

NATIONAL ENVIRONMENTAL POLICY ACT DECISION AND FINDING OF NO SIGNIFICANT IMPACT

Monsanto Company and Forage Genetics International Event KK179 Alfalfa

United States Department of Agriculture Animal and Plant Health Inspection Service Biotechnology Regulatory Services

The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) has developed this decision document to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality's (CEQ) regulations implementing NEPA, and the USDA APHIS' NEPA implementing regulations and procedures. This NEPA decision document, a Finding of No Significant Impact (FONSI), sets forth APHIS' NEPA decision and its rationale. Comments from the public involvement process were evaluated and considered in developing this NEPA decision.

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS Number 12-321-01p) by Monsanto Company and Forage Genetics International (Monsanto and FGI) for their genetically engineered alfalfa Event KK179 (hereafter referred to as KK179 alfalfa) that has reduced levels of guaiacyl lignin. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment that may result from approving the petition seeking nonregulated status for KK179 alfalfa. The EA assesses alternatives to a determination of nonregulated status of KK179 alfalfa and analyzes the potential environmental and social effects that result from the proposed action and the alternatives.

Regulatory Authority

"Protecting American agriculture" is the basic charge of APHIS. APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of genetically engineered (GE) varieties) can provide benefits to the environment, consumers, and farm income.

Since 1986, the United States government has regulated GE organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal

agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk.

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

APHIS is responsible for regulating GE organisms and plants under the plant pest provision in the Plant Protection Act of 2000 (PPA), as amended (7 USC §§ 7701 et seq.) to ensure that they do not pose a plant pest risk.

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process 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 foods.

The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the FFDCA and regulates certain biological control organisms under the Toxic Substances Control Act (TSCA). The EPA is responsible for regulating the sale, distribution, and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology.

Regulated Organisms

The APHIS Biotechnology Regulatory Services’ (BRS) mission is to protect America’s agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the Federal Plant Pest Act and further consolidated under the PPA, as amended (7 USC 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient

organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR part 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

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

APHIS' Response to Petition for Nonregulated Status

Under the authority of the plant pest provisions of the PPA and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR part 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as KK179 alfalfa. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines, based on its Plant Pest Risk Assessment (PPRA), that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the PPA and 7 CFR part 340.

Monsanto and FGI have submitted a petition (APHIS Number 12-321-01p) to APHIS seeking a determination that their genetically engineered KK179 alfalfa is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR part 340.

KK179 Alfalfa

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

Coordinated Framework Review

Food and Drug Administration

KK179 alfalfa is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced by genetic engineering. Monsanto and FGI indicated that they submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa to FDA in August 2012, identified under BNF No. 138 (Monsanto and FGI, 2013). The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014).

Environmental Protection Agency

The EPA has authority over the use of pesticidal substances and plant-incorporated protectants (PIPs) under the FIFRA as amended (7 USC §136, *et seq.*) and the FFDCA (21 USC §301, *et seq.*). APHIS considers the EPA's regulatory assessment when assessing potential impacts that may result from a determination of nonregulated status of a GE organism.

As KK179 alfalfa does not express any pesticidal properties, the EPA has no FIFRA review authority over this alfalfa product. However, if KK179 alfalfa provides for a change in use of registered herbicides, the EPA would review proposed label changes relating to these new herbicide uses. But Monsanto and FGI does not indicate any change in herbicide use associated with KK179 alfalfa that would differ from that currently registered for other alfalfa varieties.

Scope of the Environmental Analysis

Although a determination of nonregulated status of KK179 alfalfa would allow for new plantings of KK179 alfalfa anywhere in the U.S., APHIS primarily focused the environmental analysis to those geographic areas that currently support alfalfa production. A determination of nonregulated status of KK179 alfalfa is not expected to increase alfalfa production, either by its availability alone or accompanied by other factors, or cause an increase in overall GE alfalfa acreage. To determine areas of alfalfa production, APHIS used data from the National Agricultural Statistics Service (NASS) to determine where alfalfa is produced in the U.S. (USDA-NASS, 2013a). Alfalfa is cultivated in all 50 states and is also naturalized in many areas (Sullivan, 1992), but the majority of alfalfa produced in the US is grown west of the Mississippi. Approximately 17 to 23.5 million acres of alfalfa hay have been harvested annually over the past 10 years (USDA-NASS, 2013b; 2013d). Annual production has ranged from 52 to 76 million tons of hay. Average annual yields have remained fairly constant at 3.19 to 3.47 tons per acre over that same period (USDA-NASS, 2013b; 2013d). The annual value of production has ranged from \$6.7 to \$10.9 billion (due to most alfalfa being fed to livestock on-farm, the value is an estimate based on multiplying average prices with production volumes and does not correspond to actual sales) (USDA-NASS, 2013b; 2013d). Thus, alfalfa has been and continues to be an important U.S. crop.

Public Involvement

On April 22, 2013, APHIS published a notice in the Federal Register (78 FR pages 23738-23740, Docket no. APHIS-2012-0013) announcing the availability of the Monsanto and FGI petition for a 60-day public review and comment period. Comments were required to be received on or before June 21, 2013. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 55 comments were received from individuals during the comment

period. Comment documents may be viewed at <http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=APHIS-2012-0013>.

Many comments received were from individuals or organizations expressing an opinion of general opposition to GE food, the belief that GE crops harm the environment, or the belief that GE crops are not beneficial to farmers. The issues related to the Monsanto and FGI KK179 alfalfa petition which were raised in these comments are addressed in the EA; the issues raised included:

- Concerns that KK179 alfalfa will cross pollinate with other alfalfa varieties or feral populations
- The effects of KK179 alfalfa on the physical environment
- Potential for weakened plant defenses and increased susceptibility to pests or disease from reduced lignin and subsequent increased pesticide application
- Human health effects from consuming GE crops
- Impacts to pollinators
- Potential economic impacts
- Concerns about the nutritional, quality, and feed safety of KK179 alfalfa for livestock
- Concerns over the use of RNAi technology and the potential for non-target gene effects

APHIS evaluated these issues raised in the comments and provided citations. A discussion of these issues is incorporated in the EA where appropriate.

On May 30, 2014, APHIS published a notice in the Federal Register (79 FR 31082-31083, Docket no. APHIS-2013-0013) announcing the availability of the EA and PPRA for a 30-day public review period. During the comment period, APHIS received a total of 177 comments of which 13 were opposed to a determination of nonregulated status and 164 were supportive of a determination of nonregulated status. Comment documents may be viewed at:

<http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0013>. No new issues, alternatives, or new information were identified in any of the comments received by APHIS. Responses to comments are included as an attachment to this Finding of No Significant Impact.

Major Issues Addressed in the EA

The issues considered in the EA were developed based on APHIS' determination that certain genetically engineered organisms are no longer subject to the plant pest provisions of the PPA and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status for KK179 alfalfa. Issues discussed in the EA were developed by considering public concerns as well as issues raised in public comments submitted for other environmental assessments of genetically engineered organisms, concerns raised in lawsuits, as well as those issues that have been raised by various stakeholders. These issues, including those regarding the agricultural production of alfalfa using various production methods, and the environmental food/feed safety of genetically engineered plants, were addressed to analyze the potential environmental impacts of KK179 alfalfa.

The EA describes the alternatives considered and evaluated using the identified issues. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25):

Agricultural Production Considerations:

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

Environmental Considerations:

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

Human Health Considerations:

- Public Health
- Worker Safety

Livestock Health Considerations:

- Animal Feed/Livestock Health

Socioeconomic Considerations:

- Domestic Economic Environment
- Trade Economic Environment

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of a determination of nonregulated status of KK179 alfalfa. To respond favorably to a petition for nonregulated status, APHIS must determine that KK179 alfalfa is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2013), APHIS has concluded that KK179 alfalfa is unlikely to pose a plant pest risk. Therefore, APHIS must determine that KK179 alfalfa is no longer subject to 7 CFR part 340. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of KK179 alfalfa. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section of the EA.

No Action: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition for nonregulated status under 7 CFR part 340. KK179 alfalfa and progeny derived from KK179 alfalfa would continue to be a regulated article under the regulations at 7 CFR part 340. Permits or notifications acknowledged

by APHIS would still be required for introductions of KK179 alfalfa and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of KK179 alfalfa.

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

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

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

Alternatives Considered but Rejected from Further Consideration

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

1. Prohibit any KK179 Alfalfa from Being Released

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

In enacting the PPA, Congress found that

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

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed

broad principles, consistent with Executive Order 13563, to guide the development and implementation policies for oversight of products of emerging technologies (such as genetic engineering) at the agency level. In accordance with this memorandum, agencies should adhere to Executive Order 13563, and, consistent with that Executive Order, the following principle, among others to the extent permitted by law when regulating emerging technologies:

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

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

2. Approve the petition in part

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

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

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

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

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS’ purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency’s authority under the plant pest

provisions of the PPA. However, individuals might choose on their own to geographically isolate their non-GE alfalfa production systems from KK179 alfalfa or to use isolation distances and other management practices to minimize gene movement between alfalfa fields. Information to assist growers in making informed management decisions for KK179 alfalfa is available from the Association of Official Seed Certifying Agencies (AOSCA, 2010).

4. Requirement of Testing for KK179 Alfalfa

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

Environmental Consequences of APHIS' Selected Action

The EA contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

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

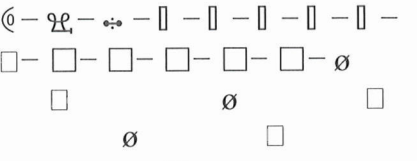
Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Agronomic Practices	General agronomic practices such as stand planting and removal, crop rotation, tillage, pest and disease management, crop nutrition, and pre-harvest and harvest practices are expected to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

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

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

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

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

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Socioeconomic		
	<p>The majority of alfalfa production is grown for animal feed. The majority of alfalfa hay is consumed on the farm where it is produced, and dairy farms are by far the main consumer. The quality of alfalfa hay is determined by the presence of weeds, fiber content, protein content, and other factors such as color and mold presence</p>	<p>Growers may realize economic benefits from increased flexibility in cutting time, resulting in either 1) increased quality of alfalfa forage with comparable yield to conventional alfalfa harvested</p> 
Domestic Economic Environment		<p>at an earlier growth phase, resulting from delayed harvesting. Growers receive greater economic returns for higher quality hay, where prices can vary as much as 50 percent between supreme and fair quality (USDA-APHIS, 2010). Flexibility in forage harvest timing will allow growers to better manage the yield-quality relationship to optimize economic return based on either market prices or intended on-farm feed use</p>

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Trade Economic Environment	In 2011, the U.S. exported approximately \$445 million in alfalfa products primarily to Japan, China, South Korea, and Taiwan. U.S. alfalfa and alfalfa products will continue to play a role in global alfalfa production, and the U.S. will continue to be a supplier in the international market. East Asia is likely to continue as a major export destination for traded U.S. alfalfa products.	The trade economic impacts associated with a determination of nonregulated status of KK179 alfalfa are anticipated to be similar to the No Action alternative because Monsanto and FGI do not intend to globally launch KK179 alfalfa until the proper regulatory approvals have been obtained.
Other Regulatory Approvals		
U.S.	Monsanto and FGI submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa to FDA in August 2012. The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014).	Monsanto and FGI submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa to FDA in August 2012. The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014).
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	Fully compliant

Finding of No Significant Impact

The analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. I agree with this conclusion and therefore find that an EIS need not be prepared. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27).

Context - The term “context” recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. This action has potential to affect conventional and organic alfalfa production systems, including surrounding environments and agricultural workers; human food and animal feed production systems; and foreign and domestic commodity markets.

Approximately 17 to 23.5 million acres of alfalfa hay have been harvested annually over the past 10 years (USDA-NASS, 2013b; 2013d). Annual production has ranged from 52 to 76 million tons of hay. Average annual yields have remained fairly constant at 3.19 to 3.47 tons per acre over that same period (USDA-NASS, 2013b; 2013d). The annual value of production has ranged from \$6.7 to \$10.9 billion (due to most alfalfa being fed to livestock on-farm, the value is an estimate based on multiplying average prices with production volumes and does not correspond to actual sales) (USDA-NASS, 2013b; 2013d). A determination of nonregulated status of KK179 alfalfa is not expected to directly cause an increase in agricultural acreage devoted to alfalfa production. The availability of KK179 alfalfa will not change cultivation areas for alfalfa production in the U.S., and there are no anticipated changes to the availability of GE and non-GE alfalfa varieties on the market.

Intensity – Intensity is a measure of the degree or severity of an impact based upon the ten factors. The following factors were used as a basis for this decision:

1. *Impacts that may be both beneficial and adverse.*

A determination of nonregulated status of KK179 alfalfa will have no significant environmental impact in relation to the availability of GE, conventional, and organic alfalfa varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of KK179 alfalfa is not expected to directly cause an increase in agricultural acreage devoted to alfalfa production. Based on the data provided by Monsanto and FGI for KK179 alfalfa (Monsanto and FGI, 2013), APHIS has concluded that the availability of KK179 alfalfa will not change the cultivation areas for alfalfa production in the U.S., and there are no anticipated changes in the availability of alfalfa varieties on the market. A determination of nonregulated status of KK179 alfalfa could add another alfalfa variety to the alfalfa market, but is not expected to change the market demands for alfalfa or alfalfa produced using organic methods. As of 2011, organic alfalfa in 30 states was harvested from 231,318 acres producing 747,555 tons, compared to approximately 19.2 million harvested acres of conventionally produced alfalfa (USDA-NASS, 2013a). In 2011, organic alfalfa production consisted of about 1.2 percent of total U.S. alfalfa production and was valued at approximately \$69.5 million, capturing roughly 0.64 percent of the overall alfalfa crop value for that year (USDA-NASS, 2012; 2013c). Based on the data provided by Monsanto and FGI for KK179 alfalfa (Monsanto and FGI, 2013), APHIS has concluded that the availability of KK179 alfalfa would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE alfalfa seed production (USDA-APHIS, 2013). A determination of nonregulated status of KK179 alfalfa will not require a change to seed production practices, nor current production practices. The introduction of KK179 alfalfa provides an alternative alfalfa variety.

2. *The degree to which the proposed action affects public health or safety.*

A determination of nonregulated status of KK179 alfalfa would have no significant impacts on human or animal health. Compositional tests conducted by the petitioner indicate that KK179 alfalfa, with the exception of the reduced lignin trait, is compositionally similar to other commercially available alfalfa (Monsanto and FGI,

2013). Monsanto and FGI indicated that they submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa to FDA in August 2012, identified under BNF No. 138 (Monsanto and FGI, 2013). The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014). Based on the assessment of laboratory data provided by Monsanto and FGI (Monsanto and FGI, 2013) in the submitted petition and an analysis of the scientific literature (USDA-APHIS, 2013), APHIS has concluded that a determination of nonregulated status of KK179 alfalfa would have no adverse impacts on human or animal health.

3. *Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.*

There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status of KK179 alfalfa. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property, wildlife habitat, or landscapes; and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of KK179 alfalfa. The product will be deployed on agricultural land currently suitable for production of alfalfa, will replace existing varieties, and is not expected to increase the acreage of alfalfa production. This action would not convert land to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to KK179 alfalfa including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of KK179 alfalfa, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to alfalfa production sites.

4. *The degree to which the effects on the quality of the human environment are likely to be highly controversial.*

The effects on the quality of the human environment from a determination of nonregulated status of KK179 alfalfa are not highly controversial. Although APHIS received public comments opposed to a determination of nonregulated status of KK179 alfalfa, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status is not expected to directly cause an increase in agricultural acreage devoted to alfalfa production. The availability of KK179 alfalfa will not change cultivation areas for alfalfa production in the U.S., and there are no anticipated changes to the availability of alfalfa varieties on the market. A determination of nonregulated status for KK179 alfalfa would add another GE alfalfa variety to the conventional alfalfa market and is not expected to change the market demands for GE alfalfa or alfalfa produced using organic methods. A determination of nonregulated status of KK179 alfalfa will not result in changes in the current agronomic practices of planting, tillage,

fertilizer application/use, cultivation, pesticide application/use, or volunteer control. Management practices and seed standards for production of certified alfalfa seed would not change. The effect of KK179 alfalfa on wildlife or biodiversity is not different than that of other GE or non-GE alfalfa produced in conventional agriculture in the U.S.

5. *The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.*

Based on the analysis documented in the EA, the possible effects on the human environment are well understood. The effects of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status of KK179 alfalfa is not expected to directly cause an increase in agricultural acreage devoted to alfalfa production, nor increase those acres devoted to GE alfalfa cultivation. A determination of nonregulated status of KK179 alfalfa will not result in changes in the current practices of planting, tillage, fertilizer application/use, pesticide application/use or volunteer control. Management practices and seed standards for production of certified soybean seed would not change. The effect of KK179 alfalfa on wildlife or biodiversity is no different than that from other alfalfa varieties currently used in conventional agriculture in the U.S. As described in Chapter 2 of the EA, well established management practices, production controls, and production practices (GE, conventional, and organic) are currently being used in alfalfa production systems (commercial and seed production) in the U.S. Therefore, it is reasonable to assume that farmers, who produce conventional alfalfa (GE and non-GE varieties), KK179 alfalfa, or produce alfalfa using organic methods, will continue to use these reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural alfalfa production. Therefore, the impacts are not highly uncertain, and do not involve unique or unknown risks.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*

A determination of nonregulated status for KK179 alfalfa would not establish a precedent for future actions with significant effects or represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340. Each petition that APHIS receives is specific to a particular GE organism and undergoes this independent review to determine if the regulated article poses a plant pest risk. Under the authority of the plant pest provisions of the PPA and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as KK179 alfalfa. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines, based on its PPRA, that the GE organism is unlikely to pose a plant pest risk, the GE organism is no longer subject to the plant pest provisions of the PPA and 7 CFR part 340. APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the PPA, as amended (7

United States Code (U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have enough information to determine if the GE organism is unlikely to pose a plant pest risk. A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the PPA or the regulations at 7 CFR part 340. The petitioner is required to provide information under §340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*

No significant cumulative effects were identified through this assessment. The EA discussed cumulative effects on alfalfa management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative effects analysis is provided in Chapter 5 of the EA. In the event APHIS reaches a determination of nonregulated status of KK179 alfalfa, APHIS would no longer have regulatory authority over this alfalfa. APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of KK179 alfalfa when added to past, present, and reasonably foreseeable future actions.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historic resources.*

A determination of nonregulated status of KK179 alfalfa will not adversely impact cultural resources on tribal properties. Any farming activities that may be taken by farmers on tribal lands are only conducted at the tribe's request; thus, the tribes have control over any potential conflict with cultural resources on tribal properties. A determination of nonregulated status of KK179 alfalfa would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historic resources. This action is limited to a determination of nonregulated status of KK179 alfalfa. Standard agricultural practices for land preparation, planting, irrigation, and harvesting would be used on these agricultural lands including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A

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

9. *The degree to which the action may adversely affect the endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*

As described in Chapter 6 of the EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of KK179 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, as required under Section 7 of the Endangered Species Act. After reviewing possible effects of a determination of nonregulated status of KK179 alfalfa, APHIS has concluded that a determination of nonregulated status of KK179 alfalfa would have no effect on federally listed TES and species proposed for listing, or on designated critical habitat or habitat proposed for designation.

10. *Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.*

The proposed action would be in compliance with all federal, state, and local laws. Because the agency has concluded that KK179 alfalfa is unlikely to pose a plant pest risk, a determination of nonregulated status of KK179 alfalfa is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. Monsanto and FGI initiated the consultation process with FDA for the commercial distribution of KK179 alfalfa and submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa to the FDA in August 2012, identified under BNF No. 138 (Monsanto and FGI, 2013). The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014).

KK179 alfalfa is compositionally similar to currently available alfalfa on the market, with the exception of the low lignin trait. Agronomic characteristics and cultivation practices required for KK179 alfalfa are indistinguishable from practices used to grow other alfalfa

varieties. There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

NEPA Decision and Rationale

I have carefully reviewed the EA prepared for this NEPA determination and the input from the public involvement process. I believe that the issues identified in the EA are best addressed by selecting Alternative 2 (Determination that KK179 alfalfa is No Longer a Regulated Article). This alternative meets APHIS' purpose and need to allow the safe development and use of genetically engineered organisms consistent with the plant pest provisions of the PPA.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative 2 is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with KK179 alfalfa, the continued regulated status of KK179 alfalfa would be inconsistent 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. For the reasons stated above, I have determined that a determination of nonregulated status of KK179 alfalfa will not have any significant environmental effects.

Janet L. Buchnell

for Michael J. Firko
Deputy Administrator,
Biotechnology Regulatory Services

9/4/2014

Date

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Response to Public Comments on KK179 Alfalfa

Summary of comments received

On April 22, 2013, APHIS published a notice in the Federal Register (78 FR pages 23738-23740, Docket no. APHIS-2012-0013) announcing the availability of the Monsanto and FGI petition for a 60-day public review and comment period. Comments were required to be received on or before June 21, 2013. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 55 comments were received from individuals during the comment period.

On May 30, 2014, APHIS published a notice in the Federal Register (79 FR 31082-31083, Docket no. APHIS-2013-0013) announcing the availability of the draft EA and draft PPRA for a 30-day public review period. During the comment period, APHIS received a total of 177 comments of which 13 were opposed to a determination of nonregulated status and 164 were supportive of a determination of nonregulated status. Comment documents may be viewed at: <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0013>. Several specific issues related to the KK179 alfalfa EA were identified from the public comments. These were organized into categories and addressed below. No new issues, alternatives, or new information were identified in any of the comments received by APHIS. Responses to comments are included as an attachment to this Finding of No Significant Impact.

Issue 1

One commenter indicated that the USDA should complete an EIS on this decision.

APHIS Response

APHIS has prepared the EA to consider the potential environmental effects of the proposed action and the reasonable alternative to that action, the no action alternative, consistent with NEPA requirements (40 CFR parts 1500-1508, 7 CFR 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from the determination of nonregulated status of KK179 alfalfa. Based on the EA, APHIS concludes that the determination of nonregulated status of KK179 alfalfa would not cause significant impacts on the environment and therefore, APHIS does not need to prepare an EIS before deregulating this product.

Issue 2

Several commenters were concerned with the use of glyphosate on KK179 alfalfa crossed with Roundup Ready alfalfa, stating potential health effects from the use of glyphosate as well as the potential for development of glyphosate resistant weeds. One commenter noted a study linking exposure to glyphosate-based herbicide with changes in sperm. The same commenter mentioned links between use of glyphosate and Parkinson's disease and leukemia but did not cite the specific studies. One comment concerned the potential development of glyphosate-resistant weeds as a result of increases in glyphosate applications.

APHIS Response

The general use of herbicides is outside of the scope of this EA. The EA has reported on the safety of the use of glyphosate in the cumulative impacts section since KK179 alfalfa itself does not contain glyphosate resistance. The safety and use of glyphosate was also reviewed in the 2010 FEIS (USDA-APHIS, 2010) on glyphosate-tolerant alfalfa and this information was incorporated into the EA by reference where appropriate.

Under the Coordinated framework, EPA regulates pesticides, including crops with plant-incorporated protectants (pesticides intended to be produced and used in a living plant) to ensure public safety from their use, including pesticide residue on food and animal feed. EPA considers the effects of herbicide use on natural resources and living organisms. FDA has primary responsibility for ensuring the safety of food and animal feed. The EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under the FIFRA. A determination of specific requirements for a pesticide is based on procedures outlined in the Label Review Manual (US-EPA, 2013b). It addresses, among other things, level and pattern of use (e.g., allowable application methods, minimum and maximum rates; timing of treatments). EPA, not USDA, regulates the use of pesticides under FIFRA. APHIS relies on the EPA's risk assessments and expertise because these are the best available information. APHIS uses this and other information from the scientific literature in its assessment. APHIS' decision on the petition is based on the plant pest risk of the subject organism. APHIS has no statutory authority to authorize or regulate the use of glyphosate, or any other herbicide used by alfalfa growers. APHIS has carefully considered the possible environmental impacts of the proposed action, and is satisfied that the EA prepared by APHIS is adequate and sufficient.

All pesticides sold or distributed in the U.S. must be registered by the EPA (US-EPA, 2013a). Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. The environmental risks of glyphosate herbicides are assessed by the EPA in the pesticide registration process. Glyphosate was first registered in the U.S. in 1974; the latest reregistration decision for glyphosate was issued in 1993 (US-EPA, 1993; 2009b; 2009a). It is currently under reregistration review, which began in July 2009 and is scheduled for completion in 2015 (US-EPA, 2009a).

Glyphosate, when used according to the label, has been shown not to have unreasonable adverse effects on species and the environment. To make such determinations, EPA reviews a large number of scientific studies and tests from applicants (US-EPA, 2013b). Prior to allowing a pesticide product to be released on the market, EPA ensures that the pesticide will not pose any unreasonable risks to wildlife and the environment. EPA evaluates the data submitted in regards to the potential hazard to non-target fish and wildlife species. In considering whether to register a pesticide, EPA conducts ecological risk assessments to determine what risks are posed by a pesticide and whether changes to the use or proposed use are necessary to protect the environment. A pesticide cannot be legally used if it has not been registered with EPA's Office of Pesticide Programs. EPA has already concluded that glyphosate poses no unreasonable risks to wildlife and the environment (US-EPA, 1993).

Agricultural workers that routinely handle glyphosate may be exposed during spray operations. Because of low acute toxicity of glyphosate, absence of evidence of carcinogenicity and other

toxicological concerns, occupational exposure data is not required for reregistration. However, EPA has classified some glyphosate formulations as eye and skin irritants. EPA's Worker Protection Standard (WPS) (40 CFR Part 170) was published in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protections to more than two and a half million agricultural workers who work with pesticides at more than 560,000 workplaces on farms, forests, nurseries, and greenhouses. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance. Furthermore, the Occupational Safety and Health Administration require all employers to protect their employees from hazards associated with pesticides and herbicides. During agricultural production of alfalfa, agricultural workers and pesticide applicators may be exposed to a variety of EPA registered pesticides (see, e.g., <http://www.cdc.gov/niosh/topics/pesticides/>). Such chemicals would be expected to include those products currently used for insect pest and plant pest management in both GE and non-GE alfalfa cultivation, including the use of glyphosate. Worker safety is taken into consideration when a pesticide label is developed during the registration process. When use is consistent with the label, pesticides including glyphosate, present minimal risk to the worker.

On a practical note, growers are required to use pesticides consistent with the application instructions provided on the EPA-approved pesticide labels. For example, pesticide labels specify the appropriate worker safety practices that must be followed, including the necessary PPE to be worn by mixers, loaders, other applicators and handlers. These label restrictions carry the weight of law and are enforced by the EPA and the states (FIFRA 7 U.S.C. 136j (a)(2)(G) Unlawful Acts).

APHIS acknowledges the occurrence of herbicide resistant weeds in the U.S. and discusses management strategies to deal with the issue in the 2010 FEIS and incorporated into this EA as appropriate. Weed resistance to herbicides is a concern in agricultural production. Using herbicides with alternate mechanisms of action can diminish the potential for the development of new glyphosate-resistant weeds. The use of multiple herbicides with different modes-of-action on crops (whether tank-mixed or applied sequentially) is already a common agricultural practice in order to manage weeds. The emergence of resistance to herbicides is not exclusive to glyphosate-resistant crops and corresponding weedy species, and presents continued challenges to growers to understand which herbicide-resistant species is present and the best agronomic practice available to manage the weed. Approving the petition for nonregulated status for KK179 alfalfa would not change the development of glyphosate-resistant weeds.

A variety of genetic, biological/ecological, and operational factors contribute to the evolution of herbicide resistance in weeds. Genetic factors include the frequency of genes in a particular weed species (that promotes resistance to a particular herbicide), the mechanism of resistance and the capacity of genes to facilitate this resistance, how resistance is inherited, and the fitness of the weed in the presence and absence of the herbicide (Georghiou and Taylor, 1986; Neve, 2008). Biological/ecological factors include the method of weed reproduction, seed production capacity, seed bank turnover, and the amount and frequency of gene flow between weed populations (Maxwell and Mortimer, 1994; Jaseniuk *et al.*, 1996). Collectively, these issues illustrate that different plant species may present different risks of resistance.

Although management plays an important role in stemming the pace of resistance, APHIS is not relying on such management strategies, to stem the evolution and adverse environmental impacts of resistant weeds. Weed management is important to any agricultural system, and growers have adopted integrated weed management techniques to prolong the usefulness and benefits of herbicide technology. The commercialization of alfalfa varieties stacked with herbicide resistant traits would allow existing and widely-adopted management strategies to continue. Management recommendations to mitigate the development of resistant weeds are guidance, and although a reasonable informed grower would be fully expected to read, know and follow such guidance to maintain safety and effectively achieve desired production results, as guidance they are not enforceable in the absence of a specific contractual obligation.

In regard to KK179 alfalfa being stacked with glyphosate-resistant traits, it is unlikely that this GE-alfalfa variety would alter any baseline influence of established management strategies that are currently practiced in GE-alfalfa cultivation systems. It is also unlikely that any GE-alfalfa variety stacked with KK179 alfalfa would increase the incidence of resistant weeds, as the factors resulting in resistance in weeds would remain unchanged.

Issue 3

Commenters expressed concerns that KK179 alfalfa, with reduced levels of lignin, could have effects on the carbon cycle.

APHIS Response

KK179 alfalfa is engineered to have reduced levels of guaiacyl lignin and so reduced overall lignin when compared to conventional alfalfa at the same stage of growth. KK179 alfalfa does not raise the maximum potential quality attainable for forage but allows for increased farmer flexibility to better manage the yield-quality relationship and harvesting schedules to maximize the profitability of alfalfa production for their farming operation (Monsanto and FGI, 2013). Based on these analyses, APHIS concludes that decomposition of KK179 alfalfa would be no different than other alfalfa varieties currently grown (both GE and non-GE), and therefore would have no different effect on the carbon cycle.

Issue 4

Concerns were raised in the comments in regard to effects of KK179 alfalfa pollen on pollinizing insects specifically alfalfa leafcutter bees and honey bees.

APHIS Response

The EA has reported on the safety of KK179 alfalfa in the environmental consequences and cumulative impacts sections under various headings, including those on animals, plants, biodiversity, microbes and human health. Based upon information and analysis presented in the petition, PPRA, and EA, APHIS has not identified any potential for harm to the environment from KK179 alfalfa.

As noted in the EA, alfalfa seed production typically requires the intentional introduction of large numbers of bee colonies in or near fields during the peak of flower production in order to

achieve high rates of pollination and uniform seed ripening. Conversely, forage production does not entail the use of bees by growers at any stage. The primary pollinators used in seed production are leafcutter bees, honey bees, and to a lesser extent alkali bees. Foraging bees would come into contact with KK179 alfalfa pollen. KK179 alfalfa was developed by insertion of *CCOMT* gene segments which suppresses endogenous *CCOMT* gene expression via the RNA interference (RNAi) pathway. Suppression of the *CCOMT* gene expression leads to lower *CCOMT* protein expression resulting in reduced synthesis of guaiacyl lignin rather than a functional protein or new enzyme (USDA-APHIS, 2013). The RNAi pathway responsible for the low lignin trait in KK179 alfalfa is designed to specifically target the *CCOMT* genes in alfalfa and it is highly unlikely that there would be an effect on non-related organisms such as insects or other types of non-target organisms. Nucleic acids are a normal part of every living organism and do not have toxic or allergenic properties. Further, nucleic acids are considered to be “generally recognized as safe” (GRAS) by the U.S. Food and Drug Administration (FDA) (US-FDA, 1992). Non-target organisms will only be exposed to non-toxic RNA; therefore there is virtually no potential for adverse effects to non-target organisms.

APHIS evaluated in the EA, Monsanto and FGI’s data on agronomic performance, disease and insect susceptibility, and compositional profiles of KK179 alfalfa (Monsanto and FGI, 2013). APHIS analysis indicates no significant differences between KK179 alfalfa and non-transgenic counterparts that would be expected to cause either a direct or indirect adverse effect on non-target organisms. Monsanto and FGI presented data that showed no statistically significant differences between KK179 alfalfa pollen and the conventional control for percent viable pollen or pollen grain diameter, as well as no visual differences in general pollen morphology (Monsanto and FGI, 2013). Monsanto and FGI also showed no statistically significant differences between KK179 alfalfa flowers and the conventional control for number of flowers per raceme, standard petal length, keel petal length, calyx tube diameter, sexual column length, and wing petal length, as well as no visual differences in flower color class, gross raceme morphology, or gross flower morphology (Monsanto and FGI, 2013).

APHIS assessed pest- and beneficial-arthropod abundance data provided by Monsanto and FGI (Monsanto and FGI, 2013). No statistically significant differences were detected between KK179 alfalfa and the conventional control for 65 out of 69 comparisons, including 39 pest-arthropod comparisons and 30 beneficial-arthropod comparisons. Of the four differences detected, there were two statistically significant differences in pest-arthropod abundance and two statistically significant differences in beneficial-arthropod abundance. The differences for these taxa were not consistently detected across collection times or sites. Thus, the detected differences in arthropod abundance were not considered to be biologically meaningful (Monsanto and FGI, 2013). The mean abundance values of KK179 alfalfa were within the respective range of the conventional commercial reference varieties for that site and collection time. Insect population diversity represents one measure of general impacts, and there were no differences observed at various times during development of the crop. In the absence of any observable acute stresses or impacts, there is no reason to presume that long term impacts would be expected, nor that a need exists to monitor for them. APHIS has carefully considered the possible environmental impacts of the proposed action, and is satisfied that the EA prepared by APHIS is adequate and sufficient.

Several commenters raised concerns that lower lignin levels in KK179 alfalfa could make the plants more susceptible to pests or disease. One commenter noted that “reduced lignin can negatively impact the agricultural fitness of alfalfa.”

APHIS Response

Monsanto and FGI evaluated how KK179 alfalfa performed in the field with respect to control plants. Environmental interactions assessed included plant response to abiotic stressors, disease damage and arthropod damage to analyze if this event was less, equal or more susceptible to pest and diseases than control plants (Monsanto and FGI, 2013). Monsanto and FGI data show that KK179 alfalfa does not show increased susceptibility or tolerance to specific abiotic stress, diseases, or arthropods when compared to the conventional control (Monsanto and FGI, 2013). KK179 alfalfa is expected to be no more susceptible to the same plant pathogens and insect pests as conventional alfalfa varieties (USDA-APHIS, 2013). Standard management practices will be used to control for disease and pests in KK179 alfalfa fields as they would in conventional alfalfa fields.

Issue 6

One commenter raised concerns about the small sample size used in field trials and that KK179 alfalfa was not tested in all states where alfalfa is grown.

APHIS Response

APHIS carefully considered the possible environmental impacts of the proposed product, and is satisfied that the EA developed for KK179 alfalfa is adequate and sufficient. The EA follows all applicable laws, regulations, and guidelines in analyzing potential impacts of this action, including those established by NEPA. In making an informed decision of potential environmental impacts, APHIS used the best available scientific information, data and expert advice.

The petitioner requesting deregulation of a product is required to provide certain information which the agency uses to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism from which it was derived. As noted in the regulations at 7 CFR part 340.6 the petition shall include all information from “Field test reports for all trials conducted under permit or notification procedures, involving the regulated article” and that “field test reports shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, non-target organisms, or the environment.” The regulations do not indicate a requirement for sample size used in field trials or locations of field trials. The data collected from field trials and compositional analysis of KK179 alfalfa was sufficient for APHIS evaluation.

Issue 7

One commenter raised concerns that KK179 alfalfa “had 30 percent lower mean canavanine levels than the controls” and that these reduced canavanine levels could impact soil chemistry and nearby microorganisms.

APHIS Response

During compositional analysis conducted by Monsanto and FGI the mean level of canavanine, an anti-nutrient, was significantly lower ($p < 0.05$) in KK179 forage than in the conventional control. The absolute difference in magnitude was 16.94 ppm, which is a relative difference of - 29.6%. However, the mean level of canavanine was within the 99% tolerance interval of the conventional commercial reference varieties and within the range of values found in the published literature (Monsanto and FGI, 2013). Lower levels of canavanine would not be adverse as it is considered an anti-nutrient in leguminous plants. Therefore, the difference in canavanine in KK179 forage compared to the conventional control is not considered biologically meaningful from a feed/food safety and nutritional perspective.

Issue 8

One commenter noted that there were no long term feeding studies done on cattle and horses to ensure that KK179 alfalfa is “in fact more easily digestible and does not have unintended side effects that could affect the health of the animals or the meat and dairy that comes from these animals.”

APHIS Response

The compositional and nutritional assessment supports the conclusion that KK179 forage is compositionally equivalent, with the exception of the intended reduction in G lignin and total lignin (ADL), to that of conventional alfalfa at the same stage of growth. The data collected from field trials and compositional analysis of KK179 alfalfa was sufficient for APHIS evaluation.

APHIS regulates GE organisms (7 CFR part 340) by authority granted by the Plant Protection Act (PPA). The PPA grants authority to regulate plant pests and noxious weeds. Under the PPA, APHIS is required to consider plant pest risks alone as a factor in determining whether or not to deregulate a regulated article. APHIS evaluated the effects of KK179 alfalfa on human health and as animal feed. The compositional and nutritional studies conducted by Monsanto and FGI are consistent with OECD guidelines for alfalfa, and found that KK179 alfalfa is similar in composition and nutrition to any other alfalfa variety. Monsanto and FGI have completed a consultation with the FDA (US-FDA, 2014). APHIS has reviewed and evaluated the studies submitted to APHIS by Monsanto and FGI and concluded that it is unlikely that KK179 alfalfa poses a hazard to human or livestock health.

Issue 9

Concerns were raised in regards to the impacts of KK179 alfalfa on organic or non-GE alfalfa crops. A number of comments focused on “the potential effects of gene flow from KK179 alfalfa to conventional or organic alfalfa fields” as well as the economic impacts from gene flow. One commenter noted that “any contamination or damage to organic alfalfa could result in huge economic losses for farmers.”

APHIS Response

The essential dynamics relating to the principals of coexistence of conventional alfalfa and organic alfalfa production would not change by the determination of nonregulated status of KK179 alfalfa. Growers have, for decades, been successfully growing crops bearing different traits and often on adjoining fields despite the method by which traits were introduced (conventional breeding or recombinant DNA technology). Studies of coexistence of major GE and non-GE crops in North America and the European Union (EU) have demonstrated that there has been no significant introgression of GE genes, and that GE and non-GE crops are coexisting with minimal economic effects (Brookes and Barfoot, 2004a; 2004b; Gealy *et al.*, 2007).

The U.S. Department of Agriculture's Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) has released a final set of recommendations on enhancing coexistence among different crop production methods (USDA, 2012). The AC21 presented its report to Agriculture Secretary, Tom Vilsack, to be used as guidance to enhance working relationships among farmers growing different types of crops, specifically GE- and non-GE crops. The committee also made recommendations to the USDA emphasizing education, stewardship and good neighbor-to-neighbor communications. The report indicates that technological innovations and market diversity have become key drivers of increased productivity and product quality for all forms of American agriculture.

However, ultimately organic producers are obligated to manage their operations to avoid unintentional contact with excluded methods. A number of techniques have been developed in order to maintain the concept of coexistence and to prevent cross-pollination. Isolation distances between fields help to minimize the effects of pollen flow. In addition to spatial isolation, growers can use reproductive isolation to minimize or eliminate cross-pollination (i.e. plant varieties with different maturity dates) or stagger planting dates (to obtain different flowering stages), with a minimum of three to four weeks difference between the planting of their crop and neighboring crop. Monsanto and FGI have proposed a technology stewardship agreement for forage growers purchasing glyphosate-resistant alfalfa seed which includes the requirement to cut forage before the 10 percent bloom stage (Monsanto Company, 2013). In addition to the technology stewardship agreement since 2011 the National Alfalfa and Forage Alliance (NAFA) has worked with alfalfa growers, using best management practices, to establish voluntary grower opportunity zones, where growers concentrate either GE or Adventitious Presence Sensitive production and exclude the other (NAFA, 2011). These strategies along with farmer communication can be successfully used to minimize the effects of pollen-mediated gene flow.

Unlike the vast majority of biotech crops grown today, the primary commodity for alfalfa is forage/hay (99.4 percent in U.S. (USDA-NASS, 2009)), not seed. Since a seed generation is required for gene flow and mature seeds are rarely formed in hay production fields, there is very little opportunity for gene flow to or between alfalfa hay fields (Putnam, 2006). As it is desirable to harvest hay fields prior to bloom to maintain hay quality, producers strive to harvest well before viable seed is established (NAFA, 2012). Harvest of organic hay before the ripe seed stage eliminates potential pollen mediated gene flow from feral plants, neighboring GE alfalfa seed or GE alfalfa forage production fields (NAFA, 2012).

APHIS acknowledges that the public may have varying perceptions of the term "organic" and the term often may take on different meanings in the context of advertising, cultural values, pharmaceuticals, chemistry, food, agriculture and contemporary thought as expressed in

literature and media. To accommodate the need for an appropriate food standard, the USDA established the National Organic Program (NOP), under the Organic Foods Protection Act and established the NOP regulations. In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) NOP definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2010). The NOP prohibits the use of excluded methods in organic operations.

Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. Under the NOP, certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Act. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2010). The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan. As noted by Ronald and Fouche (2006a), "While 100% purity (zero tolerance for any undesired components) is very difficult to attain for any agricultural commodity, standard procedures involving spatial separation, border rows, planting dates, maturity dates, cleaning of equipment, and post-harvest handling have traditionally been able to provide products that meet the production burden of supplying products for diverse market requirements."

APHIS expects KK179 alfalfa will be used to breed alfalfa varieties suitable to a range of environments and replace some of the herbicide-resistant alfalfa varieties. The effect on agricultural practices (e.g., cultivation, spray programs, crop rotation practices, planting rates, etc.) from its introduction into the environment should not be significantly different than for the previously deregulated herbicide-resistant alfalfa lines already in agricultural production, and the baseline of effects would not reasonably be expected to change. NOP-approved practices can be sufficient to maintain the integrity of a crop and the purity of seed, especially if there are economic/market motivations to implement these practices (Fernandez and Polansky, 2006; Ronald and Fouche, 2006b; Anonymous, 2010).

Major buyers of organic commodities have allowances for a certain percentage of GE traits. While some buyers may require testing for unintentional GE-trait content, this is one of the costs that presumably makes organic products more costly at purchase, and for which the grower is reimbursed. It is not likely that organic farmers or other farmers who choose not to plant transgenic varieties will be significantly impacted by the commercial use of KK179 alfalfa. APHIS therefore finds no basis of a burden being imposed, of burden shifting, or an increased burden being placed upon other farmers as a result of the determination of nonregulated status of KK179 alfalfa.

Issue 10

Several concerns were raised in regards to the use of RNAi-mediated gene suppression techniques. Several commenters raised the concern that "RNAi can actually suppress unintended genes." One commenter raised concerns that "ingesting RNA material could have unexpected effects in mammals."

APHIS Response

RNA interference (RNAi) is an RNA-based mechanism that changes endogenous gene expression in eukaryotes including plants, insects, fungi, nematodes, and mammals. RNAi-mediated gene suppression generally requires sequence homology of at least 90% between the silencing construct and the target sequence to be successful and even higher degrees of homology over 21-23 nucleotide stretches (Sharp, 2001). A complementarity between siRNAs (Short interfering RNA) and their target RNA sequences is necessary for an effective and efficient gene silencing. Short interfering RNA-mediated silencing of non-target genes, termed off-target effects (OTE), often appears to be caused by silencing genes homologs to the targeted gene and/or other genes sharing partial sequence complementarity or similarity to the si-RNA (Jackson *et al.*, 2003).

The potential unintended effects in biotech crops (e.g., compositional or agronomic changes) are important factors in the evaluation of crop safety assessment process (Cellini *et al.*, 2004). RNAi induced changes could be manifested in compositional or phenotypic changes in the genetically modified plant (Parrott *et al.*, 2010). OTE may also induce compositional and phenotypic changes and they can be compared to the intended phenotype and compared to the parental type or control. In KK179 alfalfa only the intended phenotypes were observed and the compositional and agronomic/phenotypic analysis revealed that it does not have any other unintended or off target effects other than the intended or desired phenotype in the GE alfalfa.

Recently Jim Carrington an expert on RNAi, say “There is no confirmed evidence in the scientific literature, that associates consumption of plant-derived RNA molecules of any kind with any hazards in humans, other mammals, or domesticated animals” (Carrington, 2014). It is not likely that the gene silencing in KK179 alfalfa would contribute to silencing of other genes or off target affects.

Consumption of KK179 alfalfa is unlikely to substantially affect non-target organisms, such as mammals, birds, or insects. Monsanto and FGI data demonstrates that the composition of KK179 alfalfa does not substantially differ from conventional alfalfa varieties (Monsanto and FGI, 2013). Monsanto and FGI indicated that they have submitted a safety and nutritional assessment of food and feed derived from KK179 alfalfa to the FDA in August 2012, identified under BNF No. 138 (Monsanto and FGI, 2013). The FDA completed its consultation and as of December 27, 2013 has no further questions (US-FDA, 2014). There is no evidence that animal exposure to KK179 alfalfa would have any effect or be any less attractive as food, refuge, cover and nesting sites as other varieties of alfalfa.

Issue 13

One commenter raised the concern that APHIS did not analyze the impacts of feral or roadside populations of KK179 alfalfa specifically their impact on gene flow.

APHIS Response

APHIS disagrees with this comment. Feral populations of alfalfa are discussed in Sections 2.1.2, 2.2, 2.4.3, 4.2.4, 4.4.3, 5.3, and 6.2. Section 2.4.3 specifically refers to gene flow from feral

populations and preventative measures. While gene flow from feral populations is possible, typical conditions and practices for hay and seed production all but preclude the chance of gene flow into hay or seed production fields from feral alfalfa (Van Deynze *et al.*, 2008; USDA-APHIS, 2010).

Issue 14

Concerns were raised in regards to the effects of KK179 alfalfa on domestic and export markets. One commenter was concerned about the “socioeconomic impacts on farmers whose crops may become contaminated with KK179.” The same commenter was also concerned about the “global market impacts associated with KK179 contamination of non-GE exports to countries with strict biotech regulations” noting that many foreign markets do not accept GE products, which could “prevent or limit U.S. alfalfa exports.”

APHIS Response

As described in the PPRA (USDA-APHIS, 2013), the applicant has demonstrated that KK179 alfalfa does not exhibit any differences in agronomic properties from other cultivated alfalfa. Therefore, the presence of KK179 alfalfa in the environment is not different, than the presence of other GE-alfalfa. As noted in Sections 2.1.3 and 4.2.3 – Alfalfa Seed Production, and 2.2 and 4.2.4 – Organic Alfalfa Production, in the EA, NAFA has worked with alfalfa growers to establish standards to minimize the effects of pollen flow from GE alfalfa and therefore, minimize economic impacts due to gene flow (NAFA, 2011; 2012). Growers can obtain the Association of Official Seed Certifying Agencies’ (AOSCA) reference material which describes isolation distance requirements for the certification of alfalfa seed (AOSCA, 2013). In addition to spatial isolation, NAFA has helped alfalfa growers to develop voluntary grower opportunity zones, where growers concentrate either GE or Adventitious Presence Sensitive production and exclude the other. Methods of assuring Adventitious Presence Sensitive customers of the non-GE status of alfalfa seed destined for sensitive markets are available using current methodology. These methods include: Planting of non-GE foundation seed that has been tested prior to planting, taking steps to ensure adequate isolation prior to planting, careful seed handling in the whole process to prevent comingling of non-GE and GE seed, application of an identity preserved protocol to assure lot identity and non-GE status, and use of AOSCA’s Alfalfa Seed Stewardship Production Program for customer assurance of non-GE status (NAFA, 2011; 2012).

Also as noted above in the response to Issue 9, unlike the vast majority of biotech crops grown today, the primary commodity for alfalfa is forage/hay (99.4 percent in U.S. (USDA-NASS, 2009)), not seed. Since a seed generation is required for gene flow and mature seeds are rarely formed in hay production fields, there is very little opportunity for gene flow to or between alfalfa hay fields (Putnam, 2006). As it is desirable to harvest hay fields prior to bloom to maintain hay quality, producers strive to harvest well before viable seed is established (NAFA, 2012). Harvest of hay before the ripe seed stage eliminates potential pollen mediated gene flow from feral plants, neighboring GE alfalfa seed or GE alfalfa forage production fields (NAFA, 2012).

When farmers choose to grow a GE variety of alfalfa, the approval status in foreign countries should be of major concern. The importance of this issue is well known to farmers, distributors,

and exporters, because trade disruptions over non approved GE-crops have been experienced by the industry. Global sensitivities to GE products, including international restrictions on import of GE products and inability of the petitioner to gain approval for cultivation or importation, will continue to impede trade with those countries. These challenges to international trade in GE products are already in place. Restrictions on international trade in GE products, including KK179 alfalfa, are unlikely to change with a determination of nonregulated status of KK179 alfalfa.

To support commercial introduction of KK179 alfalfa in the U.S. and avoid adversely affecting international trade, Monsanto and FGI intend to obtain import approvals from all key alfalfa import markets with functioning regulatory systems prior to commercial planting of KK179. As appropriate, notifications will be made to countries that import significant quantities of alfalfa and alfalfa products and do not have formal regulatory review processes for biotechnology-derived crops (Monsanto and FGI, 2013).

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