	East Central	0.01	0.01	0.01	0.00	0.00
Florida	Southeast	0.02	0.00	0.03	0.00	0.00

Table 3-24. Alfalfa Growing Regions and Percentage of Dry Hay Harvest by State.

State	Growing Region	Percent of harvest acres			Percent of organic harvest	
		2002	2005	2007	2002	2005
Georgia	Southeast	0.01	0.00	0.01	0.00	0.00
Louisiana	Southeast	0.03	0.00	0.01	0.00	0.00
Mississippi	Southeast	ND	ND	0.02	ND	ND
South Carolina	Southeast	0.01	0.00	0.02	0.00	0.00
Alabama	Southeast	0.04	ND	0.04	0.00	ND
Alaska		0.00	ND	0	0.00	ND
Hawaii		ND	0.00	0.00	0.00	0.00

ND = no data provided by USDA

Table 3-25. Alfalfa Dry Hay Harvest 2007 Census of Agriculture.

State	# of Farms	Acres Harvested	Lbs. Harvested	Farms Irrigated	Acres Irrigated	% of Acres	% of lbs.	Avg. Acres per Farm
United States	290,726	20,244,497	65,349,074	56,390	6,556,652	100.0	100.0	70
California	3,587	986,982	7,057,014	3,488	963,086	4.9	10.8	275
South Dakota	12,653	1,996,599	4,414,338	716	75,913	9.9	6.8	158
Idaho	8,817	1,037,520	4,254,543	7,605	861,092	5.1	6.5	118
Nebraska	14,820	1,085,921	3,955,881	4,405	389,516	5.4	6.1	73
Montana	9,711	1,868,756	3,936,445	5,444	703,960	9.2	6.0	192
Wisconsin	30,810	1,517,522	3,673,619	171	8,809	7.5	5.6	49
North Dakota	8,985	1,457,604	3,072,682	240	21,773	7.2	4.7	162
Iowa	22,040	830,440	3,054,729	62	1,198	4.1	4.7	38
Kansas	9,643	793,140	2,986,134	1,115	207,455	3.9	4.6	82
Colorado	8,648	861,053	2,887,865	7,347	707,234	4.3	4.4	100
Minnesota	20,398	944,775	2,671,173	384	15,603	4.7	4.1	46
Washington	4,294	448,588	2,192,001	2,822	334,005	2.2	3.4	104
Utah	7,780	548,570	2,172,218	7,413	507,798	2.7	3.3	71
Arizona	943	257,407	1,968,043	920	257,263	1.3	3.0	273
Oregon	3,569	428,812	1,777,894	3,043	380,679	2.1	2.7	120
Michigan	16,431	698,595	1,707,036	291	8,080	3.5	2.6	43
Wyoming	4,007	674,284	1,696,438	3,357	471,126	3.3	2.6	168
Pennsylvania	14,402	475,873	1,357,225	109	462	2.4	2.1	33
Ohio	15,354	437,658	1,256,174	17	536	2.2	1.9	29

Table 3-25. Alfalfa Dry Hay Harvest 2007 Census of Agriculture.

State	# of Farms	Acres Harvested	Lbs. Harvested	Farms Irrigated	Acres Irrigated	% of Acres	% of lbs.	Avg. Acres per Farm
Nevada	1,128	274,004	1,217,586	1,128	274,004	1.4	1.9	243
New Mexico	4,272	236,103	1,176,242	4,091	222,018	1.2	1.8	55
Illinois	12,913	322,339	1,138,512	47	906	1.6	1.7	25
Oklahoma	3,781	334,990	1,131,938	294	33,000	1.7	1.7	89
New York	7,707	450,144	1,119,421	31	901	2.2	1.7	58
Missouri	8,229	295,021	782,847	63	1823	1.5	1.2	36
Texas	2,391	153,763	721,303	1,154	98,831	0.8	1.1	64
Indiana	10,775	241,129	665,767	139	2,185	1.2	1.0	22
Kentucky	10,538	269,610	524,565	109	1,210	1.3	0.8	26
Virginia	3,063	89,213	233,807	76	679	0.4	0.4	29
Maryland	1,429	40,576	120,402	49	712	0.2	0.2	28
Vermont	571	31,769	68,624	2	(D)	0.2	0.1	56
West Virginia	1,185	28,465	62,484	5	(D)	0.1	0.1	24
New Jersey	728	20,310	51,483	39	799	0.1	0.1	28
Tennessee	1,655	20,074	45,819	28	(D)	0.1	0.1	12
Arkansas	278	11,732	28,647	15	932	0.1	0.0	42
Maine	246	10,089	23,876	0	0	0.0	0.0	41
Massachusetts	406	9,921	22,537	1	(D)	0.0	0.0	24
Connecticut	349	8,343	18,441	0	0	0.0	0.0	24
Alabama	340	7,526	16,944	13	91	0.0	0.0	22
North Carolina	758	10,322	16,755	67	360	0.1	0.0	14
Florida	141	6,951	14,993	13	1,071	0.0	0.0	49
Delaware	177	3,687	13,530	22	421	0.0	0.0	21
New Hampshire	218	5,373	13,475	5	(D)	0.0	0.0	25
South Carolina	143	4,070	8,860	20	274	0.0	0.0	28
Mississippi	159	3,931	7,113	4	35	0.0	0.0	25
Georgia	134	1,655	4,810	18	243	0.0	0.0	12
Louisiana	52	2,164	4,768	2	(D)	0.0	0.0	42
Rhode Island	63	1,035	1,806	1	(D)	0.0	0.0	16
Hawaii	5	89	267	5	89	0.0	0.0	18

D = data withheld to protect identify of individual farms
Source:
http://www.agcensus.usda.gov/Publications/2002/Volume_1,_Chapter_2_US_State_Level/st99_2_026_026.pdf

Other differences in alfalfa farming are revealed by examining the number of farms that grow alfalfa and the number of farms that irrigate.

Comparison of California and Wisconsin (table 3-25) shows that in California ~97 percent of the farms irrigate, whereas in Wisconsin only 0.5 percent of the farms irrigate. Farmers that irrigate can maintain soil moisture at near optimum levels and can withhold irrigation before harvesting, giving farmers greater control of harvest timing (Orloff et al., 1997). In areas where irrigation is uncommon, farmers rely on rain, which has natural variations that greatly influence alfalfa growth and the harvest schedule.

Another difference is farm size. The average farm size in California is much larger than in Wisconsin. It should be noted that the average farm size calculation is a bit misleading because in California some very large farms (4,000 acres) skew the average. In general, because farm size does not fit a normal distribution, the average farm size does not give an accurate picture of farm sizes. However, average farm size does relay the general trend of farm size in a state. Like any census, these data may not include all alfalfa farms.

F. Physical Environment

1. Soils

Alfalfa grows in a wide variety of soils and in all continental States, Alaska, and Hawaii. It grows optimally in fertile, well-drained, friable soils, and is adaptable for survival outside of cultivated soil. Optimal soil pH is 6.5 or above. Soil also contains animal and plant life that can affect and interact with alfalfa. For example, microorganisms account for more than 80% of the total biomass in soil, excluding roots, and can significantly affect soil nutrients and other characteristics (Kowalchuk et al., 2003). Pathogens and detrimental insects also live in and are affected by soil characteristics. Thus, impacts on soil can have an indirect effect on alfalfa – either positive or negative – if these impacts also affect other soil organisms.

Alfalfa also can affect and interact with soil. Like other legumes, alfalfa forms a symbiotic relationship with the nitrogen-fixing bacterium *Sinorhizobium meliloti*. The result is the conversion of atmospheric nitrogen to fixed nitrogen in the soil, resulting in a net increase in available nitrogen to the soil (Vance et al., 1988; USDA-FS, 2003). This and alfalfa's ability to improve soil tilth, fertility, and structure make it a valued rotational crop. Alfalfa's deep rooting characteristics also make it valued as a soil conservation crop. Because alfalfa is a perennial, the soil can remain undisturbed for years. Soil erosion is uncommon due to the heavy vegetative cover characteristics and the deep root systems during the life of the stand. This lower erosion, including on sloping terrain, can in turn reduce sedimentation in surface water. Other non-agricultural uses include rehabilitation of overgrazed rangelands, erosion-control projects in interior forests, treatment of compacted soils, revegetation of areas

damaged by wildfire, and erosion reduction in mined soils (Sullivan, 1992).

Alfalfa also interacts with soil via autotoxicity, which is the plant's release of compounds into soil that elicit a toxic reaction to germinating alfalfa seed. This characteristic, which is believed to be an evolved survival trait (to reduce competition from nearby new seedlings for scarce soil moisture), can depend on soil texture and water conditions, with toxicity greater in sandy loam versus silty clay and in older stands (Hall et al., 2004; Jennings and Nelson, 1998). Thus, an effect on these characteristics of soil can affect alfalfa's autotoxicity.

Farming practices that affect soil, such as tillage and herbicide use, can in turn affect alfalfa. Section III.E, *Land Use and Production Practices*, discusses the soil affected environment with regard to production practices such as tillage. Appendix J, *Effects of Changes in Farming Practices on Water, Soil, and Air Due to Use of Glyphosate-Tolerant Alfalfa* and appendix N, *Potential Impacts on Wildlife, Amphibians, Plants, and Ecosystems from Increased Glyphosate and Other Chemical Use* describe the wide variety of herbicides that are historically used on alfalfa. These herbicides have a wide range of behaviors in soil due to their chemical characteristics and other factors, such as the application method, time of year, and type of soil. Glyphosate does not move deep into the soil, is not transported at high levels to or through groundwater, and does not persist long in the soil (Major, 2003; Miller et al., 1995; Torstensson et al., 2005). It is highly adsorptive and remains in the soil until mineralizing bacteria break it down (Gimsing et al., 2004). The major by-product of this process is aminomethylphosphonic acid (AMPA), which further degrades in the soil to form carbon dioxide. Soil composition has an effect on glyphosate adsorption, with the presence of minerals increasing adsorption (diminishing movement of the glyphosate and minerals) and the presence of soil organic matter inhibiting adsorption (Getenga and Kengara, 2004; Vereecken, 2005). Glyphosate can also mobilize trace elements in soil, depending on various factors (Barrett and McBride, 2006). The various other pesticides historically used on alfalfa have varying chemical fates. In general, most of these pesticides are more persistent and have higher mobility in soils compared to glyphosate, making them more apt to continually contaminate surrounding water systems. Some of these herbicides are compounds that can bioaccumulate (e.g., clopyralid, EPTC, norfluzaon, sethoxydim, and trifluralin). See section III.B, *Biological Environment at Risk*, for more details on the chemical fate and transport of glyphosate in the environment.

2. Climate and Air Quality

Alfalfa farming, as with agriculture in general, can affect climate and air quality in a variety of ways. One effect is the use of tractors and other farm equipment during the typical multiple harvestings per year of alfalfa hay. This equipment use results in combustion emissions, dust, and soil

compaction (Fawcett and Towery, 2002). As discussed in appendix J, *Effects of Changes in Farming Practices on Water, Soil, and Air Due to Use of Glyphosate-Tolerant Alfalfa*, crop rotations with alfalfa result in less use of nitrogen fertilizers, and thus its emissions, due to the nitrogen fixing of alfalfa. This appendix also notes how herbicides can contribute to air pollution through drift, the movement of herbicide through the air to unintended sites, or evaporation into the air (volatility). As with soil, the behaviors of these herbicides in air range widely, due to their chemical characteristics, application method, time of year, weather, etc. One key herbicide is glyphosate, which is essentially nonvolatile at 77ºF and has not been reported as an atmospheric contaminant (Cerdeira and Duke, 2006). When glyphosate is applied directly to plant leaves, the risk of drift is low, but when glyphosate is applied broadly to a field, the risk of drift increases (Owen, 1998).

The use of post-emergence herbicides helps to promote an increase in the adoption of no-till farming, which can lead to a decrease in tractor use and to subsequent benefits in terms of reduced fuel use, emissions, dust, etc (Fawcett and Towery, 2002). Emissions related to climate change, ozone depletion, summer smog and carcinogenicity, among others, are typically lower as a result of reduced tillage (Bennett et al., 2004; Mortenson et al., 2004; Derpsch et al., 2010). Many scientists, however, have found little or no significant difference between soil carbon (a key factor in climate change potential) in no-till soils and conventional-till soils, depending on the soil, climate, and other factors (Angers et al., 2009; Bergstrom et al., 2001). Other studies have shown that no-till soils result in elevated nitrous oxide (a climate change gas) emissions for a variety of reasons including elevated moisture levels and soil characteristics (Linn and Doran, 1984; MacKenzie et al., 1998; Mkhabela et al., 2008). Nevertheless, in alfalfa farming, little opportunity appears to exist for increases in no-till farming. This is because there is already little use for tilling, which generally is conducted only two times during an alfalfa rotation – before planting and during stand removal (typically years later).

3. Water

Surface Water

As with other agricultural crops, the effects of alfalfa on surface water (e.g., lakes, streams) depends on myriad factors, such as the frequency of harvesting and thus tractor and other equipment use (which affects soil compaction and runoff), the frequency of rotation/stand life (which affects equipment use), the use of herbicides (which can enter surface waters via runoff and drift), and the adoption of conservation tillage and no-tillage practices that reduce erosion and decrease the amount of sediment in rivers and streams. As discussed above, there is little opportunity for reducing tillage on alfalfa, but herbicides used on alfalfa have varying toxicities and chemical fates, as described in appendix J, *Effects of Changes in Farming Practices on Water, Soil, and Air Due to Use of*

Glyphosate-Tolerant Alfalfa, that in turn could have varying effects on surface waters. In general, glyphosate and glyphosate metabolites are less persistent and are characterized by lower mobility in soils. This makes glyphosate less apt to continually contaminate surrounding water systems. Glyphosate adsorbs to soil particles that can become suspended in runoff water and potentially contaminate surface waters during erosion. Furthermore, once in surface water, glyphosate and its primary metabolite, AMPA, are not readily broken down by water or sunlight (U.S. EPA, 1993), but are removed through standard water purification processes such as activated carbon (U.S. EPA, 2010) and disinfection processes such as ozonation and chlorination (Speth, 1994).

In a U.S. Geological Survey (USGS) monitoring study of surface water, groundwater, and soil conducted from 2001 to 2006, the metabolite AMPA was observed more frequently than the parent compound glyphosate, and glyphosate and its metabolite AMPA were found in surface water more frequently than groundwater (Scribner et al., 2007). About half of glyphosate use at the time was from agriculture (primarily soy and corn) and half from home and other use. Groundwater and surface water contamination by glyphosate is limited because of glyphosate's tendency to adhere to variable-charged soil minerals, and because of microbial degradation of glyphosate in soils (Borggaard and Gimsing, 2007). Higher occurrences of glyphosate and AMPA in ground and surface waters were observed when samples were taken near agricultural areas that experienced a rain event shortly after glyphosate application (Scribner et al., 2007). Nevertheless, all samples collected by USGS had glyphosate levels below the EPA maximum contaminant level goals (MCLG) of 0.7 milligram per liter (see section III.B.1 above for additional discussion on glyphosate fate in surface water).

Groundwater

Similar to surface water, subsurface water or ground water can interact substantially with alfalfa and with agriculture more broadly. Rain and irrigation water percolates down through the soil into ground water, while in turn the ground water level and affect soil moisture and thus alfalfa growth and health. Herbicides used on alfalfa have varying chemical fates, with glyphosate and AMPA generally being less persistent and characterized by lower mobility in soils. Due to the strong adsorptive characteristics of glyphosate and AMPA, leaching of these chemicals is more limited to compared to other herbicides, and they are much less likely to leach to groundwater from the soil (Cerdeira and Duke, 2006; Grunewald et al., 2001). As noted above, all samples collected by USGS had glyphosate levels below EPA MCLG of 0.7 mg per L (see section III.B.1 above for additional discussion on glyphosate fate in groundwater).

IV. Environmental Consequences

This chapter evaluates the potential effects of the Deregulation Alternative (the proposed action of granting nonregulated status to glyphosate tolerant (GT) alfalfa lines J101 and J163 without restrictions), the Isolation/Geographic Restriction Alternative, and the No Action Alternative detailed in chapter 2 of this Environmental Impact Statement (EIS). This chapter considers the effects on plant genetics and gene flow, threatened and endangered species, socioeconomic implications, human health and safety impacts, implications for land use and production practices, soil, climate, air quality, and water.

A. Methodologies and Assumptions Used in Analysis

1. Models, Risk Assessment, Cause and Effect

Numerous models and assessments are used throughout this EIS to examine the cause and effects of the deregulation of GT alfalfa. These models and assessments range from those discussed within the studies in the published literature that support this EIS, to those that Animal and Plant Health Inspection Service (APHIS) developed or refined for the EIS. An example of the former is much of the modeling of the evolution of herbicide resistance in weeds described in section IV.B. For many of the genetic, biological/ecological, and operational factors that influence this evolution, accurate measurements are difficult or impossible to obtain experimentally. Thus, modeling has been used, but because of the difficulty in obtaining accurate information on these factors, the use is limited. An example of the latter type of modeling (developed or refined for this EIS) is the ecological effects risk characterization used in section IV.C, which analyzes biological impacts of herbicide use and integrates the results of exposure and ecotoxicity assessments to evaluate the likelihood of adverse ecological effects. The means by which this integration occurs is referred to as the quotient method. In this method, risk quotients (RQs) are first calculated by dividing exposure estimates by acute[20] and chronic[21] ecotoxicity values (RQ = Exposure/Toxicity). RQs are then compared to the U.S. Environmental Protection Agency (EPA) levels of concern (LOCs), which are used by the EPA Office of Pesticide Programs to analyze both potential risk to nontarget organisms and the need to consider regulatory action on pesticides.

The human health risk assessment in section IV.E uses a similar approach, utilizing screening-level exposure estimates to compare with human health toxicity benchmarks. Another key area for modeling and detailed

[20] Acute toxicity studies are those that study the effects of a single or short-term exposure to a substance.
[21] Chronic studies are those that study the effects of exposure on a large percentage of a subject's life span, such as daily exposure received by workers.

assessment is socioeconomic impacts. Numerous models and assessments are conducted to attempt to predict market behavior regarding adoption of GT alfalfa, use of farm inputs such as herbicides, influences of the organic market and consumer preferences, changes in United States and international laws and policies, etc.

Note that many of the models and assessments used in this EIS are considered screening-level, which use highly conservative assumptions to purposely overestimate results, and thus capture whether a more detailed and refined analysis is warranted. Thus, by definition APHIS recognizes that the Deregulation Alternative and Isolation/Geographic Restriction Alternative often are unlikely to have impacts similar to the results of such assessments. The models used in the impact analysis of this chapter are explained in more detail in their respective sections throughout this EIS.

2. Assumptions

The U.S. Council on Environmental Quality (CEQ) regulations for implementing National Environmental Policy Act (NEPA) provide agencies with a means of acknowledging incomplete or unavailable information when evaluating reasonably foreseeable significant adverse effects on the human environment (40 CFR §1502.22). In such cases, the agency shall always make clear in an EIS that such information is lacking. The CEQ regulations (40 CFR§1502.22) also state the following in regard to incomplete or unavailable information:

If the information relevant to reasonably foreseeable significant adverse impacts cannot be obtained because the overall costs of obtaining it are exorbitant or the means to obtain it are not known, the agency shall include within the environmental impact statement:

(1) A statement that such information is incomplete or unavailable;

(2) A statement of the relevance of the incomplete or unavailable information to evaluating reasonably foreseeable significant adverse impacts on the human environment;

(3) A summary of existing credible scientific evidence which is relevant to evaluating the reasonably foreseeable significant adverse impacts on the human environment; and

(4) The agency's evaluation of such impacts based upon theoretical approaches or research methods generally accepted in the scientific community. For the purposes of this section, “reasonably foreseeable” includes impacts which have catastrophic consequences, even if their probability of occurrence is low, provided that the analysis of the impacts is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason.

Some of the data on the effects of the deregulation of GT alfalfa are incomplete. To address data gaps or uncertainties that are needed for the

basis of the analysis of potential impacts of the proposed action and alternatives, APHIS used a variety of assumptions. Many of these assumptions are considered to be highly conservative and purposefully overestimate the effects for determining whether a more detailed and accurate assessment is needed. For example, for assessing changes in herbicide use, APHIS assumed that GT alfalfa adoption rate will be as predicted by the applicant, that pesticides will be used at the maximum amounts according to their labels, and that growers of more intensively managed alfalfa (e.g., those using herbicides) are most likely to adopt this product. Other assumptions are stated where applicable throughout chapter 4 of this EIS. Where a complete evaluation of reasonably foreseeable environmental impacts on the human environment that could result from the proposed action and alternatives are precluded by a lack of data that cannot be obtained except at an exorbitant cost or by unknown means, APHIS has complied with the regulations mandated by the CEQ. In these cases, APHIS acknowledges incomplete and unavailable information where the agency is unable to precisely estimate the potential environmental impacts that may result from the proposed action or alternatives.

B. Biology of Alfalfa

1. Gene Flow due to Pollination

The discussion throughout this section is formed in the context of the Deregulation Alternative. The discussions other alternatives follows the discussion of the preferred alternative.

Alfalfa is an insect pollinated species and can be successfully pollinated by several different pollinators. Farmers growing alfalfa for seed (bees are only stocked in seed farming, as farmers do not want or need pollination of hay fields) typically use one or more of the following three bee species: leafcutter bees, alkali bees, and honey bees. Selection of pollinators is not based on the type of alfalfa grown (e.g., GT, conventional, or organic) but on geographic location of the alfalfa field. Cultured alfalfa leafcutter bees (*Megachile rotundata* F.) are the commonly used pollinators in the cooler Pacific Northwest, while honey bees (*Apis mellifera* L.) are more commonly used in the irrigated valleys of the Desert Southwest (California, Arizona, etc.). In certain niche geographies where suitable climate and soil beds exist (e.g., southern Washington), natural and managed colonies of the ground-nesting alkali bee, *Nomia melanderi* Cockerell, contribute significantly to commercial alfalfa pollination. Occasionally, some seed producers use a blend of two managed cultured bee species for pollination to increase the rate of seed set or shorten the pollination period. Isolation distances are typically employed to reduce the likelihood of gene flow between alfalfa populations. A list of the most common alfalfa pollinators is in table 4-1, in order of abundance followed by estimated forage ranges collected from various sources (Hammon et al.,

2007). For a thorough discussion on alfalfa pollinators and pollinator behavior, see appendix V.

Table 4-1. Pollinator Foraging Distance.

Pollinator (*Species*)	Forage Distance from Nest
Alfalfa leafcutter bee *(Megachile rotundata)*	<1 mile[1]
Honey bee *(Apis mellifera)*	Measured up to 6.21 miles away, average distance depends on availability of pollen/nectar, typically 1.86 miles[2]
Alkali bee *(Nomia melanderi)*	Will forage up to 4 or 5 miles away; typical pollination within 2 mile radius[3]
Long-horned bee *(Melissodes* sp.*)*	Data not found
Mud/Digger bee *(Anthophora* spp.*)* (2)	Data not found
Bumblebee *(Bombus morrisoni)*	Data not found
Bumblebee *(Bombus griseocullis)*	Data not found
Sweat bee *(Lasioglossum sisymbrii)*	Data not found
Sweat bee *(Halictus tripartitus)*	Data not found
Sweat bee *(Halictus confusus)*	Data not found
Leafcutter bee *(Megachile texana)*	Data not found
Mason bee *(Osmia latisulcata)*	Data not found

[1] Source: Pitts-Singer (2008)
[2] Source: Beekman and Ratnieks (2000)
[3] Source: USGS, 2008

Bee habits vary based on range and climate. In general, bees will forage where they need to in order to collect pollen and nectar. If there is an abundant source of both close to the nest, then their average foraging distances will be lower than if the bees must forage further to find adequate pollen and nectar (Pasquet et al., 2008). Both honey bees and alfalfa leafcutter bees will increase their foraging distance as the distance to high-reward resources (high nectar and pollen amounts) increases and as closer resources become scarce (Strickler and Vinson, 2000). Amand et al. (2000) recorded outcrossing rates of 22.2 percent at 1000 m due to leafcutter bees, and recommended a minimum isolation distance of 1557 m to prevent gene flow between alfalfa fields (Amand et al., 2000). Research by Breazeale et al., (2008) conducted to model the relationship between bee density and yield suggests that increasing proximity between hives and alfalfa fields increases the degree of tripped flowers and thus yield of alfalfa seeds while shortening the length of time for pollination. Patchiness of the environment also affects this foraging distance, as bees can prefer certain flowers over others (depending on the species and season), and might need to travel through or around obstacles in the

environment, so they will adapt foraging habits accordingly (Greenleaf et al., 2007).

It is possible that physical contact between bees in the hive would result in passive transfer of pollen, which could hypothetically lead to a subsequent pollination event and gene flow (Mueller, 2005). DeGrandin-Hoffman (1986) tested the ability of honey bees to passively transfer pollen to nest mates and found that in-hive pollen transfer was nearly universal. This suggests that there is some potential for gene flow that might result from passive pollen transfer among cohabitating bees, despite very little accumulation of viable pollen on the surface of bees that make repeated foraging trips to an alfalfa field or feral grouping of plants. There would be essentially no potential of within-nest transfer of pollen between bees for most of the native bee species because they are solitary nesting bees. Bee behavior does not change between the Preferred, Isolation/Geographic Restrictions Alternative, or the No Action Alternative. The amount of cross pollination between any two alfalfa fields will depend on the distance between the fields, the types of pollinators in the fields, and the density of the pollinators in the field. Management choices, such as site selection and stocking density of managed pollinators, can influence cross pollination between two fields. In the Deregulation Alternative, isolation distances are not mandated by a regulatory program. FGI-BMP requires specific isolation distances as part of the contractual requirements for growing seed. These isolation distances will minimize cross pollination between conventional and GT alfalfa. FGI has set a goal of maintaining the level of gene flow below 0.5%. These practices are described in more detail in section IV H and appendix V. If growers wish to reduce gene flow further, they may try to increase isolation distances. The Isolation/Geographic Restriction Alternative does have mandatory isolation distances and creates regions where GT alfalfa hay is not grown. This alternative would likely result in a greater number of seed growers having the ability to maintain larger isolation distances than under the preferred alternative. Therefore, under this alternative, the levels of cross pollination between GT alfalfa and conventional alfalfa could be lower for most seed growers than the Deregulation Alternative. Under the No Action Alternative, GT alfalfa would be grown under permit conditions that would require both isolation distances and pollinator management to reduce gene flow. Therefore, this alternative would likely reduce cross pollination between GT alfalfa and conventional alfalfa below the other two alternatives. However, it would be unlikely to be completely eliminated.

2. Gene Flow due to Secondary Seedlings

Secondary seedlings (seedlings that are not planted directly by the farmer, but rather sprout unintentionally) are an unlikely avenue for effective gene flow into existing solid-seeded alfalfa plantings, since alfalfa plants and alfalfa debris produce compounds that elicit an autotoxic reaction to germinating alfalfa seeds. The autotoxic reaction and inter-plant

competition severely limit germination and seedling vigor of alfalfa sown or dropped into existing or newly terminated alfalfa stands. Cultivated fields do not successfully self-seed. Attempts to thicken existing alfalfa stands by deliberately inter-planting new seed into them typically fail, which is why most agronomists do not recommend the practice (Canevari et al., 2000).

A portion of seed growers plant their fields in rows instead of solid plantings. In these situations, in-crop volunteers from dropped seeds occur and the resulting seedlings could be a means of gene flow to subsequent crops. However, in order to maintain required variety and purity of the alfalfa crop, these seed growers routinely control germinating alfalfa seedlings and weeds using irrigation and/or soil-active herbicides that do not impact the pre-established, alfalfa crop. The high likelihood of autotoxicity is one reason why alfalfa growers must rotate to a different crop for at least 1 full year following stand take-out.

There are several possible pathways for the unintentional distribution of alfalfa seeds that may lead to gene flow due to secondary seedlings. A list of potential sources for gene flow due to secondary seedlings includes:

- Factors associated with the harvest, processing, or storage of alfalfa seeds. Secondary seedlings may occur if alfalfa harvests for seed production result in high rates of seed shattering in fields, leaving seeds in fields for subsequent volunteers. As mentioned above, seedlings that result from shatter of seeds into established alfalfa fields are unlikely to sprout soon after alfalfa cultivation due to alfalfa autotoxicity. Improper cleaning of shared harvesting and processing equipment could result in secondary seed dispersal (Mallory-Smith and Zapiola, 2008). Finally, spillage during transportation (failure to tarp, insecure gates, etc.) could contribute to dispersal.
- Factors associated with weather. Extreme weather phenomenon could contribute to the dispersal of seeds and result in secondary seedlings. Natural dispersal due to extreme weather events cannot be prevented (Mallory-Smith and Zapiola, 2008). For example, tornados and high winds could potentially blow swaths of alfalfa prior to harvest, flooding could result in the transportation of swaths and seeds between adjacent fields, and escape into irrigations ditches due to storm water overflow could all contribute to the potential for secondary seedlings.
- Factors associated with animals. Seed predation of ripe seeds both on standing plants and shattered seeds left in harvested fields could be transported by birds or other animals. Natural dispersal of seeds due to wildlife can contribute to gene flow and cannot be prevented (Mallory-Smith and Zapiola, 2008). Rodents could potentially spread seeds if storage bins are infested. Finally, if alfalfa seeds survive passage through

the digestion of hay and forage products consumed by livestock or wildlife, unintentional escape of secondary seedlings is possible.

Under all three alternatives, the above described factors could contribute to the establishment of secondary seedlings and gene flow from these. To the extent that some of these routes are controlled through good management, gene flow from secondary seedlings can be mitigated under all of the alternatives. Under the Deregulation Alternative and the Isolation/Geographic Restrictions Alternative, gene flow of GT alfalfa to conventional alfalfa from secondary seedlings is more likely to occur than under the No Action Alternative because there would be fewer GT alfalfa acres to serve as sources of these secondary seeds. Under the Deregulation Alternative and the Isolation/Geographic Restrictions Alternative, growers of conventional alfalfa are likely to use management practices that reduce the likelihood of secondary seedlings if they are growing certified seed as these measures are typically required to meet the certification standards. In the Isolation Distances/Geographic Restrictions alternative, the longer isolation distances between conventional and GT alfalfa seed fields may help to reduce dispersal of seeds from GT alfalfa seed fields to conventional seed fields in weather- and animal-related events. However, since these are all rare events, the total contribution of secondary seedlings to gene flow in all of the alternatives will likely be very small.

3. Seed Purity

Seed farmers are concerned with the purity of their seed stock, and follow State and Federal-mandated standards in order to produce seed of certified purity. Isolation distances between fields and threshold amounts of other varieties that are allowable in a crop vary by State, but in general, seed stock must be 99 percent of the variety or varieties stated on the label. Alfalfa seed production occurs mainly in the West and Northwest United States. California produces the most alfalfa seed in the country (30 percent of total) in both pounds and acreage (USDA NASS 2007a U.S. Census of Agriculture). This is discussed in chapter III and in appendix V.

In California, in order to cultivate *foundation* alfalfa seed (seed of the highest purity) alfalfa must not have grown on the land in the previous four years, and for *certified* seed (seed of the second highest purity), one to two years, depending on the intervening crops.[22] This delay in field planting is to limit the spontaneous germination and sprouting of seeds left in the seed bank from previous alfalfa cultivation. All volunteer plants and noxious weeds must be eradicated and definite boundaries to the field set before field use. Foundation seed fields must be isolated from alfalfa of different varieties by 900 feet, while certified fields must be isolated by 165 feet. However, the ten percent rule is followed for certified fields, where if ten percent or less of the certified field is in the 165 foot isolation

[22] http://ccia.ucdavis.edu/seed_cert/alfalfa_seedcert_standards.htm

zone, the entire field is considered certified, but if more than ten percent is in the isolation zone, then that part of the field must be separated and not harvested as certified seed. Most States have identical guidelines with only slight variations, and purity standards remain high. As shown in table 4-2, which shows seed purity standards for California, Idaho, Wisconsin, and Montana, at least 99 percent of each seed harvest must contain the pure seed variety, and there are strict limits on the allowable amounts of other crops, weeds, and inert matter as well.

Table 4-2. Seed Purity Standards by State.[1,2,3,4]

State	Type of Seed	Pure Seed (min %)	Other Crops (max %)	Other Varieties (max %)	Other Material (max %)	Isolation Distance, < 5 acres (ft)
California	Foundation	99.5	0.1	0.1	0.5	900
	Certified	99.5	0.1	0.2	0.5	165
Idaho	Foundation	99	0.1	0.0	1.1	900
	Registered	99	0.1	0.0	1.2	450
	Certified	99	0.25	1.0	1.25	330*
Wisconsin	Foundation	99	0.2	0.1	0.85	900
	Certified	99	0.75	0.25	0.95	165
Montana	Foundation	99.5	0.1	0.1	0.6	1320
	Registered	99.5	0.1	0.25	0.7	660
	Certified	99.5	0.1	1.0	0.8	330

[1] http://ag.montana.edu/msga/Seed%20Standards/alfalfa%20standards.pdf
[2] http://www.idahocrop.com/standards.aspx
[3] http://www.wisc.edu/wcia/2008StandardW.pdf
[4] http://ccia.ucdavis.edu/seed_cert/alfalfa_seedcert_standards.htm

After seed crops have been evaluated by seed labs, they are tagged with seed labels in accordance with law. Seed labs perform multiple tests mandated by the AOSCA (Association of Official Seed Certifying Agencies) on a representative sample from each submitted crop.

Assuming that the variety present in low levels has the same germination (the process of a seed beginning to sprout) and fitness (a measure of survival and reproduction) as the certified variety, one can calculate the number of plants in an acre that would be off-type.[23] A thriving alfalfa hay field can have 15 plants per square foot (Orloff et al., 1997), which equals 653,400 plants in an acre (0.5 percent of 653,400 is 3,267). If the variety present in low levels is mixed evenly in the seed batch, then there might be an off-type plant every 13.3 square feet. In older stands where plant density may be closer to five plants per square foot, there might be an off-type plant every 40 square feet. In a review of Forage Genetics International's (FGI) 2000 field studies, McCaslin et al. (2010) examined varied isolation distances and determined that isolation distance of 900

[23] Only 60 percent of the seeds germinate and emerge and only 40 percent of emerged seedlings survive the first year (Orloff et al., 1997).

feet is sufficient to limit gene flow below one percent. And FGI's review of 2000-2002 field studies (Fitzpatrick et al., 2002), which assayed 30,000 non glyphosate-tolerant (GT) alfalfa seedlings, detected 0.000 percent gene flow at 2000 ft in 2000, but a single seed at 2640 feet in 2002. The authors conclude that isolation distances of 900 feet are sufficient for maintaining varietal purity, but may need to be greater for highly trait sensitive markets (Fitzpatrick et al., 2002). As it is not possible to statistically demonstrate zero gene flow, in studies that do not detect gene flow there could be up to 0.01 percent of undetected cross-fertilization between non-GT alfalfa and a GT variety. Using the above assumed alfalfa density, this represents one seed in 10,000, or one plant in 667 square feet at a stand density of 15 plants per square foot.

Because of alfalfa seed purity concerns, the companies who produce Roundup Ready® seeds in the National Alfalfa & Forage Alliance (NAFA) agreed jointly to adopt, as a minimum, best management practices (BMPs) for Roundup Ready® alfalfa seed production in the United States. These production practices meet or exceed AOSCA standards for the seed production of Foundation Class alfalfa seed production. Compliance to the guidelines is required under a separate and binding agreement (NAFA, 2008). FGI also has expanded the required isolation distances typically used in States that follow the AOSCA standards when growing GT and non-GT alfalfa for seed production. FGI changed the isolation distances for contractors growing alfalfa seed based on scientific studies examining the travel distance of different alfalfa pollinators. FGI's Best Practices, described in more detail below, are a part of the mandatory stewardship program for licensed GT alfalfa seed growers (alfalfa hay growers follow the mandatory stewardship program as described by the Monsanto Technology/Stewardship Agreement), and states that when farmers contract with FGI to grow and produce alfalfa seed and use leafcutter bees for pollination, the distance between GT and non-GT alfalfa seed production fields must be greater than or equal to 900 feet. When using alkali bees, the isolation distance must be greater than or equal to one mile, and when honey bees are used as a pollinator, the isolation distance must be greater than or equal to three miles. Additionally, every year the companies will collectively sample conventional seed lots, test for adventitious presence (AP) of the Roundup Ready® trait, and based on proximity to GT seed production, evaluate the effectiveness of isolation distance at limiting gene flow. The companies, along with three AOSCA representatives of State crop improvement associations or their designees, will analyze the data and make recommendations for changes to required isolation distances, if appropriate.

FGI has validated their Best Practices for seed production and believes they can produce non-GT alfalfa seed reliably with >99.5 percent purity (FGI, 2007). These data are described in more detail in appendix V. To

put this in context, one seed in 200 could be from an off-variety, such as GT alfalfa seed in conventional alfalfa seed. Additionally, the Council for Agricultural Science and Technology (CAST) published a peer-reviewed study titled "Gene Flow in Alfalfa: *Biology, Mitigation and Potential Impact on Production,"* which also concludes that the gene flow from GT alfalfa can be very low when appropriate management and production practices are used (Special Publication No. 28, September 2008). Recently, AOSCA has suggested isolation distances of five miles between seed production fields and two miles between hay production fields to further decrease the potential for gene flow between fields and reduce detection of GT alfalfa in non-GT fields to non-detectable levels (AOSCA, 2010). Under the Deregulation Alternative, growers are likely to continue to use the above described seed certification standards and best management practices. Where there is a market need to further reduce the likelihood of gene flow between GT alfalfa and conventional alfalfa, growers may choose to adopt programs like the AOSCA process-based standard (AOSCA, 2010). Under the Isolation/Geographic Restrictions Alternative, the conditions are likely to result in lower levels of GT alfalfa in conventional varieties. However, while in most cases GT alfalfa off types in conventional alfalfa would not be detected in standard tests, occasionally individual seed lots may have detectable levels of GT alfalfa. Occurrence of detectable levels of GT alfalfa in conventional alfalfa under the No Action Alternative would be less likely than either of the other alternatives both, because there would be less GT alfalfa planted, and the permit conditions would segregate GT alfalfa in conventional alfalfa to the extent biologically possible. Cases of AP of GT trait in non-GT seed lots have been reported by Cal/West and Dairyland (see appendix V section 5.2.2.) under the current level of planting of GT alfalfa (approximately 200,000 acres) Over time, these would be expected to become more rare under both the Isolation/Geographic Restrictions Alternative and the No Action Alternative. Under the Isolation/Geographic Restrictions Alternative, there would be GT alfalfa free areas in which to produce seed. Under the No Action Alternative, new plantings would require conditions to maintain isolation of the GT and conventional crops.

4. Gene Flow to Other Alfalfa Crops and Wild Relatives

Gene flow (the movement of genes from one population to another) occurs naturally among alfalfa in hay fields, seed fields, feral and other alfalfa populations via bees, and through the dispersal and establishment of secondary seedlings. Wild populations of alfalfa could serve as a reservoir (harbor) for GT genes after successful GT pollen flow or GT seed dispersal. Surviving feral plants could then contribute to movement of GT genes back into cultivated alfalfa (see discussions below). APHIS examined gene flow in the Plant Pest Risk Assessment (PPRA). There is no evidence that gene flow from or to GT alfalfa occurs at a different frequency than from or to conventional alfalfa varieties.

- Hybrids between alfalfa and other *Medicago* species in the United States are limited to hybridization between *M. sativa* subspecies. As previously discussed (see chapter III, appendix I), there is no evidence for the existence of any sexually compatible, free-living or native relatives of *Medicago* species in the United States or North America. Hence, there will be no impact on the genetic resources of these species due to the release of GT alfalfa in the United States (Sinskaya, 1961; Lesins and Lesins, 1979; Ivanov, 1988). Thus, possible movement of the transgene via pollen from GT alfalfa to other members of the *Medicago* genus would not occur in the United States, or it would only occur following the introduction and establishment of a reproductively compatible, non-native species growing near GT alfalfa.
- If GT individuals were to arise through intra-specific hybridization between two different crop alfalfas or between crop and feral alfalfa, the resulting hybrids are not likely to differ from the parental lines unless exposed to glyphosate. Exposure to glyphosate would predominantly occur in managed ecosystems where glyphosate is applied for broad-spectrum weed control, where improper application of glyphosate leads to herbicide drift, and in which glyphosate is used to control weeds. As with GT alfalfa volunteers, these hybrid individuals could be controlled using other available chemical and/or mechanical means. Currently, glyphosate is not widely used to control unwanted alfalfa vegetation (Rogan and Fitzpatrick, 2004). It is reasonable to predict that hybridization between rangeland *M. sativa falcata* subspecies and GT alfalfa varieties with mostly *sativa* parentage would result in hybrids with more rangeland hardiness than the original GT alfalfa, but less rangeland hardiness than the *falcata* parent. Further discussion on *sativa* x *falcate* hybrids can be found in appendix V.

As the potential for gene flow exists only between different alfalfa crop fields and between crop and feral alfalfa, the following section discusses the factors that influence gene flow between alfalfa populations and potentially increase or decrease the chances of gene transfer between alfalfa plants. The three alfalfa populations discussed are defined as follows (based partly on Bagavathiannan and Van Acker, 2008, 2009):

- *Hay field population*: agricultural field that is intentionally planted with alfalfa and is harvested for hay (may also include some grazing).
- *Seed field population*: agricultural field that is intentionally planted with alfalfa and is harvested as seed stock.
- *Feral and other alfalfa:*

– *feral* — alfalfa growing on any nonagricultural land (including roadsides, fences, and waste lots) that reproduces without intentional human inputs, including reseeding. This is considered the "naturalized" population in the

United States because alfalfa was introduced to the continent at least 200 years ago (Putnam et al., 2001).

- *habitat/rehabilitation/erosion control* — alfalfa that is intentionally sown (most likely in a seed mix), but is not managed after planting.
- *rangeland* — seed may be sporadically sown for grazing, but land is not mowed for regular hay harvest, and populations are mostly self sustaining.
- *volunteer* — alfalfa growing unintentionally, out of rotation in an agricultural field with another crop (e.g., corn).
- *escaped volunteer* — alfalfa from seed that escaped from an agricultural field (this is the first generation of a feral population). Escaped and isolated plants could represent a founder event for new feral populations. Escaped volunteers may not persist, depending on conditions.

There are several factors that influence the probability of gene flow between these fields. The following is a list of factors adapted from Putnam (2006):

- probability of synchronous flowering (e.g., the percentage of days where several plants flower simultaneously);
- availability of pollen (e.g., the percentage of bloom during each day of synchronous flowering);
- pollinator activity on days of synchronous flowering and placement of beehives (e.g., influenced by timed bee release and weather);
- distance between fields (alfalfa populations);
- size of fields (alfalfa populations);
- probability of seed maturation; and
- probability of seed germination.

Considering the various factors mentioned above, table 4-3 below presents the relative potential of gene flow between hay fields, seed fields, and feral and other alfalfa, under the possible nine scenarios of gene flow. This topic is also discussed in appendix V.

Table 4-3. Relative Potential for Gene Flow Between Populations of Alfalfa (requires that viable seed is produced).

	Pollen Acceptor		
Pollen Donor	**Seed field**	**Hay field**	**Feral and other alfalfa**
Seed field	Between adjacent fields with synchronous flowering, gene flow would be expected to exceed 1% which is not acceptable for foundation or certified seed. The largest data set collected under actual seed production conditions using FGI Best Practices found a range of gene flow from 0.00 to 0.18 percent. Thus, FGI Best Practices that include distance between fields can manage cross-fertilization to below 0.5 percent which is FGI's goal.	Lowest risk of gene flow because hay is cut before seed is produced.[1]	Feral populations should be controlled near seed fields to preserve seed purity. However, if feral plants are present, they will likely be cross-pollinated by seed field pollen.
Hay field	Less likely than seed to seed gene flow. The percent bloom at harvest will influence how much pollen could potentially be transported to seed fields. Alfalfa population density, field size, and density and type of native pollinators also influence the potential for gene flow. Mowing hay prior to 10 percent bloom and distance (350 to 600 feet) from seed fields can manage cross-fertilization to below 0.01 percent.	Lowest risk of gene flow out of the nine scenarios. Even in fields that bloom, hay is cut before seed is produced.	The percent bloom at harvest will influence how much pollen could potentially be transported to feral populations. Mowing hay prior to 10 percent bloom can reduce pollen availability. Seed farmers will need to be aware of seeding practices in neighboring rangelands because falcata (yellow-flowered alfalfa) may become increasingly adopted for rangeland forage improvement and the Falcata seed is available commercially[2].
Feral and other alfalfa	Feral populations need to be controlled near seed fields, or purity of GT and non-GT varieties can be compromised, or the seed field edges can be harvested as a separate crop. Seed farmers will need to be aware of seeding practices in neighboring rangelands because falcata (yellow-flowered alfalfa) may become increasingly adopted for rangeland forage improvement and the Falcata seed is available commercially.	Lowest risk of gene flow because hay is cut before seed is produced.	Gene flow between feral individuals that are close to each other is likely. Gene flow between feral populations depends on proximity, pollinators, flowering timing, and environmental stresses. The GT trait is not expected to impart increased fitness in feral alfalfa.

Source: Van Deynze et al. (2008)
[1] Although immature seed cannot grow and therefore does not result in gene flow, the GT trait might still be detected during testing.
[2] http://www.windriverseed.com/15212%20-%20Falcata.pdf

Gene flow into alfalfa seed production fields, as well as gene flow between two different alfalfa seed fields, is of higher concern than gene flow into alfalfa hay fields, whether maintaining the purity of a GT variety or a non-GT variety. This is due to the differences in end product. Seed production requires full flowering and pollination of alfalfa plants, whereas hay production and hay fields are typically and preferentially harvested before ten percent of plants reach full flower to maximize hay quality (before they can be pollinated). However growers may choose to let fall cuttings mature more, because cutting after ten percent bloom helps build root reserves and prolongs stand life.

For gene flow into or between hay fields, if pollen from a GT alfalfa arrives at a non-GT hay field, further persistence and propagation of seed is limited due to the harvest of plants prior to seed maturity. However, a GT hay field at ten percent bloom can still serve as a source for pollen and as a result gene flow can occur. Where weather or equipment failures delay harvesting of GT or non-GT alfalfa hay fields past ten percent bloom, there is a limited low risk of GT gene flow into hay (Van Deynze et al., 2008). The majority of hay is harvested before pollinated flowers can set mature seeds. Alfalfa must bloom, be cross-pollinated by insects, set fruit, and then release mature seed which then must grow into a plant in order to successfully transfer genes from one plant to another. Alfalfa requires at least four weeks of appropriate environmental conditions (temperature, sunlight, nutrients, and water) before forming reproductively mature floral buds, and an additional four to six weeks after that to form mature seeds after pollination (Rogan and Fitzpatrick, 2004). Alfalfa hay normally is harvested at or before first flower, six to nine weeks before the ripe seed stage (Putnam, 2006). Given that the ripe seed stage is four to five weeks after the ten percent bloom stage, growers generally have time to harvest hay crops before seed ripens, even in the case of temporary delays caused by rain or equipment failure at the planned harvest date. It should be noted that if the GT trait does pollinate hay, then immature seed containing the GT trait can still be detected by testing the hay even if that seed is not viable. As alfalfa hay farmers do not typically stock pollinators, movement of genes out of hay fields will also be limited by the abundance and activity of local pollinators.

The factors above indicate that there is the potential for gene flow from GT alfalfa to non-GT alfalfa. However, mitigation methods, including the isolation guidelines specified by BMPs, can reduce the potential for transgene gene flow. Under rare conditions where there are a combination of effects that increase gene flow, such as large quantities of feral bees near a GT field, adverse weather conditions that result in delayed harvesting until later than ten percent bloom, synchronously flowering feral plants, not managing the borders to control escaped plants, improper cleaning of equipment, and other types of human error in following the FGI BMPs, it is possible that gene flow rates could occur

that are higher than the 0.5 percent gene flow rate threshold. While the probability that all of these events would occur simultaneously is not zero, it is very low.

Thus, there are realistic measures that conventional alfalfa farmers can employ that will effectively reduce gene flow from neighboring GT alfalfa crops. As stated by Van Deynze et al. (2008):

"Growers who wish to avoid gene flow (e.g., those who produce hay for markets that reject GE crops) should pay attention to flowering habits (avoiding simultaneous flowering) and harvest schedules, and disallow or remove commercial beekeepers' hives. Although the hay harvest date can be delayed a week or more by wet weather or equipment failure, harvesting before the ripe seed stage is possible in all but the most extreme circumstances."

Rainfall or snow during the ripening time will cause decreased seed yield and reduced seed quality (e.g., reductions in seedling vigor and reduced percent germination because of fungal pathogen infection of the seed, or seed will sprout prematurely and die while it is still in the pod) (Rincker et al., 1988), further reducing the likelihood of gene flow. Additionally, viable alfalfa seeds that fall near adult alfalfa have a harder time growing because they must compete for nutrients with the already established adults, and adult alfalfa plants secrete an autotoxic substance into the soil that inhibits root growth in seedlings (Xuan et al., 2005). In fact, reseeding fields to fill gaps from dead plants is not recommended, as the new plants do not compete efficiently enough to survive (Orloff et al., 1997).

Feral alfalfa is a concern if it is not managed near seed or hay fields and may receive the GT trait, but the trait's survival in the feral population depends partly on the selective pressure of the environment to maintain the trait (Jenczewski et al., 2003). The GT trait is not expected to enhance feral alfalfa fitness without selective pressure and thus should act as a neutral allele. In cases where gene flow is unilateral, such as between commercially grown genetically modified (GM) alfalfa and feral alfalfa, it is possible that the cumulative effects of low levels of annual gene flow from GM alfalfa to feral alfalfa could result in relatively high levels of the GT gene in feral alfalfa populations. According to Ellstrand (2003), if gene flow to wild populations of a selectively neutral allele continues for a sufficient length of time, wild populations will become increasingly crop-like, eventually becoming identical. This can theoretically result from a repeated, relatively low frequency of gene-flow events each generation. Although a high level of gene flow may not happen in practice, the frequency of the resistance allele at the population level could increase over time (Ellstrand, 2003) if previous GT trait presence is not properly managed and removed annually.

Rangeland alfalfa (*falcata* subspecies) populations could increase if ranchers intentionally seed *falcata* into rangeland to increase forage quality and soil nitrogen (Waggener, 2007; High Plains Midwest Ag Journal, 2008). Cultivated *M. sativa* and wild *M. falcata* hybrid swarms and backcross hybrids naturally occur as both diploid and tetraploid hybrids. Hybrids can be vigorous and fertile, and can thrive sympatrically with their *falcata* and *sativa* parents. Hybrid populations with *M. falcata* parentage inherit winter and drought hardiness, as well as the ability to exist in grass mixtures, making them more adaptable to resource poor environments and increasing the likelihood of feral populations (Bagavathiannan and Acker, 2009). Unless properly managed, these feral populations could serve as bridges for long-distance gene flow, facilitating the adventitious presence of novel traits, like glyphosate-tolerance, into the environment. As such, feral populations could potentially be a barrier to the coexistence of transgenic and non-transgenic alfalfa fields, and must be accounted for in landscape level gene flow models (Bagavathiannan and Acker, 2009). The potential for gene flow and effect of hybridization between GT alfalfa J101 and J163 and *falcata* is unstudied but is not expected to differ from conventional alfalfa.

Factors Decreasing Probability of Gene Flow

NAFA, FGI, and Monsanto have developed contract based, mandatory stewardship programs to address concerns regarding gene flow (FGI, 2007; NAFA, 2008).[24] The NAFA BMPs are mandatory for all contracted GT alfalfa seed growers, are science-based, and are a direct extension of well-established coexistence principles routinely used by seed growers. Seed growers who grow GT seed are required to undergo training and have to be licensed to grow GT alfalfa seed. Any farmer who purchases GT alfalfa seed for producing hay is required to sign a Monsanto Technology/Stewardship Agreement (MTA). The FGI's Best Practices for alfalfa seed growers is a mechanism for limiting gene flow under the Deregulation Alternative. Features of the NAFA, MTA, and FGI Best Practices are as follows (FGI, 2007; NAFA, 2008):

- GT alfalfa seed producers may not sell seed to any party other than FGI and growers may not save seed for any purpose.
- Beehives cannot be moved out of GT alfalfa fields until pollination is finished for the year. This prevents pollen being carried via hive between GT and non-GT alfalfa. Grower must indicate main pollinator species on the FGI Seed Grower Contract.
- Isolation through distance from other alfalfa fields is required. For pollination with leafcutter bees the distance must be greater than or equal

[24] The stewardship programs also address other concerns such as weediness potential and glyphosate-resistant weed formation.

to 900 feet, for alkali bees greater than or equal to one mile, for honey bees greater than or equal to three miles.

- The GT Seed Contractor shall report global positioning system (GPS) coordinates of all established and planned GT seed production fields to local State seed certification officials as early as possible. State officials will confirm minimum isolation and establish a State pinning map for GT seed production.
- The GT Seed Contractor will limit GT seed production contracts to the following States: Arizona, California, Colorado, Idaho, Montana, Nevada, Oregon, Texas, Utah, Washington, and Wyoming.
- The GT Seed Contractor will also respect any GE-free alfalfa seed production zone designated as such by a consensus of local seed growers.
- Stand removal and volunteer management must be sufficient to allow seed certification inspectors to validate stand removal. Stand removal date and method must be reported to FGI and verified.
- Cleaning requirements for equipment are included in the FGI Best Practices.
- The Monsanto MTA requires alfalfa hay growers to harvest at or before ten percent bloom.

Additional factors that could further decrease the potential for gene flow include:

- *Barriers between fields* — Types of barriers can include bodies of water, or other, more attractive plants for bee foraging in between fields. A border of plants at field edges has the benefit of being a buffer zone, as pollen would be deposited in the border population before leaving a GT alfalfa field. If the border were also alfalfa, this would ensure that pollinators would not preferentially avoid the border area. However, the border would need to be treated as GT alfalfa, and if it starts out as non-GT alfalfa, then the spread of genes from that population to the GT alfalfa could adversely affect the cultivation of GT alfalfa seeds by reducing seed purity. If the border were not alfalfa, but a different plant, this would prevent bees from traveling far from the field, and fewer GT genes would be spread (Amand et al., 2000). However, this could be difficult if the border plant has different growing and management requirements from the alfalfa, or if it is an attractive plant to pollinators, which would discourage the alfalfa pollinators from pollinating the alfalfa, and could encourage distant bees to forage there, increasing long-distance pollen flow. Seeds produced by a non-alfalfa plant could also reduce the purity of the alfalfa seed crop (Amand et al., 2000; Rogan and Fitzpatrick, 2004).
- *Competition for resources* — Volunteer alfalfa plants must establish themselves and compete for nutrients against adult plants.

Given proper adherence to FGI Best Practices and Monsanto's MTA, the risk of cross-fertilization is well below FGI's goal of less than 0.5 percent (unintended or unplanned presence of GT alfalfa).

In 2008, CAST published a literature review of gene flow in alfalfa (Van Deynze et al., 2008). The authors concluded that sufficient scientific data are available to design management strategies that should successfully manage gene flow from GE to conventional alfalfa hay and seed production. Regular testing is recommended, however, to monitor the effectiveness of these strategies, and adjustments should be made if and when appropriate (Van Deynze et al., 2008).

To test the effectiveness of NAFA BMPs in commercial production, limited third-party testing for AP of the GT gene was conducted in summer 2009. Data collected from over 1,000 seed lots in ten Western States indicated that the NAFA BMP system was working on a commercial scale. Continued third-party review is recommended for continued success of this program (Lowery, 2010). More information on compliance data can be found in appendix V, 6.2 and 6.5. In addition to the mandatory stewardship programs for GT alfalfa growers, AOSCA announced a voluntary Alfalfa Seed Stewardship Program (ASSP) in 2010. The program is designed: "to provide a market-specific certification

program that can be used by an alfalfa seed producer or contractor in the management of AP of GM traits in alfalfa seed production. Completion of this Stewardship program will result in the issuance of an ASSP certificate and may also result in final AOSCA certification tags." (AOSCA, 2010).

Factors Increasing Probability of Gene Flow

Certain factors have the potential to increase gene flow between alfalfa crops, as has been discussed in the technical report, *Glyphosate-Tolerant Alfalfa Presence in Human Food and Animal Feed* (appendix Q). If GT alfalfa is deregulated, there would be no restrictions or permits required to grow GT alfalfa. Factors that may increase gene flow between alfalfa populations include, but are not limited to the following:

- *Feral alfalfa creates gene flow corridors* — If feral alfalfa grows between fields of GT alfalfa and non-GT alfalfa, then it could provide a corridor for gene flow, or a strip of growth that can serve as a reservoir for the GT gene, between these fields. It could act as a stepping stone for pollinators that would be more likely to travel between flowers that are closer together than between distant fields.
- *Pest management strategy* — Some farmers use a pest management strategy which allows for a strip of uncut alfalfa during hay harvest. This alfalfa strip can act as a reserve for insect predators. If these alfalfa strips are not harvested at the same time as the rest of the field, they would have the chance to flower, receive pollinators, and set seed. If the strip was GT alfalfa, this would result in a low risk of pollinators mediating the distribution of the GT trait, potentially including feral populations if they occur nearby (Mueller, 2005).
- *Seed field proximity can increase gene flow between the fields* — The seed fields are generally found in a compact geographic area, and with pollinators that have the potential to forage over miles (honey bees, for instance), this creates the potential for cross-pollination in non-GT alfalfa seed fields (Hubbard, 2008).
- *Presence of volunteer alfalfa* — As with any agricultural crop, there is the possibility of volunteer alfalfa growing in the field during other crop rotations. If these volunteer plants were GT, normal glyphosate-based herbicide routines would not eradicate them, creating a possibility that the volunteer plants would flower, set seed, and be a source of pollen for gene flow (Altieri, 2000). Also, alfalfa produces "hard seeds," which have hard coatings that prevent moisture from germinating the seed. It is possible that these seeds can remain dormant through growing seasons and germinate at a later time, creating the possibility of adventitious presence even after alfalfa is no longer produced in a field (Hubbard, 2008; Mallory-Smith and Zapiola, 2008). Percentage of hard seededness depends on many factors, including genetics, soil, and climate during and after seed maturation. The longevity and persistence of volunteers further

depends on agronomic management practices (Bagavathiannan and Van Acker, 2009).

- *Presence of unharvested plants* — Typical harvesting practices could miss some plants along the edges or corners of a field. Other plants might be missed due to obstacles or irregularities in the terrain. The unharvested plants could be a source of pollen for gene flow.
- *Movement of honey bees* — Movement of honey bees from crop to crop could increase the chance of transferring pollen from one field to another.
- *Unintended dispersal of bees* — If farmers release too many bees to pollinate one alfalfa seed field, this can lead to unintended and wide dispersal of the bees. This is because bees respond to the competition at one field, and if there are too many in one field, they will forage to find nectar and pollen or to establish nests at alternate sites where there is less competition. This might happen before they visit any flowers of the target field, or they might visit the target field before traveling, increasing the potential of gene flow from the target field (which may be GT alfalfa) to other fields (possibly non-GT alfalfa) (Bosch and Kemp, 2005). See appendix V for additional information on flowering and pollinator behavior.
- *Not following practices* — Farmers not following mandatory BMPs, suggested BMPs and/or voluntary practices to reduce gene flow.

If alfalfa farmers take these factors into consideration and employ measures to counter these factors, such measures should also help alfalfa farmers effectively reduce or prevent gene flow between neighboring alfalfa crops.

Under all of the alternatives, following the above described practices can decrease the likelihood of gene flow between GT alfalfa and conventional alfalfa. Under the Isolation/ Geographic Restrictions Alternative, the geographic restrictions on growing GT alfalfa hay in areas of Tier III where seed is grown will decrease the likelihood of gene flow from hay to seed when compared with the Deregulation Alternative. As discussed above, low levels of pollen from flowering hay fields can fertilize plants in seed fields. It also will reduce the opportunity for the establishment of local feral GT alfalfa plants near these conventional seed fields. Under the No Action Alternative, permit conditions would require many of the recommended practices in the Deregulation Alternative as well as prohibiting the practices that increase the likelihood of gene flow. Also the lower amount of GT alfalfa in the environment will reduce the available sources for GT pollen and seed.

5. Weediness of Alfalfa and Potential for Increased Glyphosate Resistance

Weed management is an important aspect of alfalfa production. Without weeds, alfalfa can grow at a density of about 12 plants per square foot. Heavily weed-infested stands can have less than one alfalfa plant per square foot (Canevari et al., 2007b). For example, in California, if weeds are not effectively controlled, they can represent up to 76 percent of the first cutting yields (Gianessi et al., 2002). In addition to problems associated with weeds in alfalfa cultivation, crop species also have the potential to act as weeds themselves when they are found outside of cultivation. If successful pollen-mediated and seed-mediated gene flow occurred from GT alfalfa, then feral alfalfa plants could act as a weed in some environments. Additionally, the use of glyphosate in the cultivation of GT alfalfa could contribute to changes in the relative weediness of local weed species and may contribute to weed shifts.

Some of the negative effects of weeds on alfalfa cultivation include the following (Canevari et al., 2007b; Canevari et al., 2006; Van Deynze et al., 2004; Loux et al., 2007; Miller et al., 2006; Orloff et al., 1997):

- competition with weeds can reduce yield and cause thinning in the stand;
- weeds can lower the nutritional quality of alfalfa hay because many weeds are lower in protein (50 percent less protein than alfalfa) and higher in fiber compared to alfalfa;
- poisonous weeds containing toxic alkaloids (a type of chemical) can make alfalfa hay unmarketable (e.g., common groundsel, fiddleneck, yellow starthistle, and poison hemlock);
- under some conditions, weeds can accumulate toxic nitrate concentrations (e.g., lambsquarters, kochia, and pigweed);
- some weeds with a spiny texture can cause mouth and throat ulcerations in livestock (e.g., foxtail, wild barley, cheatgrass, and bristlegrass);
- weeds that are unpalatable to livestock result in less feeding and, therefore, less productivity (of either beef or milk);
- some weeds can contribute to off flavors in milk (e.g., wild celery, Mexican tea, creeping swinegrass, and mustards); and
- weeds that contain higher moisture content than alfalfa (e.g., dandelion) can cause bale problems such as mold, off-color hay, and high bale temperatures, which are a fire hazard.

Farmers are very interested in effective weed control and GT alfalfa allows the use of glyphosate to eradicate weeds without damaging the crop. Relying on glyphosate alone as the only weed removal herbicide may influence the number of weed species that may become glyphosate-resistant (weeds that inherit the ability to survive and reproduce following glyphosate applications that are normally lethal) (Puricelli and Tuesca

2005, Stoltenberg and Jeschke, n.d.). However, it is not the only factor involved in the evolution of glyphosate resistance in weeds.

A number of genetic, biological/ecological, and operational factors are involved in determining if a weed species will evolve a resistance to any herbicide (Georghiou and Taylor, 1986; Neve, 2008). Genetic factors include the frequency of genes in a weed species that promotes resistance to a particular herbicide, the ability and rate of changes to genes to cause resistance, the way genes for resistance are passed down to offspring, and the fitness of the plant in the presence and absence of a herbicide. Biological and ecological factors include how the weed species reproduces (selfing or outcrossing), seed production capacity, seed bank turnover, and amount of gene flow within and between populations (Maxwell and Mortimer, 1994; Jasieniuk et al., 1996; Neve, 2008). The genetic factors and biological/ecological factors involved highlight that different species may present different risks of resistance, depending of the genetics of the weed and the biology of the plant. Operational factors involved in the evolution of weed resistance include the type of chemistry and how the herbicide kills plants, frequency the herbicide is applied, and dose and pattern of herbicide application. For many of the genetic, biological/ecological, and operational factors that influence the evolution of herbicide resistance in weeds, accurate measurements are difficult or impossible to obtain experimentally (Jasieniuk et al., 1996).

Modeling has been used, but because of the difficulty in obtaining accurate information on the factors indicated above, the use is limited (Jasieniuk et al., 1996). Neve (2008) has used simulation modeling to examine the evolution of glyphosate resistance in weeds. Of the many assumptions in the model, an important one is that the model only accounts for the evolution of glyphosate resistance in weeds in an annual crop, like herbicide-tolerant corn, where the weeds are only removed when the crop is harvested at the end of the growing season. Alfalfa, on the other hand, is a perennial crop, and when produced as forage, is regularly harvested by mowing during the growing season. Harvesting forage alfalfa has the added benefit of also mowing weeds, which may not have had time to produce flowers, pollen, or even seed. Thus, although the genetic factors of a weed species growing in a corn and alfalfa field would likely be the same, the biological and ecological factors may be quite different because of potential reduction in reproductive capability, seed bank formation, and the amount of gene flow within and between the weed species in the alfalfa field compared to the corn field. Neve (2008) modeled the influence of seed bank turnover and seed production characteristics in a continuous glyphosate resistant crop rotation over a ten-year period. At year ten in the simulation, lower seed bank turnover and low seed production capacity, which may be comparable to the environment in a GT alfalfa forage system, can drastically reduce or even eliminate the probability of weeds becoming glyphosate resistant.

Operational factors also play an essential role in determining the risk of glyphosate use resulting in the evolution of glyphosate-resistant weeds (Hartzler, 2003). Neve (2008) found that in year three of the simulation in an annual, glyphosate resistant crop that used five applications of glyphosate at different points during the growing season (before crop seeding, at crop seeding, at pre-emergence of weed, and two post-weed emergence applications), there was a 100 percent probability that a weed species would evolve resistance to glyphosate. In contrast, for GT alfalfa forage production, glyphosate is applied, at most, four times a year. In fact, the comments submitted in January and February 2008 to the Notice of Intent for this EIS indicate that no more than two applications of glyphosate are used on GT alfalfa for forage. Furthermore, the application rate for GT alfalfa (1.55 pounds of glyphosate a.e. per acre) is reduced by half compared to the full field application (3.85 pounds of glyphosate a.e. per acre) in other GT crops. Thus, the operational factors for GT alfalfa forage production may decrease the probably of weeds evolving resistance to glyphosate.

Currently, there are no concrete data, information, or models that provide a prescriptive determination on if or how many weed species may evolve resistance to glyphosate, how many years it may take for a single weed species to evolve resistance, which management strategy will completely prevent the evolution of weed resistance to glyphosate, or which management strategy will result in all weed species evolving resistance to glyphosate. APHIS is not aware of any models that simulate the evolution of weeds resistant to glyphosate in a GT alfalfa production system.

There is potential for an overall decrease in total herbicide use due to increases in glyphosate use under some scenarios (see Glyphosate and Herbicide Use and Comparative Toxicity, below, and appendix J). However, if there is an increase in glyphosate-resistant weeds due to the adoption of GT alfalfa, there could be a corresponding increase in the amount of other herbicides used for stand removal for non-GT alfalfa.

Weediness Potential of Alfalfa

Under the Deregulation Alternative, GT alfalfa with the inserted 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) gene can be introduced in cropping systems just like cultivated alfalfa. APHIS has previously reviewed information submitted to the agency by Monsanto and FGI on the weediness characteristics of GT alfalfa and have determined that the transformation process and insertion of the CP4 EPSPS gene in GT alfalfa events J101 and J163 have not altered the weediness potential of alfalfa (USDA-APHIS, 2009). Although volunteer crops can become problem weeds in some settings, Rogan and Fitzpatrick

(2004) conclude that GT alfalfa will not be any more of a problem weed in a nonagricultural setting than non-GT alfalfa.

Information submitted relating to the use of glyphosate for control of feral alfalfa indicates that feral alfalfa is rarely controlled with herbicide and if controlled, glyphosate is not the herbicide of choice for control. Thus, the GT trait would not provide a competitive advantage to feral alfalfa unless glyphosate was directly applied or drifted from nearby improper applications, and other herbicides are available to control alfalfa that may be tolerant to glyphosate (Rogan and Fitzpatrick, 2004). GT alfalfa is not different than conventional alfalfa except for the GT trait as discussed in appendix U. When glyphosate exposure does not occur, GT alfalfa does not differ from non-GT alfalfa. Alfalfa is not considered a weed, and resistance to glyphosate without glyphosate exposure does not change this determination.

Less than 100 percent alfalfa stand termination can result in volunteer alfalfa plants in the following crop. Therefore, good stand termination procedures would still be a good method of eliminating volunteer GT alfalfa plants. Non-glyphosate herbicides and tillage are recommended for effective GT alfalfa stand removal (Orloff et al., 1997).

Monsanto's guidance for GT alfalfa stand removal is summarized in the technical report, *Effects of Glyphosate-Resistant Weeds in Agricultural Systems* (figure G-2 in appendix G). Based on the available information on this subject, alfalfa is not an important weed in the United States, but care should be taken with other GT crops that may be chosen to follow GT alfalfa in a crop rotation.

Use of GT Alfalfa for Weed Management

The following discussion of GT alfalfa and weed management was based largely on the technical report, *Effects of Glyphosate-Resistant Weeds in Agricultural Systems* (appendix G).

GT alfalfa can be used by farmers for weed management in alfalfa crops. Its unique characteristics allow for effective weed control throughout the growing season of an alfalfa crop. Compared with other GT crops that are commercially available, alfalfa and alfalfa farming practices have characteristics that will aid in the suppression of the development of glyphosate-resistant weeds. Alfalfa's perennial nature, autotoxicity, and nitrogen fixing ability are different from other GT crops, and reduce the likelihood of glyphosate-resistant weed development. Crop rotations with plants that can follow alfalfa, such as annuals (plants that sprout and die each year, and do not regrow from the same seed the next year) or plants that need high amounts of nitrogen in the soil and regular mowing to

remove weedy plant mass also help to minimize glyphosate-resistant weeds. These factors are explained below.

Alfalfa produced for forage purposes (e.g., hay and silage in either GE, conventional, or organic production systems) is mowed regularly at a recommended cutting height of three inches. This removes all plant material higher than three inches, including weeds (Orloff et al., 1997) which may not have had time to produce flowers, pollen, or even seed. This regular removal of all plant mass above three inches of the soil surface, including all weed material, greatly suppresses or eliminates seed production in weed species, and is especially effective in controlling annual weeds.

In a GT alfalfa farming system for forage, the combination of broad spectrum weed control from glyphosate (which should lead to more vigorous alfalfa competition), and regular mowing, which reduces the likelihood that any glyphosate-resistant weeds in the GT alfalfa field have had time to produce pollen or set seed, greatly decreases the probability of the development of glyphosate-resistant weeds. In seed production, mowing only occurs once, as one crop is removed each year; thus, there is a potential for greater weed seed production compared to alfalfa forage production. However, in order to maximize yield for a seed crop, alfalfa seed production currently receives significantly higher herbicide inputs to reduce weed cover than in alfalfa forage production. The additional herbicides with other modes of action may also work to reduce weed seed production and minimize glyphosate-resistant weeds in the seedbank of GT alfalfa grown for seed.

The ability for alfalfa to fix nitrogen encourages the decision to follow alfalfa in the rotation with a crop that requires additional nitrogen, such as the annual grasses like corn and various cereal crops. These subsequently rotated crops can tolerate a spectrum of herbicides substantially different from the herbicides used in alfalfa. This encourages rotation of crops and herbicides, both of which are highly recommended for reducing the probability of developing herbicide resistant weeds.

All other commercially available GT crops are either annual species or are grown as annuals. As discussed above, simulated modeling indicates that the biological/ecological factors and the operational factors for annual GT crops, point to the potential for faster evolution of glyphosate resistance in annual weeds compared to GT alfalfa. Likewise, perennial conventional alfalfa produced for several years in the same location could favor an increase in perennial weeds if the weeds have the ability to survive repeated mowing; however, no experimental data or modeling specific to GT alfalfa are available to substantiate this prediction.

The use of GT alfalfa for weed control and management may not be appropriate in the following situations (Dillehay and Curran, 2006):

- alfalfa-grass mixtures and alfalfa seeded with companion/nursery crops;
- fields that have a history of low weed populations; and
- fields that are rotated between alfalfa and other GT crop varieties (e.g., Roundup Ready® soybeans).

Van Deynze et al. (2004) reported that in field trials when Roundup® (a glyphosate-based herbicide) was applied during alfalfa stand establishment at the 3 to 4 leaf stage, weeds were controlled and usually no second application was needed. Early applications allowed for late germination of weeds while later applications allowed weeds to compete with alfalfa. If glyphosate is sprayed early enough, alfalfa plants containing the GT trait will fill in gaps left by dead weeds and non-GT alfalfa that was killed (Van Deynze et al., 2004).

Nineteen States have records of glyphosate-resistant weeds (Heap et al., 2010), and all of these States produce alfalfa. The likelihood that glyphosate-resistant weeds will appear in a GT alfalfa field increases with both the number of sites of glyphosate-resistant weeds in a State (Heap et al., 2010) and the acreage planted to alfalfa in a State (USDA-NASS, 2009). The greatest potential for overlap between glyphosate-resistant weeds and GT alfalfa fields occurs in the States of Kansas, Ohio, Illinois, and Missouri. These four States have more than 100 sites of glyphosate-resistant weeds, and each State has over 200,000 acres planted to alfalfa. Although California also has more than 200,000 acres of alfalfa, it has a slightly lower likelihood of overlap between glyphosate-resistant weeds and GT alfalfa because there are less than 70 sites with glyphosate-resistant weeds. Similarly, Indiana, Michigan, Minnesota, Kentucky, Oregon, and Pennsylvania also have greater than 200,000 acres planted to alfalfa, but each State only has ten or fewer sites of glyphosate-resistant weeds. The remaining States with records of glyphosate-resistant weeds (Arkansas, Delaware, Georgia, Maryland Mississippi, New Jersey, North Carolina, and Tennessee) have from 10 to over 500 sites of glyphosate-resistance weeds; however, these States do not have large acreages devoted to alfalfa. Rotation between perennial and annual crops along with the application of glyphosate on the GT alfalfa, alfalfa's natural autotoxicity, and the farming practice of mowing (in forage production) or intensive management practices (in seed production) decreases the probability of a single weedy species surviving these major stresses to become a glyphosate-resistant weed.

Weed Shifts in GT Alfalfa and GT Alfalfa Weed Management Options

The limiting factor for weed control in non-GT conventional alfalfa is that by the time alfalfa reaches the stage of growth that is tolerant to herbicides, weeds are also beyond the stage when they are easily killed with herbicides (Gianessi et al., 2002). Adopting new weed control strategies eventually leads to shifts in composition and/or distribution of the weeds that are of greatest concern.

Weed shifts can occur in GT alfalfa due to tillage, irrigation, soil fertility, planting date, crop rotation, and herbicide use (Hilgenfeld et al., 2004). Changing production to a no-till system results in a more diverse seedbank. Within weedy species, variations in characteristics such as seed dormancy, emergence patterns, growth plasticity (the variation in the growth of the plant), life cycle, life duration, shade tolerance, late-season competitive ability, seed dispersal mechanisms, and morphological (physical form) and physiological (biological functioning) variations help weeds escape or tolerate weed management (Hilgenfeld et al., 2004).

Factors that influence weed shifts in GT agricultural production systems include:

- composition of the weed seedbank in the soil;
- glyphosate application; and
- rotation patterns in a site-dependent manner.

The studies described below exemplify how the above factors affect weed community shifts. If the weed seedbank is largely composed of dormant seed, weed shifts may not be apparent for years, depending on the weed species present. If glyphosate-resistant weeds already occur in an area with a GT crop, glyphosate applications will promote the appearance of more glyphosate-resistant weeds in a field, causing a shift toward a glyphosate-resistant weed community (Orloff et al., 2007). Crop rotation between GT and non-GT crops and the use of non-glyphosate herbicides can reduce the populations of glyphosate-tolerant weeds, thus alter weed shifts in GT crops.

- *Composition of weed seedbank and surrounding sources of weeds —* Weed seedbanks in the soil can contain large reservoirs of dormant weed seed; thus, short-term studies (a few years) might not detect the full potential shift in weed communities (Harker et al., 2005). However, sometimes weeds shift can be observed within a few years. In a field trial in an established GT alfalfa stand in the Southwest (San Joaquin Valley) burning nettle was not controlled and the population of burning nettle increased significantly over the three-year trial period (Canevari et al.,

2004; Van Deynze et al., 2004). Tank mixtures with Velpar (hexazinone) or paraquat controlled burning nettle. Van Deynze et al. (2004) recommend that the best way to prevent weed shifts is to avoid using the same herbicide year after year, rotate herbicides and crops, and include non-herbicide strategies to control weeds. Weeds that are difficult to control with glyphosate, such as dodder and cheeseweed, may need to be treated early and may require a second application. Smother crops should be planted before alfalfa to suppress weeds. For example, sorghum-sudangrass hybrid or foxtail millet both suppressed weeds and enhanced subsequent alfalfa establishment (Forney et al., 1985).

- *Glyphosate application* — Puricelli and Tuesca (2005) found that continuous glyphosate application in field studies on three crop rotation sequences and two tillage systems lead to quantitative and qualitative changes in weed communities. They found that glyphosate application was a more important factor than crop sequence to explain weed community changes in summer crops. They also predicted that continual glyphosate application for longer than the five years in their study might lead to the development or higher increases in abundance of weeds resistant to glyphosate. Weed species diversity in conventional versus no-till plots did not differ significantly.
- *Rotation patterns in a site-dependent manner* — Harker et al. (2005) reported that field studies of spring wheat-canola-spring wheat rotations of various combinations of GT and non-GT varieties under conventional tillage or low soil disturbance direct seeding systems indicate that weed community shifts are dependent on rotation pattern in a site-dependent manner. In the western Canada field locations, within 3 years, crop systems without GT varieties were associated with green foxtail, redroot pigweed, sowthistle spp., wild buckwheat, and wild oat. The specific weeds associated with all GT variety systems included Canada thistle at the Brandon site, henbit at the Lacombe site, and volunteer wheat, volunteer canola, and round-leaved mallow at the Lethbridge site. There was high variability in wild buckwheat between the systems. Glyphosate is not very effective on wild buckwheat, so the authors proposed that wild buckwheat seed production or viability may be restricted by glyphosate more than the wild buckwheat biomass. Therefore, after glyphosate application the plant may appear visually robust, but its ability to reproduce has been effected, so in following years less wild buckwheat is observed (Harker et al., 2005).

It is plausible that the 21 weed species that are either resistant or tolerant to glyphosate and traditionally present problems in alfalfa (see chapter III) likely pose the greatest threat for weed shifts in a GT alfalfa crop system. These 21 species may be the first candidates for weed shifts in GT alfalfa. However, as discussed in the studies summarized above, weed shifts are dependent on the composition of the weed seedbank in the soil,

surrounding sources of weeds, glyphosate application, and site specific rotation patterns. All 21 of these weed species are able to grow as naturalized populations in the United States (http://plants.usda.gov/index.html). For maps of the current naturalized populations for these species refer to the technical report, *Effects of Glyphosate-Resistant Weeds in Nonagricultural Ecosystems* (appendix H).

Chapter III summarized the current distribution for glyphosate-resistant or tolerant weeds in crops. In areas where these resistant biotypes are already present in the seedbank there is a greater potential for increase of those weeds if glyphosate is used. For weed species where glyphosate-resistant biotypes have not been identified in the United States (e.g., buckhorn plantain, goosegrass, junglerice, sourgrass, and wild poinsettia) there are presumably no glyphosate-resistant biotype seedbanks in U.S. soil. Resistant biotypes of these weeds could spread to the United States either through inadvertent transportation or local evolution of resistance.

Under the No Action Alternative, the amount of GT alfalfa on the landscape is less than that of the Deregulation Alternative and the Isolation/Geographic Restrictions Alternative. Therefore there it is less likely for GT feral populations to become established. While there are likely some feral GT alfalfa plants on the landscape now these can be managed, if desired, with methods other than glyphosate.

Under the No Action Alternative the weed shifts and weed resistance discussed for the preferred action would not be likely to occur in alfalfa . Therefore the contribution of alfalfa production practices to the baseline levels of weeds shifts and weed resistance due to all agriculture would revert to pre-2005 levels.

The Isolation/Geographic Restriction Alternative has the same possibility of weed shifts and weed resistance as the Deregulation Alternative, except in the case where there is inadvertent transfer of glyphosate-resistant weed seeds from a GT field to a non-GT field. For inadvertent transfer of glyphosate-resistant weed seed the greater distances between differing of fields in the Isolation/Geographic Restriction Alternative has an advantage over the Deregulation Alternative.

Inadvertent transfer of weed seeds into new GT alfalfa fields can occur after the development of glyphosate-resistant weeds in GT fields if BMPs as described under the Deregulation Alternative are not followed, or may occur if GT alfalfa is grown in regions where glyphosate-resistant weeds or their biotypes are found and left unmanaged. However, the transferred glyphosate-resistant weeds in the non-GT field would have equal competitive advantage as the other weeds in the non-GT alfalfa field and may be eliminated with the use of a non-glyphosate herbicide. Establishment of isolation distances between GT alfalfa and conventional

alfalfa decreases the chances of transfer of glyphosate-resistant weeds from the GT fields to conventional fields.

C. Biological Impacts from GT Alfalfa

APHIS assessed the potential impacts of the alternatives on plants and animals, including threatened and endangered (T&E) species. The discussion in this section summarizes the more extensive analysis and discussion contained in the technical report, *Potential Impacts on Wildlife, Amphibians, Plants, and Ecosystems from Increased Glyphosate and Other Chemical Usage* (appendix N).

Deregulation Alternative

1. Impacts on Plants and Animals from the GT alfalfa J101 and J163 Gene Product

The Deregulation Alternative is expected to result in an increase in the prevalence of GT alfalfa compared with the No Action Alternative. As discussed in appendix J (2.7.2), the acreage of hay that may be converted to GT alfalfa hay is based on market adoption predictions provided by FGI (FGI, 2010). The FGI estimates include their expectations for regional differences in initial adoption rate, incremental increase in adoption rate, and stand life expectations. FGI estimates that 51 percent of hay acres could be GT alfalfa ten years after deregulation (see appendix J, table J-16). There is an associated increase in the likelihood of exposure of plant and animal species to the gene product. APHIS analyzed the potential impacts of GT alfalfa on animal and plant species. As part of the analysis, effects were evaluated to determine whether an impact was expected on any listed or proposed T&E species or any designated critical habitat from directly contacting, consuming, or hybridizing with GT alfalfa events J101 and J163 and/or its progeny (USFWS, 2010a; USFWS, 2010b).

GT alfalfa events J101 and J163 are not expected to become more invasive in natural environments or have any different effect on critical habitat than their parental non-GT line in the absence of glyphosate selection. This conclusion is based on results of more than 150 field trials conducted over a five-year period in 33 different States (Rogan and Fitzpatrick, 2004). The data show GT alfalfa events J101 and J163 are essentially equivalent to non-GT variations in form and shape, such as growth habit, vegetative growth, and flower and pollen morphology (USDA-APHIS, 2009). Several agronomic traits were evaluated, and no biological differences between GT and non-GT alfalfa were noted for traits that may influence weediness, including seed dormancy, seed germination, seedling emergence, seedling vigor, winter survival, spring vigor, seed yield, vegetative growth, plant dormancy, survival, and relationship with symbiotic organisms (USDA-APHIS, 2009). Although alfalfa has been documented to survive, to a small extent, outside of cultivation (Rogan and Fitzpatrick, 2004), alfalfa is not considered an invasive species (USDA NRCS, 2010; USDA ARS, 2003).

GT alfalfa is not expected to have nutritional effects on any animal species (including T&E species) that feed on it. Analysis of forage samples from several locations demonstrates that GT alfalfa is compositionally and nutritionally equivalent to other alfalfa varieties currently on the market except for the expression of the transgene protein, and therefore is not expected to have nutritional effects on any animal species that feeds upon it (technical reports, *Presence of Glyphosate-Tolerant Alfalfa in Human Food and Animal Feed* (appendix Q), and *Character and Quality of Glyphosate-Tolerant Alfalfa Traits* (appendix U), (FDA, 2004a) [appendix P], (Rogan and Fitzpatrick, 2004).

GT alfalfa events J101 and J163 are not expected to affect plant or animal species (including T&E species and critical habitat) due to the toxicity or allergenicity of the transgene protein. The EPSPS protein from plants and from the CP4 *Agrobacterium* strain are not known for pathogenic or toxic effects on humans, animals, or plants based on numerous laboratory and field studies with these purified proteins or plants expressing these proteins (technical reports, *Presence of Glyphosate-Tolerant Alfalfa in Human Food and Animal Feed* (appendix Q), and *Character and Quality of Glyphosate-Tolerant Alfalfa Traits* (appendix U), (FDA, 2004a) [appendix P]) (Rogan and Fitzpatrick, 2004). Nor do the proteins dispose plants to become more susceptible to disease (USDA APHIS, 2009). The same CP4 EPSPS enzyme is expressed in numerous glyphosate-tolerant crops already grown on millions of acres across the United States. GT alfalfa events J101 and J163 would have no impact on biodiversity. The trait itself is essentially benign in the environment (Owen, 2008). Furthermore, on the basis of information previously provided by Monsanto and FGI and reviewed in the petition as well as information provided in appendix I (technical report, *The Potential for Gene Flow from Glyphosate-Tolerant Alfalfa (Medicago sativa L.) to Related Species*), 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. Hence, there will be no impact on the genetic resources of these plant species due to the release of GT alfalfa in the United States. Possible movement of the transgene via pollen from GT alfalfa to other members of the *Medicago* genus would not occur in the United States, or it would only occur following the introduction and establishment of a reproductively compatible, non-native species growing near GT alfalfa. GT alfalfa events J101 and J163 are not expected to form hybrids with any State or federally listed threatened or endangered species of plants or plant species proposed for Federal listing.

Combs and Hartnell (2007) examined the effect of GT alfalfa forage on feed intake, milk composition and milk production in 16 multiparous (given birth two or more times), lactating Holstein dairy cows. They concluded that milk production, milk composition, feed intake, and feed efficiency were not different for dairy cows fed GT versus control alfalfa hay. GT alfalfa hay has also been used as feed extensively without incidence since deregulation in 2005. These results confirm those derived from previously conducted compositional analyses for GT alfalfa, where no differences were observed between GT alfalfa and the control, and further confirm the feed safety of glyphosate and the CP4 EPSPS protein.

After reviewing possible effects of granting nonregulated status in whole to GT alfalfa events J101 and J163, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of plant and animal species, including T&E species or species proposed for listing. Consequently, an exposure analysis for individual species is not necessary. APHIS has considered the effect of production of GT alfalfa on designated critical habitat or habitat proposed for designation and could identify no difference from impacts that would occur from the production of other alfalfa varieties (non-GT varieties or organic varieties). APHIS has reached a conclusion that the release of GT alfalfa plants J101 and J163 or their progeny, following a determination of nonregulated status, would have no effect on federally listed T&E species or species proposed for listing, nor is it expected to adversely modify designated critical habitat or habitat proposed for designation, compared to current agricultural practices. Consequently, a written concurrence or formal consultation with the United States Fish and Wildlife Service or the National Marine Fisheries Service (the Services) is not required.

No Action Alternative

Under the No Action Alternative, there would be no change in the likely exposure of plants and animals (including T&E species) to GT alfalfa events J101 and J163. Exposure due to the approximately 200,000 acres currently planted to GT alfalfa would remain the same. After the GT alfalfa stands were removed (likely after three to four years), exposure to GT alfalfa would be limited to those fields permitted for GT alfalfa. No change in effects, compared with any current effects due to non-GT alfalfa, would be expected on plants and animals (including T&E species) or critical habitat under the No Action Alternative.

Isolation/Geographic Restriction Alternative

Because the gene product, CP4 EPSPS protein, is not expected to have an adverse impact on plants and animals (including T&E species) at any level or at any distance, no adverse impacts on plants and animals (including

T&E species) from the J103 and J163 alfalfa events would occur under this alternative.

2. Impacts on Plants and Animals from Herbicides

Chemical Fate and Transport of Glyphosate in the Environment

Glyphosate exposure to plants and animals is possible due to spray drift, inadvertent direct overspray, or wind transport of soil particulates loaded with adsorbed glyphosate. Glyphosate has a low vapor pressure and Henry's law constant[25]; thus, it has a low potential to evaporate from soil and water. Glyphosate is hydrophilic (bonds with and dissolves in water), and therefore it has low potential to accumulate in the tissues of animals. It has a high solubility in water and is not broken down by water (hydrolysis) or by exposure to light (photolysis). Due to glyphosate's strong adsorptive quality with soil (strong ability to collect and remain associated or bound with soil), it is not expected to contaminate groundwater. However, runoff water could contain particulates with adsorbed glyphosate (Giesy et al., 2000).

In soil, sediment, or natural water, glyphosate is primarily broken down by microbes, creating the major metabolic byproduct, aminomethyl phosphonic acid (AMPA). It can be further degraded to CO_2, although at a slower rate than the parent glyphosate (U.S. EPA, 1993). In a U.S. Department of Agriculture (USDA) monitoring study conducted on surface water, groundwater, and soil from 2001 to 2006, the metabolite AMPA was observed more frequently than the parent compound glyphosate (Scribner et al., 2007). The sample collections were from several U.S. Geological Survey (USGS) studies including the National Stream Quality Accounting Network Program, the National Water-Quality Assessment Program, and the Toxic Substances Hydrology Program. EPA determined that, based on toxicological considerations, AMPA need not be regulated (U.S. EPA, 2006b).

Toxicology and Environmental Risk

Based on the EPA's toxicological and ecotoxicology and fate databases (U.S. EPA, 1993, 2006a), glyphosate is considered to be a toxicologically and ecologically low-risk herbicide (Cerdeira and Duke, 2006). Based on the data available on glyphosate use on GT alfalfa, chemical fate, and toxicity, and after a Tier I "high-end use case" scenario screening of hazard quotients, glyphosate is not expected to pose an acute or chronic risk to birds, mammals, terrestrial invertebrates, aquatic invertebrates, and fish.

[25] Henry's Law Constants characterize the equilibrium distribution of dilute concentrations of volatile, soluble chemicals between gas and liquid.

Birds

According to EPA standards, glyphosate is "practically nontoxic" to birds and was not found to cause reproductive effects. Toxicity in birds was assessed using single-dose, dietary, and reproductive toxicity studies. Toxicity was assessed by determining dose levels needed to kill 50 percent of a population of test animals. Glyphosate acute toxicity in the Bobwhite quail was "practically nontoxic" (U.S. EPA, 2008). Dietary studies in the Bobwhite quail and Mallard duck are considered "slightly toxic" for both birds (U.S. EPA, 1993, 2006a). Reproductive studies did not indicate any effect after glyphosate treatment in Mallard duck or Bobwhite quail. Glyphosate tested as acid produced similar results in the Bobwhite quail and Mallard duck. Studies with glyphosate tested as its isopropylamine (IPA) salt were not reported for review.

Mammals

In terms of subchronic and chronic toxicity[26] in rodents, one of the more consistent effects of exposure to glyphosate is loss of body weight. Glyphosate is a Group E carcinogen (cancer-promoting agent) which represents no evidence of carcinogenicity. Additionally, glyphosate does not increase the frequency of mutations in an animals' deoxyribonucleic acid (DNA) and was not found to cause reproductive or developmental effects in mammals. Studies with lactating goats, laying hens, rats, rabbits, and cows fed a mixture of glyphosate and AMPA indicate that the primary route of elimination was by excretion (urine and feces).

Amphibians

According to EPA standards, glyphosate is "slightly toxic" to amphibians. However, amphibians exhibited greater sensitivity to Roundup® formulations than to glyphosate tested as an acid or IPA salt. This could be due to the surfactant (e.g., polyethoxylated tallowamine [POEA]) used in agricultural formulations. POEA is a surfactant used in many herbicide formulations (such as GLYFOS®) to increase the ability of active ingredients to penetrate leaf cuticles (Lajmanovich et al., 2003). Other surfactants perform the same function.

Microorganisms and Soil Invertebrates

Microorganisms produce aromatic amino acids through the shikimate pathway, similar to plants. Since glyphosate inhibits this pathway, it could be expected that glyphosate would be toxic to microorganisms. Older field studies show that glyphosate has little effect on soil microorganisms,

[26] Subchronic toxicity studies are those that study the effects on a small percentage of a subject's life span (e.g., up to 10 percent), while chronic studies continue for a longer period of the subject's lifespan.

and, in some cases, field studies have shown an increase in microbial activity due to the presence of glyphosate (USDA–FS, 2003). A review of more recent field studies indicate shifts in soil microbial community composition that might or might not cause some adverse consequences in agricultural fields over the long term (Kremer and Means, 2009).

Terrestrial Invertebrates

Honey bees are the preferred species to assess the toxicity of herbicides on arthropods by EPA. Glyphosate is considered "practically nontoxic" according to EPA standards, based on the toxicity needed to kill 50 percent of the test animals (Giesy et al., 2000; Monsanto, 2005a, 2006a, 2007b, 2007d).

Aquatic Invertebrates

Glyphosate formulations generally are classified by EPA as "slightly" to "moderately toxic" to aquatic invertebrates (LC50 >1 and <100 mg/L). For a few species, glyphosate formulations are classified as "practically nontoxic" (Giesy et al., 2000). Several acute and lifecycle toxicity tests have been performed on a variety of freshwater aquatic invertebrates for glyphosate and various herbicide formulations. The most sensitive species to glyphosate was the buzzermidge (*Chironomus plumosus).* The most sensitive species to glyphosate herbicide end-use formulations was the water flea (*Daphnia magna).* In the case of the water flea, glyphosate formulations are several orders of magnitude more toxic than technical glyphosate.

Per the EPA's 1993 Registration Eligibility Decision for Glyphosate, "since there is such an extensive data set for this chemical, the Agency can determine that glyphosate demonstrates low toxicity to fish and oyster species, and therefore is waiving the marine fish and oyster acute[27] toxicity studies on the formulated product" (U.S. EPA, 1993).

The saltwater and marine species tested for toxicity to glyphosate and glyphosate herbicide formulations for GT alfalfa were invertebrates. The most sensitive marine animal species to glyphosate was the tiny zooplankton, *Acartia tonsa*, which is abundant in warm coastal and estuary water (LC50 = 35.3 mg a.e./L) (Tsui and Chu, 2003). However, due to glyphosate dilution in runoff, this level of exposure would not occur in marine environments.

[27] Acute toxicity studies are those that study the effects of a single or short-term exposure to a substance.

Fish

Many studies have also been performed in a variety of species of fish to determine the acute toxicity of glyphosate formulations. In general, the glyphosate formulations (herbicide plus other chemicals) were more toxic to fish than technical glyphosate (herbicide only). The increased toxicity is due to the presence of a surfactant in glyphosate formulations (Giesy et al., 2000).

The most sensitive species to the formulations considered was rainbow trout (*Oncorhynchus mykiss*) when treated with formulations similar to Roundup UltraMAX II® and Roundup WeatherMAX® (Monsanto, 2004, 2005a). In bluegill sunfish (*Lepomis macrochirus*), channel catfish (*Ictalurus punctatus*), and fathead minnow (*Pimephales promelas*), formulations of glyphosate are much more toxic than technical grade glyphosate (Giesy et al., 2000). Interestingly, many salmon species studied were less sensitive to glyphosate formulations than to glyphosate.

Plants

Glyphosate is estimated to be equally toxic to both terrestrial and aquatic plants (USDA, 2003). EPA has evaluated glyphosate's toxicity to aquatic plants based on studies submitted for the registration of the chemical and additional studies are also available (USDA, 2003) (see plant impacts discussion below under the Deregulation Alternative).

Deregulation Alternative

The deregulation of GT alfalfa under the Deregulation Alternative is expected to result in an increase in the use and application of glyphosate-based herbicide formulations on alfalfa. This would lead to an increase in the amount of incidental glyphosate exposure to animal species and terrestrial and aquatic plants in the vicinity of GT alfalfa fields either by spray drift, or transport in surface water runoff. However, in some areas, it might result in a decrease in the amount of other herbicides applied to control weeds in alfalfa fields. The reduction in other herbicides would occur if the GT alfalfa replaces alfalfa where herbicides are used.

Plants

Glyphosate is a nonselective herbicide, and therefore deregulation of GT alfalfa could indirectly result in adverse effects to nontarget plant species near GT alfalfa fields if they are exposed to glyphosate applied to the alfalfa field. Most plant species, when exposed to glyphosate, experience high levels of toxicity. Higher plants that use the shikimate pathway to produce aromatic amino acids will experience toxic effects as they metabolize glyphosate (as discussed in the technical report, *Glyphosate-Tolerant Alfalfa Presence in Human Food and Animal Feed* [appendix Q],

appendix N). These toxic effects could include the inability to photosynthesize, the inability to complete respiration, the inability to synthesize nucleic acids and amino acids, and impaired germination and/or growth characteristics (Blackburn and Boutin, 2003). Although the effects can be slow to progress, all of these toxic effects could result in plant death (USDA-FS, 2003; Giesy et al., 2000).

Possible routes of exposure are aerial drift (Blackburn and Boutin, 2003), runoff of surface waters containing glyphosate, or leaching of glyphosate into drainage systems (Borgaard and Gimsing, 2008). If aerial applications are minimized, this risk to nontarget terrestrial plants would be reduced. To mitigate potential adverse effects due to glyphosate drift, EPA has imposed specific label use restrictions for glyphosate use when applied with aerial equipment, including "the product should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, and non-target crops) is minimal (e.g., when wind is blowing away from the sensitive areas)." AMPA, the primary degradation product of glyphosate, seems to be equally or less toxic than glyphosate. Therefore, a separate risk characterization was not conducted (USDA, 2003).

Because glyphosate binds strongly to soil particles, conservation tillage and no tillage practices have the potential to mitigate impacts on aquatic plants through decreasing soil-laden runoff. For example, alfalfa can be no-till planted three ways after small-grain cereals: (1) no-till directly into the cereal stubble, (2) bale the stubble, then no-till plant, or 3) burn the stubble, then no-till plant (Shroyer et al., 2003). However, glyphosate still may reach aquatic environments in runoff and by erosion of soils. Sorption, degradation, and leaching of glyphosate vary from soil to soil (Borggaard and Gimsing, 2008). This variability and uncertainty make it difficult to predict glyphosate's fate in the soil. Borggaard and Gimsing (2008) concluded that although sorption and degradation are affected by many factors (e.g., the physical and chemical properties of the soil) which may affect the mobility of glyphosate in the soil, leaching of glyphosate is mainly determined by soil structure and rainfall. Limited leaching has been reported in non-structured sandy soils, as well as structured soils, but only when large amounts of rainfall followed glyphosate application (Borggaard and Gimsing, 2008). The potential for glyphosate transport from terrestrial to aquatic environments is limited, and glyphosate is not expected to reach groundwater due to sorption and degradation in the soil (Borggaard and Gimsing, 2008).

Increased use of glyphosate might cause crops to become more susceptible to diseases as a result of fungal stimulation, such as root-colonizing *Fusarium*. Kremer and Means (2009) discovered the frequency of *Fusarium* increased significantly after glyphosate application to GT corn

and soybean. However, Powell and Swanton (2008) concluded there is insufficient evidence to prove a link between glyphosate and crop diseases associated with *Fusarium*.

Some studies suggest that glyphosate may interfere with uptake and translocation of nutrients, particularly manganese, from soils, possibly due to binding of the nutrients with glyphosate in the soil or at the plant root (Cakmak et al., 2009; Eker et al., 2006). As a result, plant growth and seed quality may be impaired.

Animals

As mentioned above, glyphosate itself has low toxicity to mammals, birds, and fish, and is slightly toxic to amphibians. However, amphibians exhibited greater sensitivity to Roundup® formulations than to glyphosate tested as an acid or isopropylamine (IPA) salt, likely due to the surfactant, POEA, which has been used for a long time in agricultural formulations. POEA has been found to be more toxic to amphibians and other aquatic animals than the herbicide itself (Lajmanovich et al., 2003). Some researchers have suggested that, in combination with POEA, Roundup® could cause high rates of mortality to amphibians, including species of frogs and toads that could lead to eventual population declines (Relyea, 2005). POEA currently is used in only one of the five glyphosate-based herbicides approved for use on alfalfa (appendix N, table N-3). The identity of the other surfactants is a trade secret, but a goal in their development was reduced toxicity to aquatic life. Amphibians use a wide range of aquatic habitats for their breeding sites and could be exposed to glyphosate in surface water. However, impacts of the Deregulation Alternative on amphibians are unlikely because none of the glyphosate formulations that contain surfactants are approved for use over or near surface waters.

Although this raises the possibility that the Deregulation Alternative could potentially have adverse impacts on amphibian populations in watersheds where GT alfalfa is cultivated, runoff and erosional movement of soils with sorbed glyphosate and the surfactant should be limited to storm events (Borggaard and Gimsing, 2008). Where GT alfalfa is adopted, if farmers incorporate conservation measures such as no till or low till practices when planting GT alfalfa and during crop rotations, these measures should mitigate the likelihood of offsite migration of glyphosate and the surfactant by erosion or runoff. Because GT alfalfa generally will not require soil tilling, benefits to waters in the watershed could include decreased soil erosion, decreased sedimentation in runoff, and decreased turbidity in ponds, lakes, and rivers fed by surface waters. However, this benefit would only be realized if conservation tillage in GT alfalfa fields replaced fields that were tilled prior to their conversion. Because alfalfa is

not tilled during the three to eight years that the stand is hayed, alfalfa fields are often used to decrease erosion.

Threatened and Endangered Species

APHIS has no authority under the Plant Protection Act to regulate herbicide use associated with GT plants that are granted nonregulated status. The use of glyphosate is regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under FIFRA, EPA registers pesticides and prescribes the conditions for use of the pesticide. It is illegal to apply pesticides in a way that is inconsistent with the label. On the label, EPA includes instructions on how glyphosate herbicides can be applied. Directions include application restrictions that minimize impacts on nearby environments. EPA has determined that there is no unreasonable environmental risk if the user adheres to the labeled directions.

Individuals applying pesticides must do so in a manner not only consistent with Federal laws, but also consistent with State laws and regulation. In general, States have primary authority for compliance monitoring and enforcing use of pesticides by the label requirements. Violators of the regulations are liable for all negative consequences of their actions. Therefore, growers that use glyphosate are very likely to follow its label restrictions. The information in this section is provided to inform the public of the risks associated with glyphosate use on GT alfalfa.

EPA currently is conducting a registration review for glyphosate (U.S. EPA, 2009). EPA plans to conduct comprehensive human health and ecological risk assessments, including an endangered species assessment, for most uses and formulations of glyphosate, including risks due to surfactants included in formulations only for terrestrial applications. EPA estimates completing the registration review in 2015. The ecological risk assessment planned during the registration review will allow EPA to determine whether glyphosate's use has "no effect" or "may affect" federally listed threatened or endangered species or their designated critical habitat. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, EPA will consult with Fish and Wildlife Services, as appropriate, and may develop labels that restrict use or specify minimum separation distances between areas sprayed with glyphosate-based herbicides and habitats of T&E species.

There is a regional difference in the amount of herbicide used on alfalfa. In the eastern States, herbicide is applied to fewer acres of alfalfa than in the western States (NASS, 1999). In management systems and regions where little or no herbicide is used, an increased use of glyphosate would not result in a reduction in other herbicides because they are not used in the first place. Rather, adoption of GT alfalfa in these areas would result

in an increased use of herbicides, mainly glyphosate. Overall, FGI predicts about a 51 percent adoption rate for GT alfalfa (see appendix J). There are approximately 20 million acres of alfalfa fields in the United States; thus, with a 51 percent adoption rate, there would be approximately 10 million acres of GT alfalfa. The adoption rates are likely to be higher in the west where more herbicides are used on alfalfa, than in the east (see appendix J). The proportion of alfalfa acreage on which herbicides are used is 17 percent. Therefore, with a 51 percent adoption rate, 34 percent of the 20 million acres planted in alfalfa would be exposed to an herbicide, in this case glyphosate, for the first time. As a result, non-target plant species could be affected. As mentioned above, the effects on non-target plants exposed to glyphosate drift include the inability to photosynthesize, the inability to complete respiration, the inability to synthesize nucleic acids and amino acids, and impaired germination and/or growth characteristics (Blackburn and Boutin, 2003), all of which can result in plant death. Regarding impacts on animals, glyphosate has low toxicity to mammals, birds, and fish, and is slightly toxic to amphibians. Impacts on amphibians can be minimized if farmers incorporate conservation measures such as no till or low till practices when planting GT alfalfa and during crop rotations. EPA has determined that glyphosate use poses no unreasonable environmental risk if the user adheres to the labeled directions.

An adoption rate of 51 percent (or 10 million acres) GT alfalfa could diminish local or regional biodiversity. Fields previously planted with conventional alfalfa on which no herbicides were used and some weeds were tolerated would become more monotypic with the cultivation of GT alfalfa. Monotypic stands of alfalfa could result in a decline in the diversity of insect species that inhabit GT alfalfa fields, and ultimately a decline in the number of small mammal, bird, or bat species that feed on the types of insects that are associated with conventional alfalfa fields but not supported by GT alfalfa fields. However, the extent of this potential impact on biodiversity depends on the geographic region and spatial configuration of the fields converted to GT alfalfa. For example, if large, contiguous fields are converted to GT alfalfa, the impact on biodiversity would be greater than converting smaller, isolated fields.

USGS prepared an analysis and created a map of the regional distribution of glyphosate use using the 2002 agricultural census data and the typical use of glyphosate on crops over the period of 1999 to 2004 (USGS, 2010). To the extent that GT alfalfa changes this use pattern, it may change the potential exposure of T&E plants and animals to agricultural glyphosate use. This map represents glyphosate use patterns at a time prior to the original grant of nonregulated status to GT alfalfa. There was not a similar map available for the 2007 agricultural census data.

APHIS received 16 comments from GT alfalfa farmers during the public comment period for the Notice of Intent in January and February 2008 that provided quantitative details on their farming practices. These GT alfalfa farmers account for approximately 24,415 acres, or 12.2 percent of the 200,000 acres originally planted with GT alfalfa. The farmers applied either 1 or 2 applications of glyphosate on their GT alfalfa crop instead of using glyphosate during stand take-out. If these applications are ground applications, the total pounds of glyphosate (a.e.) applied to these 24,415 acres of GT alfalfa is between 37,843 (1 application) and 75,687 (2 applications) pounds. The maximum amount of glyphosate that can be applied to alfalfa under the EPA label to this same area is 146,490 lbs in one year. This maximum amount would only occur in the establishment year, if glyphosate was used for preplant ground preparation and used the maximum number of times during the season. In nonseeding years, the maximum amount that could be used on this same area is 109,868 lbs. EPA has determined that these maximum amounts will not present unreasonable risks to the environment. Therefore, fewer applications or less total glyphosate applied during the year as reported by the 16 alfalfa growers would not present an unreasonable risk.

According to these same growers of GT alfalfa, the amount of glyphosate applied to GT alfalfa is concurrent with the elimination of between two and four applications of other herbicides used during the production of non-GT alfalfa, including Arrow, Firestorm, Diuron, Velpar, Raptor, Pursuit, Poast, Treflan (all with greater environmental impact quotients [EIQs] compared to glyphosate [see table J-4 in appendix J]).

Under the Deregulation Alternative, instead of experiencing glyphosate exposure only during stand take-out, plant and animal species within and adjacent to GT alfalfa fields could be exposed to glyphosate up to four times a year (four applications of 1.5 lbs a.e./acre) via aerial drift and surface water runoff. To the extent that T&E species are found in or adjacent to alfalfa fields, they may also experience increased exposure to glyphosate. EPA considers the exposure of T&E species to glyphosate in the registration process. In some cases, risks of harm to T&E species within and adjacent to GT forage alfalfa fields might be reduced by the elimination of exposures to other herbicides (with greater EIQs compared to glyphosate), as discussed in chapter III and the technical report, *Potential Impacts on Wildlife, Amphibians, Plants, and Ecosystems from Increased Glyphosate and Other Chemical Usage* (appendix N).

In 2008, Monsanto Company released a report entitled, "Overview of the Analysis of Possible Risk to Threatened and Endangered Species Associated with Use of Glyphosate-Containing Herbicides in Alfalfa Production" (Honegger et al., 2008). The report included a risk assessment conducted to analyze the risk of direct effects of glyphosate and Roundup® agricultural herbicides to threatened and endangered

animal and plant species. This assessment follows in large measure the EPA overview document on endangered species effects determinations (U.S. EPA, 2004) and the EPA Environmental Fate and Effects Risk Assessment for the new uses of glyphosate on bentgrass (U.S. EPA, 2006a), from which the majority of the environmental fate input parameters and toxicity endpoints were taken to determine Risk Quotient (RQ) values. Based on the risk assessment, the report made the following conclusions, which are supported by an independent APHIS review (technical report, *Potential Impacts on Wildlife, Amphibians, Plants and Ecosystems from Increased Glyphosate and Other Chemical Use* (appendix N)):

- Terrestrial and aquatic T&E animals are expected to be at low risk of direct effects from exposure to glyphosate used in agriculture.
- T&E aquatic plants are expected to be at low risk of direct effects from exposure to glyphosate used in agriculture.
- Terrestrial and semi-aquatic T&E plants are expected to be at low risk of direct effects from exposure to glyphosate used in agriculture at ground application rates less than 3.5 lbs acid equivalent per acre (a.e./A).
- Terrestrial and semi-aquatic T&E plants may be at risk of direct effects from exposure to glyphosate used in agriculture at ground application rates greater than or equal to 3.5 lbs a.e./A and aerial application rates greater than or equal to 0.7 lbs a.e./A.

Because T&E plant species may be at risk from certain application rates of glyphosate in alfalfa production, a more detailed evaluation of the locations of T&E plant species relative to areas of alfalfa production was undertaken. Priester et al. (2007, 2008) determined the co-occurrence of T&E plant species and alfalfa production at the county level. Carr and Honegger (2008) carried this analysis further as they assessed the proximity of land areas where alfalfa could be grown (relevant land use) to sub-county locations of T&E plant species that had been identified as "requiring further analysis" in the county-level analysis. In this regard, the later work provided a more refined analysis. The sub-county species location data for the plant species identified in the county-level analysis were obtained from the FIFRA Endangered Species Task Force MJD (Multi-Jurisdictional Database) or from State data sources, where necessary. Geographic information system (GIS) tools were used to compare the locations of the relevant land use with the species locations to assess whether the species had overlap with or was within 250 feet of the relevant land use (Priester et al., 2007, 2008; Carr and Honegger, 2008).

The analysis determined that there are counties in 31 States where listed plant species may be in proximity to relevant land use — land that has been used historically, or is suitable for future alfalfa production. There are six animal species on Federal endangered or threatened lists that

currently utilize existing alfalfa fields as habitat. Two species, the peregrine falcon and San Joaquin kit fox use alfalfa fields peripherally for hunting of prey while other species, the giant garter snake, loggerhead shrike, Aluetian Canada goose, and Swainsons Hawk use alfalfa fields more frequently (Kuhn et al., 1996; Putnam, 1998). There are 78 plant species that have been observed to be proximate to relevant land use (Honegger et al., 2008).

Under the Deregulation Alternative, there is the possibility that some of these relevant lands will be cultivated with GT alfalfa. If so, individual plants of 78 T&E plant species are at risk for adverse impacts such as the inability to photosynthesize, the inability to complete respiration, the inability to synthesize nucleic acids and amino acids, and plant death if the individuals in these species are exposed to glyphosate and the rate of application is equal to or exceeds 3.5 lbs a.e./A or aerial application rates are equal to or exceed 0.7 lbs a.e./A (application rates that are regulated by EPA pursuant to FIFRA). Ground application rates of glyphosate on GT alfalfa currently allowed by EPA are lower (1.55 lbs a.e./A) than the application rate at which plant death might occur (3.5 lbs a.e./A). Thus, negative impacts on T&E plants due to glyphosate use on GT alfalfa are not likely to occur during ground applications. Negative impacts might occur following aerial applications, which are allowed at rates up to 1.55 lbs a.e./A and have a higher probability of drifting into neighboring fields. However, the risk due to aerial application is relatively low. Only two percent of glyphosate is applied aerially to all agricultural crops in the United States (U.S. EPA, 2009). Approximately three percent of glyphosate used in GT alfalfa is expected to be applied aerially. Further modeling analyzed the use of buffer zones between the GT alfalfa field and potential distributions of T&E plant populations and found that a 250-foot buffer negates any negative impacts on T&E plant species due to drift of glyphosate from aerial applications. Therefore, the impacts on T&E plants and biodiversity due to glyphosate use on GT alfalfa could be mitigated by following label use restrictions that maintain application rates below critical levels in the counties where listed species would be within 250 feet of GT alfalfa fields. Monsanto license agreements for the use of glyphosate require growers to check the Pre-Serve Web site (see http://www.pre-serve.org/Pre-Serve-B02/) before applying glyphosate. This Web site indicates where glyphosate use might affect endangered plant species. APHIS does not have the regulatory authority to mandate label use restrictions for glyphosate used on GT alfalfa fields, but will inform EPA of its findings for the agency's consideration in its registration review of glyphosate-based herbicides.

In conclusion, there are legal precautions in place (EPA label use restrictions) and "best practice" guidance to reduce the possibility of exposure and adverse impacts on T&E species from glyphosate application to GT alfalfa. EPA has considered potential impacts on T&E

species as part of their registration and labeling process for glyphosate, and adherence to EPA label use restrictions by the pesticide applicator will ensure that the use of glyphosate will not adversely affect T&E species or critical habitat. Based on these factors and the legal requirements for pesticide applicators to follow EPA label use restrictions, APHIS has determined that the use of EPA-registered glyphosate for alfalfa production would not adversely impact listed species or species proposed for listing and would not adversely impact designated critical habitat or habitat proposed for designation.

No Action Alternative

Under the No Action Alternative, approximately 200,000 acres of GT alfalfa would remain in production, and new planting of GT alfalfa would be regulated. The rates and volumes of glyphosate applications would remain unchanged in the context of application to alfalfa fields. In the cases that the No Action Alternative precluded conventional alfalfa fields from being converted to GT alfalfa, this would result in the continued use of an array of other herbicides that may be more toxic and persistent than glyphosate. The herbicides used in conventional alfalfa systems have higher EIQs than glyphosate (except for the herbicide Eptam [EPTC]) (Kovach et al., 1992; see table N-48 in appendix N). Therefore, the No Action Alternative has the potential to restrict the replacement of these herbicides with a more environmentally benign alternative. However, the impact of this alternative on specific plant species is unknown because the herbicides used in conventional alfalfa systems have different effects on different plant species. The herbicides currently used in conventional alfalfa production kill particular groups of plants such as annual grasses, perennial grasses, or broadleaf weed species. Glyphosate, on the other hand, is a single broad spectrum herbicide and is toxic to the vast majority of plant species.

The impacts on animals from the exposure to glyphosate due to GT alfalfa or non-GT alfalfa would be the same as they are now. Any effects due to glyphosate use in conventional alfalfa settings, as well as in other agricultural systems, will occur to the extent they occur now. No acute or chronic risk to birds, mammals, terrestrial invertebrates, aquatic invertebrates, or fish due to glyphosate use associated with GT alfalfa would be expected under this alternative. Any effects due to glyphosate use in conventional alfalfa settings, as well as other agricultural systems, will still occur. Where GT alfalfa replaces conventional alfalfa, there might or might not be a shift away from more environmentally harmful herbicides toward glyphosate in order to control weeds. Glyphosate has a lower EIQ and is considered more environmentally benign than the herbicides it replaces in alfalfa production (Kovach et al., 2007; table N-50).

If the current GT alfalfa fields were managed using ground applications of glyphosate, there likely would be no consequential impacts on T&E plant species from the use of glyphosate herbicides associated with GT alfalfa production under the No Action Alternative. Any impacts on T&E species associated with the current use of glyphosate on conventional alfalfa fields, and the impacts on T&E species associated with the current uses of any other herbicide used on conventional alfalfa fields, would still occur.

Isolation/Geographic Restriction Alternative

This alternative would likely result in more acres of GT alfalfa cultivation and increased glyphosate application compared with the No Action Alternative. However, less GT hay may be planted than under the Deregulation Alternative. This is a result of the restrictions on GT hay production in the Tier III areas. The areas in Tier III, where GT hay is not permitted, will be more similar to the No Action Alternative. In other areas, the effects on biological resources will be similar to the Deregulation Alternative.

3. Glyphosate and Other Herbicide Use and Comparative Toxicity

Several analyses of pesticide use concluded that herbicide use has been reduced due to the adoption of herbicide-tolerant crops (Brimner et al., 2005; Fernandez-Cornejo, 2006; Gianessi and Reigner, 2006; Kleter et al., 2007; Sankula, 2006; Johnson et al., 2008). Several analyses of pesticide use concluded that total amounts of herbicide application per acre per year has increased in recent years, possibly due to development of herbicide-resistant weeds (Benbrook, 2004, 2009; Young, 2006; Johnson et al., 2009), with increased numbers of glyphosate applications per year per crop acre and increased amount per application per crop acre. Despite disagreement regarding the overall quantity of herbicide application, all the studies agree that herbicide use has shifted toward glyphosate. Using standardized methods for ranking environmental impact, some researchers have concluded that glyphosate is less harmful to the environment than many other herbicides (Kleter et al., 2007).

Weeds in conventional alfalfa cannot be managed completely with glyphosate and are instead controlled using a cocktail of other herbicides (based on OMAFRA, 2008; Canevari et al., 2007b; Rogan and Fitzpatrick, 2004; Loux et al., 2007). The 20 other herbicides commonly used on alfalfa have varying chemical fates. In general, most were more persistent and were characterized by higher mobility in soils, making them more apt to continually contaminate surrounding water systems. Also, most have been found to exhibit a higher measured EIQ relative to glyphosate and have a greater general environmental impact (Kovach et al., 2007; see table N-48 in appendix N).

It is clear that glyphosate use is increasing and that glyphosate is more toxicologically and environmentally benign than most of the pesticides

that glyphosate may be replacing. In general, glyphosate has a low toxicity to terrestrial animals; however, dose-response assessment for aquatic animals indicates that some fish species such as salmonids are more sensitive to glyphosate than other species. In addition, end-use herbicide formulations, containing surfactants to enable greater leaf penetration may result in a higher toxicity to amphibians (appendix N, section 4.6), aquatic invertebrates (appendix N, section 4.7), and fish (appendix N, section 4.8).

Giesy et al. (2000) reviewed chronic studies of glyphosate acid toxicity to soil microbes (appendix N, section 4.5). Microbial activities including degradation of leaf litter, cellulose, starch, and protein showed the least sensitivity to glyphosate, while ammonification, denitrification, nitrification, and nitrogen fixation were more sensitive. However, one 3-day nitrification study produced no observable adverse effects up to a concentration of 76.7 mg a.e./kg. Alfalfa is a legume that forms a symbiotic relationship with the nitrogen-fixing bacterium, *Sinorhizobium meliloti*. The result is the conversion of atmospheric nitrogen to fixed nitrogen in the soil, resulting in a net increase in available nitrogen to the soil. GT alfalfa sprayed with glyphosate does not alter the symbiotic association with *S. meliloti* and does not negatively affect growth or yield of soybeans. However, root nodulation (indicator of the bacterium biomass) is reduced and nitrogen from the soil, rather than from the atmosphere, appears to be used for growth, suggesting that glyphosate use could result in the plant becoming increasingly dependent on soil nitrogen (Bohm et al., 2009).

Several other studies also have examined possible effects of either GT crops or glyphosate applications or both on soil microbial communities (see appendix N, section 4.5.5). Taken together, the available research indicates that microbial communities associated with glyphosate-treated GT crops may differ from microbial communities associated with conventional crops. Reported observations include apparent stimulation of the growth of disease-causing *Fusarium* spp.; reduction in disease antagonizing *Pseudomonad* spp.; reduction in the availability and uptake of soil Mn, a nutrient involved in disease resistance and other plant physiological functions; and reduction in nitrogen fixation. However, as noted by Powell and Swanton (2008), there remains limited evidence of a causative link between glyphosate and elevated levels of crop disease, and Bohm et al. (2009) noted that reduced nitrogen fixation did not affect grain yield. Because the interactions between herbicides, plants, and microbial communities are varied and complex, they are difficult to generalize and may vary on a case-by-case basis (Powell and Swanton, 2008).

Deregulation Alternative

The Deregulation Alternative for GT alfalfa would result in a further shift in herbicide use toward glyphosate. There is contradictory evidence on the effect GT alfalfa would have on the overall quantity of herbicide application. It is possible that the deregulation of GT alfalfa would lead to a decrease or an increase in the overall applied amount of other herbicides that have a higher EIQ than glyphosate. This depends on several factors, such as the exact adoption rate of GT alfalfa (see discussion in section 1.3 of the technical report, *Potential Impacts on Wildlife, Amphibians, Plants, and Ecosystems, from Increased Glyphosate and Other Chemical Usage* [appendix N]).

Based on the analyses that find glyphosate to be generally less harmful to the environment than the herbicides it replaces in GT alfalfa systems, this shift has the potential to result in lower general environmental impacts in areas where GT alfalfa replaces conventional alfalfa fields on which herbicides with higher EIQs currently are used. Therefore, for possible benefits of the Deregulation Alternative to be realized, GT alfalfa fields would have to replace the conventional alfalfa fields.

As mentioned above, in management systems and regions where little or no herbicide is used, the Deregulation Alternative would result in an increased use of herbicides, mainly glyphosate, if farmers adopted GT alfalfa. FGI predicts about a 51 percent adoption rate of GT alfalfa. The proportion of alfalfa acreage on which herbicides are used is 17 percent. Therefore, with a 51 percent adoption rate, 34 percent of the 20 million acres planted in alfalfa would be exposed to an herbicide, in this case glyphosate, for the first time. Adverse impacts on non-target plants, including plant death, could occur from spray drift. Glyphosate has low toxicity to mammals, birds, and fish, and is slightly toxic to amphibians. Impacts on amphibians can be minimized if farmers incorporate conservation measures such as no till or low till practices when planting GT alfalfa and during crop rotations. EPA has determined that glyphosate use poses no unreasonable environmental risk if the user adheres to the labeled directions.

An adoption rate of 51 percent (or 10 million acres) GT alfalfa could diminish local or regional biodiversity, including a decline in the diversity of insects, and the numbers of small mammals, birds, and bats. However, the extent of this potential impact on biodiversity depends on the geographic region and spatial configuration of the fields converted to GT alfalfa. For example, if large, contiguous fields are converted to GT alfalfa, the impact on biodiversity would be greater than converting smaller, isolated fields.

Also, the Deregulation Alternative would increase the use of other herbicides for stand removal of GT alfalfa. In conventional alfalfa fields, glyphosate is often used to remove alfalfa after three to eight years when it has become vulnerable to weeds and thinning. Therefore, for stand removal, adoption of GT alfalfa would likely result in a shift from glyphosate to other herbicides for stand takeout once every three to eight years.

No Action Alternative

Under the No Action Alternative, non-GT alfalfa would continue to be cultivated using conventional herbicide regimes or no herbicides at all, and glyphosate would continue to be used for stand take-out for non-GT alfalfa. There would be continued application of the herbicides commonly used on alfalfa, most of which have a higher measured EIQ (appendix N, table N-48). Glyphosate application on the approximately 200,000 acres currently planted as GT alfalfa would remain the same.

Isolation/Geographic Restriction Alternative

Like the Deregulation Alternative, the Isolation/Geographic Restriction Alternative could result in an increased use of herbicides, mainly glyphosate, in management systems and regions where little or no herbicide is used, if farmers adopted GT alfalfa. Conventional alfalfa fields that currently are not exposed to herbicides would be exposed to an herbicide, in this case glyphosate, for the first time, if they are converted to GT alfalfa. Adverse impacts on non-target plants, including plant death, could occur from spray drift. Glyphosate has low toxicity to mammals, birds, and fish, and is slightly toxic to amphibians. Impacts on amphibians can be minimized if farmers incorporate conservation measures such as no till or low till practices when planting GT alfalfa and during crop rotations. EPA has determined that glyphosate use poses no unreasonable environmental risk if the user adheres to the labeled directions.

Increasing GT alfalfa acreage could diminish local or regional biodiversity, including a decline in the diversity of insects and the numbers of small mammals, birds, and bats. However, the extent of this potential impact on biodiversity depends on the geographic region and spatial configuration of the fields converted to GT alfalfa. For example, if large, contiguous fields are converted to GT alfalfa, the impact on biodiversity would be greater than converting smaller, isolated fields.

This alternative may lower general environmental impacts on biological resources when there is a shift away from the use of other herbicides, if those are replaced by glyphosate. This effect would be limited to the areas where GT alfalfa production is allowed and where other herbicides are

used in conventional alfalfa systems. This alternative would increase the use of some herbicides for stand removal of GT alfalfa. In conventional alfalfa fields, after three to eight years, alfalfa stands are usually thinning and vulnerable to weeds, so the stand is removed by killing the alfalfa by either plowing or herbicide application or both (Rogan and Fitzpatrick, 2004). For stand removal, adoption of GT alfalfa would likely result in a shift from glyphosate to other herbicides for stand take out once every three to eight years due to the inability of glyphosate to remove stands of GT alfalfa.

D. Socioeconomic Impacts on Domestic Non-GT Alfalfa Markets

The discussion throughout this section is formed in the context of the Deregulation Alternative. The discussions under each heading are not broken down into a Deregulation Alternative, a No Action Alternative, or a discussion of the Isolation/Geographic Restriction Alternative. Instead, the discussion of the impacts of the alternatives occurs at the end of this section. Unless explicitly defined, all of the following considerations can be assumed to be related to the Deregulation Alternative.

1. Conventional Alfalfa Farming

Evidence of farming distinctions between GT alfalfa and conventional alfalfa come mostly from field trials and from those farmers that planted GT alfalfa during the time period in which it was deregulated (between June 2005 and March 2007). During this period over 200,000 acres of GT alfalfa are estimated to have been planted (Putnam, 2007). Much of the latter type of evidence is anecdotal, and based on the observation of one or a few GT alfalfa fields.

Canevari (2007) presents a small (non-random) survey with 24 growers in addition to a few consultants, seed and marketing dealers, and university faculty which investigated the control of weeds with glyphosate in GT alfalfa. Users of GT alfalfa were generally satisfied with weed control in GT alfalfa. According to this paper, GT alfalfa would reduce the costs of herbicides used while improving the quality of alfalfa hay due to lesser weed content. Miller et al. (2006) refer to field trials done at the University of Wyoming and University of Nebraska, and suggest the main features of GT alfalfa are its "ease of use, flexibility, and broad spectrum weed control." Individual farmers that had experimented with GT alfalfa after initial deregulation and that sent comments to APHIS provide additional reports, including that of possible increase in yields (due to lesser stunting caused by use of other herbicides), eliminating the use of other, more toxic herbicides, and a reduction in herbicide costs.

Comparisons of yield and quality of GT alfalfa and conventional alfalfa hay typically do not show systematic differences (Putnam, 2008).

Alfalfa hay yield is influenced by a wide range of factors, including seed variety, proper planting and establishment, climate, soil and moisture conditions, and weed and insect control (Dixon et al., 2005). Hundreds of alfalfa varieties have been developed for use in North America, including a large number of GT alfalfa cultivars (cultivated plants selected because of its useful characteristics). These varieties are adapted to the various major alfalfa production zones and all contain genes selected for high yield and resistance to diseases, insects, and nematodes (Van Deynze et al., 2004). There is no conclusive evidence on whether GT alfalfa presents higher or lower yields than non-GT alfalfa. As shown in table 4-4, variety trial results do not indicate any systematic hay yield advantage or disadvantage for GT alfalfa hay cultivars.

Table 4-4. Comparative Variety Trial Yield Results.

Variety Trial Location and Date	Average Annual Yield, All GT Alfalfa Varieties (Tons/Acre)	Average Annual Yield, All Varieties (Tons/Acre)
Illinois (Freeport), 2007[1]	6.10	6.17
Iowa (Ames), 2007[2]	4.61	4.64
Kansas (Thomas Co.), 2007[3]	8.22	8.41
Nebraska (Havelock), 2006[4]	5.04	5.12
New York (Cobleskill), 2006[5]	2.6	2.9
South Dakota (Brookings Co), 2006[6]	3.81	3.86
Montana (Huntley), 2006[7]	6.24	6.18
Michigan (East Lansing), 2006[8]	5.48	5.03

[1] Source: http://vt.cropsci.uiuc.edu/forage.html
[2] Source: http://www.croptesting.iastate.edu/alfalfa/results/2007-alfalfa.xls
[3] Source: http://kscroptests.agron.ksu.edu/07/07alf/7a-thi6.asp?Loc=thi6
[4] Source: http://varietytest.unl.edu/alfalfa/2006/Roundup-Havelock2006table06.xls
[5] Source: http://plbrgen.cals.cornell.edu/programsandprojects/departmental/foragetest/alfalfa06.htm
[6] Source: http://plantsci.sdstate.edu/forages/Alfalfa%20Trials/SD_Alfalfa_Trials.html
[7] Source: http://animalrangeextension.montana.edu/Articles/Forage/Main-varieties.htm
[8] Source: http://web1.msue.msu.edu/fis/research/past%20trials/08alfsum_%20tables.pdf

Dr. Daniel Putnam, a leading alfalfa research agronomist at the University of California-Davis, has been conducting variety trial testing of GT and other alfalfa cultivars throughout California. Putnam (2008) notes that in general, the yield performance of GT alfalfa cultivars (as a group) are no different than what could be expected from similar conventional lines of equal fall dormancy characteristics. Moreover, he notes that there are differences between conventional varieties that are due to fall dormancy and due to the superiority of individual cultivars within a dormancy group, but the range of variation observed in conventional cultivars is similar to the range of variation observed in GT cultivars (Putnam, 2008).

With respect to quality, conventional alfalfa hay varies in terms of weed content, and so it is difficult to make direct comparisons between GT and conventional alfalfa hay from a weed content standpoint. Putnam (2008) argues that while the relative weed-free nature of GT alfalfa tends to give it an edge in terms of quality over conventional alfalfa, one cannot systematically attribute higher quality to GT alfalfa over conventional alfalfa, since sometimes conventional weed control systems can be quite effective. However, Van Deynze et al. (2004), Dillehay and Curran (2006), and Rankin (undated) all report better weed control in GT alfalfa using the glyphosate weed management system, suggesting there is the potential for higher quality forage from GT alfalfa.

Based on the discussion above, scenarios were developed in the Technical Report *Changes in the Economics of Alfalfa Farming with Deregulation of Glyphosate-Tolerant Alfalfa* (appendix K) to illustrate the potential impact of adoption of GT alfalfa by conventional alfalfa farmers. They should not be interpreted as likely differentials in costs and returns between conventional and non-GT alfalfa in any particular setting, since the differences in management systems between the two varieties are likely to involve other factors not taken into consideration in the scenarios (such as the time spent by farmers with weed control) and the impact of the deregulation of GT alfalfa on the prices paid for alfalfa of various qualities is ignored. In addition, results would be very different under other circumstances (e.g., regions where no herbicide is used in alfalfa production). However, given the importance of differences in seed, herbicide use and potentially in alfalfa forage quality between conventional and GT alfalfa, these scenarios provide insight into the economic incentives for adoption or not of GT alfalfa.

The scenarios are based on the same University of Wisconsin Integrated Pest Crop Management Roundup Ready® Alfalfa Calculator used in chapter III and details are in appendix K. No differences in yield are assumed between GT alfalfa and non-GT alfalfa, and no additional differences in management systems are assumed. Results are shown for the seeding year.

Based on the existing literature, the following values (sometimes ranges) are adopted in the scenarios below. This information can also be found in section III.C.1.

- *GT alfalfa seed costs* — Sold at U.S. $6-7.50/lbs during its deregulation period, including its technology fee of $125/50/lbs bag east of the Rocky Mountains, and $150/50/lbs bag west of the Rocky Mountains (http://www.purdue.edu/UNS/x/2007a/070323NeesAlfalfa.html; http://ipcm.wisc.edu/WCMNews/tabid/53/EntryID/208/Default.aspx; http://www.roundupreadyalfalfa.com/home.aspx?page=valuecalculator).

- *Glyphosate costs* — Prices have ranged from $56.30 per gallon in 1998 (USDA NASS, 1998) to $28.90 per gallon in 2007 (USDA NASS, 2007); 2008 prices of glyphosate ($40.50 per gallon) seem to have rebounded from a few years of reduced prices (USDA NAAS, 2008). The number of glyphosate applications used in the scenarios is one or two per year at 22 ounces per acre.
- *Weed content* — No glyphosate resistance is assumed and only glyphosate is used as an herbicide. Improvements in weed content are built into the scenarios as increases in the quality of hay (for example, from good to premium or to supreme) with reflections on prices, according to USDA available alfalfa hay prices for the relevant locality and year.

In all scenarios summarized in table 4-5, there would be an increase in returns over total costs with the use of GT alfalfa already in the seeding year, as long as the cost of the technology fee is distributed throughout the life of the stand, and in two of the four scenarios even if the cost of the technology fee were fully paid for in the seeding year. Profit per acre would be higher for GT alfalfa in years following that of the seeding year. The increased returns are the result of lower herbicide costs, improved hay quality, or both.

Again, the comparison above should not be interpreted as suggesting that GT alfalfa is necessarily superior to other varieties in the returns it provides farmers. However, under certain circumstances this would likely be the case, and GT alfalfa would be expected to be adopted to the extent that it is able to provide farmers with advantages over other varieties.

Table 4-5. Cost Scenarios for GT Alfalfa.

		Technology fee paid in first year	Technology fee distributed throughout life of stand	Two Apps[1] ($35 /Gallon)		Two Apps ($40/Gallon)		One App, Improved Hay Quality ($110/Ton: a 10% Price Increase[2], $40/Gallon)	
	Conv[3]	GT	GT[4]	Conv	GT	Conv	GT	Conv	GT
Seed cost/50 lbs ($)	$200	$250	$250	$200	$250	$200	$250	$200	$250
Lbs of seed per acre	12	12	12	12	12	12	12	12	12
Tech. fee/bag ($/bag)	$0	$125	$125	$0	$125	$0	$125	$0	$125
Yld seeding yr (t/a DM)[5]	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5
Herbicide cost ($/acre/application)	$20	$6	$6	$20	$6	$20	$7	$20	$7
Herb. app. cost ($/acre)	$10	$10	$10	$10	$10	$10	$10	$10	$10
Number of herb. apps	1	1	1	2	2	2	2	1	1
Value of ease of roundup use ($/acre)	$0	$0	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Yield depression from pursuit/raptor (t/a DM)	0.3	0	0	0.3	0	0.3	0	0.3	0
Expected stand life (yrs including seeding year)	3	3	3	3	3	3	3	3	3
Value of hay per ton DM)	$100	$100	$100	$100	$100	$100	$100	$100	$110
Fixed costs/acre/year	$180	$180	$180	$180	$180	$180	$180	$180	$180
Harvesting costs per acre per harvest	$35	$35	$35	$35	$35	$35	$35	$35	$35
Number of harvests	2	2	2	2	2	2	2	2	2

Table 4-5, continued

Seeding Year Production Costs/Results									
	Conv	GT	GT[4]	Conv	GT	Conv	GT	Conv	GT
Seed cost (prorated + tech fee) per acre[5]	$16	$50	$30	$16	$50	$16	$50	$16	$50
Total seed and herb. cost per ton of hay	$14	$19	$13	$23	$23	$23	$24	$14	$19
Total cost/ ton hay- seeding yr	$86	$90	$85	$95	$95	$95	$95	$86	$91
Profit/ acre - seeding year	**$50**	**$34**	**$54**	**$17**	**$18**	**$17**	**$16**	**$50**	**$68**

Source: first 2 data columns: Integrated Pest Crop Management, U. of Wisconsin; other columns elaborated from base numbers.

[1]Apps = glyphosate applications; 2 applications in these columns contrasts with the single application of the first two columns

[2] Data from various Midwestern markets suggest $100/ ton was the price paid for good quality hay within the last year, while premium quality hay would go for 15-35% more, so the quality improvement assumed is quite modest.

[3] Conventional

[4] Original numbers - shown in the first two columns - prorate seed cost over life of stand but leave full technology fee in seeding year. This assumption is maintained in this table, except for in the third column where the technology fee is prorated as well.

[5] t/a DM = Tons per acre Dry Matter

Supply of Conventional Alfalfa for Forage

The discussion above suggests a possible reduction in average costs necessary to produce alfalfa of a given quality or an increase in the quality of alfalfa hay at a given production cost. To the extent that GT alfalfa is adopted by conventional alfalfa farmers the overall impact could be an increase in the supply of high quality alfalfa and a possible reduction in the supply of low quality alfalfa.

Demand of Conventional Alfalfa for Forage

The main possible impact of GT alfalfa deregulation on the domestic demand for conventional alfalfa hay depends on the existence of a GT-sensitive market among domestic consumers of alfalfa hay. If glyphosate tolerance is seen as an undesirable quality in alfalfa hay by some, these consumers would seek to substitute their purchases by: (a) seeking imported non-GT alfalfa hay; (b) seeking some form of non-GE certification; (c) using non-GE hay based on other crops; or (d) shifting to organic alfalfa hay to minimize the intended presence of GT alfalfa.

The extent to which GT alfalfa deregulation would impact the domestic demand for conventional alfalfa hay is not clear. As discussed in chapter III, existing domestic consumer preference for non-GE foods does not necessarily translate to a reduction in domestic demand under the possibility of AP of genetically engineered content. Other genetically engineered crops (e.g., corn, soybeans, and canola) have been deregulated in the United States for a number of years with no substantial drop in demand for conventionally produced dairy products or meat, the main source of demand for alfalfa hay (Fernandez-Cornejo and Caswell, 2006; Putnam, 2005). Potential impacts on export markets are addressed further below.

Conventional Alfalfa Seed Markets

The main possible advantage of GT alfalfa for seed production is in weed control. Canevari (2007) notes that the ability to control post-emergence dodder (a genus of parasitic plants) before seeding and without injury to alfalfa "would be a significant breakthrough." However, as noted in the cost studies reported in chapter III, weed control, although fundamental for seed acceptance in the market, is a lesser cost in seed production than other operational costs such as pollination and insect control.

The market for seed would likely follow the tendency of the market for alfalfa hay, since it is a derived demand. As the quantity of alfalfa hay produced and consumed is expected to increase in a scenario of GT alfalfa deregulation, so would the demand for GT alfalfa seeds. The supply of

conventional seeds would be partially occupied by GT alfalfa, according to demand.

Conventional alfalfa seed markets could also be impacted by the potential for unintended AP of genetically engineered content in conventional alfalfa seed fields. At present, both the National Alfalfa and Forage Alliance (NAFA) and the Association of Official Seed Certifying Agencies (AOSCA) have developed stewardship programs for production of non-GMO seed. These programs could, although not necessarily, increase the cost of conventional seed production Lowry (2010). Because demand for alfalfa seed is relatively inelastic to prices, the impact on demand of increased costs is likely to be small. However, an increase in the share of the domestic conventional seed market supplied by imported seed is possible.

The above discussion summarizes the analysis developed in the technical report *Economic and Social Impacts on Conventional and Organic Farmers of Deregulation of Glyphosate-Tolerant Alfalfa*. For further analysis and details on the potential impacts of GT alfalfa deregulation on the supply and demand of conventional alfalfa hay and seed, see the technical report in appendix S.

2. Impacts on Domestic Organic Alfalfa Markets

Organic alfalfa would not be able to adopt GT alfalfa because genetic engineering is an excluded method, and GE crops may not be certified as organic. However, organic alfalfa markets could be impacted by the AP of genetically engineered content in alfalfa hay and seed fields. USDA organic certification does not require testing for GE content and focuses on the process used to grow the product—the farming operations—rather than on content of the product itself. From the preamble of the final rule for the National Organic Program:

"Certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the [Organic Foods Protection] Act and the [National Organic Program] regulations. This regulation prohibits the use of excluded methods in organic operations. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods [including genetically engineered crops] as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation."

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Organic alfalfa producers could be negatively impacted by GT alfalfa deregulation, however, to the extent that: a) the demand (sales) of organic products would decrease under the potential AP of genetically engineered content in organic alfalfa; and b) current organic practices and GT alfalfa stewardship are insufficient to minimize the AP of genetically engineered content in non-GT alfalfa. Under these circumstances, organic alfalfa farming production costs could increase and returns could decrease because of:

(1) *Avoidance costs* — If organic alfalfa producers want to avoid unintended presence, whether through adopting buffer zones or requiring testing for GT alfalfa traits in alfalfa seeds used for production, there is a cost of avoidance that would have to be incorporated into production costs.

(2) Loss in production — If organic alfalfa producers cannot avoid unintended presence above those levels found acceptable by the market, any alfalfa seeds or forage previously destined to those markets that contain unintended presence of GT alfalfa traits would have to be shifted to markets (i.e., non-organic) that could pay a lower price.

On the first condition, the demand for organic alfalfa is a demand derived from the demand for organic dairy and beef. Organic dairy represented nearly 90 percent of the total sales value of the combined U.S. organic dairy and meat market in 2006 (Organic Trade Association, 2007) and is by far the main client for organic alfalfa hay. As in the case of conventional foods, although there is evidence of consumer preference for foods free of genetically engineered content, the extent to which this preference would translate to decreased demand (sales) for organically certified products under a scenario of GT alfalfa deregulation is not clear. The market for organic products is likely more sensitive to the presence of genetically engineered content in foods than the conventional market, given evidence that the preference for GE-free foods could be correlated with the growth of organic food markets (Anderson et al., 2006; Dhar and Foltz, 2005; Larue et al., 2004). It also seems to be the case that non-genetically modified organism (GMO) labeling initiatives have been developed to cater to a demand largely overlapping that for organic foods (Non-GMO Project, 2010b). However, National Organics Program (NOP) certified foods have had to deal with the past deregulation of other feed crops such as soybeans and corn and yet continued to grow at a rapid rate. In addition, to the extent that consumers perceive organic products as having less genetically engineered content (limited to AP), there is actually a possibility of an increase in the consumption of organic foods from organic alfalfa fed dairy and beef cattle.

The second condition is that current organic practices and/or GT alfalfa stewardship measures are insufficient to minimize cross-fertilization. The likelihood of gene flow between GT alfalfa fields and non-GT alfalfa fields is discussed in section IV.B. Although gene flow is more likely to seed fields than to hay fields, both NAFA and AOSCA have developed stewardship programs to minimize any unwanted AP of genetically engineered content in alfalfa seed fields and to safeguard the domestic production of alfalfa seeds for GE sensitive markets. In addition to these stewardship programs, organic certification under the NOP requires that organic producers develop organic system plans, outlining steps to avoid contact or mixing with unapproved substances for use in organic production systems. Under the NOP, a buffer zone must be sufficient in size or have other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact with prohibited substances applied to adjacent land areas.

Typically, more than one method is used under organic practices to prevent unwanted material from entering their fields including; isolation of the farm, physical barriers or buffer zones between organic production and non-organic production, as well as formal communications between neighboring farms (NCAT, 2003). Farmers using organic methods are requested to let neighboring farmers know that they are using organic production practices and request that the neighbors also help the organic farmer reduce any AP (NCAT, 2003; Krueger, 2007). The organic plan used as the basis for organic certification should also include a description of practices used to prevent or reduce the likelihood of unwanted substances, like GE pollen or seed, at each step in the farming operation, such as planting, harvesting, storing, and transporting the crop (Riddle, 2004; Krueger, 2007; Kuepper et al., 2007). Organic plans should also include how the risk of GE pollen or seed co-mingling will be monitored (Kuepper et al., 2007). Practices that help organic farmers minimize the risk of unintended GE presence in their field include: (1) Use seed that is from a known, non-GE stock (lists of organic seed suppliers can be found at www.attra.org); (2) Use temporal buffers such that alfalfa being produced using organic methods is receptive to pollen at a different time of year than when the neighboring alfalfa flowers; (3) Harvest alfalfa at ten percent bloom to reduce the number of flowers available for pollination (however, harvesting alfalfa prior to formation of seed (approximately four weeks after bloom) would also minimize the potential of gene flow into an organic alfalfa forage field; see table 4-3); (4) remove beehives surrounding alfalfa fields prior to alfalfa blooming period; (5) Maintain physical isolation from GT alfalfa (either through distance or natural barrier (e.g., tree rows)); and (6) Plant alfalfa at the edge field to act as a trap for GE pollen and harvest these buffer rows separately.

Still on the demand side, in addition to the possible segmentation of the organic alfalfa markets in GT sensitive and non-GT sensitive segments, demand for organic alfalfa hay could decline under two possible scenarios:

(1) If organic dairy and meat farmers consider shifting to conventional farming due to the decreased costs of high quality conventional alfalfa (and presumably increased returns).

(2) If the decreased costs of high quality conventional alfalfa are transmitted to conventional dairy and meat costs, increasing the price differential between conventional and organic dairy and meat, stimulating organic dairy and meat consumers to purchase conventional products.

There is no evidence that the first scenario would occur. To the extent that organic farmers have chosen organic production out of philosophical values and/or to supply the organic alfalfa market, the economic incentive to switch to conventional farming should not influence this decision.

The likelihood of the second scenario is also not clear. A report by the U.S. General Accounting Office (2001) studied the factors influencing farm and retail dairy prices. The report notes that changes in milk production costs do not necessarily reflect in changes in retail prices of dairy. Farmer milk prices represent roughly 40 percent of retail milk prices and are affected by federal and state programs establishing minimum prices. The process of transmission of dairy farms costs to prices is not a simple one to determine. In the case of meat, alfalfa is likely a lower share of feed costs in cow-calf production than it is in dairy production since the main source of feed is grazing (Short, 2001). As cattle move on to feedlots (sometime through stocker operators), feed becomes mostly grain based ration. Short (2001) argues that prices paid for cattle tend to be similar across the country, despite differences in cow-calf production costs, because cattle are routinely transported. This suggests that any transfer of cost changes to prices down the chain would be unlikely.

To the extent that any of the two scenarios above do occur, the demand for organic products could decline, even in the absence of GT sensitivity in sales.

To the extent that some unwanted AP of genetically engineered content does occur in organic alfalfa fields and to the extent that this increases costs to organic producers or lead to market losses, the impact on supply and demand would be best understood by imagining two separate market segments: a GT-sensitive market (a market that will not accept unintended AP of GT alfalfa in the feed used along the production chain of organic products and would require testing to ensure undetected presence of GT alfalfa content in feed) and a non-GT sensitive one (a market that will not require routine testing and would tolerate unintended AP of GT alfalfa in

the feed used along the production chain of organic products without requesting routing testing). If there is loss in production destined to the GT-sensitive market or an increase in costs of supplying that market, supply would be reduced, as indicated by a leftward shift of the supply curve. If some farmers redirect their production to non-GT alfalfa sensitive markets due to the presence of GT alfalfa, or because they are not able to continue supplying the existing market given the increased costs, supply to the non-GT alfalfa sensitive market would expand, as indicated by an outward shift of the supply curve. To the extent that there is any decrease in the demand for organic products, the resulting impact would be illustrated by figure 4-1 below

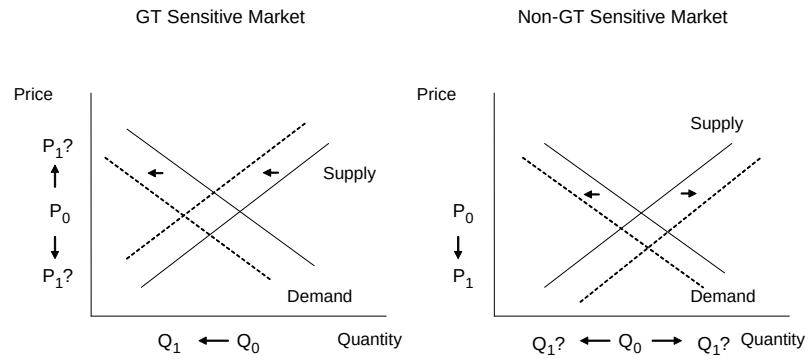

Figure 4-1. Impact of GT alfalfa deregulation on organic alfalfa for forage with glyphosate-sensitive domestic markets and decreased demand.

The result of GT alfalfa deregulation under this scenario would depend on the extent of the GT sensitive market within the organic market. The larger the GT-sensitive market is, the more likely quantities sold would decrease, although with an unclear effect on prices. The larger the GT alfalfa-tolerant market is, the more likely prices would decrease, but with unclear effect on quantities.

A numerical estimation of the impact GT alfalfa deregulation under the above scenario is not possible given the lack of available information. As previously argued, it is unclear that the demand (sales) for organic products would decrease at all, as well as the extent to which AP of genetically engineered alfalfa would occur in organic alfalfa fields. In addition, a quantification of the impacts would require additional information regarding the share of organic sales that is sensitive to unintended presence of GT alfalfa in feed, and what the sensitivity of the

demand and supply curves to changes in prices (the price-elasticity of demand and supply) is, since this would determine how much the price would change with shifts in the supply and demand curves.

The discussion above is largely a summary of the analysis done in the technical report, *Economic and Social Impacts on Conventional and Organic Farmers of Deregulation of Glyphosate-Tolerant Alfalfa.* For an expanded and more detailed analysis, see appendix S.

3. Impacts on Dairy and Beef Markets

As previously discussed, although there is some evidence of consumer preference for non-GE foods in the United States, other genetically engineered crops (e.g., corn, soybeans, and canola) have been deregulated in the United States for a number of years with no substantial drop in demand for conventionally produced dairy products or meat (Fernandez-Cornejo and Caswell, 2006; Putnam, 2005). The extent to which consumer preferences for non-GE food translates to reduced demand (sales) of organic products, under the possible AP of genetically engineered content in feed is unclear. However, to the extent that a reduction in the domestic demand for dairy, meat and livestock and pet feed that is perceived as having been produced with GT alfalfa does occur, and to the extent that organic markets are unable to retain confidence of consumers in existing process based standards, the result could be an increase in imports or increased demand for testing in niche markets, as reflected in recently developed private standards and labels for food free of genetically engineered content.

On the supply side, alfalfa is likely a considerable share of dairy feed costs. Short (2004) reports hay and straw (presumably mostly alfalfa) represents roughly a third of feed costs. Alfalfa can additionally be used in cubes or pellets. In some regions (Wisconsin, Minnesota), haylage is also a significant share of feed. As adoption of GT alfalfa could increase the quality of alfalfa for forage without an increase in costs, this could increase productivity of GT alfalfa-tolerant dairy farms and allow for an increase in production without an increase in costs. The impact on dairy farms would be to increase the feasibility of operations. MacDonald et al. (2007) report that currently many small dairy farms are operating with incomes above operational costs but below total costs (they are not covering overhead and capital recovery costs). The impact on reduced costs would, however, impact farms of all sizes, since feed seems to be of similar importance to all farms. If GT alfalfa requires less labor, this could be to the advantage of smaller farms where labor is a greater share of costs. Whether decreased dairy farm production costs and a potential increase in production would translate into reduced prices for dairy is not clear, as previously mentioned, given governmental regulation of farmer milk prices. As stated above, the effect of GT alfalfa deregulation on the

supply of organically produced alfalfa would depend on the extent of the GT-sensitive portion of sales within the organic market.

In the case of meat, alfalfa is likely a lower share of feed costs in organic or conventional cow-calf production than it is in dairy production since the main source of feed is grazing (Short, 2001). The impact of potentially reduced alfalfa costs on meat production could be important for cow-calf production, particularly in areas where supplementary feeding is more important in winter, such as the North Central region—Iowa, Illinois, and Missouri (Short, 2001). If the alfalfa used is often of lower quality (Klonsky et al., 2007), the impact would depend on the extent to which reduction in prices of high quality alfalfa also decreases the prices of lower quality alfalfa. It is unlikely; however, that GT alfalfa deregulation would have significant impact on organic or conventional meat farming costs or meat prices, given the relatively low share of alfalfa in production costs.

The discussion above is largely a summary of the analysis done in the technical report *Downstream Effects to Organic Production and Marketing of Deregulation of Glyphosate-Tolerant Alfalfa.* For an expanded and more detailed analysis, see appendix T.

4. Impacts on Trade

There is considerable dissimilarity among countries on regulation pertaining to GE food and feed (Gruère, 2006). While most countries lack any regulations at all, Japan, Saudi Arabia, and South Korea, main U.S. alfalfa export markets, all have approval processes for GE products and labeling requirements.

Japan has zero tolerance for non-approved GE foods and conducts inspection and testing of cargoes arriving in Japan, inspecting up to 50 percent of all cargoes (Grueré, 2006). In cases where a GE product has not yet been approved for use in Japan, a one percent threshold for unintended or unplanned presence of GE content in feed is allowed as long as the GE product has been approved by the exporting country and the exporting country is considered to have safety assessments equivalent to Japan's (Grueré, 2006). Because Monsanto's J101 and J163 are approved for use as feed in Japan, there are no restrictions to its sale. Labeling is mandatory for all GE foods as long as GE content can be detected, the GE ingredient is one of the first three ingredients of a product, and the GE content accounts for more than five percent of the total weight (Grueré, 2006).

Because alfalfa hay is predominantly used as feed, the impacts of deregulation associated with the export market in Japan could be similar to those of soybeans and corn. Japanese regulations do not seem to have had a significant impact on these crops and labeling is not required for

products from GE fed animals–at least not for meat–and corn used for feed is typically GE corn (Grueré, 2006).

However, there is some indication that Japanese alfalfa importers are concerned with importing GE alfalfa. Putnam (2005) states that foreign importers have asked for non-GE alfalfa and that this has led U.S. exporters to require signed contracts from producers asserting the non-GE status of alfalfa sold to them. Similar anecdotal evidence is provided by Woodward (2004) and recognized by the National Alfalfa and Forage Alliance (2008b).

South Korea has similar approval processes and labeling requirements as Japan. Labeling in South Korea is mandatory for unprocessed GE food and for unprocessed non-GE food containing more than three percent unintended presence of GE content. In the case of processed foods, labeling is required if the GE ingredient is among the top five and is detectable in the final product. GE animal feed must also be labeled (USDA-FAS, 2008a). Processed food with non-detectable levels of GE content, such as dairy, meat, and vegetable oils do not require labeling.

Non-government Organizations (NGOs) in South Korea have increasingly advocated for expansion of labeling requirements to products using GE ingredients, independently of whether these can or cannot be detected in the final product (USDA-FAS, 2008a). USDA-FAS (2008a) notes that labeling of feed does not seem to have an impact in the market because most feed is GE, but that an expansion of food labeling requirements to include use of GE ingredients even when not detectable could turn South Korea into a non-GE market. As in the case of Japan, there is evidence of consumer negative views of GE products (Cho, Undated; USDA-FAS, 2008a). South Korean businesses, however, have been opposing expansion of GE labeling given the potential increase in their costs from buying non-GE products.

For alfalfa seed, the most important export markets are Saudi Arabia, Mexico, Canada, and Argentina. None of these countries would currently import GT alfalfa seed. Saudi Arabia does not allow imports of genetically engineered seeds. Saudi Arabia, however, could be gradually reducing their imports of conventional alfalfa seeds as well due to internal policies stimulating the growth of less water intensive crops. No genetically modified seed has currently been approved for commercial planting in Mexico, including GT alfalfa, even though Monsanto's J101 and J163 Alfalfa have been approved for food and feed consumption (USDA FAS, 2010). Canada has approved GT alfalfa seed, but commercial use would require registration and there are currently no registered GT alfalfa seed varieties in Canada. The GT alfalfa approval process is still underway in Argentina. Non-GT alfalfa seed exporters, however, could face increased stewardship costs for access to GT alfalfa

sensitive markets, including testing, and could find themselves at an increased disadvantage in competing with alfalfa seed exporters from countries where GT alfalfa is not deregulated. The acceptable levels of unintended presence of genetically engineered content in conventional seeds are typically determined by the market and the seed industry has typically adopted self-governing processes to meet such market demands. In a scenario of GT alfalfa deregulation, each export market would gradually determine what levels of unintended presence of genetically engineered content are acceptable in conventional alfalfa seeds. The NAFA has recommended measures to be taken by the seed industry to enable coexistence of GT alfalfa and non-GT alfalfa seed production for access to sensitive export markets (NAFA, 2008a) as well as for coexistence of GT alfalfa and non-GT alfalfa hay production for access to sensitive export markets (NAFA, 2008b).

Mexico, the main downstream export market for dairy, seems to have no significant trade barriers to foods derived from biotechnology. GT alfalfa has been approved for food and feed in Mexico, and Mexico regularly imports and consumes GE corn, soybeans, and cotton from the United States (USDA-FAS, 2008b). Mexico's existing labeling requirements for GE products have not been implemented, according to Gruère (2006). In the case of Canada, another important market for alfalfa downstream products from the United States, GT alfalfa has also been approved and there is no mandatory labeling for GE products (Gruère, 2006).

Regarding organic standards, the United States has an equivalence agreement with Canada, the main importer of U.S. organic products, recognizing the national organic standards of each country as equivalent, and allowing NOP certified products to be sold as organic in Canada. An export arrangement allows U.S. organic products to be sold as organic in Japan, the second largest foreign market for U.S. organic products, conditional to specific requirements.

The discussion above is largely a summary of the analysis done in the technical report *Impacts on United States Trade of Deregulation of Glyphosate-Tolerant Alfalfa.* For an expanded and more detailed analysis, see appendix R.

5. Social Impacts

GT alfalfa adoption by farmers, cross-fertilization of non-GT alfalfa fields, and the demand response to GT alfalfa deregulation could have several social impacts, which are further discussed in the technical report, *Economic and Social Impacts on Conventional and Organic Farmers of Deregulation of Glyphosate-Tolerant Alfalfa* (appendix S).

Businesses Lost and Gained

Farmers adopting GT alfalfa would possibly face decreased costs or improved markets for the possibly less expensive GT alfalfa, while GT alfalfa-sensitive farmers would possibly face a reduction in demand for the more expensive organic alfalfa. Early GT alfalfa adopters could gain markets while conventional non-GT alfalfa farmers producing high quality alfalfa could lose, due to potentially higher costs and lower quality when compared to GT alfalfa. If there is GT alfalfa sensitivity of organic sales under the possibility of AP of GT alfalfa in feed, those organic farmers that are most affected by the unintended presence of GT alfalfa could lose markets, while organic farmers less affected could gain.

Market Structure

It is unclear whether the deregulation of GT alfalfa would have any impact on farm size. To the extent that non-GT alfalfa farmers attempt to avoid the presence of GT alfalfa through extended buffer zones or relocation, they could face increased land costs, more easily absorbed by larger alfalfa farmers. However, because gene flow to alfalfa hay fields is considered relatively unlikely and because there are other methods available to minimize the presence of GT alfalfa in GT-sensitive alfalfa fields, it is not clear that any increased expenses with land would actually occur. In the case of alfalfa grown for seed, any impact of increased land costs on seed production would be mitigated by the highly inelastic demand for seeds. In other words, as seed quality is important for alfalfa forage producers and seed costs are a small cost of their total production costs, increases in seeds costs should not significantly affect sales of seeds.

If adoption rates of GT alfalfa were high, alfalfa seed farmers would face increased demand for GT alfalfa seeds and would shift production to this variety, potentially leading to an increased market concentration in the supply of alfalfa seed technology. Because farmers who do not use herbicide in alfalfa would have little incentive to adopt GT alfalfa and because use of herbicide in alfalfa varies greatly among U.S. regions, it is difficult to predict adoption rates of GT alfalfa. As noted in FGI 2010, FGI projects a 51-percent adoption rate of GT alfalfa among alfalfa farmers in a ten-year horizon.

Distribution of Costs of Loss of Production and Avoidance

Based on the assumption that there is a level of presence of GT alfalfa that the organic market would not bear, and the assumption that current alfalfa production practices are not already in place to protect against unintended presence of GT alfalfa in GT-sensitive alfalfa fields, organic producers could bear a cost in either loss of production or measures to reduce the likelihood of unintended presence. However, APHIS is not aware of nor

has been provided with any reliable evidence that currently establishes or supports either of these assumptions.

Social Aspects of Organic Farming

The absence of a GT-sensitive domestic demand (sales) for organic products does not mean GE products are necessarily welcome by organic consumers, but rather that any sensitivity to GE content might not translate into a decrease in sales of organic alfalfa. Organic producers (and consumers) would possibly still be unhappy with the outcome. To the extent that organic farming involves broader life choices related to philosophical attitudes, this discontent would be a negative impact. This situation could conceal a market for non-GE products in need of development.

Environmental Justice

The existence of disproportionately high and adverse human health and environmental effects depends on the existence in the affected area of minority or low-income populations and on the existence of significant impacts of a proposed alternative, or of multiple and cumulative exposures to an environmental hazard. If differential patterns of consumption of water or subsistence consumption of indigenous fish, vegetation, or wildlife is important to minority populations, low-income populations, or Indian tribes in the affected area, these differential patterns of consumption could also lead to disproportionately high and adverse impacts.

Because no significant impacts of GT alfalfa deregulation were identified in the analyses conducted in this chapter IV, no disproportionately high and adverse human health and environmental effects would occur with GT alfalfa deregulation. To the extent that impacts are felt by alfalfa farmers catering to GT alfalfa sensitive markets, there is no indication that these farmers represent a minority or low-income population. APHIS found no evidence that cumulative or multiple exposures to impacts associated with GT alfalfa deregulation would disproportionately affect minority or low-income populations. Nor did APHIS find evidence of disproportionately high and adverse effects that could be expected through differential patterns of consumption of fish, water, vegetation, or wildlife or of cumulative or multiple exposures to environmental hazards.

No Action Alternative Socioeconomic Impacts

Under the No Action Alternative, the opportunity for improved quality and/or reduced costs of alfalfa hay would be lost for most growers. This would mostly have a negative financial impact on alfalfa hay and dairy farmers. Marketing and business efforts conducted around the over

200,000 acres of GT alfalfa planted during the time in which GT alfalfa was deregulated would also be lost. Organic farmers would neither be negatively affected by potential (although unlikely) increased production costs or decreased demand, nor would it have the opportunity to gain GT-sensitive conventional consumers. Exporters would possibly continue to lose alfalfa hay markets to competitors and exports of alfalfa seed and hay to GT-sensitive markets would not be harmed by any potential AP of GT alfalfa.

Isolation/Geographic Restriction Alternative

In Tier I states the impacts are the same as those for the Deregulation Alternative. There is no commercial alfalfa seed production in these states. GT alfalfa for hay production would be available to growers. Adoption rates of GT alfalfa hay in Tier I states are likely to be similar to those of the Deregulation Alternative. However, the restriction on growing GT hay in Tier III states could increase the number of growers in Tier I states who opt to grow GT hay for the premium market. This would occur if there is a high demand for GT hay for livestock feed. Growers in Tier II are more likely to adopt GT alfalfa than those in Tier I.

Tier II states consist mostly of hay growers with some seed production (each state grows less than one percent of the total alfalfa seed produced in the United States). GT hay would be allowed in this tier. The only restriction on hay production is that for GT hay that is within 165 feet of seed production the hay must be harvested at or before ten percent bloom. Growers of seed in Tier II states could require additional buffers if they are growing for a GT alfalfa-sensitive market. Hay growers in Tier II states have similar costs to those for the preferred alternative because the Monsanto TUG already requires harvest of hay at ten percent bloom when the hay field is near a seed-production field. Growers of seed who are selling to markets that are not sensitive to AP of GT alfalfa seed would not incur any additional costs.

Tier III states grow the majority of alfalfa seed. They also grow alfalfa hay. About 40 percent of the nation's alfalfa hay is grown on 32 percent of the nation's alfalfa acres in these states. About 23 percent of the nation's hay production would be excluded from GT alfalfa hay production because it is currently located in counties that produce alfalfa seed. GT hay production would be segregated from conventional seed production. Counties with seed production would not have new GT alfalfa forage planting. Therefore any that remains from when the crop was not regulated would be replaced over the next five years. Growers who might want to grow GT hay in these counties would not have this option. For these hay growers, any profit that could be obtained through the sale of GT hay would be lost under this alternative. Seed growers in these same counties would grow only conventional (non-GT alfalfa). These seed

growers would sell their seed to the conventional alfalfa domestic market and export market. Growers of seed for GT alfalfa-sensitive markets would not incur the additional costs of maintaining segregated plantings and buffers as under the preferred alternative. Hay growers in Tier III counties designated for hay production would be able to grow GT alfalfa hay with some restrictions. They would need to report GPS coordinates for their fields and they would need to harvest at ten percent bloom any hay field that is within 165 feet of a seed field. Because there is no commercial seed currently reported in these counties, the likelihood that the hay field would be near a seed field is remote. The additional costs incurred by collecting GPS coordinates are small. This alternative could create a preference for growing GT alfalfa hay in the Tier III hay counties because it could fill a local niche for high-quality alfalfa.

E. Human Health and Safety Impacts

The discussion throughout this section is formed primarily in the context of both the Deregulation Alternative and the Isolation/Geographic Restriction Alternative given the impacts are expected to be very similar in terms of human health and safety. The discussion of the impacts of the No Action Alternative is located at the end of this section. Therefore, unless explicitly defined, the considerations in the following two subsections (public health and safety and worker health and safety) can be assumed to be related to the Deregulation Alternative and the Isolation/Geographic Restriction Alternative.

1. Public Health and Safety

As described in section III.D, the affected environment related to GT alfalfa includes all aspects of direct and indirect human contact with alfalfa. Deregulation would affect this environment in three key ways: (1) further introduction (in addition to the brief deregulation that has already occurred) of a specific gene product into foods consumed by humans; (2) further introduction of the gene product into animal feed for livestock; and (3) change of herbicide use profiles for alfalfa.

Introduction of Gene Product into Foods

Section III.D discusses the routes of human exposure to conventional alfalfa, including through ingestion of sprouts, teas, food supplements, and food additives. After deregulation, people are expected to be exposed to GT alfalfa and its non-native gene product in a similar way, with the exception of consumption of GT alfalfa sprouts.

As discussed in section III.I and appendix Q, the applicant has incorporated the gene sequence from a native soil microorganism, *Agrobacterium*, into the alfalfa genome in order to make alfalfa tolerant to glyphosate. The expressed gene product in GT alfalfa is a protein, EPSPS, derived from the CP4 strain of *Agrobacterium*, and thus it is called CP4

EPSPS. This gene, along with its regulatory sequences, was introduced into these alfalfa plants via the well-characterized *Agrobacterium*-mediated transformation method. The protein is structurally and functionally similar to the native plant EPSPS enzymes. The herbicide glyphosate blocks the action of the natural EPSPS enzymes only, and thus the CP4 EPSPS protein is not inhibited by the herbicide glyphosate. In other words, it is the insertion of this gene sequence and the production of the CP4 EPSPS protein that makes GT alfalfa events J101 and J163 tolerant to glyphosate.

This gene insertion and protein production were the focus of the U.S. Food and Drug Administration (FDA) consultation described in section III.D. As part of the consultation, the applicant discussed its findings with regard to the CP4 EPSPS protein produced by GT alfalfa (U.S. FDA, 2004a, 2004b—see appendix P):

1. The protein is biochemically and functionally equivalent to CP4 EPSPS proteins produced by other GT crops, as well as to the family of EPSPS proteins that naturally occur in crops.
2. *Agrobacterium* species are not known for human or animal pathogenicity; *Agrobacterium* sp. CP4 EPSPS has a history of use as a genetic donor in numerous glyphosate tolerant crops, which humans and animals have consumed since 1996. There is an absence of immunologically relevant gene sequences, as determined by comparison of the amino acid sequence of the CP4 EPSPS to sequences in several allergen databases. The protein does not have biologically relevant structural similarities to protein toxins known to cause adverse health effects in humans or animals.
3. The CP4 EPSPS protein is susceptible to rapid proteolytic digestion in simulated gastric fluid.
4. The CP4 EPSPS protein is only a small portion of the total protein in GT alfalfa (approximately 0.5 percent).

Also, EPA previously conducted a review of the CP4 EPSPS protein pursuant to section 408(d) of FFDCA and established an exemption from the requirement for a pesticide tolerance for the protein (and the genetic material necessary for the production of the protein) in or on all raw agricultural commodities (40 CFR 180.1174).

Regarding allergenicity and toxicity more broadly, the current weight-of-evidence from similar genetically engineered (GE) crops such as GT wheat, GT soybeans, GT corn, GT cotton, and GT sugarbeets suggests that the transgenic CP4 EPSPS protein present in GT alfalfa poses negligible risk to humans (ASSAF, 2010; Lemaux, 2009; Peterson ,2005; NRC, 2004).

In addition to the lack of allergenicity and toxicity noted above, section III.D (and item 5 above) highlights the minor direct human intake and food uses of alfalfa, and thus GT alfalfa. Most alfalfa is consumed directly by humans as freshly sprouted seedlings (sprouts), compressed leaf material in dietary supplements, herbal teas, and food additives. Several agreed-upon provisions prevent the use of GT alfalfa seeds for sprouts, beyond what was considered in the FDA consultation. These provisions are detailed in addendum 1 of the applicant's petition (Rogan and Fitzpatrick, 2004). For example, the applicant, pursuant to its mandatory Technology/Stewardship Agreement (MTA) for growing GT alfalfa lines, does not intend to allow GT alfalfa to be planted for sprouts. Also, GT alfalfa seed will be clearly identified as such on each seed bag, seed tag, and on the purchase agreement. All GT alfalfa seed produced by the applicant will be pre-treated with a colored coating that will contain bacterial (*Sinorhizobium meliloti*) inoculants to promote nodulation and/or a fungicide such as metalaxyl for control of seedling damping off fungi, and because treated seeds and seed produced for planting purposes should not be used for sprouting purposes, the coating applied to GT alfalfa seed along with packaging in labeled seed bags will uniquely identify seed that contains the trait and preclude its use as a starting material for the production of alfalfa sprouts. Also, outbreaks of food-borne illness associated with sprouts containing the microbial pathogens *Salmonella* spp, *Escherichia coli* O157:H7, or *Listeria monocytogenes* have resulted in greater scrutiny of seed production practices in recent years and likely have heightened the awareness of seed sources—the primary source of these microbial outbreaks.

While alfalfa in general is not a major direct source of food for people, and GT alfalfa even less so, as discussed above, the nutritional makeup of GT alfalfa is important to consider if only because a compositional evaluation is useful for identifying unintended effects of introducing genes and gene products into an organism, beyond just changes in nutritional makeup. Appendix U, *Character and Quality of Glyphosate-Tolerant Alfalfa Traits*, describes in detail the compositional analysis conducted on GT alfalfa, which was subsequently reviewed by both APHIS and FDA. Briefly, GT alfalfa varieties were grown at five replicated field sites across the alfalfa-producing regions of the United States during the 2001 field season. Plots containing GT alfalfa lines were treated with a glyphosate herbicide. Forage samples were collected from all plots and analyzed for protein, fibers, lignin, amino acids, minerals, and other components (a total of 35). Statistical evaluation of the composition data concluded that forage derived from J101 and J163 was compositionally equivalent to forage produced by conventional alfalfa. In general, reviews on the nutritional quality of GE foods have generally concluded that there is no significant nutritional difference in conventional versus GE plants (Flachowsky et al., 2005; Faust, 2002).

Under the Deregulation Alternative, it is likely that some GT alfalfa gene and gene product would be incorporated into foods by low level gene flow or mixing with conventional crops and other products (beyond the current incorporation into food due to the GT alfalfa currently in production; see section III.D and appendix S 3.2.3). Nevertheless, as discussed above, the GT alfalfa lines J101 and J163 have both successfully completed the voluntary consultation process with FDA, and FDA concluded that it had no further questions concerning the safety and legal status of food derived from alfalfa event J101 or event J163 (U.S. FDA, 2004a, 2004b—see appendix P). Furthermore, the above findings indicate a lack of allergenicity, toxicity, exposure, and compositional difference regarding GT alfalfa compared to conventional alfalfa.

Under the Isolation/Geographic Restriction Alternative, GT and non-GT alfalfa seed would be geographically segregated during production. For the majority of seed this would mean that there is a very low probability that non-GT seed batches would contain GT alfalfa seed, even at low levels. Assuming that seeds for sprouts and other direct consumption would be procured from the non-GT seed market, the probability of GT alfalfa seeds occurring in alfalfa for sprouts would be extremely low as there will be very little GT alfalfa pollen in the local environment to fertilize plants used for sprout seed production. There is also a low likelihood that alfalfa used for other human consumption purposes will have the EPSPS gene because there will be very limited opportunities for gene flow.

Introduction of Gene Product into Animal Feed

GT alfalfa is intended primarily as an animal feed, and thus if GT alfalfa is approved for use, the gene product, CP4 EPSPS, would be introduced into animal feed and indirectly into the human diet via animal products such as meat and milk. As with the introduction of gene product directly into food, as discussed above, FDA regulates additives to animal feed. The applicant thus chose to undergo the voluntary consultation process with FDA. The GT alfalfa lines J101 and J163 have both successfully undergone this process. FDA concluded that it had no further questions concerning the safety and legal status of feed (or food) derived from alfalfa event J101 or event J163.

In this EIS analysis, APHIS considered the fact that studies on the persistence of plant-derived recombinant DNA in livestock have indicated that feed-ingested DNA fragments do survive in the terminal gastrointestinal (GI) tract and that uptake into GI tissue does occur, just as with the naturally occurring DNA (Faust, 2002). There is presently no evidence to indicate that recombinant DNA, which includes all of the inserted genetic material, would be digested and metabolized in a manner different from that of the genetic material of conventional feed products

(For more information on the inserted genetic material in GT alfalfa, please see appendix W.) Additionally, no negative effects of CP4 EPSPS protein or gene consumption on the nutritional characteristics of dairy cattle, livestock, or poultry have been reported (Combs and Hartnell, 2007). Combs and Hartnell (2007) showed that milk production, milk composition, feed intake, and feed efficiency were not different for dairy cows fed GT alfalfa hay versus control alfalfa hay. Furthermore, as described in appendixes O and Q, field and laboratory observations of GT alfalfa events J101 and J163 have revealed no negative effects of the transgene on nontarget organisms such as bees and earthworms, and no effects have been observed on pollen harvest behavior of workers bees or on survival and development of honey bee eggs, larvae, or pups following exposure to the CP4 EPSPS protein—these studies further confirm the feed safety of the CP4 EPSPS protein. The section above on human food provides further discussion about the compositional characteristics of GT alfalfa.

Several additional factors regarding the introduction of gene product into animal feed parallel those described above on human food: The protein is biochemically and functionally equivalent to CP4 EPSPS proteins produced by other GT crops, as well as to the family of EPSPS proteins that naturally occur in crops; there is an absence of known credible reports of allergies to or pathogenicity of *Agrobacterium* species; the protein does not have biologically relevant structural similarities to protein toxins known to cause adverse health effects; no treatment-related adverse effects were observed in an acute toxicity test of doses that likely is thousands of times higher than livestock intakes; the CP4 EPSPS protein is susceptible to rapid proteolytic digestion; and the CP4 EPSPS protein is only a small portion of the total protein in GT alfalfa. Finally, findings from similar GE crops, such as GT wheat, GT soybeans, GT corn, GT cotton, and GT sugarbeets, suggests that the transgenic CP4 EPSPS protein present in GT alfalfa poses negligible risk to humans (ASSAF, 2010; Lemaux, 2009; Peterson, 2005; NRC, 2004).

If GT alfalfa is deregulated, it will be available to consumers for livestock feed. Conventional alfalfa will also be available. In that conventional alfalfa there may be low levels of GT alfalfa. Because GT alfalfa is nutritionally equivalent, the presence or absence of the EPSPS gene product will not change the nutritional quality of the forage. To the degree that the GT alfalfa has fewer weeds, it may improve forage quality and be more nutritious (Van Deynze et al., 2004).

Under the Isolation/Geographic Restriction Alternative, GT and non-GT alfalfa seed would be geographically segregated during production. For the majority of seed this would mean that there is a very low probability that non-GT seed batches would contain GT alfalfa seed, even at low levels. Assuming that seeds for hay would be procured from the non-GT

seed market, the probability of GT alfalfa seeds occurring in non-GT alfalfa seeds for hay would be extremely low, as there will be very little GT alfalfa pollen in the local environment to fertilize plants used for non-GT hay.

Herbicide Use

As described in detail in appendix J, *Effects of Changes in Farming Practices on Water, Soil, and Air Due to Use of Glyphosate-Tolerant Alfalfa*, the deregulation of GT alfalfa will probably change alfalfa herbicide use profiles. Glyphosate use on alfalfa is likely to increase with the adoption of GT alfalfa. Other herbicide use could decrease slightly, remain relatively flat, or increase, depending on several factors, including especially the acreage of alfalfa that converts to GT alfalfa and the extent to which glyphosate resistance becomes a problem. Overall, glyphosate use has been increasing on both GT and non-GT acreage over the last decade, while other herbicide use has decreased. Whether herbicide use is increasing or not, EPA's registration process is designed to ensure that currently registered pesticide products, when used in accordance with the product labeling, will not pose unreasonable risks or adverse effects to humans or the environment.

The herbicide that is likely to increase the most due to deregulation, glyphosate, is of relatively low oral and dermal (via the skin) acute toxicity. For this reason, glyphosate has been assigned by EPA to Toxicity Categories III and IV for these effects (Toxicity Category I indicates the highest degree of acute toxicity, and Category IV the lowest). An acute inhalation study was waived by EPA because glyphosate is a nonvolatile solid and the studies conducted on the end-use product formulation are considered sufficient.

In order to develop a conservative impact analysis for human health effects, APHIS has independently conducted a screening-level human health risk assessment for the general population, as described below and as detailed in the technical report, *Health and Safety Risks to the General Population* (appendix L). As defined by EPA, screening-level risk assessments "are conservative assessments in that they provide a high level of confidence in determining a low probability of adverse risk, and they incorporate uncertainty in a precautionary manner" and "are not designed nor intended to provide definitive estimates of actual risk" (U.S. EPA 2001). Rather, the purpose of screening-level risk assessments is to assess the need to conduct a detailed risk assessment (EPA, 2001). By definition, APHIS recognizes that the Deregulation Alternative and Isolation/Geographic Restriction Alternative are unlikely to have impacts similar to the results of the assessment, and the assessment is intended to disclose very conservative potential impacts.

To help frame the screening risk assessment, APHIS first examined the EPA risk assessments developed as part of the pesticide registration process. These assessments concluded that the general public is not at a high risk of exposure to substantial levels of glyphosate under typical use conditions (U.S., 1993; USDA, 2003). Nevertheless, in the 1993 EPA RED (Reregistration Eligibility Decision) dietary risk assessment, EPA developed 85 tolerances (maximum residue limits in or on food and feed) for residues of glyphosate and its metabolite, AMPA, in or on a wide variety of crops and crop groups (including alfalfa), as well as in many processed foods, animal feed and animal tissues (40 CFR 180.364, 40 CFR 185.3500 and 40 CFR 186.3500). EPA also determined that non-nursing infants under one year of age are at highest risk of adverse effects associated with glyphosate exposure (U.S. EPA, 1993). EPA completed an additional risk assessment for glyphosate in 2006 to address its specific use on Indian mulberry and dried peas (U.S. EPA, 2006b). In this later assessment, EPA similarly found that infants under one year of age have the highest exposure.

Dermal and inhalation routes of exposure to the public are not considered relevant for this GT alfalfa analysis because GT alfalfa is not expected to be grown by members of the general public or in close proximity to nonfarm populations. Members of the general public could be exposed orally though via consumption of foods that have been treated by herbicides containing glyphosate, whether accidentally or not. Therefore, exposure scenarios were developed to evaluate both the acute (short term) and chronic (long term) effects from consumption of fruit and vegetables contaminated with residues of glyphosate by adults, the elderly, and infants less than one year of age. APHIS conducted this screening level risk assessment based on factors such as an assumed overspray of nearby fruits and vegetables, glyphosate application rate, residue rates on a crop, and amount of fruit and vegetable consumption.

To conduct the screening-level risk assessment, high-end estimates of exposure are compared with a health benchmark specific to glyphosate. USDA (2003) used a chronic (long term) reference dose (RfD) for glyphosate of 2 mg per kg of body weight per day to assess both acute (i.e., short term or accidental) and chronic (i.e., long term) exposure scenarios. This means that individuals with exposure doses equal to or less than 2 mg per kg of body weight per day are not at risk of adverse effects associated with exposure to glyphosate. The risk metric that is used to characterize risk of adverse effects is called the hazard quotient (HQ). The HQ is the ratio of the estimated exposure dose to the chemical-specific health benchmark (e.g., RfD) (see equation below).

$$HQ = \frac{Exposure}{RfD}$$

Where:
HQ = Hazard quotient (*no units*)
Exposure = Estimated exposure dose (mg per kg body weight per day)
RfD = Reference dose (mg per kg body weight per day)

If the HQ is estimated to be less than 1—or given the screening level nature of the assessment at or even somewhat above 1—no adverse effects are expected as a result of exposure to the chemical of concern. If the HQ is much greater than 1, adverse health effects are possible. As noted above, the nature of this screening-level risk assessment precludes any conclusions regarding the likelihood of adverse health effects. Please see the technical report, *Health and Safety Risks to the General Population* (appendix L) for further details and discussion on the approach and results of this assessment.

The results of this screening analysis are shown in tables 4-8 and 4-9. Most of the screening level HQs are under 1. Some of the upper estimate screening HQs do exceed 1, but as discussed elsewhere these are based on very conservative screening-level assumptions for estimates of exposure and, for the acute assessment, are based on the highly conservative assumption of a chronic RfD for acute toxicity. The age group with the highest exposure is infants under 1 year of age, which is consistent with the EPA findings (U.S. EPA, 2006b, 1993). The upper estimate screening HQ for infants with acute exposure to fruit was approximately 3. The upper estimate screening HQs for all age groups with acute exposure to vegetables ranged from approximately 2 to 6. Due to the screening level nature of this assessment, APHIS believes that the actual result

Table 4-6. Acute Screening Level HQs by Age Group and Scenario.

Scenario	Age Group	Central Estimate	Lower Estimate	Upper Estimate
Fruit	Adults	0.01	0.00	0.62
Fruit	Elderly	0.02	0.01	0.23
Fruit	Infants	0.10	0.09	3.16
Vegetable	Adults	0.16	0.09	2.30
Vegetable	Elderly	0.18	0.11	2.55
Vegetable	Infants	0.31	0.00	6.07

Table 4-7. Chronic Screening Level HQs by Age Group and Scenario.

Scenario	Age Group	Central Estimate	Lower Estimate	Upper Estimate
Fruit	Adults	0.01	0.00	0.34
Fruit	Elderly	0.01	0.00	0.12
Fruit	Infants	0.06	0.00	1.73
Vegetable	Adults	0.09	0.05	1.26
Vegetable	Elderly	0.10	0.06	1.40
Vegetable	Infants	0.17	0.00	3.32

in HQs from the implementation of the Deregulation Alternative or Isolation/Geographic Restriction Alternative would be less than 1. The upper estimates of risk are based on highly conservative fruit and vegetable intake rates and a high estimate of glyphosate residue concentrations. Furthermore, the use of a chronic toxicity RfD for assessing acute toxicity is also conservative given (1) acute RfDs typically are much higher—usually by more than an order of magnitude—than chronic RfDs, and (2) EPA has concluded that that no relevant toxic effects are expected to result from single-dose oral exposure to glyphosate.

In summary, this screening-level analysis of exposure to the general public considers the possibility that any type of fruit or vegetable could contain residues of glyphosate. Central, upper, and lower estimates of consumption rates were used to estimate exposure and risk for adults, infants, and the elderly. The results of this analysis are based on a screening-level assessment using highly conservative assumptions that when combined do not reflect actual risk. These assumptions include:

- The upper-bound exposure and risk estimates are based on fruit and vegetable consumption rates characteristic of the 100th percentile of the population (the maximum consumption rate).
- In assuming a spray drift of 1 for all scenarios, this analysis assumes that all of the overspray deposits on the fruits and vegetables as if they were sprayed directly, with no reduction due to dilution, dispersion, and removal by air and rain.
- Application rates are specific to herbicides used to treat GT alfalfa forage fields, which is not meant for human consumption, as opposed to rates specific to fruits and vegetables.
- This analysis assumes that 100 percent of the glyphosate residue remains on the produce, i.e., none is removed during washing or other processing.
- This analysis uses a chronic toxicity RfD for assessing acute toxicity, which will overestimate acute risk because (1) acute RfDs typically are

much higher—usually by more than an order of magnitude—than chronic RfDs, and (2) EPA has concluded that that no relevant toxic effects are expected to result from single-dose oral exposure to glyphosate.

Based on the results of this screening-level assessment, APHIS has determined a detailed assessment is not needed. If GT alfalfa is deregulated, there is an increased possibility that the general public will have more sources of exposure to glyphosate and possibly other herbicides through residues in and on food crops and other foods, although there are no indications that higher residue levels will occur, that tolerances will be exceeded, or that the risk standard of "reasonable certainty of no harm" would be violated. With the deregulation of GT alfalfa, GT alfalfa will likely be grown in many areas of the country. The addition of another GT crop to agricultural production might lead to a greater chance of a GT crop, including GT alfalfa, being grown near food crops. This could lead to higher exposures to glyphosate and possibly other herbicides in the general public because there would be more chance for residues to affect food crops. More people also likely would be exposed. Nonetheless, any such increases in exposure to herbicide residue or increase in the number of people exposed likely would not result in increased risks to the general population, given the results of the screening-level risk assessment and because all such herbicides have enforceable tolerance levels developed by EPA. Moreover, the potential exists for decreases in the applications and subsequent residues of more toxic herbicides if GT alfalfa is deregulated.

Under the Isolation/Geographic Restriction Alternative, the impact would be similar to the Deregulation Alternative. Geographic isolation might decrease the number of people exposed or chance of exposure to herbicide residues by the general public compared to the deregulation, due to the general reduction in the amount of GT alfalfa produced and herbicide applied.

2. Worker Health and Safety

More workers would be exposed to GT alfalfa gene product under deregulation, beyond the current exposure due to the GT alfalfa currently in production. Nevertheless, as discussed above for public health and safety, APHIS found no indications of allergenicity or toxicity regarding GT alfalfa compared to conventional alfalfa.

To determine if workers are at risk of adverse effects associated with herbicides, screening-level estimates of exposure were compared with a health benchmark specific to glyphosate (given its expected increase in use). USDA (2003) used a dermal reference dose (RfD) for glyphosate of 2 mg per kg of body weight per day to assess both acute (i.e., accidental) and chronic (i.e., general) dermal exposure scenarios. See tables 4-6 and 4-7 for screening HQs calculated for both chronic (general) and acute dermal exposures, which are based on the amounts of chemicals handled

per day, the application rates, the acres treated per day, and the dermal absorption rate, among other factors. These calculations are described in further detail in the technical report, *Health and Safety Risk to Field Workers* (appendix M). Screening-level exposure values were used for all of these calculations to use highly conservative assumptions and inputs. Similarly, the use of a chronic RfD for assessing acute toxicity is typically considered a highly conservative assumption because acute RfDs are typically much higher—usually by more than an order of magnitude—than chronic RfDs.

Table 4-8. Chronic Dermal Screening Level HQs for General Worker Exposure Scenarios.

Scenario	Central Estimate	Lower Estimate	Upper Estimate
Directed Foliar	0.0131	0.0005	0.0800
Broadcast Foliar	0.0224	0.0007	0.1512
Aerial	0.0147	0.0002	0.0800

Table 4-9. Acute Dermal Screening Level HQs for General Worker Exposure Scenarios.

Scenario	Central Estimate	Lower Estimate	Upper Estimate
Spill on hands	0.007	0.002	0.025
Spill on legs	0.017	0.005	0.062

As discussed above, EPA considers glyphosate to be of low acute and chronic toxicity by the dermal route of exposure. Glyphosate is considered a Category IV dermal toxicant and is expected to cause only slight skin irritation. This is corroborated by the low HQs determined from the worker assessments, where there is the greatest likelihood of dermal exposure. Workers using the methods of application analyzed above to apply herbicides, and workers who accidentally spill herbicides, are not at risk of adverse effects associated with chronic or acute dermal exposure to glyphosate.

If GT alfalfa is deregulated, more workers likely would use glyphosate and possibly other herbicides and be exposed to the gene product, but there would likely be no change in the impact on risk to individual workers. While glyphosate use would increase, the evaluation of risk is largely based on factors that do not change based on the amount of GT alfalfa grown or the number of workers exposed. Risk likely remains essentially the same for both general, chronic exposure and accidental, acute exposures to workers.

No Action Alternative

Under the No Action Alternative, the probability of GT alfalfa seeds occurring in alfalfa for sprouting is extremely low as there will be very little GT alfalfa pollen in the environment to fertilize plants used for sprout seed production. There is also a low likelihood that alfalfa used for tea will have the EPSPS gene because there will be very limited opportunities for gene flow. This is unchanged from the current situation. Thus, for the acres of GT alfalfa currently in production, the gene product in GT alfalfa would likely have no adverse effects on livestock or humans. If further plantings of GT alfalfa were to require a permit, risks to human health and safety from the gene product fertilization of livestock feed would not change from current conditions. The gene product in GT alfalfa is already present in animal feed (e.g., GT corn). The potential of unintended presence itself would remain low if GT alfalfa remained regulated. Fewer people would be exposed to the gene product compared to the deregulation alternatives.

If GT alfalfa is not deregulated, there will be no change in the current exposure to glyphosate residues or to the current exposure to the other herbicides currently used in alfalfa. Continuation of GT alfalfa as a regulated article will result in no change in risk to the general population. Glyphosate, along with other herbicides, will still be used in the production of conventional alfalfa, GT soybean, GT cotton, GT corn, GT sugar beet, other conventional crops, natural areas, home landscapes, and managed public lands. It will be used on the 200,000 acres of GT alfalfa currently under production. The use of currently registered pesticide products containing glyphosate in accordance with the label will not pose unreasonable risks or adverse effects to humans or the environment. There will be no change in the current exposure to glyphosate residues, as well as no change in the current exposure to residues from herbicides currently used in alfalfa production.

For workers, exposure to glyphosate or other herbicide residues would remain the same as current exposure. Exposure to herbicides presently used in alfalfa production, which includes glyphosate during stand takeout, would not change. Gene product would not be present. Fewer workers would be exposed the gene product when compared to the deregulation alternatives.

F. Land Use and Production Practices

The Deregulation Alternative is the deregulation of GT Alfalfa. The discussion throughout this section is in the context of the Deregulation Alternative, the deregulation of GT alfalfa. The impact of GT alfalfa cultivation is discussed as it applies to seed and hay production through conventional/ non-GT alfalfa and organic farming practices. At the end of

this section, there is a discussion of the impacts of the No Action and Isolation/Geographic Restriction Alternative.

In general, the decision to use agricultural or other lands for alfalfa production is largely a market-driven decision, and the availability of a new weed control option where other options already exist is not expected to impact land use decisions to any great extent. As such, the deregulation of GT alfalfa is expected to have a minimal impact on the overall amount of land devoted to alfalfa cultivation. However, there will likely be varying degrees of impact on the land use and production practices of non-GT alfalfa and organic alfalfa growers.

1. Implications for Cultivation Practices

Alfalfa is cultivated for forage, grazing, seed production (forage and sprouts), human consumption, and honey production. Alfalfa can also be used for erosion control, green manure, and as a trap crop for insect control. While there are regional differences, 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). Weeds are the most damaging pest during early stand establishment. Alfalfa farming practices are divided into three categories: organic, conventional (non-GT), and for the two years GT alfalfa was on the market, GT alfalfa.

Conventional and GT Alfalfa Production

As discussed in section III.E, alfalfa is a perennial crop grown for forage, seed, or sprouts. If a crop is being harvested for hay, it is harvested multiple times per growing season, from two to seven times depending on region. In contrast, seed crops are harvested once at the end of each growing season (Putnam et al., 2001). These varying parameters include: harvest time, weed control method (herbicides or mowing), crop rotation, companion crop choice, insect and other pest control measures, and stand removal techniques. The options and likely choices for controlling insect pests and other pests (e.g., small mammals, nematodes, and diseases) are the same for conventional and GT alfalfa. Weed control is the only pest control method for which conventional and GT alfalfa differ.

Farming GT alfalfa is mostly the same as farming conventional alfalfa, with a few important exceptions. First, in GT alfalfa weeds can be controlled by the application of glyphosate directly on top of growing alfalfa. Second, when GT alfalfa stands reach the end of their life cycle, herbicides other than glyphosate, combined with tillage, are required to obtain 100 percent removal of an unwanted stand. Third, because several of the recommended GT alfalfa stand removal herbicides result in restrictions regarding what crops can be planted next, careful crop rotation plans are necessary when using GT alfalfa. Fourth, glyphosate can be used to prepare a field for alfalfa in the stand establishment year and also to mitigate areas of GT alfalfa fields that fail to establish following

seeding, preventing the buildup of mature weed populations within field boundaries. Farmers can apply glyphosate early to weed patches within fields that have failed to establish followed with reseeding of GT alfalfa. Finally, for producers using companion crops, another important difference is that non-GT crops cannot be used as companion crops for GT alfalfa.

Based on the adoption of other GT crops and the use of GT alfalfa during the two years it was on the market, FGI projects that GT alfalfa will replace 51 percent of conventional alfalfa hay acres, with the highest adoption percentages in regions where a high level of crop management is used (e.g., west and southwestern states). See appendix J for more detailed analysis of adoption rates. In contrast, GT alfalfa is predicted to have lower adoption rates in areas where alfalfa is minimally managed and where inputs are low. Low management areas include pastures, hay fields, road sides with mixed stands of perennial grasses and other perennial forage legumes, and in other areas where herbicides are generally not used to control weeds (FGI, 2010).

Herbicide Use

Expected herbicide use under the alternatives is more fully discussed in the technical report *Effects of Changes in Farming Practices on Water, Soil, and Air Due to Use of Glyphosate-Tolerant Alfalfa*, appendix J, including all baseline data, assumptions, and results.

To evaluate the potential impact of the adoption of GT alfalfa on herbicide use, a range of plausible scenarios were developed to attempt to predict a range of possible herbicide use outcomes. Numerous assumptions were developed or used, including the adoption rates projected by FGI and various herbicide use profiles.

APHIS first determined a baseline level of herbicide usage. Herbicide use data for alfalfa were available from Hower et al. (1999), based on surveys covering the five year period from 1988 to 1992. These data, based on alfalfa acres planted for both hay and seed, on average per year from 1988 to 1992, are presented below (table 4-10).

Table 4-10: Yearly Average Alfalfa Acreage, 1988 to 1992

	Total Acreage[1]	Acres Treated With Herbicides*	% of Acreage Treated
Alfalfa for Hay	23,024,800	3,833,500	16.65%
Alfalfa for Seed	179,100	140,200	78.28%

[1]From Hower et al. (1999), table 33

The acreage of hay that would be converted to GT alfalfa hay is based on market adoption predictions provided by FGI (FGI, 2010) and APHIS assumptions. The FGI estimates include considerations for regional differences in initial adoption rate, incremental increase in adoption rate, and stand life expectations. FGI estimates that 51 percent of hay acres could be GT alfalfa ten years after deregulation (table 4-11). The FGI estimates start with the hay acre count from the 2007 USDA census.

Table 4-11: Projected Market Adoption Rates by Region, Glyphosate-Tolerant Alfalfa (FGI 2010)

Group[1]	Existing Hay Acres	Year 3		Year 5		Year 10	
		Acres	Percent	Acres	Percent	Acres	Percent
Alaska	0	-	0%	-	0%	-	0%
E. Central	3,481,278	313,315	9%	696,256	20%	1,148,822	33%
Hawaii	89	-	0%	-	0%	-	0%
Intermountain	4,188,766	733034	18%	1,396,255	33%	2,303,821	55%
N. Central	6,746,940	1012041	15%	2,024,082	30%	3,103,592	46%
Plains	2,367,814	532758	23%	986,589	42%	1,479,884	63%
Pacific Northwest	2,188,924	591009	27%	1,094,462	50%	1,379,022	63%
Southeast	26,297	2367	9%	5,259	20%	8,678	33%
Southwest	1,244,389	513310	41%	777,743	63%	914,626	74%
Grand Total	20,244,497	3,697,835	18%	6,980,647	34%	10,338,445	51%

States included in each group are as follows: **Alaska**: Alaska; **E**. **Central**: Arkansas, Connecticut, Delaware, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, Missouri, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Vermont; **Hawaii**: Hawaii; **Intermountain**: Colorado, Montana, Utah, Wyoming; N. **Central**: Iowa, Minnesota, North Dakota, South Dakota, Wisconsin; Plains: Kansas, Nebraska, Oklahoma, Texas; **Pacific Northwest**: Idaho, Nevada, Oregon, Washington; **Southeast**: Alabama, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, West Virginia; **Southwest**: Arizona, California, New Mexico.

To allow for a scenario with less market penetration, an estimated market adoption rate of 16.7 percent was also considered. This lower rate of adoption is based on an assumption that only acreage that historically used herbicides would be converted to GT alfalfa. Hower et al. (1999) indicates that 16.7 percent of hay acres (yearly average for 1988 to 1992) were treated with maintenance herbicides (stand removal herbicides not included). This 16.7 percent of acreage is considered "under weed pressure" for this analysis. However, the assumption that the percentage of acres under weed pressure is the same between the baseline year and year ten probably does not reflect possible changes in weed pressure. Weed pressure from glyphosate-resistant weeds has been increasing and will likely continue to increase (Heap et al., 2010), but the rate of future increases is not clear and will depend on farmer weed-management practices that cannot be predicted.

APHIS assumed that all acreage grown for hay and treated with herbicides, as reported in the baseline calculations, will make the transition to GT alfalfa. For estimating projected herbicide use on GT alfalfa at year ten, different maintenance schedules for herbicide use were used in various modeling scenarios (the scenarios were based on percent adoption and maintenance schedules). Only a few of the possible herbicides that could be used in tank mixtures were considered. Factors such as ease of use, price, farmer safety perceptions, rotation plans, and personal experience influence the choices farmers make. While the average stand life was calculated based on weighted regional differences, it is possible that stand life could extend up to eight years or be as little as two years (Rogan and Fitzpatrick, 2004).

APHIS used the seed data provided from Hower et al. (1999) for the baseline of the herbicide usage analysis in seed crops. Seed acreage adoption predictions were not provided by FGI. GT alfalfa seed acreage for year ten was based on an extrapolation from the hay acreage prediction provided by FGI. The same herbicide application schedules and scenarios adapted for use in the herbicide analysis for alfalfa hay crops were used during the alfalfa seed crop analysis. It was assumed that the 51 percent of acreage switching to GT alfalfa is solely from those acres that are currently treated with herbicides, the remaining acreage that is conventional alfalfa is treated the same way as it was before adoption (approximately 37 percent), and the remaining acreage is not treated with any herbicides (approximately 22 percent).

Based on the data available from Hower et al. (1999) for alfalfa grown for seed, the estimated herbicide usage for GT alfalfa grown for seed would decrease in all usage scenarios. Given the relatively large and diverse usage profile for herbicide use on conventional seed, adoption of GT

alfalfa for seed production would both simplify and decrease overall herbicide use. Estimates based on data for 2002 and 2007 both show overall decreases in the amount of herbicides used, as well as decreases in the amount of non-glyphosate herbicides used. A large proportion of the decrease in herbicide use for seed production overall can be explained by the total number of acres in production. The data from Hower et al. (1999) show that 179,100 acres were in seed production, on average, between 1988 and 1992. Data available from the Census of Agriculture for 2002 and 2007 showed 84,115 and 105,351 acres in production, respectively.

Based on the usage scenario and year of data from the Census of Agriculture used for projection (2002 or 2007), the per-acre usage of glyphosate *increases* from baseline (with a range of increase of 1.13 to 2.44 lbs ae/acre, depending on treatment scenario), whereas the per-acre usage of non-glyphosate herbicides *decreases* from baseline (with a range of decrease of 3.07 to 1.3 lbs. ai/acre). These changes are driven primarily by the recommended treatment strategies for GT alfalfa, which relies heavily on glyphosate use for weed control.

Overall, alfalfa grown for hay as opposed to seed dominated the results and thus only hay results are described here. Briefly, across the five scenarios analyzed, glyphosate use increases, with a range of 5.4M to 24M lbs. Non-glyphosate use ranges from a decrease of 3.8M to an increase of 4.9M lbs. Overall herbicide use increases across the scenarios, with a range of 1.6M to 23.2M lbs. In contrast, EPA (2009) estimates that current agricultural use of glyphosate is about 135M lbs/year. Some of the main drivers of the increase in total herbicide use, as well as the increase in glyphosate use, include the change from primarily non-glyphosate herbicides to primarily glyphosate herbicides, and for some scenarios, the large number of acres treated with herbicides compared to baseline. All GT alfalfa acres would require herbicide treatment; though the herbicide applied the majority of the time would be glyphosate, according to the assumptions of this analysis. However, given the large increase in the number of acres treated for some scenarios, up to approximately 50 percent more non-glyphosate herbicides would be used overall. It is important to note that the latter scenario reported here is based on an herbicide treatment schedule which involves a number of tank-mix herbicides and assumes multiple applications of these herbicides throughout the stand life.

The use of glyphosate may impact crop rotation decisions. Many of the non-glyphosate herbicides have follow-up planting restrictions that limit crop rotation choices in conventional farming. For example, following clopyralid (Curtail® or Stinger®), pea, lentil, potato, and dry bean cannot be planted for 18 months. Picloram (Tordon®) can only be followed by grasses for the year after application. Sunflower, dry bean, and potato should not be planted for several years following picloram (Miller et al.,

2006). Dicamba (Banvel®) should not be used prior to soybean and is also limited seasonally in California (Dillehay and Curran 2006). Because of these restrictions, alfalfa stand removal and rotation schedules should be closely coordinated. Non-glyphosate herbicides are available to manage both GT and non-GT alfalfa volunteers in wheat, oats, barley, sugar beet, and corn (Rogan and Fitzpatrick, 2004). Therefore, rotations from GT alfalfa to those crops should be similar to rotations with non-GT alfalfa (Rogan and Fitzpatrick, 2004).

Seed

Alfalfa seed production is localized predominantly in the Western regions in the United States. Most of the production (by pounds and acreage) occurs in California, Washington, and Idaho. California produces about 19 million pounds of seed every year, while Washington and Idaho produce approximately 11 and 9 million pounds annually, respectively (2007 U.S. Census of Agriculture). Cultural practices used to produce seed are distinct from those used to produce forage. Most alfalfa grown for seed production is planted in widely-spaced rows and is not cut monthly. Therefore, relative to forage stands, weeds in seed fields have more time and open area to proliferate and compete with the alfalfa. As a result, weeds are intensively managed in seed production systems using chemicals that preclude inclusion of alfalfa seed for food or sprouting purposes. Therefore alfalfa seed products for hay planting and sprouting are kept distinct from each other, with current management systems in place to prevent crops grown for seed from being consumed as a grain and or from use directly as a food or feed product. Seed certification standards have thresholds for presence of weed seeds, so weed control is very important in seed producing fields.

All GT alfalfa seed growers are under contract with FGI and must follow the stewardship practices in their contractual agreements. Professional seed growers usually grow seed under terms of a two or three year term seed company contract by variety name. Usually, stands of alfalfa grown for seed production only are maintained for an average of three production seasons. Seed production contracts and AOSCA variety certification standards generally predetermine the stand life of the seed stand.

Forage

Alfalfa stands have two growing phases, establishment of seedlings (first year) and established alfalfa fields (typically two to eight years). As discussed in section III.E, weed management differs for each phase (Orloff et al., 1997). Depending on the region, alfalfa is harvested (mowed) every 22 to 40 days depending on growth conditions, local weather patterns, and alfalfa variety. While growers in the Southwestern United States can harvest ten to eleven times a year, most alfalfa is only cut three to four

times a year (Putnam et al., 2001) and in some regions it is only harvested once or twice. These management practices and regional differences in the frequency of field cutting will impact farmers' decision to adopt GT alfalfa, but is not expected to alter the environmental impacts of cultivation of GT alfalfa.

There has been some speculation that weed-free alfalfa stands may result in longer stand life, which may subsequently cause a change in land use. Extended stand life provides positive economic and environmental benefits because a significant amount of the total production costs over the life of the stand are associated with the establishment year and stand removal is also expensive. These costs include those associated with seed bed preparation, seed, fertilizer, herbicides, and pesticides (Ward, 2007). After the stand is successfully established, costs diminish, and extending a healthy stand will increase profitability. In addition, increased stand life would result in less tillage of agricultural lands and growth of additional alfalfa harvests. Additionally, the *Rhizobium*-alfalfa symbiotic relationship results in a positive contribution of soil nitrogen that is usable by the next rotation crop (Vance et al., 1988). Thus, growing alfalfa could possibly reduce the need for nitrogen fertilizer application. Thus, removal of weeds in the final years of the stand without crop injury provides the opportunity to maintain a healthy and weed-free stand.

Adventitious Presence Impact on Conventional Cultivation Practices

Low levels of AP of the GT trait in conventional seed stock would impact conventional cultivation practices in the following ways:

- Stand establishment would not be impacted.
- Stand maintenance would not be impacted.
- Weed control options would not be impacted.
- Stand removal would only be impacted if the farmer chooses to use glyphosate only as a stand removal herbicide, which is uncommon as glyphosate is not effective for removal of conventional alfalfa (Endres, 1999; Mayerle, 2002; Manitoba Agriculture and Food, 2002). Hower et al. (1999) reported that herbicides used for stand removal occurred on only 2 percent of hay acreage per year, which implies that the other 98 percent of alfalfa fields are either not at the end of their stand life, or are being removed through tillage. In the cases when farmers choose to use herbicide for stand removal, the farmer would need to supplement glyphosate use with spot usage of another stand removal herbicide to remove the GT alfalfa.

Organic Alfalfa Production

Organic alfalfa growers would not be able to adopt GT alfalfa because GE is an excluded method under the National Organic Program, and GE crops may not be certified as organic. However, organic alfalfa markets could be impacted by the AP of genetically engineered content in alfalfa hay and seed fields (Greene et al., 2009; Leake, 2008; Cameron, 2008). Although USDA organic certification does not require testing for GE content in products, retailers often do require a demonstration that the product is "GMO-free." In cases where GE content is detected, the organic grower may sell to "non-GMO-free" markets, but not in premium "GMO-free" and organic markets (Holmes and Macey, 2010). Such economic losses are discussed in more detail in section IV.D of this document.

Organic farming practices, as outlined by the USDA NOP and discussed in more detail in section III.E, focus on an auditable crop management system. The objective of this system is to use only farming methods approved by the USDA-NOP, and minimize potential exposure to prohibited products, including genetically engineered crops. As a result, organic alfalfa producers could be negatively impacted by the deregulation of GT alfalfa because of decreased demand (sales) of organic products due to potential AP of genetically engineered content in organic alfalfa and increased costs to modify current organic practices to minimize the AP instances through commingling and/or gene flow. The socio-economic impacts of these circumstances are discussed more fully in section IV.D, *Socioeconomic Impacts on Domestic non-GT Alfalfa Markets*. Potential impacts on organic production methods are discussed below. In general, practices that help organic farmers minimize the risk of unintended GE presence in their field include: (1) Use seed that is from a known, non-GE stock (lists of organic seed suppliers can be found at www.attra.org); (2) Use temporal buffers such that alfalfa being produced using organic methods is receptive to pollen at a different time of year than when the neighboring alfalfa flowers; (3) Harvest alfalfa at ten percent bloom to reduce the number of flowers available for pollination (however, harvesting alfalfa prior to formation of seed (approximately four weeks after bloom) will also minimize the potential of gene flow into an organic alfalfa forage field; see table 4-3); (4) remove beehives surrounding alfalfa fields prior to alfalfa blooming period (5) Maintain physical isolation from GT alfalfa (either through distance or natural barrier (e.g., tree rows)); and (6) Plant alfalfa at the edge field to act as a trap for GE pollen and harvest these buffer rows separately.

Seed

The likelihood of gene flow between GT alfalfa fields and non-GT alfalfa fields is discussed in more detail in section IV.B. Although gene flow is more likely to seed fields than to hay fields, both NAFA and AOSCA have

developed stewardship programs to minimize any unwanted AP of genetically engineered material in alfalfa seed fields and to safeguard the domestic production of alfalfa seeds for GE sensitive markets. In addition to these stewardship programs, organic certification under the NOP requires that organic producers develop organic system plans, outlining steps to avoid contact or mixing with unapproved substances for use in organic production systems. Under the NOP, a buffer zone must be sufficient in size or have other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact with prohibited substances applied to adjacent land areas. However, more than one method is used under organic practices to prevent unwanted material from entering their fields. In addition to isolation of the farm, physical barriers or buffer zones between organic production and nonorganic production, as well as formal communications between neighboring farms are possible mechanisms to prevent AP instances (NCAT, 2003).

Forage

Organically grown alfalfa for forage is typically intended for use by dairy, meat, and pet food producers desiring to market their products in organic markets. Although the intended market for organic alfalfa forage differs from organic alfalfa seed, the issues related to farming practices remain similar. Organic alfalfa producers would need to take the necessary crop management steps necessary to ensure, to the degree possible, that no commingling and/or gene flow between GT alfalfa and organic alfalfa occurs. As discussed above, the USDA-NOP rests upon organic crop management practices developed to prevent the introduction of prohibited products. While not required, purchasers of organic alfalfa for redistribution as forage may require testing. In cases where organic alfalfa growers are unable to meet the testing requirements for organic markets, they may sell their alfalfa in non-premium markets.

If GT alfalfa is not detected in the feed of animals on organic dairy or meat farms, it is unlikely that the presence of CP4 EPSPS would be detected in the final meat or dairy product.

Adventitious Presence Impact on Organic Production Practices

The AP of GT trait in non-GT alfalfa is discussed in chapter IV.B. The economic impacts of AP are discussed in IV.D. This section only discusses the impact on farming practices due to AP. Organic seed farmers would need to adopt measures to limit AP in their organic seeds stocks as much as possible as described above.

2. Implications for Non-Agricultural Uses for Alfalfa

Alfalfa is used for non-agricultural purposes such as to seed rangeland, for rehabilitation and erosion control, and to seed Conservation Reserve Program (CRP) lands. Use of GT alfalfa in these settings would be a violation of the MTA. AP of GT alfalfa in seed stock used for these setting could result in GT alfalfa growing in these environments. If the site manager then wanted to remove the alfalfa, glyphosate would not kill the GT alfalfa and other means of removal would be needed. Conventional alfalfa is most susceptible to glyphosate in the fall when it is building root reserves. For thorough control of non-GT alfalfa in non-agricultural lands, it is likely that glyphosate alone would not provide complete control. If a tank mix is being used anyway, then the AP of GT alfalfa would not impact the practices for non-agricultural lands (Endres, 1999; Mayerle, 2002; Manitoba Agriculture and Food, 2002).

No Alternative

The No Action Alternative would impact the cultivation options for the farmers who adopted GT alfalfa between 2005 and 2007 and the farmers who would like to adopt GT alfalfa. These farmers would have to grow conventional alfalfa and would be limited to the production practices associated with conventional varieties as described above.

The No Action Alternative would impact organic growers because GT alfalfa would likely be rare in the market as current GT alfalfa fields reach the end of their stand life and new ones can only be grown under permit. Organic growers would not have to modify their production practices to increase buffers. There also would be less likelihood that contracts would require testing for GT alfalfa.

Isolation/Geographic Restriction Alternative

The Isolation/Geographic Restriction Alternative would allow GT alfalfa to be produced in Tier I, Tier II, and portions of the Tier III areas. Land use decisions in Tier I and Tier II would be very similar to that in the Deregulation Alternative. People growing alfalfa for high quality hay market may chose to grow GT alfalfa. These growers may implement different planting methods or management methods than the growers of conventional alfalfa. If growers chose to use GT alfalfa in conjunction with a no-till or low-till method they could change the management of the GT fields compared to the more traditional seeding methods. Conventional alfalfa can also be grown under no-till or low-till methods. There is no evidence that GT alfalfa growers will adopt this method more than non-GT alfalfa growers. Because of the limited availability of the product, no studies have yet been conducted.

Growers of GT alfalfa in Tier II and III states may have additional costs associated with managing GT alfalfa. This alternative would require that any grower within 165 ft of a conventional alfalfa seed field to harvest forage at or before ten percent bloom. In some years this may require the grower to harvest the hay at a time that does not maximize profits. For example, hay may reach ten percent bloom at a shorter height under water stress.[28] In these cases the grower may need to harvest before there is sufficient forage to make the harvest profitable.
Frequent cutting can also decrease stand life.[29] Growers within this distance of a conventional seed grower may chose to locate their alfalfa in an alternate location or plant non-GT rather than harvest at or before ten percent bloom continually for the life of the stand.

Growers in Tier III areas in counties that allow planting of GT alfalfa may choose to plant GT alfalfa to meet local markets that this product serves. Because some growers in neighboring counties would not be allowed to plant GT alfalfa, certain growers in permitted counties may chose to plant additional acres of GT alfalfa to sell in the restricted counties if there is local demand for the product.

Seed production of GT alfalfa and non-GT alfalfa would be segregated under this alternative. In areas where GT alfalfa seed is permitted, the concentration of alfalfa seed fields may increase. Because only a limited number of growers can complete for GT alfalfa seed contracts due to the required isolation distances, growers in these areas may convert land from other uses to alfalfa seed production.

G. Physical Environment

This section on the physical environment parallels and builds on that of the affected environment in section III.F by addressing impacts in three subsections: (1) soils, (2) climate and air quality, and (3) water. The discussion is primarily within the context of both the Deregulation Alternative and the Isolation/Geographic Restriction Alternative, given the impacts are expected to be very similar in terms of physical environment. The discussions of the impacts of the No Action Alternative are located at the end of each of the three subsections.

1. Impacts on Soils

As discussed in section III.F, alfalfa interacts with soil in many different ways, including by providing a beneficial increase in fixed nitrogen in the soil due to its symbiotic relationship with the bacterium *Sinorhizobium meliloti* in root nodules, and by improving soil tilth and structure due to its deep rooting characteristics, which in turn helps make alfalfa a valued

[28] http://www.ag.ndsu.edu/pubs/plantsci/hay/r571-2 htm#Drought
[29] http://www.americasalfalfa.com/AlfalfaResources/AlfalfaManagementGuide/stellent/groups/public/documents/web_content/ecmd0004919.pdf

rotational and soil conservation crop. Given the importance of this symbiotic relationship and its effect on soil, any potential change resulting from the GT alfalfa gene product or changes to soil resulting from changes to herbicide use patterns will also be discussed.

The petitioner provided data on GT alfalfa's characteristics that in turn have the potential to impact soil. These data included nodule formation observations as well as phenotypic observations that would be affected by modification of the nitrogen fixing process, such as seedling growth, levels of total protein, asparagine, and aspartate, and forage yield (see appendix U, *Character and Quality of Glyphosate-Tolerant Alfalfa Traits*). No statistically significant differences were noted for any of these symbiotic nitrogen-fixing relationships. Some research has indicated that the number and mass of root nodules could be lower for GT soybeans (without glyphosate) compared to conventional soybeans (also without glyphosate), but it is unclear whether this difference was due to the gene product or to differences between the soybean varieties (Kremer and Means, 2009). A compositional analysis conducted on GT alfalfa more broadly, as discussed in section IV.E, concluded that forage derived from J101 and J163 was compositionally equivalent to forage produced by conventional alfalfa. In general, reviews on the nutritional quality of GE foods have generally concluded that there is no significant difference in conventional versus GE plants (Flachowsky et al., 2005; Faust, 2002), so the contribution to soil composition and quality would be equivalent. Thus, no additional impacts, including the availability of nitrogen or other nutrients, would be expected on soil from GT alfalfa compared to conventional varieties.

Adoption of GT alfalfa would result in an increase in the use of glyphosate herbicide formulations on alfalfa when compared to the No Action Alternative. Glyphosate adsorbs strongly to soil and does not generally move vertically below six inches through the soil. Glyphosate can also either inhibit or mobilize various elements, including Al, Fe, Cu, Zn, Ni, P, Si, and As in soil, depending on various factors such as the amount of clay or organic matter (Barrett and McBride, 2006). Glyphosate is degraded in agricultural soils, depending on soil conditions, with a half-life ranging from 1.7 to 197.3 days, but typically less than 60 days (Giesy et al., 2000). Soil microbes degrade glyphosate into AMPA, and observed concentrations of AMPA in glyphosate treated areas are many times lower than levels with potentially adverse effects (Gimsing et al., 2004; USDA, 2003). Nevertheless, because soil is the habitat for a wide variety of microorganisms, impacts of glyphosate on soil microorganisms were examined further. Some data has indicated that while many microorganisms produce aromatic amino acids through the same metabolic pathway that glyphosate inhibits in plants, there is little empirical evidence to support the conclusion that glyphosate application results in a negative impact on soil microbes and, in some cases, field

studies have shown an increase in microbial activity (USDA-FS, 2003). In the cases where GT alfalfa is cultivated using no-till or conservation till systems, there may be positive impacts on soil microbes (Giesy et al., 2000). However, as discussed further in section IV.C more recent field studies indicate shifts in soil microbial community composition that might or might not cause some adverse consequences in agricultural fields over the long term. Furthermore, as discussed below the extent to which GT alfalfa would result in less tillage and other soil conservation practices when compared to conventional alfalfa is unclear.

Mechanical (tillage) and cultural methods for weed control (e.g., tillage and companion crops) have been used for ~80 percent of the spring planted alfalfa and 18 percent of the fall planted alfalfa (Hower et al., 1999). Converting to GT alfalfa could lead to a reduction in tillage and the impact of this conversion would increase if GT alfalfa is adopted beyond the percentage of acres currently using herbicides, as is predicted by the petitioner. Some evidence indicates that a trend toward less tillage intensive practices has occurred with the adoption of GT soybeans (Fawcett and Towery, 2002). An increase in conservation tillage and no-tillage practices could improve soil quality due to increasing the retention of soil organic matter that helps soil nutrient binding and prevents losses to runoff, erosion, and leaching (Leep et al., 2003). Conservation tillage and no-tillage practices also have the potential to mitigate potential minor effects on soil biological/chemical properties because it leads to enhanced organic carbon and plant residues in surface soils. However, these potentially positive changes could be offset if tillage is increased for stand removal of GT alfalfa.

Frequent mowing can compact and otherwise negatively impact soil. As discussed in IV. B.4, *Gene flow to other alfalfa crops and wild relative* and appendix V.2.0, mowing of GT alfalfa at ten percent bloom for fields near a seed field must be employed by agreement with the seed manufacturer to prevent alfalfa flowering in GT alfalfa systems. However, conventional alfalfa is also commonly mowed to prevent flowering. Conventional alfalfa is also mowed as a weed control technique, however (Van Deynze et al., 2008), and thus, the Deregulation Alternative and Isolation/Geographic Restriction Alternative might require less mowing for weed control, which could result in less frequent mowing of alfalfa fields and less soil compaction.

Under the No Action Alternative, conventional alfalfa would continue to be used and thus there would be no changes to the affected environment. The 200,000 acres of GT alfalfa currently under production likely would remain in the field, and at these sites there would be little or no impact on soils. Under No Action, there would be little potential for a large conversion of conventional agricultural systems (alfalfa or other crops) to commercial GT alfalfa fields. This could preclude an increase in the

amount of acres managed using conservation tillage and no-tillage systems and may result in adverse impacts on soils compared to the action alternatives if conservation tillage is adopted. Possible impacts under No Action for those areas that do not contain GT alfalfa may include increased soil erosions and disturbances to soil microorganisms.

2. Impacts on Climate and Air Quality

The deregulation of GT alfalfa and the increase in acres of GT alfalfa cultivation is expected to result in greater amounts of glyphosate herbicide application, but it is unclear whether the mechanical tillage of alfalfa fields would change when compared to the No Action Alternative If the use of glyphosate as a post emergence herbicide resulted in an increase in no-till farming, a corresponding decrease in the use of mechanical tilling by tractors and other equipment would result if GT alfalfa were deregulated. Emissions related to climate change, ozone depletion, summer smog, and carcinogenicity, among others, would decrease. Some evidence indicates that such emissions are found to be lower in other GT crop systems than conventional systems (Bennett et al., 2004), but given the uncertainties in the extent to which such changes would be seen with regard to GT alfalfa, as discussed above for soil impacts, these positive effects may not be as high as expected and may be essentially neutral, depending on soil, climate, and other factors.

Because glyphosate is not volatile at normal temperatures and is not considered an atmospheric contaminant, the deregulation of GT alfalfa is not expected to result in adverse impacts on air quality. If glyphosate is applied aerially, the risk of drift through the air increases, but this can be minimized by limiting aerial application on GT alfalfa.

Under the No Action Alternative, conventional alfalfa would continue to be used and thus there would be no changes to the affected environment. For those 200,000 acres currently planted with GT alfalfa, glyphosate would still be applied, and there may be a possible decrease in mechanical tillage of those fields. Any new, regulated plantings of GT alfalfa would be limited and so would not measurably contribute to changes in air quality or climate change. This would result in no changes from current conditions to air quality, and no changes to other factors of air pollution and greenhouse gases made possible by shifting from tillage to no-till practices, assuming any such shifts would occur. There is also no change in the type of herbicides applied, either by ground or aerial application.

3. Impacts on Water and Water Use

Surface Water

As discussed in section III.F, conservation tillage can reduce erosion and decrease the amount of sediments in rivers and streams. While the extent to which GT alfalfa overall would result in less tillage when compared to conventional alfalfa is unclear, in the cases where GT alfalfa is cultivated

using no-till or conservation till systems, there may be beneficial impacts on surface water, such as reducing the amount of sediments in rivers and streams. It should be noted that alfalfa (under conventional, organic, and GE management practices) is often used in crop rotations to decrease erosion because of its deep roots and perennial growth.

Sedimentation increases the turbidity (cloudiness of the water due to suspended particles) of water bodies, reducing light penetration, impairing photosynthesis, and altering oxygen levels, which can cause a reduction in food sources for some aquatic organisms. Sedimentation can also cover spawning beds and impact fish population levels. Phosphorous (a major component of fertilizer) bound to soil particles can be transferred to lakes and rivers via soil erosion, giving rise to high levels of phosphorous in surface waters, which may lead to algal blooms that can impact desirable fish populations. Section IV.C discusses these effects in more detail.

A compositional analysis conducted on GT alfalfa, as discussed in section IV.E, concluded that forage derived from J101 and J163 was compositionally equivalent to forage produced by conventional alfalfa. In general, reviews on the nutritional quality of GE foods have generally concluded that conventional and GE plants are not different (Flachowsky et al., 2005; Faust, 2002). Thus, no impacts would be expected on surface water in this regard. Therefore, for any GT alfalfa that does enter surface waters, there is no evidence that the gene product has any impact on nutritional load or other compositional changes.

Regarding herbicide use, deregulation of GT alfalfa would likely lead to the increased application of glyphosate herbicides, and either a decrease, no change, or an increase in the application of other herbicides, depending on a variety of factors (discussed in section IV.F, *Land Use and Production Practices*). Herbicides that adsorb strongly to soil, such as glyphosate, will be protected from degradation and volatilization, and will not readily reach surface waters. Glyphosate, which has a half-life in soil ranging from days to months (typically less than 60 days), will be found in surface water runoff when erosion conditions (e.g., during seeding, crop rotation, or flooding) lead to the loss of surface particles (Geisy et al., 2000). However, as discussed above for soils, deregulation of GT alfalfa could lead to an increase in conservation tillage and no-tillage systems, which would result in less mechanical disturbance of the soil during alfalfa cultivation and thereby decrease the loss of surface soil. Such benefits, however, could be offset if tillage also increases during stand removal of GT alfalfa, as discussed in section IV.F of this EIS.

Additionally, the conversion of conventional alfalfa to GT alfalfa could lead to a shift away from other herbicides toward glyphosate for weed control. As described in section IV.E.5., the other herbicides used on alfalfa have varying chemical fates, but in general, most were more

persistent and were characterized by higher mobility in soils, making them more apt to continually contaminate surrounding water systems. However, under some adoption scenarios, use of other herbicides increases with the adoption of GT alfalfa. This change could result in higher amounts of these herbicides in surface water than under the No Action Alternative. Whether other herbicide use increases or decreases depends on the management practices adopted and the weed pressure in the fields.

Under the No Action Alternative, no impacts on surface waters are expected to result from the increased application of glyphosate and the resulting low level presence of glyphosate in surface waters from glyphosate runoff. Other herbicides will still cause impacts on surface waters. However, the No Action Alternative would not change the amount of agricultural land managed by conservation tillage and no-tillage systems, and would not result in any of the potential benefits to surface waters associated with this practice. In this respect, the No Action Alternative may represent increased negative impacts on surface waters due to more sedimentation and turbidity compared to the other alternatives.

Groundwater

As indicated in section III.F, groundwater can be affected by GT alfalfa due to changes in herbicide use profiles. Herbicides used on alfalfa have varying chemical fate characteristics, with glyphosate and its primary degradation product, AMPA, generally being less persistent and characterized by lower mobility in soils than other herbicides. Due to glyphosate and AMPA's strong adsorptive characteristics, they are not likely to leach to groundwater from the soil (Cerdeira and Duke, 2006; Grunewald et al., 2001). Because of glyphosate's low potential to leach into groundwater, neither the Deregulation Alternative nor Isolation/Geographic Restriction Alternative is likely to have any adverse impacts on groundwater. It is possible that a reduction in number and type of other herbicides resulting from a transition from conventional to GT alfalfa could potentially reduce negative impacts on groundwater from those herbicides, as described in appendix J, *Effects of Changes in Farming Practices on Water, Soil, and Air Due to Use of Glyphosate-Tolerant Alfalfa*; however, no specific studies have been produced to substantiate such a conclusion, nor is it clear whether the use of other herbicides will decrease, remain the same, or increase. Increased weed pressure from weeds not controlled well by glyphosate could result in an increase in non-glyphosate herbicides.

Under the No Action Alternative, there would be no change to the impacts on groundwater associated with the cultivation of alfalfa. Herbicide use associated with the cultivation of alfalfa would still continue under the No

Action Alternative, and thus herbicides will continue to leach into groundwater from the soil. The No Action Alternative could inhibit any shift away from herbicides currently used on conventional alfalfa toward glyphosate, which is considered more environmentally benign. The continuing use of more other herbicides with more soil mobility and higher EIQs could result in a more environmentally harmful contingent of herbicides in groundwater compared to other alternatives; however, no studies have been produced to substantiate this conclusion and more analyses are needed before this relationship can be more fully established.

H. Mitigation Measures

1. Introduction to Mitigation Measures

As defined in the CEQ regulations implementing NEPA (§ 1508.20) mitigation includes:

- avoiding the impact altogether by not taking a certain action or parts of an action;
- minimizing impacts by limiting the degree or magnitude of the action and its implementation;
- rectifying the impact by repairing, rehabilitating, or restoring the affected environment;
- reducing or eliminating the impact over time by preservation and maintenance operations during the life of the action; and
- compensating for the impact by replacing or providing substitute resources or environments.

The measures listed below, if employed, would lessen adverse impacts associated with the Deregulation Alternative. The Isolation/Geographic Restriction Alternative requires some of these mitigation measures (see description in Chapter II). Whether these mitigation methods are required through a regulatory program or are used as part of industry led stewardship programs, they can be effective. See chapters IV.B through IV.G for a discussion of specific impacts resulting from the action alternatives. A summary of mitigation measures are presented by resource area below. Note that not all mitigation measures would work for all users. The mitigation measures discussed below do not apply to the No Action Alternative because GT alfalfa would be grown under the regulations in 7 CFR part 340. Conditions would be used to confine the plantings. Many of the recommendations below would be incorporated into the conditions. Any GT alfalfa grown under the No Action Alternative would be subject to conditions in the associated growing permit for the regulated biotechnology crops.

2. Mitigation Measures by Resource Area

Measures to Minimize AP of Genetically Engineered Content in Conventional and Organic Alfalfa for GE Sensitive Markets

- Forage Genetics has developed BMPs, which all growers of certified GT alfalfa seed varieties are required to follow. These measures are designed to keep gene flow to non GT alfalfa seed below 0.5 percent.
- Increasing isolation distance from GT alfalfa would be an important mitigation strategy for non-GT seed production, especially for seed destined for GE sensitive markets. The new AOSCA program for facilitating successful seed production for GE sensitive markets specifies the required isolation in this process-based certification (AOSCA, 2010): five miles from any AOSCA unaffiliated alfalfa production, two miles from any hay GT production, and 900 feet from any and all feral alfalfa with bloom monitoring. This standard is meant to provide seed that is process certified to be unlikely to have detectible GT transgene in standard testing procedures.
- Any farmer who purchases GT alfalfa seed for producing hay is required to sign and comply with a mandatory agreement, MTA. Although this requirement is not verified by APHIS, APHIS assumes that growers would fulfill their contractual obligations associated with growing GT alfalfa, and that Monsanto and FGI would effectively monitor and enforce compliance with their mandatory MTA and Best Practices.
- Additionally, the companies who produce Roundup Ready® seeds in the NAFA agreed jointly to adopt, as a minimum, BMPs for Roundup Ready® alfalfa seed production in the United States. These production practices meet or exceed AOSCA standards for the seed production of Foundation Class alfalfa seed production. Compliance to the guidelines is required under a separate and binding agreement (NAFA, 2008). The FGI and NAFA Best Practices for seed growers are the primary mechanism for limiting gene flow. To ensure these practices are working, the companies would collectively sample conventional seed lots annually, test for AP of the Roundup Ready® trait, and based on proximity to GT seed production, evaluate the effectiveness of isolation distance at limiting gene flow. Features of the NAFA, MTA, and FGI Best Practices are as follows:

– GT alfalfa seed producers may not sell seed to any party other than FGI and growers may not save seed for any purpose.
– Bee hives cannot be moved out of GT alfalfa until pollination is finished for the year. This prevents pollen being carried via hive between GT and non-GT alfalfa. Growers must indicate main pollinator species on the FGI Seed Grower Contract.
– Isolation through distance from other alfalfa fields is required. For pollination with leafcutter bees, the distance must be greater than or equal to 900 feet, for alkali bees greater than or equal to one mile, for honey bees greater than or equal to three miles.
– The GT Seed Contractor shall report GPS coordinates of all established and planned GT seed production fields to local State seed certification

officials as early as possible. State officials will confirm minimum isolation and establish a State pinning map for GT seed production.

- The GT Seed Contractor will limit GT seed production contracts to the following States: Arizona, California, Colorado, Idaho, Montana, Nevada, Oregon, Texas, Utah, Washington, and Wyoming.
- The GT Seed Contractor will also respect any GE-free alfalfa seed production zone designated as such by a consensus of local seed growers.
- Stand removal and volunteer management must be sufficient to allow seed certification inspectors to validate stand removal. Stand removal date and method must be reported to FGI and verified.
- Cleaning requirements for equipment are included in the NAFA and FGI Best Practices.
- The Monsanto MTA requires hay growers to harvest at or before ten percent bloom.

The establishment of barriers between fields can mitigate gene flow. Types of barriers can include bodies of water or other, more attractive plants for bee foraging in between fields. A border of plants at field edges has the benefit of being a buffer zone, as pollen would be deposited in the border population before leaving a GT alfalfa field.

Measures to Reduce Volunteer Alfalfa and Glyphosate Resistance in Weeds

- Volunteer alfalfa can be reduced with stringent stand termination procedures. Less than 100 percent alfalfa stand termination can result in volunteer alfalfa plants in the following crop. Therefore, good stand termination procedures would be an appropriate method of eliminating volunteer GT alfalfa plants. Non-glyphosate herbicides and tillage are recommended for effective GT alfalfa stand removal (Orloff et al., 1997).
- Monsanto's guidance for GT alfalfa stand removal (Monsanto, 2008) can help ensure 100 percent stand removal. It is summarized below and in the technical report, *Effects of Glyphosate-Resistant Weeds in Agricultural Systems* (appendix H).
- Use appropriate commercially available treatments alone for reduced tillage systems or in combination with tillage to terminate the GT alfalfa stand.
- Refer to regional technical bulletins for specific stand takeout recommendations.
- If necessary, use tillage and/or additional herbicide application(s) after stand takeout, and before planting of the subsequent rotational crop to manage any newly emerged or surviving alfalfa.

- Rotate crops with known and available mechanical or herbicidal methods for managing volunteer alfalfa, keeping in mind that glyphosate will not terminate GT alfalfa stands.
- Rotations with certain broadleaf crops are not advisable if the grower is not willing to implement recommended stand termination practices.
- In the event that there are no known mechanical or herbicidal methods to manage volunteer alfalfa in the desired rotation crop, it is suggested that another crop with known management practices be used.
- Timely in-crop mechanical or herbicide treatments for managing alfalfa volunteers must be used to ensure that the volunteers do not become too large to control or compete with the rotational crop.

- Correct application of herbicide would allow for control of volunteer alfalfa. For example, farmers are not able to use glyphosate to control volunteer GT alfalfa in other GT crops. However, eleven other herbicides and mixtures of those herbicides are available to control volunteer GT alfalfa. These are the same herbicides that are used to control non-GT alfalfa, with the exception of glyphosate.

- As discussed in appendix H-1, the development of weed resistance to glyphosate can be minimized through farming practices. Farming practices, such as mowing, limit the likelihood of weed occurrence, which in turn reduces the possibility of weed shifts to glyphosate resistant or tolerant weeds, and the new development of glyphosate resistance in weeds by reducing the likelihood of weeds going to seed. However weeds that are adapted to complete their lifecycle under this type of mowing schedule would still be under glyphosate selection in GT alfalfa.
- To further reduce the probability of weed shifts and/or the development of glyphosate resistance in weeds, rotations between GT and non-GT crops and the use non-glyphosate herbicides are recommended. These actions can reduce the populations of glyphosate-tolerant weeds, thus reducing weed shifts in GT crops. Farmers using GT cropping systems are advised to include some years of non-GT crops in rotation.
- Additionally, growers should monitor for glyphosate resistant weeds. Any weeds that are suspected to be glyphosate resistant should be destroyed and/or treated with other herbicides to ensure that they do not persist in the environment.
- MTA requires growers to follow the applicable provisions in the Monsanto Technology Use Guide (TUG), which includes Monsanto's weed resistance management stewardship program for GT alfalfa (Monsanto, 2008):

- Scout fields before and after each herbicide application.
- Use the right herbicide product at the right rate and at the right time.

- To control flushes of weeds in established alfalfa, make applications of Roundup WeatherMAX®herbicide at 22 to 44 oz per acre before weeds exceed six inches, up to five days before cutting.
- Use other herbicide products tank-mixed or in sequence with Roundup® agricultural herbicide if appropriate for the weed control program.
- Report repeated nonperformance to Monsanto or your local retailer.

Measures to Minimize Impacts on the Biological Environment

- Volunteer GT alfalfa, weed shifts, and glyphosate resistance in weeds can all be minimized through appropriate management practices. As discussed in section IV.H.2.I, the presence of volunteer alfalfa can be reduced through stringent stand removal and weed shifts and glyphosate resistance can be reduced through appropriate weed management practices.
- Correct glyphosate use, by following instructions on the label and using the product as recommended, can minimize potential impacts from glyphosate on the biological environment.
- To minimize impacts on T&E species, all licensees of crops with Roundup Ready® technology are required to observe all mitigation instructions on the web site http://www.pre-serve.org/Pre-Serve-B02/. These instructions help licensees determine if they can apply glyphosate on their land or if there are T&E species in the area of which they should be aware. More information on T&E species can be found in section III.B.
- As discussed in III.E and appendix J and N, conservation tillage and no tillage practices associated with GT alfalfa have the potential to mitigate impacts on aquatic plants through decreasing runoff and erosion of soil particles with absorbed glyphosate.

Measures to Minimize Human Health and Safety Impacts

- Adhere to herbicide label requirements, including application rates and techniques.

Measures to Minimize Impacts on the Physical Environment

- As discussed in appendix J, GT alfalfa stands likely would result in an overall increase in herbicide use, with non-glyphosate herbicides either increasing or decreasing depending on weed pressure. Herbicide shifts due to stand removal, which occurs only once every three to eight years, would be smaller in magnitude than herbicide shifts due to weed control on a yearly basis. Extending the stand life would further minimize the impacts from the non-glyphosate herbicides used during stand removal.
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I. Other Impacts

1. Unavoidable Impacts

The Deregulation Alternative is the deregulation of GT alfalfa events J101 and J163 under the regulations at 7 CFR part 340, and once deregulated these GT alfalfa lines can be grown anywhere in the United States. Under the No Action Alternative, APHIS would not deregulate GT alfalfa events J101 and J163, they would continue to be regulated articles, and permits issued by APHIS would be required for new introductions of J101 and J163 plants.
APHIS has also considered the Isolation/Geographic Restriction Alternative, which segregates GT alfalfa and non-GT alfalfa seed production. The specific conditions are defined by tiers that were created based on the current State and County level alfalfa seed and forage production.

The Deregulation Alternative of granting non-regulated status to GT alfalfa would result in an increase in the amount of GT alfalfa produced in the United States and a corresponding increase in the prevalence of the gene product in the environment when compared to the No Action Alternative. As discussed in section IV.B and appendix V, unintentional gene flow from GT alfalfa to non-GT alfalfa and unintentional mixing of GT alfalfa seed with non-GT alfalfa seed would likely result in AP of GT alfalfa in non-GT alfalfa. Under the Deregulation Alternative, GT-alfalfa seed producers are required by contract to follow FGI Best Practices, which include isolation distances from non-GT alfalfa seed production and cleaning of equipment to reduce the possibility of unintentional mixing of GT alfalfa seed (appendix V) to below 0.5% of GT alfalfa seed in conventional varieties. Under the Isolation/Geographic Restriction Alternative, isolation distances and geographic restrictions would segregate GT alfalfa and non-GT alfalfa seed production, and this alternative would reduce the likelihood of AP of GT alfalfa in conventional alfalfa seed below that of the Deregulation Alternative. Segregation of the two markets is likely to result in the majority of conventional seed lots have no detectable GT alfalfa present.

The Isolation/ Geographic Restrictions Alternative, like the Deregulation Alternative, would also result in a change in alfalfa cultivation and management practices, such as herbicide use, which has implications for ecosystems and the human environment. See section IV.B through IV.G for a discussion of specific impacts resulting from the action alternatives. As described in sections IV.C, IV.E, and IV.G, the Deregulation Alternative and the Isolation/Geographic Restrictions Alternatives might diminish certain agricultural impacts due to a possible shift to herbicide regimes with lower EIQs or soil mobility, but only in the instances that GT alfalfa farming directly replaces conventional alfalfa that is managed with herbicides and weed pressure from weeds not well controlled by glyphosate is low.

2. Short-term Versus Long-term Productivity

The NEPA states in section 102 (42 U.S.C. § 4332) that all agencies of the Federal government shall:

(C) include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on --

(iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity,…

This portion of the NEPA regulations recognizes that short-term uses and long-term productivity of the environment are linked, and that opportunities that are acted upon have corollary opportunity costs in terms of foregone options and productivity that could have continuing effects well into the future.

With appropriate management, deregulation of GT alfalfa may have both short-term and long-term positive impacts on alfalfa productivity. By allowing for post-emergence control of weeds through glyphosate application, GT alfalfa would likely reduce weeds in alfalfa stands and may increase alfalfa yield and quality. As stated in appendix G, without weeds, alfalfa can grow at a density of about 12 plants per square foot. Heavily infested stands can have less than one alfalfa plant per square foot (Canevari et al., 2007b). In California, if weeds are not effectively controlled, they can represent up to 76 percent of the first cutting yields (Gianessi et al., 2002).

As discussed in appendix G, in field trials when glyphosate was applied during GT alfalfa stand establishment at the three to four trifoliolate stage, weeds were controlled and usually a second application was not needed (Van Deynze et al., 2004). McCordick et al. (2008) reported that in two year field trials with GT alfalfa, weed control with glyphosate was more consistent than with other herbicides, and that GT alfalfa treated with glyphosate yielded the highest alfalfa dry matter in both years (McCordick et al., 2008).

The ability of glyphosate to reduce weed pressure in GT alfalfa fields and increase alfalfa productivity is only effective if the weeds are killed by glyphosate. As discussed in appendix G, the wide-spread adoption of GT crops and the corresponding increase in glyphosate use, has also resulted in increased selection pressure for glyphosate-resistant weeds. For example, since 1998, 19 new glyphosate-resistant weeds have been found globally, ten of which have glyphosate-resistant biotypes in the United States (appendix G).

The increased glyphosate use in GT alfalfa fields, as would be predicted from the Deregulation Alternative and the Isolation/Geographic Restrictions Alternative, could result in an increased chance of evolving glyphosate-resistant weeds if not managed appropriately. If glyphosate-resistant weeds become established in GT alfalfa fields, the long-term productivity of GT alfalfa could be reduced. While the No Action Alternative could reduce the number of GT alfalfa acres under production as compared to the Deregulation Alternative, selection pressure for glyphosate-resistant weeds would still occur for the above stated reasons and would likely reduce the long-term productivity of GT crops.

As discussed in appendix G, BMPs can help control the development of glyphosate-resistant weeds. These include: a) identifying weeds and monitoring for escapes to determine if current practices need to be modified to achieve acceptable levels of weed control; b) using proper herbicide rates and timing; c) using crop rotation to facilitate use of different modes of action over time; d) using agronomic management practices to supplement herbicide weed control; e) alternating herbicides with different modes of action; and f) tank mixing herbicides of different modes of action (appendix G).

3. Irreversible Commitment of Resources

Irreversible resource commitments represent a loss of future options. It applies primarily to the use of nonrenewable resources and to factors that are renewable only over long time spans. An irretrievable commitment of resources represents opportunities that are foregone for the period of the proposed action. It relates to the use of renewable resources, such as timber or human effort, as well as other utilization opportunities that are foregone in favor of the proposed action. NEPA section 102 (42 U.S.C. § 4332) and Council on Environmental Quality (CEQ) regulations (40 CFR § 1502.16) require that all agencies of the Federal government shall:

(C) include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on --

(v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

Based on available data, there is no indication that there would be an irretrievable loss of resources. Further, it is expected that much of the land that would be used for GT alfalfa cultivation under the Deregulation Alternative and Isolation/Geographic Restriction Alternative is presently already used for alfalfa production or for other agricultural production. Additionally, the overall land devoted to alfalfa is more closely linked to the price of alfalfa hay than it is to the availability of GT technology.

4. Cumulative Impacts

This section describes potential cumulative impacts in connection with deregulating GT alfalfa events J101 and J163. APHIS considered potential direct and indirect impacts of the proposed action and alternatives in chapter IV of this EIS in combination with the potential impacts of other relevant past, present, and reasonably foreseeable future actions that may have an impact on the same resources. These combined impacts are called cumulative impacts.

CEQ regulations (40 CFR § 1500 to 1508) that implement the procedural requirements of (42 U.S.C. § 4321 et seq.) NEPA require a cumulative impacts analysis of the action as part of the Environmental Impact Statement (EIS) process. CFR § 1508.7 defines cumulative impacts as:

[T]he impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.

In this section, actions that could have effects that coincided in time and space with the effects from the proposed deregulation and associated activities, are identified and considered in combination with the impacts of other Federal, non-Federal, and private actions.

Structure of the Cumulative Impacts Analysis

For this EIS, the analysis of cumulative impacts follows the analysis steps described in *Considering Cumulative Effects Under the National Environmental Policy Act* (CEQ, 1997):

- Specify the class of actions for which effects are to be analyzed.
- Designate the appropriate time and space domain in which the relevant actions occur.
- Identify and characterize the set of receptors to be assessed.
- Determine the magnitude of effects on the receptors and whether those effects are accumulating.

Class of Actions to be Analyzed

This analysis addresses large, regional, and national-scale trends and issues that have impacts that may accumulate with those of the Deregulation Alternative and the Isolation/Geographic Restriction Alternative. This analysis does not evaluate site-specific cumulative impacts, primarily because alfalfa is grown in every state and is rotated with other crops in agricultural system. The decision to be made by the agency does not dictate specific locations for planting; therefore, site specific analysis is not possible.

Geographical and Temporal Boundaries for the Analysis

The alternatives are discussed in chapter II. For the Deregulation Alternative, APHIS is proposing the deregulation of GT alfalfa without geographic restrictions other than those mandated at the municipal and State level. GT alfalfa has been cultivated in 1,552 counties in 48 States after it was deregulated in 2005. Therefore, the spatial domain for past, present, and reasonably foreseeable future actions considers the entire nation and in some cases, has international implications. This analysis focuses more on geographic interaction of activities than timing of interactions because the actual timeframes for many of the reasonably foreseeable future actions are uncertain.

APHIS considers reasonably foreseeable actions as those future actions for which there is a reasonable expectation that the action could occur, such as a project that has already started or a future action that has obligated funding. APHIS has identified activities relevant to the cumulative impacts analysis from reviews of information available from government agencies, such as Environmental Impact Statements, land-use and natural resource management plans, and from private organizations. Not all actions identified in this analysis would have cumulative impacts on all resource areas.

Resources Analyzed

Resources evaluated in this cumulative impacts analysis include the resource areas discussed in chapters III and IV: Biological; Socioeconomic; Human Health and Safety; Land Use and Production Practices; and Physical Environment. However, as discussed in sections IV.B through IV.G, resources that would experience impacts from the deregulation of GT alfalfa in combination with other actions are described, and an analysis of the cumulative effects to the resource is presented below.

Magnitude of Effects on Resources

The potential extent of the impacts of the Deregulation Alternative and the Isolation/Geographic Restriction Alternative combined with other actions, and the duration of those impacts are considered in determining the magnitude of cumulative effects that impact each resource area. When possible, the assessment of the effects on a resource is based on quantitative analysis; however, many effects are difficult to quantify. In these cases, a qualitative assessment of cumulative impacts is made. CEQ regulations at 40 CFR § 1502.22—incomplete or unavailable information, directs agencies on how to proceed when evaluating effects on the human environment in an Environmental Impact Statement when there is incomplete or unavailable information. While information describing the characteristics and potential effects of other projects and activities within the time and space domain is primarily qualitative and in some cases is incomplete or unavailable, there is enough information to consider the cumulative effects of the deregulation of GT alfalfa. This qualitative approach is used when necessary throughout this section and for each resource area. For this section if a topic is discussed qualitatively, further quantitative details about the topic are either incomplete or unavailable.

As suggested by the CEQ (1997) handbook, *Considering Cumulative Effects Under the National Environmental Policy Act,* this EIS considered the following basic types of cumulative effects that might occur due to the Deregulation Alternative and the Isolation/Geographic Restriction Alternative:

- *Additive* — loss of a resource from more than one incident.
- *Countervailing* — adverse effects are compensated by beneficial effects.
- *Synergistic* — total effect is greater than the sum of effects when considered independently.

In the following analysis, cumulative impacts should be considered additive unless designated as otherwise. In the case of most resources that may experience cumulative impacts, the Deregulation Alternative and the Isolation/Geographic Restriction Alternative is only responsible for a contribution of an incremental portion the total impact on the resource. The past, present, and reasonably foreseeable connected actions typically contribute to the majority of impacts experienced by the resource, and would continue to have impacts on the resource even if the No Action Alternative were implemented.

Analysis of Cumulative Impacts by Resource Area

The past, present, and reasonably foreseeable actions that relate to the cumulative impact of the Deregulation Alternative and the

Isolation/Geographic Restriction Alternative on all resources include the deregulation of other GT crops and the shift in some herbicide regimes to glyphosate formulations. According to the U.S. Department of Agriculture – Economic Research Service (USDA ERS 2010), U.S. farmers have widely adopted GE crops since their introduction in 1996. Soybeans and cotton genetically engineered with herbicide-tolerant traits have been the most widely and rapidly adopted GE crops in the United States, followed by insect-resistant cotton and corn. Figure 4-2 shows the percentage of acres of GE crops in the United States between 1996 and 2010.

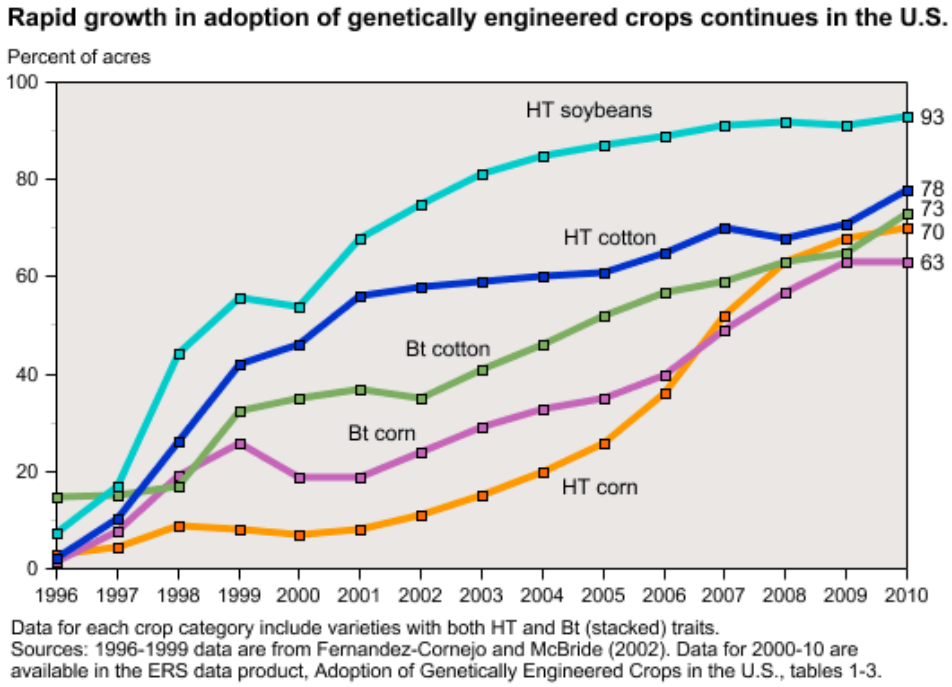

Figure 4-2. Rapid Growth in Adoption of Genetically Engineered Crops in the United States.

Source: Graph from USDA ERS 2010

Herbicide-tolerant crops, which are engineered to survive application of specific herbicides that previously would have damaged the crop, provide farmers with a broader variety of options for effective weed control. Based on USDA survey data, herbicide tolerant soybeans went from 17 percent of U.S. soybean acreage in 1997, to 68 percent in 2001, and 93 percent in 2010. Plantings of herbicide-tolerant cotton expanded from approximately ten percent of U.S. acreage in 1997 to 56 percent in 2001 and 78 percent in 2010. The adoption of herbicide tolerant corn was slower in previous years, but has reached 70 percent of U.S. corn acreage in 2010 (USDA ERS, 2010).

Corn growers use the largest volume of herbicides. Approximately 96 percent of the 62.2 million acres used for growing corn in the ten major corn-producing states were treated with more than 164 million pounds of herbicides in 1997 (USDA ERS, 2010). Soybean production in the United States also uses a large amount of herbicides. Approximately 97 percent of the 66.2 million soybean acres in the 19 major soybean-producing states were treated with more than 78 million pounds of herbicides in 1997 (USDA ERS, 2010). Cotton production relies heavily on herbicides to control weeds, often requiring applications of two or more herbicides at planting and post-emergence herbicides later in the season (Culpepper and York, 1998). Close to 28 million pounds of herbicides were applied to 97 percent of the 13 million acres devoted to upland cotton production in the 12 major cotton-producing states in 1997 (USDA ERS, 2010).

Several studies have analyzed the agronomic, environmental, and economic effects of adopting GE crops, including actual pesticide use changes associated with growing GE crops (McBride and Brooks, 2000; Fernandez-Cornejo et al., 1999, 2002; Gianessi and Carpenter, 1999; Culpepper and York, 1998; Marra et al., 1998; Falck-Zepeda and Traxler, 1998; Fernandez-Cornejo and Klotz-Ingram, 1998; Gibson et al., 1997; ReJesus et al., 1997; Stark, 1997). Many of these studies have concluded that herbicide use is reduced with herbicide-tolerant varieties (USDA ERS, 2010). Studies conducted by the USDA also show an overall reduction in pesticide use related to the increased adoption of GE crops. Based on the adoption of GE crops between 1997 and 1998 (except for herbicide-tolerant corn, which is modeled for 1996–1997), the decline in pesticide use was estimated to be 19.1 million acre-treatments, 6.2 percent of total treatments (USDA ERS, 2010). Most of the decline in pesticide acre treatments was from less herbicide used on soybeans, accounting for more than 80 percent of the reduction (16 million acre-treatments) (USDA ERS, 2010). GT crops allow farmers to limit and simplify herbicide treatments based around the use of glyphosate, while a conventional weed control program can involve multiple applications of several herbicides. However, other studies suggest this downward trend of pesticide use may be changing. Data presented by Benbrook (2009) and Brookes and Barfoot (2010) indicate increasing use (i.e., lbs per acre) of glyphosate on GT corn and soybeans from 1996 to 2008, without much change in use of other herbicides on those crops.

In addition and more importantly, herbicide-tolerant crops often allow farmers to use more benign herbicides (USDA ERS, 2010). Heimlich et al. (2000) noted that using glyphosate has resulted in the replacement of herbicides that are at least three times as toxic and persist almost twice as long as glyphosate. Gianessi and Carpenter (2000) had similar conclusions. Trewavas and Leaver (2001) conducted an analysis that concluded that 3.27 million kg of other herbicides have been replaced with 2.45 million kg of glyphosate in soybean fields in the United States.

Carpenter and Gianessi (2003) concluded that the introduction of GT soybeans has resulted in a decrease in the total volume of herbicides used. The National Research Council recently reported that planting of GT soybean, cotton, and corn has resulted in the use of fewer alterative herbicides than glyphosate, but that glyphosate is often applied in higher doses and in greater frequency than the herbicides it replaced (NRC, 2010). The amount of active ingredients of herbicide applied (including glyphosate and other herbicides) varied by crop; for soybean and cotton it increased from 1996–2007, but for corn it decreased over the same time period (NRC, 2010). Gianessi's (2005) calculations indicate that if GT sugar beets were adopted, reduction in herbicide use would not be as great as for combined GT crops, because the herbicides used now in non-transgenic sugar beets are mainly low-use rate compounds in the United States. Kleter et al. (2008) analyzed data on GT sugar beet production in Europe and found that quantities of herbicides applied to glyphosate-resistant beets are reduced compared their conventional counterparts (Kleiter et al., 2008). Like other GT crops, glyphosate use on GT alfalfa would increase under the two action alternatives. Based on different adoption scenarios, the amount of other herbicides used may decrease or increase depending on the type of management regime used. The magnitude of change will depend on the adoption rate of GT alfalfa. There are known benefits associated with the use of glyphosate herbicides compared to other herbicides currently used by alfalfa producers. Glyphosate has documented favorable characteristics with regard to risk to human health, non-target species, and the environment (Malik, 1989; Giesy et al., 2000; Williams et al., 2000). As GT alfalfa is adopted, it is uncertain whether glyphosate-containing herbicides would replace other herbicides currently used in alfalfa, which are more harmful to the environment.

Biological Impacts

As discussed in section IV.C, the alternatives are not expected to result in adverse impacts on biological resources from GT alfalfa per se (i.e., the gene product). However, the Deregulation Alternative and the Isolation/Geographic Restriction Alternative are expected to lead to increased use of glyphosate (compared to the No Action Alternative), which could have adverse impacts on biological resources. An increase in the use and application of glyphosate-based herbicide formulations would lead to an increase in the amount of incidental glyphosate exposure to terrestrial and aquatic plants and animals in the vicinity of GT alfalfa fields, either by spray drift or transport in surface water runoff. As stated in section IV.C, increased glyphosate use is not expected to pose an acute or chronic risk to birds, mammals, terrestrial or aquatic invertebrates, fish, and microorganisms. Glyphosate is slightly toxic to amphibians and is not expected to be a risk to amphibian populations. Non-tolerant and non-resistant plants experience high levels of toxicity when exposed to

glyphosate which can result in plant death. Additionally, as described in appendix G, the Deregulation Alternative and the Isolation/Geographic Restriction Alternative could contribute to an increase in the number of glyphosate-resistant weeds. Therefore, the Deregulation Alternative and the Isolation/Geographic Restriction Alternative, when combined with other past, present, and reasonably foreseeable actions, could result in cumulative impacts on biological resources. The potential cumulative impacts from the Deregulation Alternative and the Isolation/Geographic Restriction Alternative are discussed in the following paragraphs.

Plants

The GT alfalfa plant does not itself affect plant communities differently from non-GT alfalfa. Alfalfa is not considered to be invasive or a weed in most settings, and is even promoted in rangeland for grazing and in areas undergoing erosion control or rehabilitation (see appendix H). The use of GT alfalfa does result in glyphosate usage, which impacts agricultural systems and plants close enough to fields to experience glyphosate drift.

As described in sections III.B.2 and IV.C, when exposed to glyphosate or other herbicides, non-resistant and non-tolerant plant species experience high levels of toxicity. When sprayed with glyphosate, plants that use the shikimate pathway to produce aromatic amino acids experience toxic effects as they metabolize glyphosate. These toxic effects could include the inability to (1) photosynthesize, (2) complete respiration, and (3) synthesize nucleic acids and amino acids. Although the effects can be slow to progress, all of these toxic effects could result in plant death. Therefore, when added to other past, present, and reasonably foreseeable future actions, the Deregulation Alternative and the Isolation/Geographic Restriction Alternative could result in cumulative impacts on plants. Although the impacts of both alternatives would be similar to the extent that less GT hay might be planted under the Isolation/Geographic Restriction Alternative, the degree of cumulative impacts likely would be lesser under the Isolation/Geographic Restriction Alternative compared to the Deregulation Alternative. Impacts of glyphosate on plants include:

- Reduced non-resistant and non-tolerant plants in fields where glyphosate is applied. This impact is the reduction of weeds, is intended, and is considered beneficial for farmers.
- Selective pressure for weed populations to evolve resistance to glyphosate and for weed shifts to tolerant biotypes (discussed in appendix G).
- Glyphosate drift during application to nearby plants that border fields, causing harm to non-resistant and non-tolerant plant species.

All of the above impacts are discussed in chapters III and IV, but are examined in the context of all agriculture in this chapter. GT alfalfa is one

of several GT crops. For example, small-scale root production of GT sugar beets began in 2006 and 2007. The impact of GT sugar beets on the cumulative use of glyphosate is minimal, however, because of the relatively small acreage devoted to sugar beets (less than 1.4 million acres). For comparison, there are approximately 10 million acres of available alfalfa production which could be converted to GT alfalfa (based on a 51 percent adoption rate [see appendix J]). Additionally, 93 percent of current soybean acreage, 78 percent of cotton acreage, and 70 percent of corn acreage (totally approximately 130 million acres) is herbicide tolerant (USDA ERS, 2010). Petitions for non-regulated status are pending for commercial production of GT corn, creeping bent grass, and sugar beets.[30] If deregulated, the production of these GT crops would lead to increased glyphosate application, and in the instances that it is cultivated in or near the same geographic areas where GT alfalfa is produced, this could lead to a cumulative impact on plants affected by the Deregulation Alternative and the Isolation/Geographic Restriction Alternative.

However, as mentioned in section IV.C, a program named Pre-Serve was developed to address aerial spraying in areas where T&E plants may be located. Following label use instructions and use limitations described in Pre-Serve would address any such risk of exposure. Furthermore, APHIS does not have the authority under the Plant Protection Act to regulate herbicide use associated with GT plants that are granted non-regulated status. The use of glyphosate is regulated by the FIFRA restrictions administered by the EPA, which mandate registration and use of all pesticides. EPA includes instructions and restrictions on how glyphosate herbicides can be applied, and has determined that there is no unreasonable environmental risk when used according to the label directions. Violators of the regulations are liable for all negative consequences of their actions. Therefore, it is expected that farmers who use glyphosate are very likely to follow its label restrictions, and adverse impacts from the predicted increased glyphosate use would be minimized.

Potential cumulative impacts of glyphosate on aquatic plants from runoff are expected to be negligible. Practices in application of glyphosate (observing the legally-mandated maximum aerial and ground-based application rates that are governed by FIFRA regulations) would likely decrease the amount of drift and lessen the impacts of the Deregulation Alternative and the Isolation/Geographic Restriction Alternative on aquatic plant species. Additionally, because glyphosate binds strongly to soil particles, alfalfa's long stand life provide additional assurance that the impacts to aquatic plants are minor. Following legally-mandated instructions and applying conservation practices could result in a decrease in the incremental impacts on aquatic plants due to both alternatives, and

[30] http://www.aphis.usda.gov/brs/not_reg html

could therefore lower the net cumulative effect of the other present and reasonably foreseeable actions.

As stated above, the rapid and extensive adoption of GT crops has resulted in glyphosate becoming the main herbicide to control weeds, and other herbicide use appears to have decreased (see sections IV.E.5 and III.D.2). GT crops have resulted in glyphosate becoming an in-crop, post-emergent, selective herbicide for use in annual, agronomic crops (Duke and Powles, 2009). Additionally, the increased weed control from post-emergence glyphosate use with GT crops has allowed farmers to use conservation tillage practices, especially in soybean and cotton (Locke et al., 2008; Powles, 2008).

While both of these actions are associated with positive environmental impacts (reduced use of toxic herbicides and reduced soil loss), they have also resulted in high levels of selection pressure on the weed population for glyphosate resistance. As described in appendix G, continuous use of a single herbicide applies selection pressure to the weed population and no-till practices allow weed seeds to accumulate in the soil bank. This selection pressure and accumulation of weed seeds in crop fields, combined with acres of GT crops currently being grown not using the recommended weed management practices, have contributed in an increase in the number of glyphosate-resistant weeds. Since 1998, 20 new glyphosate-resistant weeds have been found globally, eleven of which have glyphosate-resistant biotypes in the United States. Eight of the new glyphosate-resistant weeds known globally are also known to be weeds in alfalfa stands (appendix G).

Deregulation of GT alfalfa would encourage the use of glyphosate, as that would be the most effective way of achieving weed-free alfalfa stands. This increased glyphosate use from the Deregulation Alternative or the Isolation/Geographic Restriction Alternative, if not managed well, could result in an increased chance of evolving glyphosate-resistant weeds or weed shifts to weed not controlled well with glyphosate (both tolerant and resistant weeds). If GT alfalfa is widely adopted in areas where alfalfa is a major crop, the potential that alfalfa acreage would overlap with glyphosate-resistant weed locations increases. For a discussion of the current range of glyphosate resistant weeds, see appendix G.

As discussed in appendix G, the perennial nature of alfalfa and the production characteristic of harvesting through mowing can delay weed shifts in GT alfalfa. For example, repeated mowing is effective in retarding weeds from setting seed due to the removal of the growing tip at the top of the weed (appendix G). Also because alfalfa is a perennial crop (a single stand can typically last three to eight years), farmers are more likely to use different herbicides after the crop is established. For example, glyphosate offers significant crop safety advantages at seeding of GT

alfalfa (Canevari et al., 2004), but after stand establishment, growers might be more inclined to use a soil residual herbicide, since glyphosate does not have soil residual activity. Additionally, although weeds can be a problem in alfalfa, once alfalfa is established, it acts as a suppressor of weeds and is commonly used in rotations for weed reduction (appendix G).

As discussed in appendix G, BMPs can help control the development of glyphosate-resistant weeds. These include: a) identifying weeds and monitoring for escapes to determine if current practices need to be modified to achieve acceptable levels of weed control; b) using proper herbicide rates and timing; c) using crop rotation to facilitate use of different modes of action over time; d) using agronomic management practices to supplement herbicide weed control; e) alternating herbicides with different modes of action; and f) tank mixing herbicides of different modes of action (appendix G).

If glyphosate-resistant weeds become established in a particular GT alfalfa field, then production practices would favor the use of additional herbicides. In these cases, glyphosate use would not displace other herbicide use. It is likely that glyphosate will be combined with other herbicides as needed. Future deregulation of other GT crops, such as creeping bentgrass or other varieties of corn, soybeans, and sugar beets whose proposals for deregulation are pending, would impact the potential for weed shifts in a similar fashion. While the No Action Alternative might reduce the number of GT alfalfa acres under production as compared to the Deregulation Alternative or the Isolation/Geographic Restriction Alternative, selection pressure for glyphosate-resistant weeds would still occur for the above stated reasons.

Animals

Increased glyphosate use is not expected to pose an acute or chronic risk to birds, mammals, terrestrial or aquatic invertebrates, fish, and microorganisms (EPA, 1993). Glyphosate itself is slightly toxic to fishes and aquatic invertebrates, but toxicity data suggest certain surfactants in glyphosate formulations result in a higher toxicity. For GT alfalfa use, glyphosate exposure does not result in risk exceeding levels of concern for fishes or aquatic invertebrates; however, the end use herbicide concentration (Roundup®) could not be estimated to enable a quantitative risk assessment. Therefore, impacts on fishes and aquatic invertebrates resulting from the Deregulation Alternative and the Isolation/Geographic Restriction Alternative cannot be determined. As is the case with amphibians (discussed below), this does not preclude the possibility that the surfactants found in the end-use herbicide could result in adverse impacts on fishes and aquatic invertebrates. As with plants, although the impacts of both alternatives on animals would be similar since less GT hay

may be planted under the Isolation/Geographic Restriction Alternative, the degree of cumulative impacts might be lesser under the Isolation/Geographic Restriction Alternative compared to the Deregulation Alternative.

Glyphosate is slightly toxic to amphibians and is not expected to be a risk to amphibian populations. However, amphibians exhibited greater sensitivity to Roundup® formulations than to glyphosate tested as an acid or IPA salt. This could be due to the surfactant (POEA) used in agricultural formulations, which has been found to be potentially more toxic to amphibians and other aquatic animals than the herbicide itself (Lajmanovich et al., 2003). Some researchers have suggested that, in combination with POEA, Roundup® could cause high rates of mortality to amphibians, including species of frogs and toads that could lead to eventual population declines (Relyea, 2005). POEA currently is used in only one of five glyphosate-based herbicides approved for use on alfalfa (appendix N, table N-3). The identity of the other surfactants is a trade secret, but a goal in their development was reduced toxicity to aquatic life. Amphibians use a wide range of aquatic habitats for their breeding sites and could be exposed to glyphosate in surface water. However, impacts of the Deregulation Alternative and the Isolation/Geographic Restriction Alternative on amphibians are unlikely because none of the glyphosate formulations that contain surfactants are approved for use over or near surface waters. Therefore, the Deregulation Alternative and the Isolation/Geographic Restriction Alternative are not expected to contribute to cumulative impacts on amphibians. As mentioned above, EPA includes instructions and restrictions on how glyphosate herbicides can be applied, and has determined that there is no unreasonable environmental risk when used according to the label directions.

Habitat loss and degradation are by far the greatest threat to amphibians, fishes, and aquatic invertebrates at present. Habitat loss and degradation can result from several broad classes of actions. These include:

- grazing, logging, mining, and other extractive industries;
- pollution and pesticide use (including pH and metals toxicity);
- dams, other water diversions, and water extraction;
- transportation and energy infrastructure development; and
- urban and suburban development.

In the case of impacts on amphibians, fishes, and aquatic invertebrates, the above activities have the potential to contribute cumulatively to adverse impacts. Glyphosate-laden agricultural water runoff (a minimal effect if label use restrictions are followed) would place an additional stress on populations that could be affected by ongoing habitat loss, leading to

smaller populations in the watershed (area of land where all the water that is under it or drains off of it goes into the same place). However, a shift to glyphosate from more toxic herbicides, if it occurs, may lessen any effects that are due to agricultural water runoff. Widespread habitat degradation from human activities such as housing construction, transportation infrastructure development, and water pollution could also potentially compound the incremental impacts resulting from the alternatives' effects on water quality.

Many species of fishes are being affected by over-fishing, which can negatively impact fish populations. The demand for certain species, such as salmon, has continued to increase while population levels have decreased. A possible overall decrease in fish populations due to incremental mortality from exposure to glyphosate and/or other herbicide formulations, combined with ongoing present and future over-fishing impacts, could result in cumulative adverse impacts on commercially and recreationally valuable species. The stress of the Deregulation Alternative and the Isolation/Geographic Restriction Alternative on fish populations is minimal when compared to the stress of over-fishing.

It is important to note that the impact on amphibians, fishes, and aquatic invertebrates resulting from the Deregulation Alternative and the Isolation/Geographic Restriction Alternative is uncertain. In addition, tillage practices that may be adopted under both alternatives would lessen potential adverse impacts on aquatic amphibian habitat due to the decrease in erosion and sedimentation (see section IV.G.3). Additionally, adherence to the label restrictions for glyphosate herbicides has been determined not to lead to unreasonable environmental impacts by the EPA. This minimizes, but does not eliminate, the environmental risks of the Deregulation Alternative and the Isolation/Geographic Restriction Alternative.

Socioeconomic Impacts

Glyphosate-Resistant Weeds

Both the Deregulation Alternative and the Isolation/Geographic Restriction Alternative would likely lead to increased use of glyphosate on alfalfa forage fields. This use would be in addition to the increased use of glyphosate seen in other GT crops. There could also be either a decreased or increased use of other herbicides used in alfalfa production. These changes would likely be regional, as the western U.S. uses more herbicides in alfalfa production than the eastern U.S. (NASS, 1999). As stated above in section IV.I.5 and in appendix G, there have been reports of glyphosate-resistant weeds as glyphosate use has increased globally with the adoption of GT crops. The Deregulation Alternative and the

Isolation/Geographic Restriction Alternative could contribute to the development of glyphosate-resistant weeds if it is not managed correctly.

If there are glyphosate-resistant weeds in GT alfalfa fields that require the use of other herbicides for control of such weeds, this would most likely result in an increase in production costs for GT alfalfa. To the extent that weed shifts occur under the Deregulation Alternative and the Isolation/Geographic Restriction Alternative, leading to weed control costs that are currently not present in conventional alfalfa, production costs could increase. As noted in the section IV.I.5 introduction above, there is some evidence of increased use of glyphosate (and increased costs) in fields of previously deregulated GT crops due to the presence of glyphosate-resistant weeds. If less GT hay were to be planted under the Isolation/Geographic Restriction Alternative, the degree of cumulative impacts could be lesser under the Isolation/Geographic Restriction Alternative compared to the Deregulation Alternative.

Seed Market Technology Concentration

If acceptance among alfalfa farmers of GT alfalfa is high, there would likely be an increased concentration in the market for alfalfa seed technology. Increased market concentration is often associated with monopoly rents and decreased welfare. Fernandez-Cornejo and Schimmelphenning (2004) note that the commercial seed market has already gone through a process of consolidation since the early 1990s, the importance of this consolidation is enhanced by the fact that research and development in crop varieties has become mostly a private sector activity in the United States since the late 1980s. Fernandez-Cornejo and Schimmelphenning (2004) suggest there is some evidence that this market consolidation—in an activity increasingly undertaken by the private sector—has been accompanied by a decrease in the intensity of public research in crop variety development, suggesting a possible negative impact of market concentration on future research and development. If less GT hay were to be planted under the Isolation/Geographic Restriction Alternative, the seed market penetration of the GT technology could be lesser under the Isolation/Geographic Restriction Alternative compared to the Deregulation Alternative.

Feed Costs

A recent USDA document (USDA-ERS 2008b) suggests feed costs would increase in the coming years due to increased production of corn for ethanol. To the extent that dairy farms are affected by this increase in feed costs, the Deregulation Alternative and the Isolation/Geographic Restriction Alternative could help mitigate these effects by providing an option for improving the quality of available alfalfa without necessarily an increase in costs.

Growth of Organic Markets

Section IV.D notes that there is not enough information to predict the impact of the Deregulation Alternative and the Isolation/Geographic Restriction Alternative on organic markets. Any impact, however, would likely be magnified or diminished by the current growth trend in organic markets. As shown in chapter III, organic alfalfa acreage has grown since 2000. To the extent that organic products continue to be perceived by consumers as having less genetically engineered content than other options, the Deregulation Alternative and the Isolation/Geographic Restriction Alternative may give additional impulse to the demand for organically certified products. On the other hand, if meeting consumer demands requires additional testing, and increased stewardship costs such as increased buffer zones or even relocation, this growth may be slowed. Additional stewardship costs are less likely under the Isolation/Geographic Restriction Alternative because GT alfalfa and non-GT alfalfa seed growing areas would be isolated from each other.

Export Markets

The Deregulation Alternative could imply losses in exports of alfalfa seed and hay to the main U.S. clients (Saudi Arabia and Japan, for each product respectively). The extent of these losses and the extent to which they would be regained in the future would depend on evolving regulations for trade in genetically engineered crops. Regulations and markets for GE products are still being largely developed in most countries. In the case of Japan, where GT alfalfa hay is approved, there is not enough information on whether genetically engineered content in animal feed would become increasingly rejected or accepted by consumers. In the case of an increased rejection, much of this market could be lost, depending on the level of market tolerance (beyond standards) for adventitious presence. In the case of an increased acceptance, the United States could actually benefit from the increased competitiveness of GT alfalfa in a market where competitors (e.g., Australia) are currently gaining ground.

The Isolation/Geographic Restriction Alternative would allow for segregation of GT hay production and conventional seed production. Increased rejection of GT alfalfa seed in foreign markets would possibly not impact U.S. exports if conventional seed marketing is able to convey the added safeguard generated by the segregation of conventional seed production from GT hay. Acceptance of conventional hay by foreign markets under this alternative could also benefit if exporters from Tier III states are able to show isolation from GT hay production through the GPS information system implanted in those states.

Global Climate Change

Global climate change refers to long-term fluctuations in global surface temperatures, precipitation, ice cover, sea levels, cloud cover, ocean temperatures and currents, and other climatic conditions. Scientific research has shown that in the past century, Earth's surface temperature has risen by an average of about 1.3 degrees Fahrenheit (°F) (0.74 °C); sea levels have risen 6.7 inches (0.17 meter); Arctic sea ice has shrunk by 2.7 percent per decade, with larger decreases of 7.4 percent in summer; and mountain glaciers and snow cover have decreased (IPCC, 2007). Most scientists now agree that this climate change is largely a result of greenhouse gas emissions from human activities. The Intergovernmental Panel on Climate Change (IPCC) recently asserted that, "Most of the observed increase in global average temperatures since the mid-20th Century is *very likely* due to the observed increase in anthropogenic [human-caused] greenhouse gas concentrations" (IPCC, 2007).

A recent U.S. Climate Change Science Program (Backlund et al., 2008) report suggests forage production may benefit from increased temperatures through the lengthening of the growing seasons, but may also be negatively affected by reduced water availability. Precipitation was the main factor determining different predictions of global climate change impacts on alfalfa yields when various studies were compared, with yields more likely to increase in the Pacific Northwest and to decrease in the central regions. The same report suggests both positive and negative effects of global climate change on forage quality are possible, and that productivity of dairy cows may decrease with higher temperatures. The quality improvements of GT alfalfa hay may help mitigate some of the potential negative consequences of global climate change on alfalfa and dairy production.

On the other hand, the same report suggests there is some evidence that the effectiveness of glyphosate could be reduced under higher CO_2 levels, and the type of photosynthetic pathway used by weeds (either C_3 or C_4) could play a role.[31] Recent research on the impacts of current and increasing CO_2 concentrations in the atmosphere suggest that rising CO_2 concentrations could increase glyphosate tolerance in a C_3 weedy species (Ziska et al., 1999). This finding was supported by another study where a reduction in glyphosate efficacy at higher CO_2 levels was observed concurrently with the stimulation of C_3 weeds in field grown Roundup Ready® soybean (Ziska and Goins, 2006). While in general, relative impacts of increasing CO_2 concentrations have been observed to be greater

[31] Ziska and Goins (2006) did not investigate the effectiveness of glyphosate under higher CO_2 levels for a third photosynthetic pathway in plants, the CAM pathway).

for C_3 weeds, there have been species –specific responses which demonstrate a range to impacts within C_3 and C_4 weeds. The Ziska and Goins 2006 study on Roundup Ready® soybean concluded that depending on weed species (C_3 vs. C_4), elevated CO_2 can increase weed biomass, decrease yields, and reduce glyphosate efficacy for Roundup Ready® soybean. It is possible that C_3 weeds, such as lambquarters and Canada thistle, which are found in GT alfalfa, would be affected similarly as CO_2 concentrations increase. This impact of increasing CO_2 concentrations may add to the adverse cumulative effects of development of glyphosate-resistant weeds in GT alfalfa.

Global climate change alone could also result in a cumulative effect to plant species. Global climate change can lead to changes in local and regional temperature and precipitation patterns. When weather has changed to the extent that plant populations are no longer suited to tolerate that area, this can result in population decline, extirpation, or local extinction. Studies have noted the response of biological and chemical characteristics of ecosystems to climate conditions, especially temperature change. Substantial research has examined the effects of climate change on vegetation and wildlife, leading to the conclusion that the changing climate is already having a real and demonstrable effect on a variety of ecosystem types (CCSP 2008a). As noted in the IPCC report, plants and animals can reproduce, grow, and survive only within specific ranges of climate and environmental conditions (Fischlin et al., 2008). Changes in climate can affect terrestrial ecosystems by shifting range boundaries or densities of individuals within their ranges or causing extirpation or extinction (Rosenzweig et al., 2007).

The potential incremental effect of increased mortality due to glyphosate exposure, combined with larger competition pressures from ongoing species migrating as temperature and precipitation patterns change (Parmesan and Yohe, 2003), could result in population declines or even local extinction of some plant species. However, it is worth noting that the effect of glyphosate use on plant population structure and distribution is small when compared to the impacts of global climate change, and the effect of glyphosate use on plant population structure would likely be the same or less than the use of other herbicides. Historical data for many parts of the United States indicate an increase in the frequency of high-precipitation events (e.g., >5 cm in 48 hours) correlated to global climate change, and this trend is projected to continue for many regions (CCSP 2008b). This can lead to field flooding, increased sedimentation, and leaching of nutrients and agricultural chemical into surface water. These effects, compounded with the incremental effect of glyphosate runoff expected as a result of the Deregulation Alternative, could also constitute an adverse cumulative effect on aquatic plant species if the comparison was glyphosate use compared to no herbicide use. Again, however, glyphosate is currently used in alfalfa, and it has some potential to replace

other herbicides currently used in alfalfa production if GT alfalfa is deregulated. Thus, the overall cumulative impact of increasing glyphosate and decreasing other herbicides is likely small given the context of conventional agricultural production.

Global climate change may also be affecting amphibian, fish, and aquatic invertebrate populations. While more analysis is needed, the potential impacts of global climate change are clear. Extreme weather events or other factors that would affect the timing of breeding and amphibian life cycles are unlikely to be the primary cause for the observed decline in amphibian populations in many regions. However, global climate change may play an enabling role, or magnify other, more direct causes of mortality, for amphibians as well as fishes and aquatic invertebrates (CCSP 2008b). Although no data are presently available that can be analyzed to determine the combined impact of global climate change and herbicide application on amphibian species, it is possible that the poleward migration of disease agents known to result in increased frog mortality, such as the Chytrid fungus (NSTC, 2008) enabled by a warming climate, would have a greater impact on amphibian populations whose vitality has been compromised by exposure to herbicides. Given that glyphosate is less toxic than other herbicides, and would be used instead of current uses of more environmentally harmful herbicides in GT alfalfa, it is likely that the increased use of glyphosate in GT alfalfa would have little cumulative effect on amphibians, even if other herbicide use also increases somewhat.

A warming climate is expected to increase water temperatures and modify regional patterns of precipitation, and these changes can have effects on water quality. As temperature increases, the ability of water to hold dissolved oxygen declines, and as water becomes anoxic, aquatic species begin to experience suboptimal conditions (NSTC, 2008). This could act in concert with the toxic effects of herbicide exposure to result in adverse cumulative impacts on amphibian, fish, and aquatic invertebrate populations. Glyphosate use is likely to increase in GT alfalfa, as might other herbicide use, but the use of other herbicides might also decrease under the Deregulation Alternative, and thus the cumulative effect of glyphosate use is likely to be small.

Global climate change is also likely to result in increased high-precipitation events throughout the United States (Backlund et al., 2008). An increase of intense rainfall events leading to field flooding would impact amphibians, fishes, and aquatic invertebrates through higher levels of sedimentation and nutrient and chemical leaching in agricultural systems. This has the potential to magnify effects of herbicide use by further increasing the amount of glyphosate and other herbicide accumulation in surface water over what would be expected, due to the Deregulation Alternative or the Isolation/Geographic Restrictions Alternative.

Moreover, many fish species depend on spring snowmelt for the water to fill the streams and rivers in which they live and breed. Global climate change resulting in increasing temperatures decreases the amount of winter snowpack (CCSP 2008b). This can impact the water levels in fish habitat, and may result in an adverse impact to certain fish populations. The potential for cumulative impacts exists if snow-fed streams and rivers are also fed by runoff from GT alfalfa fields. In these cases, the addition of potentially toxic impacts of the herbicide formulations would further impact fish populations already under stress from decreased snowmelt and available habitat. However, the label restrictions for glyphosate should preclude impacts on aquatic habitats.

Previous GT Alfalfa Deregulation Time Period

GT alfalfa was deregulated between June 2005 and March 2007. During this period an estimated 200,000 total acres were planted (Putnam, 2007). This corresponds to one to two percent of total alfalfa hay acreage. The 2005–07 deregulation time period might affect the speed of acceptance of GT alfalfa in the market place, given that some farmers are now familiar with the variety.

Colony Collapse Disorder (CCD)

Incidence of CCD in honey bees in the United States was first reported in 2006, when beekeepers reported that honey bee populations in the United States had decreased by 30 to 90 percent (USDA-ARS, 2010). Sustained decreases in the honey bee population may affect the cost of pollination, an important cost in alfalfa seed production, especially in California where honey bees are the primary pollinator. Eventual increases in pollination costs would likely be transmitted to seed prices, given that demand for alfalfa seed is highly inelastic (Myer et al., 1998). However, the impact on alfalfa hay farming would likely be minor, given the small participation of seeds on total hay farming costs. It is possible that this impact would be outweighed by reduced costs from GT alfalfa in the case of deregulation. Sustained incidence of CCD in honey bees could presumably lead to a greater concentration of alfalfa seed production in areas where other bee species, such as alkali bees and leafcutter bees, are more commonly used for pollination, or it could lead to the practice of transporting other bee species to fields previously pollinated by honey bees (For more information, see "*Technical White Paper on Colony Collapse Disorder and Glyphosate-Tolerant Alfalfa*" (appendix O)).

Spread of Subspecies "falcata"

Future spreading of the *Medicago sativa* subspecies *falcata,* which is naturalized in the northern and western United States, and is being promoted as a rangeland enhancer for grazing, could result in increased

hybridization of *falcata* with GT alfalfa. There is some evidence for heterosis in crosses between *saltiva* and *falcata* for plant height and width. These plants do not tolerate frequent mowing like that of hay fields (Riday and Brummer, 2004). Therefore, hybrids of *falcata* and sativa may be more fit in unmanaged environments. In areas where both are cultivated, these hybrid plants may form feral populations. As discussed in section IV.B.4, hybrids with mostly *sativa* parentage are predicted to be hardier than the original GT alfalfa, but have less rangeland hardiness than the *falcata* parent (Bagavathiannan and Van Acker, 2009).

The *falcata* hybrid possessing the GT trait may potentially become established in rangeland habitats and serve as a reservoir for the GT trait. If the future use of *falcata* increases in rangelands, conventional alfalfa seed farmers may have to protect their seed crop from GT gene flow with neighboring rangelands. Also, the risk of gene flow from GT fields to organic beef and dairy farmland could increase if *falcata* is promoted. *Falcata* can be considered part of the feral population. It is not expected to pose any weed risk different from other feral varieties.

Human Health and Safety Impacts

The direct and indirect effects of the deregulation of GT alfalfa to human health and safety are described in section IV.E, which concludes that under present and expected conditions of use under both the Deregulation Alternative and the Isolation/Geographic Alternative, GT alfalfa does not pose a health risk to humans. Impacts from past actions that add to cumulative impacts related to human health and safety include the past deregulation of other GT crops and the resulting change in herbicide use. As more GT crops were deregulated, glyphosate use increased along with a related decrease in the use of other, more toxic and persistent herbicides (see sections IV.E.5 and III.D.2). This impact of other GT crop deregulation, along with the deregulation of GT alfalfa (and an associated increase in glyphosate and possibly other herbicide use), would result in an increase in exposure to glyphosate and possibly other herbicides for the general public. With more GT crops, there is a greater chance that crops grown for human consumption would be found planted near GT crops, which could result in a greater chance for unintentional glyphosate and other herbicide applications on food crops and a subsequently greater chance for the general public to be exposed. This chance would increase with the deregulation of GT alfalfa under the Deregulation Alternative, but is less in certain areas under the Isolation/Geographic Alternative. However, glyphosate and other herbicides are subject to enforceable tolerance levels on crops that have been determined by EPA to pose a reasonable certainty of no harm, and thus there would be no cumulative impact to human health and safety from the Deregulation Alternative or the Isolation/Geographic Restriction Alternative.

There is a risk that the incremental effect of the deregulation of GT alfalfa, when combined with the effect of past deregulation of other GT crops, may cumulatively lead to the development of glyphosate-resistant weeds due to the selection pressure of the predominant use of glyphosate. If this happens, farmers would likely adopt herbicide use practices that include different herbicides. The risk to human health would then include exposures to both glyphosate and additional herbicides. However, as discussed above, glyphosate and other herbicides are subject to enforceable tolerance levels on crops that have been determined by EPA to pose a reasonable certainty of no harm, and thus there would be no cumulative impact to human health and safety from the Deregulation Alternative or the Isolation/Geographic Restriction Alternative.

The Roundup® herbicide (glyphosate) label states that the product can be used for numerous noncrop uses such as airports, apartment complexes, Christmas tree farms, ditches, driveways, dry canals, fencerows, golf courses, greenhouses, industrial sites, landscape areas, municipal sites, natural areas, office complexes, parks, parking areas, pastures, public areas, railroads, recreation areas, roadsides, schools, sports complexes, storage areas, and wildlife management sites (http://www.monsanto.com/monsanto/ag_products/pdf/labels_msds/roundup_orig_max_label.pdf). The U.S. Forest Service uses glyphosate primarily in conifer release (58.2 percent), noxious weed control (15.5 percent), and site preparation (16.4 percent). Other minor uses (10.3 percent) include hardwood release, facilities maintenance, recreation improvement, rights-of-way maintenance, seed orchard protection, wildlife habitat improvement, and other weed control (agricultural, aquatic, or nursery). In 2001, the total annual use of glyphosate by the U.S. Forest Service was approximately 44,700 pounds applied to approximately 19,000 acres (USDA-FS, 2003). In 2007, total agricultural use was approximately 135 million pounds (EPA, 2009). All of these data combines to show that glyphosate is currently a widely-used herbicide, and in numerous applications other than agricultural. The additional incremental increased use of glyphosate that would occur with the deregulation of GT alfalfa under either the Preferred or Isolation/Geographic Alternatives, along with the current use as described here, could minimally increase exposure to the general public, especially given the tolerances noted above.

It is not likely that GT alfalfa would be grown for human consumption (sprouts) in the near future because the Monsanto Technology Agreement does not permit growth for human consumption. But because glyphosate is currently undergoing reregistration, there is a chance that glyphosate regulations, including those regarding labels and crop tolerances, may change. However, the exact changes are not known at this time and therefore cannot be incorporated into this analysis. If the regulations do change substantially, then they would have the potential to affect the

cumulative impacts of deregulation of GT alfalfa under the Preferred or Isolation/Geographic Alternatives.

Land Use and Production Practices

The direct and indirect effects of the deregulation of GT alfalfa to land use and production practices are described in section IV.F. These include: the expected displacement of other non-GT alfalfa varieties where alfalfa is highly managed; the replacement of other forms of weed control with glyphosate; less tillage of soils if there is longer stand life; a possible reduction in the amount of nitrogen fertilizers applied; and changes in crop rotation. Factors such as herbicide use, weed resistance, crop rotations, isolation zones, and GT alfalfa-free zones all interact cumulatively to impact land use and production practices. However, there are other actions, that when added to the deregulation of GT alfalfa, may cause cumulative impacts on land use and production practices.

The previous deregulation of other GT crops would influence both herbicide use and crop rotations for GT alfalfa. As discussed above in the section IV.I.5 introduction, in appendix G, and sections IV.E.5 and III.D.2, the wide-spread adoption of GT crops and the corresponding increase in glyphosate use has also resulted in increased selection pressure for glyphosate-resistant weeds. For example, since 1998, 20 new glyphosate-resistant weeds have been found globally, eleven of which have glyphosate-resistant biotypes in the United States (appendix G).

As discussed above in the section IV.I.5 introduction, the perennial nature of alfalfa and the production characteristic of harvesting through mowing can delay weed shifts in GT alfalfa. Additionally, although weeds can be a problem in alfalfa, once alfalfa is established, it acts as a suppressor of weeds and is commonly used in rotations for weed reduction (appendix G).

As discussed in appendix G, BMPs can reduce the development of glyphosate-resistant weeds. These practices include: a) identifying weeds and monitoring for escapes to determine if current practices need to be modified to achieve acceptable levels of weed control; b) using proper herbicide rates and timing; c) using crop rotation to facilitate use of different modes of action over time; d) using agronomic management practices to supplement herbicide weed control; e) alternating herbicides with different modes of action; and f) tank mixing herbicides of different modes of action (appendix G).

If glyphosate-resistant weeds become established in alfalfa, then production practices would likely include an increase in the use tillage and an increase in use of other herbicides. Future deregulation of other GT crops, such as creeping bentgrass or other varieties of corn, soybeans, and

sugar beets whose proposals for deregulation are pending, would impact the potential for weed shifts in a similar fashion. While the No Action Alternative reduces the number of GT alfalfa acres under production as compared to the Deregulation Alternative or the Isolation/Geographic Restrictions Alternative, selection pressure for glyphosate-resistant weeds would still occur for the above stated reasons.

As discussed in appendix J and section IV.F, adoption of GT alfalfa may affect crop rotations because glyphosate cannot be used for stand removal or volunteer alfalfa control. Therefore other herbicides, which might have rotation restrictions, might need to be used along with tillage to remove GT alfalfa stands. GT alfalfa stands might also last longer than non-GT alfalfa stands; therefore, adoption of GT alfalfa might influence the number of years that alfalfa is in a rotation. It is recommended that rotations not consist of all GT crops. Because several of the crops that are popular in rotation with alfalfa (corn, soybeans) have GT varieties, farmers might have to decide which GT crop provides the most benefit to the rotation plan and overall farm production.

Global climate change also has the potential to impact future land use and production practices, as alfalfa cultivation is heavily based on climate. Research has shown that as CO_2 levels increase, as is possible with global climate change, glyphosate loses its efficacy on weeds (Ziska et al., 1999). If this were to happen, then farmers would need to adapt herbicide use and change production practices of GT alfalfa. Thus, climate change may necessitate an increase in the use of glyphosate, and could amplify the impacts of the Deregulation Alternative or the Isolation/Geographic Restriction Alternative.

Physical Environment

As described in section IV.G.3, the Deregulation Alternative is not likely to lead to adverse impacts on surface water when compared to the No Action Alternative. However, glyphosate use in agriculture generally can have the potential to lead to adverse impacts on surface water. This is chiefly due to the chemical fate of glyphosate and its metabolite when adsorb to soil particles that become suspended in runoff water and can potentially contaminate surface waters as a result of erosion of this soil. Glyphosate would be found in surface water runoff when erosion conditions lead to the loss of surface soil particles. However, the amount of glyphosate found in surface water can be mitigated. It is speculated that deregulation of glyphosate-tolerant alfalfa could increase stand life, which would result in less tillage of agricultural lands and growth of additional alfalfa harvests (section IV.F). This reduction in the frequency of tillage could mitigate the increase application of glyphosate by decreasing sedimentation of glyphosate-laden soil particle in surface water runoff (Wiebe and Gollehon, 2006). The quality of surface water may also be

improved by reduced tillage, as it reduces erosions and decreases the amount of sediments in rivers and streams (see sections III.E.5 and IV.G.1 for further discussion on this topic). Also, it should be noted that the half life of glyphosate in soil is 2 to 174 days, and in water, the half life is less than seven days (Monsanto 2006a). Additionally, EPA label restrictions result in application rates and practices that have no unreasonable environmental risk.

Past actions contributing to impacts on surface water pollution include agriculture, industry, resource extraction, urban, suburban, and rural development, and other human activities. GT crop systems have led to an increase in the amount of glyphosate herbicide formulations applied in recent years and at least a temporary decrease in the amount of other herbicides applied.

There are several other actions that have the potential to contribute to cumulative impacts on surface water.

- *Global climate change* — This could lead to high-intensity rainfall events increasing field flooding, sedimentation, nutrient loading, and accumulation of agricultural chemicals in surface waters. The impact of the deregulation of GT alfalfa on surface water would be magnified by high-intensity rainfall events, which could lead to a greater quantity of glyphosate in surface water runoff.
- *Livestock grazing*—Widespread grazing has led to desertification in the western United States, resulting in impacts on surface water via increased sedimentation in runoff. If grazing impacts watersheds that are home to GT alfalfa fields, there is a potential cumulative impact on surface waters due to the sedimentation from grazing, combined with the glyphosate runoff from GT alfalfa.
- *Human activities resulting in non-point source pollution* — These include construction activities, land development, agricultural practices, lawn chemical application, soil erosion, and storm water runoff. These activities have the potential to cumulatively impact the surface water through sedimentation and pollutants in runoff. If future activities contributing to these impacts occur in watersheds where GT alfalfa is cultivated, there may be potential for adverse cumulative impacts on surface water. Because the impacts would not be a simple incremental increase in the amount of glyphosate in surface water, but would be an interaction of increased glyphosate combined with other pollutants and/or increased sedimentation, the nature of the cumulative impact would be more complex than some of the additive impacts described above.
- *Increase in impervious surfaces* — This has occurred due to the construction of roads, buildings, parking lots, and other impervious structures. This leads to increased quantity and decreased quality of storm water runoff into watersheds. These actions often have the added effect of

removing soil stabilizing vegetation, which increases erosion and sedimentation in water runoff. If future activities contributing to these impacts occur in watersheds where GT alfalfa is cultivated, there may be the potential for adverse cumulative impacts on surface water.

- *Deregulation of other GT crops* — Petitions for Non-regulated Status are pending for GT corn, sugar beet, and creeping bentgrass (http://www.aphis.usda.gov/brs/not_reg.html). If deregulated, the production of these GT crops may lead to increased glyphosate use, and in instances where it is cultivated in the same watersheds where GT alfalfa is produced, this may lead to a cumulative impact on surface water in these areas from glyphosate runoff. GT crops that have been deregulated in the past, such as GT cotton and soybeans, may have also contributed to an increase in the incidence of glyphosate-resistant weeds. As these weeds become more widespread and a problem for GT alfalfa, weed management techniques would adapt in response. Farmers would likely increase their use of mechanical weed control techniques to replace glyphosate use, such as tillage, which could lead to cumulative impacts on surface water from soil erosion and surface water runoff (Fawcett and Towery, 2002).

Summary

In conclusion, APHIS examined the cumulative impacts of GT alfalfa and herbicide use on the biological environment; socioeconomic environment; human health and safety; land use and production practices; and the physical environment. In many cases, only a qualitative assessment was conducted due to a lack of available quantitative information.

The past actions that relate to the cumulative impact of the deregulation of GT alfalfa on biological resources include the deregulation of other GT crops, and the shift in herbicide regimes to glyphosate and possibly other herbicides. EPA has determined that there is no unreasonable environmental risk when using glyphosate or other regulated herbicides when the user adheres to the label restrictions, as they are legally required to do.

Predicting potential cumulative impacts is difficult due to the dynamics of other factors that come into play. For example, cumulative impacts are not likely to occur unless aerial drift or surface water runoff from both GT alfalfa fields and other GT fields reach the same plant species, animal species, or sector of the environment. Even under these speculative and hypothetical circumstances, it is unlikely that cumulative impacts on any given populations would result, unless fields of GT alfalfa and other GT crops were located adjacent to each other, label restrictions were not observed, the decreased use of other, less toxic herbicides did not result in the protection of some species or environmental attribute, and no other herbicides were used in any agricultural production. Additionally, end use herbicide formulations, including the use of surfactants, could not be

estimated to enable a quantitative risk assessment. Moreover, the impacts of cumulative use of glyphosate are incrementally small in comparison to the many other much greater threats to plant and animal species in the environment (such as over-fishing, habitat loss degradation due to grazing, logging, urban and suburban development, transportation and energy infrastructure development, pollution, dams, global climate change, etc.).

If the increased use of glyphosate leads to an increase in the presence of glyphosate-resistant weeds in GT alfalfa—as well as in crops with which GT alfalfa is rotated—then glyphosate would have to be substituted for or complemented by other herbicides. As stated previously, although GT alfalfa is likely to result in an increased use of glyphosate, that increased glyphosate use does not immediately or directly result in glyphosate-resistant weeds. Because GT alfalfa is a perennial and the production of GT alfalfa includes mowing, weeds that cannot set seed in alfalfa are not under selective pressure for novel glyphosate resistance (i.e., the development of new glyphosate resistant biotypes). Therefore, it is more likely that weed shifts to weeds not well managed by glyphosate would occur (biotypes already resistant to glyphosate or weeds tolerant to glyphosate).

Currently, APHIS is unable to locate enough quantitative information to predict the impact of GT alfalfa deregulation on organic markets. Any impact, however, would likely be magnified or diminished by the current growth trend in organic markets. If this growth is associated with a growth in demand for non-GE foods, GT alfalfa deregulation may give additional impulse to the demand for organically certified products. If deregulation increases organic production costs associated with isolation, buffer zones, or relocation, this growth may be slowed.

Deregulation of GT alfalfa could imply losses in exports of conventional alfalfa seed and hay to the main U.S. clients (Saudi Arabia and Japan, respectively). If GE content in animal feed becomes increasingly rejected by international markets, much of this market could be lost. If GE content becomes increasingly accepted, the United States may benefit from the increased competitiveness of GT alfalfa in a market where international competitors are currently gaining ground.

The analysis of the direct and indirect effects of the deregulation of GT alfalfa to human health and safety concludes that under present and expected conditions of glyphosate use, GT alfalfa or the glyphosate herbicide are unlikely to pose a health risk to humans. In terms of herbicide use in conjunction with deregulating GT alfalfa, the cumulative impacts related to the past deregulation of other GT crops increases glyphosate use, and possibly changes in other herbicide use. With more GT crops, there is a greater chance that crops grown for human consumption would be found planted near GT crops, which could result in

a greater chance for unintentional glyphosate and possibly other herbicide applications on food crops and a subsequently greater chance for the general public to be exposed. This chance would increase with the deregulation of GT alfalfa. However, if glyphosate were to replace other herbicides, the overall risk to human health, cumulatively, could decrease with the deregulation of GT alfalfa. However, if it were to increase of herbicide use, exposure to those herbicides might increase. However, glyphosate and other herbicides are subject to enforceable tolerance levels on crops that have been determined by EPA to pose a reasonable certainty of no harm, so the potential effect to human health is negligible Additionally, glyphosate is currently a widely-used herbicide, and in numerous applications other than agricultural. The additional incremental increased use of glyphosate that would occur with the deregulation of GT alfalfa, along with the current use as described here, would minimally increase exposure to the general public.

Past actions contributing to impacts on surface water pollution include agriculture, industry, resource extraction, urban, suburban, and rural development, and other human activities. Glyphosate would be found in surface water runoff when erosion conditions lead to the loss of surface soil particles. However, deregulation of glyphosate-tolerant alfalfa might lead to an increase in conservation tillage and no tillage systems, which could mitigate the increased application of glyphosate by decreasing sedimentation of glyphosate-laden soil particle in surface water runoff (Wiebe and Gollehon, 2006). The quality of surface water may also be improved by conservation tillage, as it reduces erosions and decreases the amount of sediments in rivers and streams.

5. Compliance with Statutes, Executive Orders, and Regulations

Executive Orders

Executive Order (EO) 12898 (US-NARA, 2008), "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 or low-income communities from being subjected to disproportionately high and adverse human health or environmental effects. EO 13045 (US-NARA, 2008), "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) required each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children. Each alternative was analyzed with

respect to EO 12898 and 13045. Based on the information submitted by the applicant and assessed by APHIS, GT alfalfa lines J101 and J163 are not different than conventional alfalfa and have successfully completed FDA consultation for food and feed use. Therefore, GT alfalfa lines J101 and J163 are not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

EO 13112 (US-NARA, 2008), "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. GT alfalfa lines J101 and J163 are very similar in fitness characteristics to other alfalfa varieties currently grown and are not expected to become weedy or invasive (see USDA-APHIS 2010 for the plant pest risk assessment of GT alfalfa lines J101 and J163).

EO 13186 (US-NARA, 2008), "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. Data submitted by the applicant has shown no difference in compositional and nutritional quality of GT alfalfa lines J101 and J163 compared to conventional alfalfa, apart from the presence of EPSPS. Based on APHIS' assessment of GT alfalfa lines J101 and J163, it is unlikely that granting non-regulated status to these alfalfa varieties would have a negative effect on migratory bird populations.

Compliance with Federal Statutes

This EIS evaluated the changes in alfalfa production due to the unrestricted use of GT alfalfa lines J101 and J163, as well as the Isolation/Geographic Restriction Alternative. GT alfalfa is unlikely to lead to the increased production of alfalfa in U.S. agriculture, that is, an increased in the total number of acres planted with alfalfa in the United States. There is no expected change in water use due to the production of GT alfalfa. In addition, it is not anticipated that air quality, food quality, or pollution in general would change due to the production of GT alfalfa. If APHIS grants nonregulated status to GT alfalfa, APHIS would be fully compliant with the Clean Water Act; the Clean Air Act; the Federal Insecticide, Fungicide, and Rodenticide Act; the Pollution Prevention Act; and all other Federal statutes.

Endangered Species Act

Potential Impact on Threatened or 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, on behalf of the American people, 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 lists 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, in accordance with the ESA, 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 critical habitat. To facilitate APHIS' ESA consultation process, APHIS met with the USFWS to discuss factors relevant to their effects analysis for petitions for nonregulated status, and developed a process for conducting an effects determination. This process is used by APHIS to

assist the program in fulfilling their obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

As part the environmental review process, APHIS thoroughly reviews GE product information and data to inform the ESA effects analysis, and if necessary, the biological assessment. For each transgene(s)/transgenic plant the following information, data, and questions are considered by APHIS:

- 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 impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant); and
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES.

In following this process, APHIS evaluated the potential effects of granting the petition for GT alfalfa on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation. APHIS obtained a list of TES species (listed and proposed) for the United States, because alfalfa is grown in the U.S., from the USFWS Environmental Conservation Online System (ECOS) (http://ecos.fws.gov/tess_public/pub/listedAnimals.jsp and http://ecos.fws.gov/tess_public/pub/listedPlants.jsp) (accessed September 30, 2010).

Potential effects of GT alfalfa and agricultural production practices.

Commercially cultivated alfalfa properly belongs to the *M. sativa* complex, a group of closely related subspecies that are reproductively compatible. The most commonly cultivated alfalfa in the world is *M. sativa* subsp. *sativa*, but subspecies *falcata* is also cultivated on a limited basis, primarily under rangeland conditions and in colder regions (e.g., Canada and Siberia). Other subspecies in the complex include subsp. *glutinosa*, subsp. *coerulea*, subsp. x *tunetana*, subsp. x *varia*, subsp. x *polychroa*, and subsp. x *hemicycla* (Quiros and Bauchan 1988). Two other closely related species, *M. prostrata* and *M. glomerata*, can be

considered capable of limited natural hybridization with alfalfa (Quiros and Bauchan 1988); however, they do not occur naturally in North America (See appendix I and V. 5.5).

Current native populations of members in the *M. sativa* complex to which cultivated alfalfa would hybridize, as well as other perennial *Medicago* species, exist particularly in Europe, Asia, the Middle East, and North Africa (Sinskaya 1961, Lesins and Lesins 1979, Ivanov 1988). Based on a search for *Medicago* populations in the United States, 12 matches were found (see table 3-3) (http://www.natureserve.org/explorer). All of the 12 matches were to plants non-native to North America and were either conspecific (belonging to the same species) to *Medicago sativa* (two) or naturally sexually incompatible with *M. sativa* complex (ten).

After reviewing the list of TES species, APHIS has determined that GT alfalfa would not be sexually compatible with any listed TES plant or plant proposed for listing. To identify negative effects or significant impacts on TES animal species, APHIS evaluated the risks to TES animals from consuming GT alfalfa. Risk is a combination of hazard and exposure. APHIS first conducted hazard identification for GT alfalfa. APHIS assessed the composition and nutritional quality of GT alfalfa, and compared the composition of GT alfalfa to the composition of a non-genetically engineered control alfalfa lines and the natural variation found in commercial alfalfa varieties. The data presented in the petition suggests there is no difference in compositional and nutritional quality of GT alfalfa compared to conventional alfalfa, apart from the presence of the enzyme EPSPS (Rogan and Fitzpatrick, 2004).

The enzyme EPSPS that confers glyphosate tolerance is from the bacterium *Agrobacterium* sp. strain CP4. The gene that produces this enzyme is similar to the gene that is normally present in alfalfa and is not known to have any toxic property. The lack of known toxicity for this enzyme suggests no potential for deleterious effects on beneficial organisms, such as bees and earthworms. The high specificity of the enzyme for its substrates makes it unlikely that the introduced enzyme would metabolize endogenous substrates to produce compounds toxic to beneficial organisms.
Even though the likelihood of toxicity is low for the CP4 EPSPS protein, a number of researchers have conducted laboratory investigations with different types of arthropods exposed to genetically engineered crops containing the CP4 EPSPS protein (Goldstein, 2003; Boongird, 2003; Jamornman, 2003; Harvey, 2003). Representative pollinators, soil organisms, beneficial arthropods, and pest species were exposed to tissues (pollen, seed, and foliage) from GE crops that contain the CP4 EPSPS protein. These studies, although varying in design, all reported a lack of toxicity observed in various species exposed to these crops (Nahas, 2001; Dunfield and Germida, 2003, Siciliano and Germida 1999). In addition to

a lack of toxicity demonstrated by the CP4 EPSPS protein, its potential to be a food allergen is minimal (OECD 1999).

Since the composition of GT alfalfa is similar to other commercial alfalfa plants with the exception of the expression of the CP4 EPSPS protein[32], it is unlikely that GT alfalfa poses a hazard to TES animal species. If no hazards are identified, then the risk of GT alfalfa harming TES animal species is also unlikely, regardless of exposure.

As part of the ESA analysis, APHIS considered if the new phenotype imparted to alfalfa may allow the plant to be grown or employed in new habitats, and especially if it will be able to naturalize in the environment. In doing so, APHIS assessed whether GT alfalfa is any more likely to become a weed than the nontransgenic recipient alfalfa line or other currently cultivated alfalfa. Weediness could potentially affect TES and/or critical habitat if GT alfalfa were to become naturalized in the environment. The assessment considers the basic biology of alfalfa and an evaluation of unique characteristics of GT alfalfa. The parent plant in this petition, *Medicago sativa*, is not listed as a weed on any of the major weed lists (See appendix W) nor is it listed as a noxious weed species by the U.S. Federal Government (7 CFR Part 360). It is listed on Interactive Encyclopedia of North American Weeds Version 3.0 (NCWSS 2005) as a weed. (For a more detailed discussion see Appendix W). As described in section III A., alfalfa can form feral populations. These are typically in disturbed areas, such as along road sides or on the margins of agricultural fields. Information submitted relating to the use of glyphosate for control of feral alfalfa indicates that feral alfalfa is rarely controlled with

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[32] The Food and Drug Administration (FDA) published a policy in 1992 on foods derived from new plant varieties, including those derived from transgenic plants (FDA, 1992). The FDA's policy requires that genetically engineered foods meet the same rigorous safety standards as is required of all other foods. Consistent with its 1992 policy, FDA completed the consultation for GT alfalfa events J101 and J163 on December 10, 2004 - Biotechnology Notification File #84 (FDA, 2004). FDA reached an opinion that "Monsanto and Forage Genetics have concluded that their glyphosate-tolerant alfalfa event J101 and event J163, and the feeds and foods derived from them, are not materially different in safety, composition, or any other relevant parameter from alfalfa now grown, marketed, and consumed. At this time, based on Monsanto's and Forage Genetics' description of its data and information, the Agency considers this consultation on alfalfa event J101 and event J163 to be complete."
http://www.fda.gov/Food/Biotechnology/Submissions/ucm155620.htm

herbicide, and if controlled, glyphosate is not the herbicide of choice for control (Rogan and Fitzpatrick 2004). Thus, the GT trait would not provide a competitive advantage to feral alfalfa unless glyphosate was directly applied or drifted from nearby applications. Other herbicides are available to control feral alfalfa that may be resistant to glyphosate (Rogan and Fitzpatrick 2004).

APHIS considered the potential for GT alfalfa to extend the range of alfalfa production and also the potential to expand agricultural production into new natural areas. The genetic transformation does not impart any phenotypic characteristic that would allow for the planting of GT alfalfa in areas unsuitable to alfalfa varieties currently available. As described in the petition, the agronomic properties of GT alfalfa varieties are not statistically different from currently available alfalfa varieties. Therefore, APHIS has concluded that production of GT alfalfa would be unlikely to expand to areas not currently suitable for alfalfa production.
In conclusion, GT alfalfa exhibits no known toxicity, will not invade natural areas as a weed, and is not expected to be planted in new lands not already used for agricultural production.

After reviewing possible effects of granting nonregulated status to GT alfalfa, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. As a result, a detailed exposure analysis for individual species is not necessary. APHIS has considered the effect of GT alfalfa production on designated critical habitat or habitat proposed for designation, and could identify no difference from effects that would occur from the production of other alfalfa varieties. Based on these factors, APHIS has determined that the introduction of GT alfalfa for production of seed and forage will have no effect on listed species or species proposed for listing and would not affect designated critical habitat or habitat proposed for designation. Because of this no effect determination, consultation and/or the concurrence of the USFWS and/or the NMFS are not required.

Glyphosate Use

As the action agency for pesticide registrations, EPA has the responsibility to conduct an assessment of effects of a registration action on endangered species. The EPA Endangered Species Protection Program web site (http://www.epa.gov/espp/) describes the EPA assessment process for endangered species. Some of the elements of that process, generally taken from the web site, are summarized below.

When registering a pesticide or reassessing the potential ecological risks from use of a currently registered pesticide, EPA evaluates extensive exposure and ecological effects data to determine how a pesticide will move through and break down in the environment. Risks to birds, fish,

invertebrates, mammals and plants are routinely assessed and used in EPA's determinations of whether a pesticide may be licensed for use in the U.S.

EPA's core pesticide risk assessment and regulatory processes ensure that protections are in place for all populations of nontarget species, including TES. These assessments provide EPA with information needed to develop label use restrictions for the pesticide. These label restrictions carry the weight of law and are enforced by EPA and the states (Federal Insecticide, Fungicide, and Rodenticide Act 7 USC 136j (a)(2)(G) Unlawful acts). Because TES may need specific protection, EPA has developed risk assessment procedures described in the *Overview of the Ecological Risk Assessment Process* (US EPA, 2004) to determine whether individuals of a listed species have the potential to be harmed by a pesticide, and if so, what specific protections may be appropriate. EPA's conclusion regarding the potential risks a pesticide may pose to a listed species and any designated critical habitat for the species, after conducting a thorough ecological risk assessment, results in an "effects determination" in accordance with Section 7 (a)(2) of the ESA.

As a part of EPA's TES effects assessment for the California red-legged frog (US EPA, 2008b), EPA evaluated the effect of glyphosate use at rates up to 7.95 lbs a.e./acre on fish, amphibians, aquatic invertebrates, aquatic plants, birds, mammals, and terrestrial invertebrates. This assessment determined that at the maximum application rate for in-crop applications of glyphosate to GT alfalfa (1.55 lbs a.e. /acre), there would be no effects of glyphosate use on the following taxa of threatened and endangered species: fish, amphibians, birds, and mammals. The EPA assessment was uncertain of the effects on terrestrial invertebrates, citing the potential to affect small insects at all application rates and large insects at the higher application rates. EPA considered these potential effects as part of their review process and label use restrictions imposed under authority of FIFRA. To mitigate potential adverse effects to TES, EPA has imposed specific label use restrictions for glyphosate use when applied with aerial equipment, including "The product should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g., when wind is blowing away from the sensitive areas)."

To facilitate pesticide applicators adherence to EPA label use restrictions for glyphosate, Monsanto has designed a web-based program (www.Pre-Serve.org), designed to ensure no effect of glyphosate applications on threatened and endangered plant species. Pre-Serve instructs growers to observe specific precautions, including buffer zones when spraying glyphosate herbicides on glyphosate-tolerant crops near threatened and endangered plant species that may be at risk. In addition, label

requirements for Monsanto's Roundup® formulations and glyphosate formulations marketed by other manufacturers prohibit application in conditions or locations where adverse impact on federally designated endangered/threatened plants or aquatic species is likely.

In conclusion, there are legal precautions in place (EPA label use restrictions) and "best practice" guidance to reduce the possibility of exposure and adverse impacts to TES from glyphosate application to GT alfalfa; EPA has considered potential impacts to TES as part of their registration and labeling process for glyphosate; and adherence to EPA label use restrictions by the pesticide applicator will ensure that the use of glyphosate will not adversely affect TES or critical habitat. Based on these factors and the legal requirements for pesticide applicators to follow EPA label use restrictions, APHIS has determined that the use of EPA registered glyphosate for alfalfa production will not adversely impact listed species or species proposed for listing, and would not adversely impact designated critical habitat or habitat proposed for designation.

International Implications

EO 12114 (US-NARA, 2008), "Environmental Effects Abroad of Major Federal Actions," requires Federal officials to take into consideration any potential environmental effects outside the United States, its territories, and possessions that result from actions being taken. APHIS has given this due consideration and does not expect a significant environmental impact outside the United States should nonregulated status be granted to GT alfalfa lines J101 and J163. It should be noted that all the considerable, 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 non-regulated status under 7 CFR part 340. Any international traffic of GT alfalfa lines J101 and J163 subsequent to a determination of nonregulated status for 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).

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, 2008); the protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds. The IPPC set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (173 countries as of September 2009). In April 2004, a standard for pest risk analysis (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 would 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' plant 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 includes those modified through biotechnology. The Protocol came into force on September 11, 2003, and 160 countries are parties to it as of November 5, 2010 (CBD, 2010). Although the United States is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters would still need to comply with domestic regulations that importing countries that are parties to the Protocol have put in place to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) would 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 web site that provides the status of all regulatory reviews completed for different uses of bioengineered products (NBII, 2008). These data would 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 United States, and within the Organization for Economic Cooperation and Development. NAPPO has completed three modules of a standard for the Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries (NAPPO, 2008). APHIS also participates in the North American Biotechnology Initiative (NABI), a forum for information exchange and

cooperation on agricultural biotechnology issues for the United States, Mexico, and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held with other countries including Argentina, Brazil, Japan, China, and Korea.

Determination of Nonregulated status for Monsanto and Forage Genetics International Roundup Ready® Alfalfa Events J101 and J163

In response to petition (designated 04-110-01p) from Monsanto Company and Forage Genetics International (FGI), APHIS has determined that the petitioners genetically engineered alfalfa transformation Events J101 and J163 and progeny derived from them are unlikely to pose a plant pest risk and are no longer to be considered regulated articles under APHIS's biotechnology regulations at 7 CFR part 340. In fact, there is no evidence of plant pest risk associated with these two alfalfa events. Permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation under those regulations are no longer a requirement for alfalfa transformation Events J101 and J163 and its progeny. Importation of seeds and other propagative material will still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and Federal Seed Act regulations at 7 CFR part 201.

This determination is based on APHIS' analysis of field, greenhouse, and laboratory data, references provided in the petition, and other relevant information as described in the Plant Pest Risk Assessment for alfalfa Events J101 and J163, the Environmental Impact Statement prepared for this determination, and in APHIS's response to public comments (http://www.aphis.usda.gov/brs/not_reg.html) that indicate that alfalfa Events J101 and J163 are unlikely to pose a plant pest risk.

The Plant Pest Risk Assessment[1] (http://www.aphis.usda.gov/brs/not_reg.html) concluded that Monsanto and FGI alfalfa Events J101 and J163 are not likely to pose a plant pest risk and should be granted nonregulated status for the following reasons: (1) They exhibit no plant pathogenic properties – although a plant pathogen was used in their development, these plants are not infected by this organism nor do they contain genetic material from pathogens used as a donor organism that can cause plant disease. (2) They exhibit no characteristics that would cause them to be weedier than the non-transgenic parent alfalfa or other cultivated alfalfa and several control options besides glyphosate are available for control of feral or volunteer plants or for stand take-out. (3) Gene introgression from J101 and J163 to native, introduced, or naturalized species of *Medicago* in the United States is extremely unlikely and even if it were to occur, is not likely to increase the weediness potential of any resulting progeny any more than would introgression from other cultivated alfalfa. (4) Disease and insect susceptibility and compositional profiles (other than the intended CP4 EPSPS protein conferring glyphosate tolerance) of J101 and J163 are similar to those of the parent variety and other alfalfa cultivars grown in the United States, therefore pest and disease control methods are expected to be similar and no direct or indirect plant pest effect on raw or processed plant commodity is expected. (5) Field observations,

[1] APHIS prepared the revised Plant Pest Risk Assessment and EIS in response to ruling on February 13, 2007, by the United States District Court for the Northern District of California that vacated a previous determination of deregulated status of J101 and J163 alfalfa that was effective from June 14, 2005. On March 23, 2007, APHIS published a notice in the *FR* (72 *FR* 13735-13736 APHIS Docket No. 04-085-1) announcing the Court's decision that Monsanto and FGI GT alfalfa lines J101 and J163 were once again regulated articles under 7 CFR part 340.

compositional data including components related to nitrogen fixation and nodulation, and data on the safety of the engineered EPSPS protein all indicate that J101 and J163 should not have a greater potential than other cultivated alfalfa to damage or harm organisms beneficial to agriculture. (6) Horizontal gene transfer from these alfalfa Events to organisms with which they cannot interbreed is highly unlikely to occur, and is not expected to pose a plant pest risk.

APHIS also concludes that new varieties bred from glyphosate-tolerant alfalfa Events J101 and J163 are unlikely to exhibit new plant pest properties, i.e., properties substantially different from any observed for glyphosate-tolerant alfalfa Events J101 and J163, or those observed for other alfalfa varieties not considered regulated articles under 7 CFR part 340.

APHIS has completed an Environmental Impact Statement (EIS) (http://www.aphis.usda.gov/brs/not_reg.html) that assesses the possible impacts of a determination of non-regulated status for glyphosate-tolerant alfalfa Events J101 and J163 on the quality of the human environment consistent with APHIS obligations under the National Environmental Policy Act as amended, Council on Environmental Quality (CEQ) regulations for implementing NEPA, the USDA regulations implementing NEPA, and the APHIS National Environmental Policy Act (APHIS NEPA) of 1969 Implementing Procedures. The EIS also includes an analysis of the effects of to federally listed and proposed threatened and endangered species and their designated critical habitat and habitat proposed for designation consistent with our obligations under the Endangered Species Act (ESA) of 1973, as amended.

Cindy J. Smith

Cindy J. Smith
Administrator
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

1/28/11

Date

Record of Decision

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

Overview

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

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

Background

Coordinated framework

APHIS is one of the Federal agencies with regulatory responsibilities under the 1986 Federal Coordinated Framework for the Regulation of Biotechnology (hereafter Coordinated Framework) published by the Office of Science and Technology Policy (OSTP), Executive Office of the President. The Coordinated Framework is a policy statement which "describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products." The Coordinated Framework explains the proper allocation and coordination of oversight responsibilities under the several relevant statutes and among the several relevant federal agencies.

The Coordinated Framework thus addressed who shall have oversight authority in each instance, but did not address how that authority should be exercised in the frequent situations in which a statute leaves the implementing agency latitude for discretion. To that end, OSTP published a notice of Federal policy in the Federal Register in 1992 in which it set forth "the proper basis for agencies' exercise of oversight authority within the scope of discretion afforded by statute." The notice describes "a risk-based, scientifically sound approach to the oversight of planned introductions of biotechnology products into the environment that focuses on the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created. Exercise of oversight in the scope of discretion afforded

by statute should be based on the risk posed by the introduction and should not turn on the fact that an organism has been modified by a particular process or technique."

The policy statement of 1992 states further: "In order to ensure that limited federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, oversight will be exercised only where the risk posed by the introduction is unreasonable, that is, when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed. The extent and type of oversight measure(s) will thus be commensurate with the gravity and type of risk being addressed, the costs of alternative oversight options, and the effect of additional oversight on existing safety incentives."

APHIS regulation of biotechnology

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

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

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

The PPA defines a plant pest as:

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

7 U.S.C. §7702(14).

[2] A"regulated article" is defined as: "Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions." (7 CFR 340.0).

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

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

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

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

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

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

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

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

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

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

Purpose and Need for Agency Action

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

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

[3] The FEIS can be viewed at http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gt_alfalfa%20_feis.pdf
[4] A transcript of the meeting can be found at
http://www.aphis.usda.gov/newsroom/content/2010/12/printable/alfalfa_meeting_12_20_10_transcript.pdf

Public comment on the FEIS

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

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

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

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

Decision

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

APHIS is selecting Alternative 2 because:

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

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

- The FEIS informed USDA on the interaction of GT alfalfa and coexistence programs. As noted above, USDA hosted a meeting on December 20, 2010, with representatives from a wide array of stakeholders, including representatives from the plaintiffs in the alfalfa litigation. The meeting brought together this diverse group of stakeholders for a dialogue, to explore practical, reasonable approaches that would support coexistence among the various forms of alfalfa production. The preparation of the FEIS, the stakeholder discussion that followed, and the comments received on the FEIS have clarified for USDA the broad range of coexistence issues and stakeholder needs, and highlighted the complexities and difficulties of finding solutions that meet the needs of all stakeholders involved.
- In view of the regulatory requirements in the PPA, the complexity and broad scope of issues involved in fostering coexistence, and considering the positive steps already taken by industry groups to promote best management practices and stewardship measures[5], APHIS believes Alternative 2 best meets the overall purpose and need for agency action identified in the FEIS.

Plant Pest Risk Assessment

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

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

(1) They exhibit no plant pathogenic properties – although a plant pathogen was used in their development, these plants are not infected by this organism nor do they contain genetic material from pathogens used as a donor organism that can cause plant disease.

(2) They exhibit no characteristics that would cause them to be weedier than the non-transgenic parent alfalfa or other cultivated alfalfa and several control options besides glyphosate are available for control of feral or volunteer plants or for stand take-out.

(3) Gene introgression from J101 and J163 to native, introduced, or naturalized species of *Medicago* in the United States is extremely unlikely and even if it were to occur, is not likely to increase the weediness potential of any resulting progeny any more than would introgression from other cultivated alfalfa.

[5] http://www.alfalfa.org/CSCoexistenceDocs.html

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

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

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

Alternatives considered in the FEIS

Alternative 1: No Action Alternative

Under the No Action Alternative, APHIS would deny the petition to grant nonregulated status to glyphosate-tolerant (GT) alfalfa events J101 and J163. The events would continue to be subject to the regulation pursuant to 7 CFR part 340. Permits or notifications would continue to be required to introduce viable GT alfalfa plant material[6]. Permit conditions would be specified by APHIS. These conditions would be designed to confine GT alfalfa. The size of planting would be limited to help maintain confinement. In addition, the number of permits granted would be limited by agency resources, both in terms of the number of permits which could be reviewed by APHIS, and in APHIS' ability to inspect the fields and enforce compliance with regulations. Therefore, the number of acres planted and the amount of seed and hay transported between states would likely be far less than the current commercial production of conventionally-bred alfalfa for seed and hay in the U.S. In time it is expected that the number of acres of GT alfalfa would decrease because the alfalfa that was planted while GT alfalfa had nonregulated status would be replaced by conventional varieties.

Alternative 2: Grant the petition for nonregulated status

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

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

imposes contract restrictions on growers.[7] These nonregulatory restrictions include managing hay to prevent seed production, harvesting at or before ten percent bloom in areas where seed is produced, and prohibitions on use in wildlife feed plots. Similarly, Forage Genetics International (FGI) requires contracted growers who raise alfalfa seed to follow FGI Best Practices. These management practices include pollinator management, specific isolation distances, stand termination documentation, and product segregation[8]. The developer, Forage Genetics International, predicts that approximately 50 percent of the alfalfa acres may eventually be planted with GT alfalfa. The majority of these acres are predicted to be located in the western U.S. Glyphosate is not labeled for use on seed in all states. Therefore, GT alfalfa seed production will likely only occur in the states where glyphosate can be used in its production.

Alternative 3: Grant the petition for nonregulated status in part

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

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

Environmental Consequences Associated with Granting Nonregulated Status

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

Gene flow in Alfalfa

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

[7] http://www.monsanto.com/SiteCollectionDocuments/Technology-Use-Guide.pdf
[8] http://www.foragegenetics.com/pdf/ValidationFGIBestPractices.pdf.

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

Herbicide Use

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

Weeds in Alfalfa

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

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

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

Additional potential Impacts of GT Alfalfa

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

- Several agronomic traits were evaluated and no biological differences between GT and non-GT alfalfa were noted for traits that could influence weediness, including seed dormancy, seed germination, seedling emergence, seedling vigor, winter survival, spring vigor, seed yield, vegetative growth, plant dormancy, survival, and relationship with symbiotic organisms. Therefore GT alfalfa is not expected to become more invasive in natural environments or have any different effect on critical habitat than their parental non-GT event. In addition, the nutritional profiles of GT alfalfa and non-GT alfalfa are not different (within normal cultivar variations); therefore animal nutrition is not expected to be different. There are also no palatability differences.

- Analysis of forage samples from several locations demonstrated that GT alfalfa is compositionally and nutritionally equivalent to other alfalfa varieties currently on the market except for the expression of the transgene protein, and therefore is not expected to have nutritional effects on any animals that feed upon it.

- GT alfalfa is not expected to be toxic or allergenic to plants or animals. The 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein from plants and from the CP4 *Agrobacterium* strain is not known to have pathogenic or toxic effects on humans, animals, or plants based on numerous laboratory and field studies with these purified proteins or plants expressing these proteins.

- Hybrids between alfalfa and other *Medicago* species in the United States are limited to hybridization between *M. sativa* subspecies. Evidence of any sexually compatible, free-living, or native relatives of *Medicago* species in the United States or North America is nonexistent. Hence, the genetic resources of these plant species will not be affected by

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

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

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

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

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

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

Socioeconomic Impacts

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

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

Human Health and Safety

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

Land Use and Physical Environment

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

Decision not to choose Alternative 3

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

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

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

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

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

APHIS has decided not to select Alternative 3 because:

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

Environmentally Preferred Alternative

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

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

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

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

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

Mitigations of Impacts Associated with Alternative 2

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

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

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

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

Compliance with Applicable Laws, Executive Orders, and Regulations.

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

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

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

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

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Date