Syngenta Biotechnology, Inc. Petition (07-108-01p) for Determination of Nonregulated Status of Lepidopteran-Resistant Event COT67B Cotton

OECD Unique Identifier:
SYN-IR67B-1

Draft Environmental Assessment

April 2011

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I. Purpose & Need

Regulatory Authority

“Protecting American agriculture” is the basic charge of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). APHIS provides leadership in ensuring the health and care of plants and animals. 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 varieties) can provide benefits to the environment, consumers, and farm income.

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

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

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

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act. 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. All food and feed derived from GE crops currently on the market in the United States have successfully completed this 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 food.

The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and 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 Service's (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 Code of Federal Regulations (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 Plant Protection Act or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

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

Petition for Determination of Nonregulated Status: Syngenta Biotechnology, Inc. Lepidopteran-Resistant Event COT67B Cotton

Syngenta Biotechnology, Inc. (Syngenta) submitted a petition (APHIS Number 07-108-01p) to APHIS seeking a determination of nonregulated status of their genetically engineered Event COT67B cotton (COT67B (OECD Unique Identifier SYN-IR67B-1)) that expresses a Cry1Ab protein to protect cotton plants from lepidopteran insect damage. COT67B cotton is currently regulated under 7 CFR part 340. Interstate movements, importations, and field testing of COT67B cotton have been conducted under notifications acknowledged by APHIS.

Purpose of Product

Syngenta has developed a new genetically engineered cotton event, COT67B cotton (OECD Unique Identifier SYN-IR67B-1) via recombinant DNA techniques with broad spectrum lepidopteran insect resistance. COT67B cotton produces a full-length Cry1Ab protein originally derived from *Bacillus thuringiensis* subsp. *kurstaki* HD-1 which has activity against several important lepidopteran pest species of cotton. These include, but are not limited to, *Helicoverpa zea* (cotton bollworm), *Heliothis virescens* (tobacco budworm), *Pectinophora gossypiella* (pink bollworm), and *Trichoplusia ni* (cabbage looper).

Cotton producers in the U.S. are among the most technically advanced in the world, annually harvesting about 17 million bales or 7.2 billion pounds of cotton (US-EPA 2009). Since the adoption of new technologies, including agronomic traits delivered through biotechnology, the yields of cotton lint per acre in the U.S. ranks among the highest in the world (Reed and Stone 2007). Since the introduction of GE insect-resistant and herbicide-tolerant cotton, transgenic varieties have been widely adopted by U.S. cotton farmers (Fernandez-Cornejo and Caswell 2006). These varieties offer excellent protection from the damage incurred by insect pests, as well as an economical alternative to broad-spectrum insecticides (Reed and Stone 2007).

Cotton producers are currently limited to insect-resistant cotton varieties containing three *Bacillus thuringiensis* Cry1 endotoxin protein-based plant incorporated protectants. Each is deregulated by the USDA and registered by the US-EPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). The three proteins are Cry1Ac (Bollgard)—a combination of CrylAc and Cry2Ab2 (Bollgard II), and Cry1F and Cry1Ac (Widestrike) (Reed and Stone 2007). In 1996 Bollgard and Bollgard II varieties were planted on more than 99% of the cotton acreage having transgenic varieties (Reed and Stone 2007). These transgenic varieties offer almost complete protection against tobacco budworm, but may require additional applications of insecticide for control of cotton bollworm. Hence, despite the wide adoption of these Bt cotton varieties to control lepidopteran insects, these same species continue to be the most economically important pests of the crop. In 2007, it was estimated that the Heliothine complex of tobacco budworm and cotton bollworm infested 6.7 million acres of cotton and reduced yields across the Cotton Belt by 229,186 bales (Williams 2008). Total 2007 cost and loss estimates for arthropod cotton pests were $877 million dollars (Williams 2008).

Current insect resistance management strategies have delayed the development of resistance to Bt toxins. However, in a review of genetically engineered crops Lemaux (Lemaux 2009) reports that some cotton lepidopteran-insect resistance to Bt toxins has occurred. The availability of additional lepidopertan-insect resistant traits in cotton further reduces the likelihood of pest resistance to existing pest control methods (Gould 2003).

Event COT67B cotton produces a unique full-length Cry1Ab (FLCry1Ab) protein which, when expressed in COT67B cotton provides excellent protection against cotton bollworm, tobacco budworm, pink bollworm, and cabbage looper (Reed and Stone 2007). Event COT67B, either alone or when combined by traditional breeding with other genetically-modified insect resistant cotton varieties, will provide growers with an additional pest management option for lepidopteran-insect pest control and will contribute to a reduction in the likelihood of insect resistance to Bt insect-resistant cotton varieties.

APHIS Response to Petition for Nonregulated Status

Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR part 340, APHIS has issued regulations for the safe development and use of genetically engineered organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of genetically engineered organisms, including genetically engineered plants such as Syngenta COT67B cotton. When a petition for nonregulated status is submitted, APHIS must make a determination if the genetically engineered 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 the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

COT67B cotton has been field tested in the U.S. since 2003 as authorized by APHIS. Associated notifications approved by APHIS are listed in Table 1-1 of the petition (Reed and Stone 2007). The list compiles more than 40 test sites in diverse regions of the U.S. including the major cotton growing areas and winter nurseries in Hawaii and Puerto Rico. Field tests conducted under APHIS oversight allow for evaluation in agricultural settings under confinement measures designed to minimize the likelihood of persistence in the environment after completion of the field trial. Under confined field trial conditions, data are gathered on multiple parameters and used by applicants to evaluate agronomic characteristics and product performance. These data are also valuable to APHIS for assessing the potential for a new variety to pose a plant pest risk. The evaluated data may be found in the APHIS Plant Pest Risk Assessment (USDA-APHIS 2009).

APHIS has prepared this environmental assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with NEPA regulations (40 CFR parts 1500-1508, 7 CFR 1b, and 7 CFR part 372) and the USDA and APHIS NEPA implementing regulations and procedures. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from the deregulation of Syngenta COT67B cotton.

Coordinated Framework Review

COT67B cotton is designed for human and animal consumption and as such, may also be subject to regulation by the FDA. 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 biotechnology-derived food. Syngenta submitted a summary of its safety and nutritional assessment to FDA for COT67B cotton. Syngenta concluded that, with the exception of the intended change in fatty acid composition, the COT67B cotton and the foods and feeds derived from it are no different in composition, safety, or any other relevant parameter from cotton now grown, marketed, and consumed (Reed and Stone 2007). In February 2009, FDA completed Syngenta's consultation on COT67B cotton regarding the safety and nutritional

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[1] Under NEPA regulations, the “human environment” includes “the natural and physical environment and the relationship of people with that environment” (40 CFR §1508.14).

assessment for the cotton and had no further questions (US-FDA No.000112). To view the text of the FDA's scientific and regulatory assessment response for COT67B cotton refer to Appendix A or http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing&page=1.

Tolerance exemptions and conditional pesticide registrations have been granted for the plant-incorporated protectant in COT67B cotton and the genetic material necessary for its production. On July 16, 2008, the EPA granted an exemption from the requirement of a tolerance for residues of FLCry1Ab in or on food and feed commodities of cotton (73 FR 40760-40764). Likewise, on October 29, 2008, EPA approved the conditional registration of FLCry1Ab produced in COT67B cotton for use as a lepidopteran insecticide (73 FR 64323-64324) (US-EPA 2008).

Public Involvement

APHIS routinely seeks public comment on draft environmental assessments prepared in response to petitions to deregulate GE organisms. APHIS does this through a notice published in the Federal Register. The issues discussed in this 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 cotton using various production methods, and the environmental and food/feed safety of genetically engineered plants were addressed to analyze the potential environmental impacts of COT67B cotton.

This EA, the petition submitted by Syngenta, and APHIS's Plant Pest Risk Assessment will be available for public comment for a period of 60 days (7 CFR § 340.6(d)(2)). Comments received by the end of the 60-day period will be analyzed and used to inform APHIS' determination decision of the regulated status of COT67B cotton and to assist APHIS in determining whether an Environmental Impact Statement is required prior to the determination decision of the regulated status of this cotton variety.

Issues Considered

As stated above, the issues considered in this EA were developed based on APHIS' determination to deregulate certain genetically engineered organisms, and for this particular EA, the specific deregulation of Syngenta COT67B cotton.

Management Considerations:

- Acreage and Areas of Cotton Production
- Cropping Practices
- Seed Production
- Organic Farming
- Specialty Cotton Production

Environmental Considerations
- Water Use
- Soil
- Air Quality
- Climate Change
- Animals
- Plants
- Biological Diversity
- Gene Movement

Public Health Considerations
- Human Health
- Worker Safety
- Animal Feed

Socioeconomic Considerations
- Domestic Economic Environment
- Trade Economic Environment
- Social Environment

II. Affected Environment

Agricultural Production of Cotton

Acreage and Areas of Cotton Production

Cotton (*Gossypium* spp.) is a member of the Malvaceae family and is the world’s most widely grown fiber crop (Hartman, Flocker et al. 1981). Cotton is a perennial plant that is cultivated as an annual crop (USDA-ERS 2009a). The *Gossypium* genus is made up of 39 species, but worldwide only four are cultivated (Fryxell 1979). Ninety-seven percent of U.S. cotton crop is the cultivated species *G. hirsutum* (upland cotton) (USDA-NASS 2010a). Another species, *G. barbadense*, known as American Pima or extra long staple (ELS) cotton accounts for less than 5% of U.S. cotton production (Womach 2005). ELS has limited growth in Hawaii and irrigated regions of the southwestern U.S. (Hartman, Flocker et al. 1981; USDA-ERS 2009a). Along with *G. barbadense*, *G. arboretum*, and *G. herbaceum* are also grown around the world (USDA-ERS 2009a). In the U.S., two wild cotton species *G.thurberi* and *G. tomentosum* can be found in Arizona and Hawaii, respectively (USDA-ERS 2009a). Wild or feral populations of upland cotton (*G. hirsutum*) can be found in the Florida Keys and the Everglades National Park of southern Florida (Wozniak 2002). These populations are apparently self-sustaining because there is no commercial production of cotton in this region (Wozniak 2002).

Cotton production is a labor intensive commodity crop. As a result, the agricultural production of cotton is limited to countries having cheap labor or in countries, such as the U.S., where production is completely mechanized (Hartman, Flocker et al. 1981). Maximum productivity of cotton is achieved in regions of high temperatures, high light intensity, good soil moisture, and soil fertility (Hartman, Flocker et al. 1981). Cotton requires at least 180 to 200 frost-free days from planting to maturity (Hartman, Flocker et al. 1981; USDA-ERS 2009a). Production in the U.S. is geographically limited to the Cotton Belt, which extends from Virginia southward and westward into California (McGregor 1976). The southwestern region includes irrigated lands of west Texas, southern New Mexico, southern Arizona, and southern California where the dryness of those areas makes it easier to control insect pests (Fite 1984).

Cotton acreage in the U.S. rose slightly during the first half of the 2000s, continuing a multi-decade trend. In the 1970s and 1980s, the area planted for cotton averaged about 12 million acres (USDA-ERS 2009a). The area rose to about 14 million acres in the 1990s and averaged over 14.5 million acres during the first half of the 2000s (USDA-ERS 2009a). Since 2006, however, U.S. cotton planted acreage has been considerably lower as relative prices have favored the planting of alternative crops such as corn and soybeans (USDA-ERS 2009a). All regions of the Cotton Belt have experienced significant declines compared with the first half of the 2000s (USDA-ERS 2009a).

According to the Census of Agriculture, U.S. cotton farms numbered 18,605 in 2007, down from 24,805 in 2002 (USDA-ERS 2009a). While the number has fallen, cotton acreage per farm has risen, averaging 564 acres per farm in 2007 compared with 502 acres in 2002. The percentage of large cotton farms (over 1,000 acres) has continued to increase while the share of small cotton farms (under 100 acres) declines (USDA-ERS 2009a).

In 2009, GE cotton was planted on 88% of all cotton acres in the U.S., which was less than for soybeans (91% of total soybean acres), but slightly more than corn (85% of total corn acres) (USDA-ERS 2010a). GE cotton expressing insect-resistant traits (Bt cotton), first approved for commercial production in the U.S. in 1996, has been widely adopted by U.S. farmers (USDA-AMS 2009; USDA-NASS 2009). Plantings of Bt cotton have expanded rapidly in the U.S., from 15% of total cotton acreage in 1997 to 65% in 2009 (USDA-ERS 2010a). Most of the farmers adopting Bt cotton did so mainly to increase yields through improved pest control (Fernandez-Cornejo and Caswell 2006). Grower benefits are likely to be higher with Bt cotton in areas and years with high infestation levels of the target insect pests (Fernandez-Cornejo and Caswell 2006; US-EPA 2008). The use of herbicide-tolerant (HT) cotton has also been widely adopted by farmers for effective and more economical weed control (USDA-ERS 2010a). HT cotton planting has grown from 10% of U.S. acreage in 1997 to 71% in 2009 (USDA-ERS 2010a). Glyphosate-tolerant cotton was first deregulated by APHIS in July 1995 (USDA-APHIS 2005a) and has been on the market since 1997. The herbicide glyphosate replaces many other synthetic herbicides that are at least three times more toxic to humans, is less leachable in the soil, less persistent in the soil, and less costly to farmers (Fernandez-Cornejo and McBride 2002). HT cotton also helps control soil erosion and soil degradation by facilitating the use of conservation tillage (Fernandez-Cornejo and McBride 2002).

Cropping Practices

Growers can choose from many cultivars of cotton marketed by companies that produce seed including GE varieties (USDA-AMS 2009). Planting of cotton occurs after any danger of frost has passed and soil temperatures are at least 20^{o} C (68^{o} F) (Hartman, Flocker et al. 1981). Planting dates vary depending on the region but generally range from early March in southern Texas to early May or June in the northern areas of the Cotton Belt. Cotton requires 180 to 200 days from planting to maturity (Hartman, Flocker et al. 1981). Therefore, cotton planted in March or April is ready for harvest in September.

Crop rotations (successive planting of different crops on the same land) are used to optimize soil nutrition and fertility, and reduce pathogen loads (Hoeft, Nafziger et al. 2000). Cotton is often rotated with other crops in order to control various cotton pests including nematodes, verticillium wilt, seedling diseases, and pink bollworm (Hartman, Flocker et al. 1981; University of California IPM Online 2008a). Rotation crops may include small grains, cowpea, corn, sorghum, alfalfa, onions or garlic, and nematode-resistant tomatoes. Rotations may last for two or three years. Winter cover crops are also utilized in cotton. These cover crops are used to provide winter soil cover and protection, build soil nitrogen and organic matter, reduce nitrogen leaching, suppress weeds, and provide a habitat for beneficial predatory and parasitic insects and spiders (Guerena and Sullivan 2003).

Cotton production in the U.S. is highly mechanized and involves the extensive use of agronomic inputs and technology (Hartman, Flocker et al. 1981). One of the goals of a cotton producer is to maximize profitability (Hogan, Stiles et al. 2005). Cost of production includes annual direct costs (seed, fertilizer, chemicals, irrigation, etc.), annual fixed costs (depreciation on equipment), and annual rent (Hogan, Stiles et al. 2005). These costs will vary depending on region and practices used. Cotton seed, fertilizer (commercial fertilizers, soil conditioners, and manure), and chemicals accounted for 54% of the total dollars spent per planted acre (USDA-ERS 2010b). The use of fertilizers, pesticides, and water may affect segments of the environment including, but not limited to, waterways by increases in nutrient pollution; biodiversity because pesticide inputs cause species changes; the water table because of excessive irrigation practices; and productive fields because irrigation increases salinity (Hoeft, Nafziger et al. 2000). Sediment and siltation, nutrients, pesticides, salinity, and pathogens are primary agricultural pollutants (USDA-ERS 2005).

Pest management in agricultural crop production is achieved through various management methods including chemical (pesticides), cultural (mechanical cultivation, planting/harvesting dates, crop rotation etc.), biological (antagonistic organisms), and bioengineered (primarily herbicide-tolerant and insect-resistant crops) (USDA-ERS 2005). Weed control is the primary pesticide target for soybeans, wheat, and corn. Pesticide use for disease control in fall potatoes and insect control in cotton surpasses herbicide use for weed control in these crops (USDA-ERS 2005).

Throughout the world, cotton has proven vulnerable to the attack of many insect species.
In the U.S., the cotton industry has consistently relied heavily on insecticide use strategies to manage arthropod pests (Gianessi and Carpenter 1999). However, the overall availability of novel insecticides has decreased due to difficulties in the discovery of new chemistry, the significant cost of registration and re-registration, cancellation of uses, and the development of insect resistance to insecticides (Reed and Stone 2007). Resistance to commonly used insecticides (pyrethroids, organophosphates, and carbamates) has led to a need for new pesticide

chemistries or other novel approaches such as the use of sterile insects, pathogens, and transgenic cotton (Gianessi and Carpenter 1999).

The most damaging insect pests of cotton attack the cotton square (the flower bud) or the cotton boll (ovary containing developing seeds and fibers) (Hartman, Flocker et al. 1981). In 2007, the most damage was caused by the bollworm/budworm complex (Williams 2008). It is referred to as a complex because the larvae of these moth insects are identical when observed in the field (Gianessi and Carpenter 1999). The complex consists of the cotton bollworm (*Helicoverpa zea*) and tobacco budworm (*Helicoverpa virescens*) whose small larvae feed on smaller squares and terminal buds, but whose older, larger larvae devour buds, flowers, and bolls consuming both lint and seed (Gianessi and Carpenter 1999). The major insect pests of U.S. cotton in 2007 are listed in Table 1 (Williams 2008). Thrips (*Frankliniella occidentalis*), aphids (*Aphis spp.*), the budworm/bollworm complex and lygus (*Lygus hesperus*) each infested more than half of the U.S. crop. The budworm/bollworm complex, which infested 62% of the acreage, was the leading cause of yield loss due to insects. The complex reduced yields by 0.913% or (Williams 2008) 229,186 bales of cotton (Williams 2008). While the pink bollworm (*Pectinophora gossypiella*) caused significant losses to cotton in the past, the overall impact has been reduced due to eradication measures, which include the use of GE Bt cotton (USDA-ERS 2009a). All caterpillar pests are reduced to some extent in Bt cotton, but it provides very good control of pink bollworm and tobacco budworm (Stewart 2007).

Table 1. Pest, % U.S. cotton yield reduction, number of cotton acres infested, rank by % yield loss, and % of U.S. cotton infested by pests in 2007 (Williams 2008).

Pest	**% Reduction**	**Acres Infested**	**Rank by % Loss**	**% Infested**
Bollworm/Budworm	0.9130	6,704,830	1	62.4
Lygus	0.6830	5,429,167	2	50.5
Thrips	0.5780	9,595,718	3	89.3
Cotton Fleahoppers	0.4770	5,258,805	4	48.9
Aphids	0.3200	6,806,780	5	63.3
Stink Bugs	0.2740	4,833,869	6	45.0
Spider Mites	0.2420	3,293,087	7	30.6
Silverleaf Whitefly (*Bemisia*)	0.0590	691,388	8	6.4
Fall Armyworm	0.0480	1,764,045	9	16.4
Boll Weevil	0.0130	612,393	10	5.7
Beet Armyworm	0.0040	10,000	11	0.1
Other Insects	0.0030	46,138	12	0.4
Cutworms	0.0019	662,695	13	6.2
Saltmarsh Caterpillars	0.0009	706,734	14	6.6
Pink Bollworm	0.0010	94,369	15	0.9
Loopers	0.0005	804,017	16	7.5
Grasshoppers	0.0001	850,452	17	7.9

Seed Production

Public cotton breeding programs began in California in 1898 and private programs began in the early 1920s (Marra and Martin 2007). This resulted in a continuous improvement in cotton germplasm and a steady stream of higher yielding cultivars even through the period of boll weevil eradication. The development of lepidopteran pest resistance to pyrethroid-based insecticides and some weeds to the ALS-inhibitor (acetolactate synthase) class of herbicides resulted in transgenic cotton varieties resistant to caterpillar pests and broadleaf and grassy weed herbicides (Marra and Martin 2007). Cotton growers and professionals in the cotton industry have ranked improved cotton varieties and transgenic cotton varieties as the most important cotton innovations in recent history only behind the boll weevil eradication program (Marra and Martin 2007).

Once a new cultivar has been identified and selected, the breeder or contracted growers carefully multiply this limited number of seed in increase blocks to produce the breeder seed (Lee 1987). Breeder seed is under the control of the plant breeder. The breeder seed is multiplied in limited amounts by selected growers to produce foundation seed. The foundation seed is increased by commercial cotton seed growers to produce registered seed. The registered seed is then used to produce large amounts of certified seed for sale to farmers for general crop production (Hartman, Flocker et al. 1981; Lee 1987). Foundation seed, registered seed, and certified seed production is controlled by public or private seed certification programs. Seed certification programs are established to protect and maintain the genetic quality of the cultivar (Hartman, Flocker et al. 1981). Cotton planting seed is usually grown in arid regions to achieve maximum seed quality (Lee 1987). On an annual basis, certified seed of all varieties of cotton combined must be able to plant over 9.4 million acres in the U.S. alone (USDA-NASS 2009). This requires between 60,000 and 70,000 short tons of planting seed (National Cottonseed Products Association 2010).

Maintaining genetic purity has been a feature of cotton cultivation and other cultivated species for decades as part of varietal seed and specialty crop production. The cultivation of *G. hirsutum* and *G. barbadense* for commercial seed production is regulated by various state, federal, and international institutions to preclude gene flow between species and varieties (Wozniak 2002). Common practices include maintaining isolation distances to prevent pollen movement from other cotton sources, and planting border or barrier rows to intercept pollen (Wozniak 2002). Field monitoring for off-types, other crops, weeds, disease etc. is carried out by company staff and state crop improvement associations. Seed handling standards are established by the Association of Official Seed Certifying Agencies to reduce the likelihood of seed source mixing during planting, harvesting, transporting, storage, cleaning, and ginning (AOSCA 2003).

The US-EPA has concluded that there is a possibility for some gene flow from Bt cotton to native or escaped populations of *Gossypium* (Wozniak 2002). Cotton is generally considered a self-pollinated crop, but there is some natural cross-pollination due to insects (Niles and Feaster 1984). Insect pollination can be considerable if pollinator populations are high during the blooming period (Hartman, Flocker et al. 1981). Wind pollination in cotton is considered unimportant because the pollen is heavy and sticky. There have been restrictions placed on the planting of Bt cotton in certain regions of the U.S. and its territories because of the possibility of unintended gene flow (Wozniak 2002). The EPA has placed stringent restrictions on the use of Bt upland cotton in Hawaii because it can hybridize with native Hawaiian cotton (*G. tomentosum*), in southern Florida where it can hybridize with feral populations of upland cotton, and in the U.S. Virgin Islands and Puerto Rico where upland cotton can hybridize with feral upland and ELS cotton (Wozniak 2002).

Organic Farming

Organic farming as defined in this document includes any production system that falls under the USDA National Organic Program (NOP) definition of organic farming and is a certified organic production system (USDA-AMS 2010a). The NOP is administered by USDA's Agricultural Marketing Service (AMS). Organic farming operations as described by the NOP requires organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods. Excluded methods include a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes. In NOP organic systems, the use of synthetic pesticides, fertilizers, and GE crops, such as COT67B cotton, is strictly limited (USDA-AMS 2010a).

In accordance with NOP, an accredited organic certifying agent conducts an annual review of the certified operation's organic system plan and makes on-site inspections of the certified operation and its records. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards. Practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields (USDA-APHIS 2010a). Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS 2010a). 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. Organic certification of a production or handling operation is a process claim, not a product claim (USDA-AMS 2010a).

Certified organic cotton acreage is a relatively small percentage of overall cotton production in the U.S. The most recently available data show 15,377 acres of certified organic cotton production in 2008 (USDA-ERS 2010c). This is 0.16% of the total 9.41 million acres of cotton planted in 2008 (USDA-ERS 2009a). Bayer CropScience FM 958 and ADF 2485 were the predominate varieties planted in 2009 by organic cotton producers (USDA-AMS 2009).

Specialty Cotton Production

In addition to the specialization adopted across the industry to enable varietal seed production for upland cotton, which represents 98% of U.S. cotton production, a number of other specialty cottons are produced (USDA-NASS 2010a). These include ELS varieties of Pima and Acala which represented less than 2% of total U.S. cotton planted in 2009 (USDA-NASS 2010a). Historically, ELS cotton acreage has ranged from a low of 63,000 acres in 1983 to a high of 377,000 acres in 1989 (National Cotton Council of America 2010). This represented 0.83% and 3.5% of the total cotton acreage planted for those years, respectively. The most recently available data for certified organic cotton productions was 15,377 acres in 2008 (USDA-ERS 2010c). Naturally colored cotton acreage was reported to be 4,000 acres in 1992 (Dickerson, Lane et al. 1999) and between 5,000 and 7,000 acres in 1995 (Lee 1996). In 2006, there were at least six companies offering organic and/or colored cottonseed in the U.S. in Massachusetts, Texas, Virginia, Arizona, and North Carolina (Reed and Stone 2007). Similar to the production of conventional seed, industry quality standards for specialty crop products have led these seed producers and growers to employ a variety of techniques to ensure that their products are not pollinated by or commingled with conventional or genetically engineered crops (Bradford 2006). Common practices include maintaining isolation distances to prevent pollen movement from other cotton sources, planting border or barrier rows to intercept pollen, and employing natural barriers to pollen (Wozniak 2002, NCAT 2003, USDA-AMS 2010b). Field monitoring for off-types, other crops, weeds, disease etc. is also carried out by company staff and state crop improvement associations (Bradford 2006). Seed handling standards are established by the Association of Official Seed Certifying Agencies (AOSCA) to reduce the likelihood of seed source mixing during planting, harvesting, transporting, storage, cleaning, and ginning (AOSCA 2003). In general, the conventional management practices used for conventional seed production are generally sufficient to meet standards for the production of specialty crop seed (Bradford 2006).

Physical Environment

Water Resources

Cotton's global water footprint represents about 2.6% of the world's water use and is lower than soybeans, maize, wheat, and rice (Cotton Incorporated 2010a). Cotton plant water use varies according to the environment it is growing in. Cotton grown in the desert southwestern U.S. requires about 40 inches of water per acre per year (Hunsaker 1999). Cotton grown in humid regions of the southeastern U.S. can require as little as 18 inches of water per acre per year (Bednarz, Ritchie et al. 2002). Much of this cotton is grown from central Texas east is without supplemental irrigation (Cotton Incorporated 2010a). Where irrigation water is needed (approximately 35% of the U.S. cotton grown), cotton yields are also much higher (Cotton Incorporated 2010a). In order to maximize irrigated cotton yields, it is important that irrigation be timed properly so that plant growth is steady throughout the season (Hartman, Flocker et al. 1981). Despite high production levels in irrigated areas, higher value crops, alternative land use, and a lack of affordable water resources has resulted in a considerable decline in the harvested acres of cotton in California, Arizona, and New Mexico (Cotton Incorporated 2010a).

Soil

According to the USDA National Resource Conservation Service, there have been significant reductions in the loss of soil from croplands in the U.S. (USDA-NRCS 2006). Total soil loss on highly erodible croplands and non-highly erodible croplands decreased from 462 million tons per year to 281 million tons per year or by 39.2% from 1982 to 2003. These reductions were due to a combination of effective conservation practices and the decrease in number of acres of highly erodible cropland (USDA-NRCS 2006). Over the last 10 years, cotton has contributed to this reduction in soil loss through a shift towards conservation tillage and the use of cover crops (Cotton Incorporated 2010a). In the U.S., conservation tillage in cotton has increased from 0.5 million acres in 1990 to about 2.75 million acres in 2004 (Cotton Incorporated 2010a).

Conservation tillage practices, such as minimum tillage and no-tillage, promote crop production by preserving crop residues on the soil surface (NCSU 2001). By definition, conservation tillage leaves at least 30% of the soil covered by crop residue (NCSU 2001). The new crop is planted into the plant residue or in narrow strips of tilled soil. This is in comparison to conventional tillage where the seedbed is prepared through plowing (to turn the soil surface over), disking (to reduce the size of soil clods created by plowing), and harrowing (to reduce the size of clods left by disking) (Hartman, Flocker et al. 1981). Benefits of reduced tillage practices include maintenance of soil organic matter and beneficial insects, increased soil water-holding capacity, less soil and nutrient loss from the field, reduced soil compaction, and less time and labor required to prepare the field for planting (NCSU 2001).

Besides the economic and environmental benefits of soil conservation, farmers, including cotton growers, producing crops on highly erodible land are required by law to maintain a soil conservation program approved by the National Resources Conservation Service (USDA-ERS 1997). The 1985 Food Security Act introduced the Conservation Compliance and Sodbuster programs to minimize soil erosion. In 1995, 90 million acres of cropped highly erodible lands in the U.S. were subject to conservation plans (Cotton Today 2010).

Weed control in conservation tillage cotton is primarily through the use of herbicides (Alabama Cooperative Extension System 1996). Preplant “burndown” herbicides such as paraquat and glyphosate and some pre-emergent herbicides make up the primary weed control methods. Winter and cover crops are also utilized in conservation tillage with one purpose to be the suppression of weeds (Alabama Cooperative Extension System 1996). Wheat and rye are commonly employed because of their ease in killing prior to cotton planting. The use of herbicide-resistant cotton has allowed cotton growers to more readily adopt soil conservation practices because it provides an economical, effective means of controlling weeds in post-plant cotton (Alabama Cooperative Extension System 1996; McClelland, Barrentine et al. 2000).

Air Quality

Many agricultural activities affect air quality including smoke from agricultural burning, tillage, traffic and harvest emissions, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizer (Hoeft, Nafziger et al. 2000; Aneja, Schlesinger et al. 2009). These agricultural activities individually have potentially adverse environmental impacts on air quality. Tillage contributes to the release of greenhouse gases (GHG) because of the loss of CO_2 to the atmosphere, and the exposure and oxidation of soil organic matter (Baker, Southard et al. 2005). Emissions released from agricultural equipment (e.g., irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (US-EPA 2010). Nitrous oxide may also be released following the use of nitrogen fertilizer (US-EPA 2010). Aerial application of pesticides may cause impacts from drift and diffusion. Pesticides may volatilize after application to soil or plant surfaces and move following wind erosion (Vogel, Majewski et al. 2008). Agriculture, including land-use changes for farming, is responsible for an estimated 6% of all human-induced GHG emissions in the U.S. and N_2O emissions from agricultural soil management are a large part of this—68% of all U.S. N_2O emissions (US-EPA 2010).

Climate Change

Climate change is possibly interrelated with agriculture in several relevant ways. Production of agricultural commodities is one of the many human activities that could contribute GHG to the air (Iserman 1993; Hoeft, Nafziger et al. 2000; Aneja, Schlesinger et al. 2009). First, this may occur through the combustion of fossil fuels to run farm equipment, the use of fertilizers, or the decomposition of agricultural waste products including crop residues and animal wastes. Second, the classes of crops planted are relevant to climate change, whether trees, grasses, or field crops (Cole, Duxbury et al. 1997; Freibauer, Rounsevell et al. 2004). The location and the soil types in which they are planted also affect production of greenhouse gases (Flessa, Wild et al. 1998; Kamp, Steindl et al. 2001). Third, climate change itself may force changes to agricultural practices by extending the ranges of weeds and pests of agriculture (IPCC 2007). The influences that GE agricultural organisms may have on global climate change are unclear. Many of the indirect effects of these organisms will be determined by the traits engineered into organisms and the management strategies used in the production of these organisms. APHIS will continue to monitor developments that may lead to possible changes in the conventional production system likely to result from GE products brought to APHIS for approval. Some of the crops submitted by developers may clearly promote changes that may have impacts on greenhouse gases or the climate.

Climate changing greenhouse gas production will not be significant unless large amounts of crop plantings produce changes in measureable concentrations. The contribution of agriculture to climate change is largely dependent on the production practices employed to grow various commodities, the region in which the commodities are grown, and the individual choices made by growers. A recent IPCC forecast (IPCC 2007) for aggregate North American impacts on agriculture from climate change actually projects yield increases of 5-20% for this century. The IPCC report notes, however, that certain regions of the U.S. will be more heavily impacted because water resources may be substantially reduced. While agricultural impacts on existing crops may be significant, North American production is expected to adapt with improved cultivars and responsive farm management (IPCC 2007).

Animal and Plant Communities

Animals

Intensive agricultural land, such as used in crop production, usually has low levels of biodiversity compared to adjacent natural areas. Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest results in a low diversity of plants and animals (Lovett, Price et al. 2003). However, the implementation of better cropland management strategies can increase the value of crop fields to wildlife (Sharpe 2010). Some of these strategies include:

- Conservation tillage and no-till practices have a positive impact on wildlife. Benefits include improved water quality, retention of cover, availability of waste grain on the soil surface for feed, and increased populations of invertebrates as a food source for turkey, quail, and songbirds (Sharpe 2010).

- Crop rotations reduce the likelihood of crop disease, insect pests, weed pests, and the need for pesticides (University of California IPM Online 2008a). Reduced pesticide use has a direct positive effect on wildlife by reducing direct exposure of birds, mammals, and fish to pesticides. Indirect benefits include less alteration of suitable wildlife habitat and an available food supply of insects for insectivores (Palmer and Bromley 2010; Sharpe 2010). Crop rotations with legumes and small grains have been shown to provide excellent wildlife nesting cover, food, and brood-rearing habitat for quail in North Carolina (Sharpe 2010).

- Field edges can be managed to promote wildlife. These borders are often the least productive areas in a farm field and in some cases the cost of producing a crop in these areas exceeds the value of the crop produced (Sharpe 2010). Allowing field edges to return to volunteer vegetation does not contribute to major pest problems in the crop field itself (Sharpe 2010). Volunteer border vegetation such as ragweed, goldenrod, asters, and forbs quickly develops into nesting and brood habitat for quail and a multitude of songbirds (Sharpe 2010). Research conducted at North Carolina State University and the North Carolina Wildlife Resources Commission found quail populations to double when field borders were used (Sharpe 2010).

- Contour-strip cropping is another management practice that can be used to promote wildlife habitat. This practice alternates strips of row crops with strips of solid stand crops with the strips following the contour of the land. The solid crop stands are usually grasses, legumes, or small grains (Hartman, Flocker et al. 1981). The primary purpose of contour-strip cropping is to reduce soil erosion and water runoff, but the solid stand crop also provides nesting and roosting cover for wildlife (Sharpe 2010).

- Drainage ditches, hedgerows, riparian areas, and adjacent woodlands to a cotton field also contribute to wildlife populations. Ditch banks, for example, function as narrow wetlands that provide nesting sites and cover, serve as wildlife corridors, and provide areas for the wildlife to occupy when crop fields lack cover (Sharpe 2010). Ditches have

> been shown to support birds, rodents, reptiles, furbearers, amphibians, fish, and aquatic organisms (Sharpe 2010). Minimizing pesticide exposure of ditches, aquatic habitats, border areas, strip-crop areas, and non-crop habitats will help protect fish and wildlife resources (Palmer and Bromley 2010).

Although many of the invertebrate organisms found in cotton-producing areas are considered pests, such as the cotton bollworm and tobacco budworm, most invertebrates are considered beneficial (University of Arkansas Cooperative Extension Service 2006). Beneficial insects include a wide variety of predators which catch and eat smaller insects and parasitic insects that live on or in the body of other insects during at least one stage of their life cycle. Other beneficial insects, such as bumble bees (*Bombus spp*.), black bees, (*Melissodes spp*.), and honey bees (*Apis mellifera*) serve as pollinators (McGregor 1976). Flowers of *G. tomentosum* are pollinated by moths. Other beneficial organisms, including earthworms, termites, ants, beetles, millipedes, and others contribute to the decay of organic matter and the cycling of soil nutrients (Ruiz, Lavelle et al. 2008).

Since the mid-1990s, transgenic corn and cotton lines have been commercialized without substantiated reports of significant deleterious impacts on non-target organisms (Mendelsohn, Kough et al. 2003; OECD 2007; US-EPA 2008; USDA-APHIS 2009). The use of transgenic cotton producing the Cry1Ab proteins has been shown to reduce the use of broad spectrum insecticides[2] without significant impact on diversity of non-target insects (Dively 2005; Torres and Ruberson 2005; Whitehouse, Wilson et al. 2005; Naranjo 2005a; Cattaneo, Yafuso et al. 2006; Romeis, Meissle et al. 2006; Torres and Ruberson 2006; Marvier, McCreedy et al. 2007). COT67B cotton is expected to be similar with respect to the low potential harm to the environment (Appendix 6, Supplements 12 through 19 of the petition and letter from Syngenta dated July 20, 2007 which summarizes the data from the referenced Supplements); (US-EPA 2008). Because Cry1Ab receptors are not present in non-target birds and mammals (Hofmann, Luthy et al. 1988a; Hofmann, Vanderbruggen et al. 1988b; Van Rie, Jansens et al. 1989; Van Rie, Jansens et al. 1990; Shimada, Murata et al. 2006a; Shimada, Miyamoto et al. 2006b), these insecticidal proteins are not expected to adversely affect these organisms. There has been one study that demonstrates safety on juvenile channel catfish (US-EPA 2008). In addition, Syngenta provided evidence from laboratory studies, field studies, and other peer reviewed studies showing that these insecticidal proteins are not expected to adversely affect terrestrial and aquatic non-target invertebrates (Reed and Stone 2007; USDA-APHIS 2009).

Plants

The landscape surrounding a cotton field varies depending on the region. In certain areas, cotton fields may be bordered by other cotton (or any other crop) fields or may also be surrounded by woodland, rangelands, and/or pasture/grassland areas. These plant communities may be natural

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[2] Broad spectrum insecticides are chemical insecticides which kill insects that are causing injury to plants and also kill other insects that are not causing injury to the plant. Insects that are inadvertently killed by the application of insecticide are called “non-target” insects. Because the Cry1Ab protein is specific for a narrow range of insects, use of Cry1Ab to control plant pests is recognized as being beneficial to the survival of non-target insects (EPA 2008).

or managed plant habitats for the control of soil and wind erosion and/or serve as wildlife habitats.

Some plants are weeds and compete with cotton for space, water, mineral nutrients and sunlight (USDA-APHIS 2008). Cotton is more susceptible to weeds than soybeans or corn because it is easily outgrown during its early season growth (USDA-APHIS 2008) and total crop failure can occur if weeds are not properly controlled (Alabama Cooperative Extension System 1996). Weed control typically involves the use of herbicides, crop rotation, weed surveillance, and weed monitoring (USDA-APHIS 2008). The types of weeds in and around a cotton field depend on the immediate area in which the cotton is planted. Those weed species also vary depending on the geographic region in which the cotton is planted. For example, California has over 50 common weeds found in cotton (University of California IPM Online 2008b). Common weeds in cotton include annual and perennial grasses (monocots), broad-leaf weeds (dicots), and sedges (*Cyperus spp.*). To assist growers in managing weeds, individual states, typically through their state agricultural extension service, will list the prevalent weeds of a crop and what is the most effective means for their control. For example, common weeds in California cotton and recommended herbicidal control can be found at University of California IPM Online (2008b; 2008c).

The abundance and diversity of wild plants could be reduced if feral populations of GE cotton, or hybrids of GE cotton with wild species, establish and spread into semi-natural or natural habitats (Reed and Stone 2007). The organisms that rely on these wild plants for food or shelter could also be altered (Raybould and Wilkinson 2005). The passage of the transgene to a cross-compatible wild relative could allow the wild relative to become more abundant in the habitat or to invade new habitats because of its lepidopteran resistance (Wilkinson 2004). This increased resistance of the wild relative to one group of insects could alter the balance of other insect herbivores, predators, and parasites (Wilkinson 2004). The introgressed wild crop relative could also impact other plants through interspecific (between species) competition and indirectly affect the insect pollinators, herbivores, predators, and parasites of those species (Wilkinson 2004).

Cotton volunteers within agricultural fields are most common where a failed cotton crop is replanted to soybeans. These cotton volunteers typically do not reduce crop yield but can act as reservoirs for insect pests of cotton (Stewart, York et al. 2003). Successful control of cotton volunteers, including herbicide-resistant varieties, is accomplished through using various combinations of herbicides (Stewart, York et al. 2003; Miller, Culpepper et al. 2004).

Biological Diversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Vandermeer and Perfecto 1995). Biodiversity provides valuable genetic resources for crop improvement (Harlan 1975) and also provides other functions beyond food, fiber, fuel, and income. These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri 1999). The loss of biodiversity results in a need for costly external inputs in order to provide these functions to the crop (Altieri 1999).

The degree of biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management; and 4) extent of isolation of the agroecosystem from natural vegetation (Southwood and Way 1970). The reintroduction of woodlots, fencerows, hedgerows, wetlands, etc. is one way to reintroduce biodiversity into large scale monocultures. Some enhancement strategies include intercropping (the planting of two or more crops simultaneously to occupy the same field), agroforestry, crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically for the purpose of incorporating it into the soil in order to provide nutrients and organic matter), addition of organic matter (compost, green manure, animal manure, etc.), and hedgerows and windbreaks (Altieri 1999). To some degree these practices are being utilized by cotton growers to increase biodiversity (Cotton Incorporated 2010a).

Habitat preservation and biodiversity, as well as cotton production, have benefited from modern cotton technology. It is now possible to grow 50% more cotton on the same land required 40 years ago (Cotton Incorporated 2010a). Increased productivity on the same amount of land allows growers to preserve habitat while maintaining food and fiber security. Various methods for promoting animal and plant wildlife in and around cotton fields have already been discussed above. However, habitat preservation and biodiversity have an equally large impact on insect populations. Research conducted by Altieri (Altieri 1994) and Altieri and Letourneau (Altieri and Letourneau 1982; Altieri and Letourneau 1984) indicates:

1) Maintaining some weeds harbors and supports beneficial arthropods that suppress herbivore insect pests;
2) Polycultures of plants support lower herbivore populations because they provide a more stable and continuous availability of food and habitat for beneficial insects; and
3) Adjacent wild vegetation provides alternate food and habitat for natural enemies to pest herbivores.

The use of no-till, cover crops, crop rotation, intercropping, and good ditch/border/hedgerow management contributes to biodiversity in and around cotton fields (Palmer and Bromley 2010; Sharpe 2010).

The use of broad-spectrum insecticides is one of the most severe constraints for biological diversity in crops (Croft 1990). One of the benefits of Bt cotton has been the reduction of broad-spectrum insecticide use during cotton production (Fernandez-Cornejo and Caswell 2006). However, there is concern over the non-target effects of transgenic cotton, especially Bt cotton, on beneficial insects and non-target pests. Research in Arizona has shown that Bt cotton has a minimum effect on both the number and function of foliar-dwelling arthropod natural enemies (Naranjo 2005a; Naranjo 2005b). On the other hand, broad-spectrum insecticide use caused a 48% reduction in 13 of the 22 taxa that were studied. A comparison of non-transgenic and transgenic cotton revealed no substantial impact on ant and beetle diversity in cotton fields, but broad-spectrum insecticide use considerably reduced this diversity (Cattaneo, Yafuso et al. 2006).

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

Bt toxin has been found to be present in every major part of Bt cotton plants (leaves, stems, and roots) (Vadakattu and Watson 2004). Bt cotton roots were also found to release the Bt protein into the soil (Vadakattu and Watson 2004). However, the presence of Bt toxin in the soil may not influence microbial diversity or activity. The effects of Bt on non-target soil microorganisms in Bt maize and Bt cotton cultivation found that microbial biodiversity and activity was not different from that of their non-Bt counterparts (Shen, Cai et al. 2006; Icoz, Saxena et al. 2008). The possibility of gene transfer from plants to bacteria is discussed in the next section.

Gene Movement

G. hirsutum is a perennial plant that is cultivated as an annual in the U.S. where it is grown from Virginia southward and westward to California (McGregor 1976; USDA-NASS 2009). The cotton flower is perfect, containing both male and female parts, and can self- or cross-pollinate (Hartman, Flocker et al. 1981). However, the flowers of most cotton species, including *G. hirsutum*, are generally considered to be self-pollinating (Hartman, Flocker et al. 1981). Cross-pollination due to wind is considered insignificant because cotton pollen is sticky and heavy (Khan and Afzal 1950; Thies 1953). Some insect cross-pollination of cotton can occur if suitable insects are present and in large enough numbers (McGregor 1976; Fryxell 1979). The primary pollinators of cotton are bumble bees (*Bombus spp.*), black bees (*Melissodes spp.*), and honey bees (*Apis mellifera*) (McGregor 1976). However, pollen movement by insects is considered to be low. McGregor (1976) reported that a cotton field surrounded by a large number of honey bee colonies showed less than 2% movement of fluorescent tracer particles by insects at 150 to 200 feet from the source. A majority of field-based research with cotton shows an outcrossing rate of 10% or less within 1 meter of the pollen source (Andersson and Carmen de Vicente 2010). While bees are the primary pollinators of most cotton species, the native species *G. tomentosum* appears to be pollinated by moths (Fryxell 1979). In addition, the flowers of *G. tomentosum* are receptive to pollination at night while *G. hirsutum* are receptive during the day (Wozniak 2002). This would minimize the possibility of cross-pollination between these two cotton species which have closely related genomes and can produce fully fertile F1 plants (Andersson and Carmen de Vicente 2010). There are no published reports of naturally occurring hybrids between these two species (Andersson and Carmen de Vicente 2010). In assessing the risk of gene introgression from COT67B cotton to its sexually compatible relatives, APHIS considered two primary issues: 1) the potential for gene flow and introgression and 2) the potential impact of introgression.

Although most of the cultivated cotton grown in the U.S. is *G. hirsutum*, *G. barbadense* (Pima cotton) is also grown (USDA-NASS 2009). In addition to these cultivated species, *G. thurberi* and *G. tomentosum* are found in the mountains of southern Arizona and in Hawaii, respectively. None of the above are listed (or proposed) as endangered or threatened under federal (US-FWS 2011) or state listings (Hawaii 2001; Arizona 2009) with the exception of *G. hirsutum*.

Wild populations of *G. hirsutum* have been listed as threatened and endangered by the State of Florida (Coile and Garland 2003). However, in Florida, wild *G. hirsutum* is not present in the northwestern panhandle where cotton cultivation occurs (Coile and Garland 2003; USDA-NASS 2009; Wunderlin and Hansen 2010). Additionally, because the terms and conditions of EPA's conditional registration for FLCry1Ab in cotton prohibits commercial cultivation south of Route 60 near Tampa (US-EPA 2008), COT67B cotton is neither expected to be planted commercially in the areas of Florida where wild populations of *G. hirsutum* occur nor would they likely be impacted by COT67B cotton planted north of Route 60. Therefore, because they are not likely to be present in close proximity, cultivated *G. hirsutum* is not likely to cross with wild populations of *G. hirsutum*.

G. tomentosum is native to the Hawaiian Islands, occurring primarily in arid, rock, or clay coastal plains (Wagner, Herbst et al. 1999). In laboratory and greenhouse breeding programs with hand pollination, *G. tomentosum* and *G. hirsutum* are sexually compatible and form viable progeny. However, DNA marker analyses have not found evidence of genes from *G. hirsutum* occurring in native populations of *G. tomentosum* (DeJoode and Wendel 1992). It is possible that the lack of evidence of movement of *G. hirsutum* genes into *G. tomentosum* is the result of lack of opportunity because cotton has not been grown commercially in Hawaii for at least the last 45 years (USDA-NASS 2009). *G. tomentosum* is not known to be weedy or to have invasive characteristics (Holm, Plucknett et al. 1977; Holm, Doll et al. 1997; University of Hawaii at Manoa 2001), and is considered a rare plant in Hawaii (University of Hawaii at Manoa 2001). Because *G. tomentosum* is not a weedy plant, even if FLCry1Ab did introgress into *G. tomentosum* it is not likely to become weedy or invasive. Finally, EPA's conditional registration for FLCry1Ab prohibits commercial use of COT67B cotton in Hawaii (US-EPA 2008), therefore it would not be planted in Hawaii and the probability of outcrossing would not exist.

The difference in chromosome numbers precludes sexual compatibility of *G. hirsutum* with *G. thurberi* (OECD 2008). Outcrossing of genes from COT67B cotton to *G. thurberi* is unlikely to occur because *G. thurberi* contains only the D genome whereas *G. hirsutum* contains both the A and D genome. In addition, in Arizona, *G. thurberi* was eradicated near cotton growing areas as part of the cotton boll weevil control program (Kearney and Peebles 1960; Benson and Darrow 1981) and the probability of outcrossing would be very unlikely. Therefore, USDA has determined that any adverse consequences of gene flow from COT67B cotton to wild or weedy species in the U.S. are highly unlikely.

Horizontal gene transfer and expression of DNA from a plant species to bacteria is unlikely to occur (Keese 2008). First, many bacteria (or parts thereof) that are closely associated with plants have been sequenced, including *Agrobacterium* and *Rhizobium* (Kaneko, Nakamura et al. 2000; Wood, Setubal et al. 2001; Kaneko, Nakamura et al. 2002). There is no evidence that these organisms contain genes derived from plants. Second, in cases where review of sequence data implied that horizontal gene transfer occurred, these events are inferred to occur on an evolutionary time scale in the order of millions of years (Koonin, Makarova et al. 2001; Brown 2003). Third, transgene DNA promoters and coding sequences are optimized for plant expression, not bacterial expression (Reed and Stone 2007). Thus, even if horizontal gene transfer occurred, proteins corresponding to the transgenes are not likely to be produced.

Public Health

Public health concerns surrounding GE cotton, like COT67B cotton, focus primarily on human and animal consumption. Non-GE cotton varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for food or feed safety prior to release in the market. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from COT67B cotton must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. FDA evaluates the submission and responds to the developer by letter (US-FDA 2010).

Socioeconomic

Cotton has been one of the most important crops since the beginning of civilization (Hartman, Flocker et al. 1981). Cotton is grown primarily for its lint fibers which are made into textiles (OECD 2004). The fibers originate as protuberances of epidermal cells from the cotton ovule (Hartman, Flocker et al. 1981). Seed formation and the elongation of the epidermal cells into lint fibers begin shortly after flower opening and fertilization (Hartman, Flocker et al. 1981). At maturity, the central cavity (lumen) of the elongated lint fiber dries and collapses resulting in a convoluting of the fiber that allows for easily spinning the fibers into threads (Hartman, Flocker et al. 1981; USDA-ERS 2009a). Cotton seed also produces valuable food oil and the remaining seed residue (cottonseed meal and hulls) is used as livestock feed and as a high-protein flour (Hartman, Flocker et al. 1981).

Cotton lint yields in the United States averaged 774 pounds per acre in 2009 and ranged from a low of 664 pounds in Texas to a high of 1,714 pounds in California (USDA-NASS 2010a). Texas, California, Arkansas, Georgia, and Mississippi had the highest value of cotton sold in 2007 (USDA-NASS 2009). In 2007, total cotton cultivated land in the U.S. was about 10,800,000 acres (slightly larger than the combined size of the states of Maryland and Connecticut) with a market value of about $5 billion dollars (USDA-NASS 2009).

The U.S. cotton industry generates about 200,000 jobs among the various sectors from farm to textile mill, and accounts for more than $25 billion in products and services annually (USDA-ERS 2009a). Cotton is produced in 17 southern states from Virginia to California. Major concentrations include areas of the Texas High and Rolling Plains; the Mississippi, Arkansas, and Louisiana Delta; southern Georgia; and California's San Joaquin Valley (USDA-ERS 2009a).

Cotton production in the U.S. during the first half of the 2000s continued a rising trend, paralleling advances in technology (seed varieties, fertilizers, pesticides, and machinery) and production practices (reduced tillage, irrigation, crop rotations, and pest management systems) (USDA-ERS 2009a). The impact of these changes has been particularly evident, with yields and production reaching new highs (USDA-ERS 2009a). While U.S. cotton production decreased considerably following the area reductions of the late 2000s, consistently higher yields helped limit the effect of these acreage declines (USDA-ERS 2009a).

Consumption of cotton by U.S. textile mills peaked in 1997 (USDA-ERS 2009a). Since then, U.S. mill use of cotton has plummeted, dropping about 50% by 2005 and nearly 70% by 2009. While the end of the Multifibre Arrangement's (MFA) quotas in 2005 was a factor, much of the decline in U.S. textile production occurred before then. The MFA had been established in 1974 to regulate global trade in textile and apparel products in order to slow the export growth rate of developing country suppliers (Dayaratna-Banda and Whalley 2007). Under MFA, Canada, the U.S., and the European Union could set limits on the amount of foreign made apparel and textiles they would allow into their countries (USDA-ERS 2009a). Capital investment by global textile suppliers near the turn of the century provided increased concentration and market share, accelerating a long-standing trend of textile production moving to developing countries. Despite this, U.S. consumer demand for cotton products remains strong, but imported clothing now accounts for most purchases by U.S. consumers (USDA-ERS 2006).

The world's four largest cotton-producing countries are China, India, the United States, and Pakistan, which together account for nearly 75% of world production. Other major producers include Brazil, Uzbekistan, and Turkey (USDA-ERS 2009a). While cotton is generally a Northern Hemisphere crop, about 8% of the world's output comes from south of the equator (primarily Brazil and Australia) and is harvested during the Northern Hemisphere's spring (USDA-ERS 2009a). Many of the leading cotton producers are also leading mill users of raw cotton. The top three consumers are China, India, and Pakistan, which together account for two-thirds of world consumption. Turkey and Brazil are the fourth and fifth largest mill users of cotton, bumping the U.S. to sixth place among consuming nations (USDA-ERS 2009a).

Trade is particularly important for cotton. About 30% of the world's consumption of cotton fiber crosses international borders before processing, a larger share than for wheat, corn, soybeans, or rice. Through trade in yarn, fabric, and clothing, much of the world's cotton again crosses international borders at least once more before reaching the final consumer (USDA-ERS 2009a).

The cotton industry continues to face many of the supply and demand concerns confronting other field crops. However, since cotton is used primarily in manufactured products, such as clothing and home furnishings, the industry faces additional challenges associated with the economic well-being of downstream manufacturing industries as well as the economic well-being of the final consumer (USDA-ERS 2009a).

III. Alternatives

This document analyzes the potential environmental consequences of a determination of nonregulated status of COT67B cotton. To respond favorably to a petition for nonregulated status, APHIS must determine that COT67B cotton is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS 2009) APHIS has concluded that COT67B cotton is unlikely to pose a plant pest risk. Therefore, APHIS must determine that COT67B cotton is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

Two alternatives will be evaluated in this EA: (1) no action and (2)determination of nonregulated status of COT67B cotton. APHIS has assessed the potential for environmental impacts for each alternative in the "Potential Environmental Consequences" section.

A. No Action: Continuation as a regulated article

Under the No Action Alternative, APHIS would deny the petition. COT67B cotton and progeny derived from COT67B cotton would continue to be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of COT67B cotton 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 COT67B cotton.

This alternative is not the Preferred Alternative because APHIS has concluded through a Plant Pest Risk Assessment (USDA-APHIS 2009) that COT67B cotton is unlikely to pose a plant pest risk. 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.

B. Preferred Alternative: Determination that COT67B cotton is no longer a regulated article

Under this alternative, COT67B cotton and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. COT67B cotton is unlikely to pose a plant pest risk (USDA-APHIS 2009). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of COT67B cotton and progeny derived from this event. This alternative best meets the agency's purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that COT67B cotton is unlikely to pose a plant pest risk, a determination of nonregulated status of COT67B cotton is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Under this alternative, growers may have future access to COT67B cotton and progeny derived from this event if the developer decides to commercialize Syngenta COT67B cotton.

C. Alternatives considered but rejected from further consideration

APHIS assembled a list of alternatives that might be considered for COT67B cotton. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for COT67B cotton. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

Prohibit any COT67B 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 COT67B cotton, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that COT67B cotton is unlikely to pose a plant pest risk (USDA-APHIS 2009).

In enacting the Plant Protection Act, Congress found that

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

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

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

Based on our Plant Pest Risk Assessment (USDA-APHIS 2009) and the scientific data evaluated therein, APHIS has concluded that COT67B cotton is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of COT67B cotton.

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 COT67B cotton is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

Isolation distance between COT67B cotton and non-GE cotton and geographical restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating COT67B cotton from non-GE cotton production. However, because APHIS has concluded that COT67B cotton is unlikely to pose a plant pest risk (USDA-APHIS 2009), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of COT67B cotton based on the location of production of non-GE cotton in organic production systems in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' plant pest risk assessment for COT67B cotton, there are no geographic differences associated with any identifiable plant pest risks for COT67B cotton(USDA-APHIS 2009). This alternative was rejected and not analyzed in detail because APHIS has concluded that COT67B cotton does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Nevertheless, APHIS is not expecting significant effects. However, individuals might choose on their own to geographically isolate their non-GE cotton productions systems from COT67B cotton or to use isolation distances and other management practices to minimize gene movement between cotton fields.

Requirement of Testing For COT67B Cotton

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing to identify GE products in non-GE production systems. APHIS notes there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because COT67B cotton does not pose a plant pest risk (USDA-APHIS 2009), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Therefore, imposing such a requirement for COT67B cotton would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

D. Comparison of Alternatives

Table 2. Issues of potential impacts and consequences of alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	**No**	**Yes**
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS 2009)
Management Practices		
Acreage and Areas of Cotton Production	Unchanged	Unchanged
Cropping practices	Unchanged	Unchanged
Pesticide use	Unchanged	Minimal
Seed Cotton Production	Unchanged	Unchanged
Organic Farming	Unchanged	Unchanged
Impact to Specialty Cotton	Unchanged	Unchanged
Environment		
Water use	Unchanged	Unchanged
Soil	Unchanged	Unchanged
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Animals	Unchanged	Unchanged
Plants	Unchanged	Unchanged
Biological Diversity	Unchanged	Unchanged
Gene Movement	Unchanged	Unchanged
Human and Animal Health		
Risk to Human Health	Unchanged	Unchanged
Risk to Worker Safety	Unchanged	Minimal
Risk to Animal Feed	Unchanged	Unchanged

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Socioeconomic		
Domestic Economic Environment	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged
Social Environment	Unchanged	Unchanged
Other Regulatory Approvals		
U. S.	FDA completed consultations, EPA tolerance exemptions and conditional pesticide registrations granted	FDA completed consultations, EPA tolerance exemptions and conditional pesticide registrations granted
Compliance with Other Laws		
CWW, CAA, EOs	Fully compliant	Fully compliant

IV. Environmental Consequences

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, namely taking no action and a determination by the agency that COT67B cotton does not pose a plant pest risk.
Potential environmental impacts from the No Action Alternative and the Preferred Alternative for COT67B cotton are described in detail throughout this section. A cumulative effects analysis is also included for each environmental issue. Certain aspects of this product and its cultivation would be no different between the alternatives; those are described below.

Scope of the Environmental Analysis

Although the Preferred Alternative would allow for new plantings of COT67B cotton to occur anywhere in the U.S., APHIS will limit the environmental analysis to those areas that currently support cotton production. To determine areas of cotton production, APHIS used data from the National Agricultural Statistics Service (NASS) 2007 Census of Agriculture to determine where cotton is produced in the U.S. (USDA-NASS 2010d). Cotton was produced in 17 states including Alabama, Arizona, Arkansas, California, Florida, Georgia, Kansas, Louisiana, Mississippi, Missouri, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia.

Other Assumptions

The environmental consequences of the different alternatives described above will be analyzed under the assumption that farmers, who produce conventional cotton, COT67B cotton, or produce cotton using organic methods, are using reasonable, commonly accepted best management practices for their chosen system and varieties during agricultural cotton production. However, APHIS recognizes that not all farmers follow these best management practices for cotton. Thus, the analyses of the environmental effects will also include the assumption that some farmers do not follow these best management practices.

Agricultural Production of Cotton

One of APHIS's missions is to improve American agricultural productivity. Best management practices, such as planting dates, seeding rates, and harvest times are commonly accepted, practical ways to grow cotton, regardless of whether the cotton farmer is using conventional practices with non-GE or GE varieties, or organic practices. These well-established, widely-practiced means to produce cotton can be obtained through local Cooperative Extension Service offices and their respective websites (NSFC-IPM 2010).

GE and non-GE cotton varieties are continually under development. Cotton acreage averaged over 14.5 million acres during the first half of the 2000s. Since 2006, however, U.S. cotton planted acreage has been considerably lower as relative prices have favored the planting of alternative crops, such as corn and soybeans. Total cotton acreage was about 9.1 million acres in 2009 (USDA-NASS 2010a). Most of the cotton acreage in the U.S. is planted to GE varieties. GE cotton reached 88% of the acreage in 2009 (USDA-ERS 2010a). GE insect-tolerant Bt cotton use—first approved for commercial production in the U.S. in 1996—has expanded rapidly from 15% of total acreage in 1997 to 65% in 2009 (USDA-NASS 2010a). Based upon these trends, conventional production practices that use GE varieties will likely continue to dominate in terms of acreage, or perhaps increase in acreage, with or without a determination of nonregulated status of COT67B cotton.

Organic Production of Cotton

APHIS recognizes that producers of non-GE cotton, particularly producers who sell their products to markets sensitive to genetically engineered traits (e.g., organic or some export markets), can be reasonably assumed to be using practices on their farm to protect their crop from unwanted substances and maintain their price premium. For example, the National Organic Program (NOP) has recognized the feasibility of protecting organically-produced crops, and the investment farmers put into their production practices, by requiring that organic production plans include practical methods to protect organically-produced crops.

> "Organic crops must be protected from contamination by prohibited substances used on adjoining lands (for example, drifting pesticides, fertilizer-laden runoff water, and pollen drift from genetically engineered…)" (NCAT 2003).

Typically, growers use more than one method under organic practices to prevent unwanted material from entering their fields including: isolation of the farm, physical barriers or buffer zones between organic production and non-organic production, as well as formal communications between neighboring farms (NCAT 2003). The organic plan used as the basis for organic certification should include a description of practices used to prevent or reduce the likelihood of unwanted substances, like GE pollen or seed, at each step in the farming operation, such as planting, harvesting, storing, and transporting the crop (Riddle 2004; Krueger 2007; Kuepper, Born et al. 2007). Organic plans should also include how the risk of GE pollen or co-mingling of seed will be monitored (Kuepper, Born et al. 2007). Farmers using organic methods are requested to let neighboring farmers know that they are using organic production practices and request that the neighbors also help the organic farmer reduce contamination events (NCAT 2003; Krueger 2007). Recommended organic production practices for cotton are also readily available (Kuepper 2002). Thus, commonly used production practices for cotton, and the practical methods typically used by organic cotton farmers to protect their crop and maximize their profits and price premiums from cotton under organic production, currently provide many measures that greatly reduce the likelihood of accidental gene flow between COT67B cotton and non-GE cotton fields. APHIS will use the assumption that farmers are already using, or have the ability to use, these common, reasonable practices as its baseline for the analyses of the following alternatives below.

Acreage and Areas of Cotton Production

Most of the cotton acreage in the U.S. is planted to GE cotton. Of the total cotton acres planted in 2009, 88% were GE cotton and 65% of that GE cotton acreage was GE insect-resistant (Bt) cotton (USDA-ERS 2010a).

No Action: Acreage and Areas of Cotton Production

Based on current acreage trends, conventional cotton production practices with GE varieties will likely continue to dominate, or perhaps increase in acreage under the No Action Alternative. Cotton is currently produced commercially in 17 states (USDA-NASS 2010a) and under the No Action Alternative, this range of production will be unchanged.

Preferred Alternative: Acreage and Areas of Cotton Production

In 2009, GE cotton was planted on 88% of all cotton acres currently in production in the U.S., and the use of GE cotton has steadily increased over the last 10 years (USDA-ERS 2010a). Most cotton is planted on farms that have been in cotton production for at least five years (USDA-NASS 2009). Syngenta field tested the COT67B cotton since 2004 across 22 representative cotton growing areas (Table 1-1 in petition). For the majority of the traits assessed, COT67B cotton was not statistically different from its control counterparts. APHIS also assessed whether COT67B cotton is any more likely to become a weed than the isogenic nontransgenic cotton line or other cotton varieties currently under cultivation (USDA-APHIS 2009). Based on the agronomic field data and literature survey about cotton weediness potential, COT67B cotton lacks the ability to persist as a troublesome weed. The introduced lepidopteran-resistant trait in

COT67B cotton is not intended to confer any competitive advantage in terms of weediness or to extend the range of cultivation outside of existing cultivation areas.

Thus, under the Preferred Alternative, a determination of nonregulated status of COT67B cotton is not expected to increase cotton production, either by its availability alone or accompanied by other factors, or cause an increase in overall GE cotton acreage. Impacts would be similar to the No Action Alternative.

Cumulative Effects: Acreage and Areas of Cotton Production

Cumulative effects of a determination of nonregulated status of COT67B cotton are unlikely. Neither the No Action Alternative nor a determination of nonregulated status of COT67B cotton is expected to directly cause an increase in agricultural acreage devoted to cotton production, or those cotton acres devoted to GE cotton cultivation. The availability of COT67B cotton will not change cultivation areas for cotton production in the U.S. and there are no anticipated changes to the availability of GE and non-GE cotton varieties on the market under either alternative.

Cropping Practices: Crop Rotation, Tillage, and Pesticide Use

Cotton is often rotated with other crops such as small grains, cowpea, corn, sorghum, alfalfa, onions or garlic, and nematode-resistant tomatoes. These rotations are done in order to control various cotton pests including nematodes, verticillium wilt, seedling diseases, and pink bollworm (Hartman, Flocker et al. 1981; University of California IPM Online 2008a). Rotations are also beneficial in preserving soil quality and biodiversity. Conventional or conservation tillage practices are utilized by cotton growers. In conventional tillage the seedbed is prepared through plowing, disking, and harrowing (Hartman, Flocker et al. 1981). Little plant residue is left on the soil surface. Conservation tillage practices, such as minimum tillage and no-tillage, preserve crop residues on the surface and have been shown to promote crop production (NCSU 2001). Conservation tillage provides many benefits to the soil and environment and requires less time and labor in preparing the field for planting (NCSU 2001). In the U.S., conservation tillage in cotton production has increased from 0.5 million acres in 1990 to about 2.75 million acres in 2004 (Cotton Incorporated 2010a). Insect control is one of the biggest challenges for conventional cotton farmers, with lepidopteran pests of cotton being the most damaging (USDA-APHIS 2008; Williams 2008). Appendix B lists U.S. pesticide usage characteristics for the control of the lepidopteran pests: cotton bollworm, tobacco budworm, and pink bollworm. At the same time, the availability of commonly used cotton insecticides and the resistance of insect pests to them has led to a need for new pesticide chemistries and other novel approaches for control, including Bt cotton (Gianessi and Carpenter 1999). One of the documented benefits of Bt cotton has been the reduction in the use of broad-spectrum insecticides during cotton production (Benson and Darrow 1981; Fernandez-Cornejo and Caswell 2006; Benbrook 2009).

There are 11 primary insecticides used to control the budworm/bollworm complex in cotton (USDA-NASS 2008). The carbamate insecticide aldicarb is the most widely used and accounted for 3.02 million (28%) acre-treatments (% acres treated x no. of acres planted x no. of applications) of the insecticides used in 1996 (USDA-NASS 2008). Although this number declined to 1.9 million acre-treatments of aldicarb by 2007, aldicarb still represented 67% of the insecticide acre-treatments that were applied. Other commonly used insecticides include Bt sprays, carboflurin, cyfluthrin, cypermethrin, emamectin benzoate, indoxacarb, parathion methyl, profenofos, thiodicarb, and tralomethrin. From 1996 to 2007 the number of acre-treatments of these 11 insecticides declined from a total of 10.65 million to 2.8 million. This is attributed to the widespread adoption of Bt cotton, introduced commercially in 1996, which increased from 1.73 million acres of cotton planted to 7.6 million acres in the U.S. during the same time period (Benbrook 2009).

No Action: Cropping Practices: Crop Rotation, Tillage, Production, and Pesticide Use

Under the No Action Alternative, cotton production practices, including pesticide use will remain as it is practiced today by the farming community. Growers will continue to have access to existing deregulated GE lepidopteran-resistant cotton products as well as conventional cotton varieties.

Preferred Alternative: Cropping Practices: Crop Rotation, Tillage, Production, and Pesticide Use

Cotton growers and professionals in the cotton industry consider herbicide-tolerant cotton, insect-protected cotton, conservation tillage, and no-till to be among the top ten most important innovations in cotton production since 1996 (Marra and Martin 2007). Expanded weed and insect control in the form of biotech traits, along with drought resistant cotton and improved cotton varieties are perceived by this group to be the most important future innovations for cotton production (Marra and Martin 2007). GE lepidopteran-resistant cotton accounted for 65% of the total cotton acreage planted in 2009 and has increased in use over the last 10 years from about 15% in 1996 (USDA-ERS 2010a). Commercialization of Bt crops has resulted in fewer insecticide applications and thus, lower management costs (Cattaneo, Yafuso et al. 2006; US-EPA 2008; Benbrook 2009). The EPA has compiled its analysis of the effect of Bt cotton on insecticide-use patterns and has determined that the use of FLCry1Ab is in the public interest and that it will not cause any unreasonable adverse effects on the environment (US-EPA 2008).

Under the Preferred Alternative, cotton production practices are expected to be unchanged, except for the availability of an additional Bt cotton variety to those that are currently available to farmers. Studies demonstrate COT67B cotton is essentially indistinguishable from other cotton varieties used in terms of agronomic characteristics and cultivation practices (Reed and Stone 2007). If COT67B cotton is adopted, a reduction in the use of budworm/bollworm insecticides applications and the number of acre-treatments per year is expected to occur. Overall impacts would be similar to the No Action Alternative.

Cumulative Effects: Cropping Practices: Crop Rotation, Tillage, Production, and Pesticide Use

A determination of nonregulated status of COT67B cotton will not result in changes in the current practices of crop rotation, tillage, and overall pesticide use. Studies demonstrate COT67B cotton is essentially indistinguishable from other cotton varieties used in terms of agronomic characteristics and cultivation practices (Reed and Stone 2007). It is anticipated that broad-spectrum insecticide use will continue the trend of reduced usage by cotton growers due to the adoption of Bt cotton and other cultural practices. APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to affect changes in crop rotation, tillage, and pesticide use.

Seed Production

Maintaining genetic purity has been a feature of cotton cultivation and other cultivated species for decades as part of varietal seed and specialty crop production. The cultivation of *G. hirsutum* and *G. barbadense* for commercial seed production is regulated by various state, federal, and international institutions to preclude gene flow between species and varieties (Wozniak 2002). Common practices include maintaining isolation distances to prevent pollen movement from other cotton sources, planting border or barrier rows to intercept pollen, and employing natural barriers to pollen. The isolation distance, as dictated by the USDA Agricultural Marketing Service's Federal Seed Act for Foundation, Registered, and Certified seeds in 7 CFR Part 201 are 1,320; 1,320; and 660 feet, respectively (USDA-AMS 2010b). Field monitoring for off-types, other crops, weeds, disease etc. is carried out by company staff and state crop improvement associations. Seed handling standards are established by the Association of Official Seed Certifying Agencies (AOSCA) to reduce the likelihood of seed source mixing during planting, harvesting, transporting, storage, cleaning, and ginning (AOSCA 2003).

No Action: Seed Production

The availability of conventional and GE seed, and the production practices used to grow cotton seeds will remain the same under the No Action Alternative.

Preferred Alternative: Seed Production

Under this alternative, COT67B cotton would be available to growers. A potential environmental impact to be considered as a result of planting this cotton, as with any other commercially-available cotton, is the potential impacts arising from gene introgression of COT67B cotton with other sexually compatible species. APHIS evaluated the potential for gene introgression to occur from COT67B cotton to sexually compatible species and considered whether such introgression would impact the production of non-GE and specialty cotton seed. APHIS does note that gene flow can take place between a field planted with COT67B cotton and a neighboring cotton crop, just as it can for all cotton, genetically engineered or not. However, the frequency of such an occurrence decreases with increasing isolation distances. The isolation measures currently in place to minimize pollen flow, as described above, will minimize this issue just as it does for the production of foundation seed (AOSCA 2003; USDA-AMS 2010b).

Syngenta has also submitted data on the agronomic characteristics, seed productivity, and quality characteristics of COT67B and the controls, COT67B(-) and Coker 312 (Reed and Stone 2007). The insertion and expression of the *flcry1Ab* does not significantly alter the agronomic characteristics of COT67B cotton (Table 5-16, 5-17 and 5-18 of the petition), increase the seed productivity of COT67B cotton (Table 5-21 of the petition) or the germination, viability, and dormancy characteristics of COT67B cotton seed (Table 5-23 of the petition). Any significant differences that were measured were small and usually showed COT67B cotton to be intermediate between COT67B (-) and Coker 312. In addition, Syngenta expects that COT67B cotton will primarily replace other Bt cotton products currently on the market and will not alter the acreage of cotton produced for seed.

Based on the data provided by Syngenta for COT67B cotton (Reed and Stone 2007), as well as previous experience with other Bt cotton varieties that have been widely adopted by growers since their introduction in 1996 (USDA-ERS 2010a), APHIS has concluded that the availability of COT67B cotton would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE seed production, nor pose a plant pest risk (USDA-APHIS 2009). The overall impact on the availability of conventional and GE seed, and the production practices used to grow cotton seeds would be similar to the No Action Alternative.

Cumulative Effects: Seed Production

Based on current acreage trends, GE cotton varieties will likely continue to dominate, or perhaps increase in acreage. The availability of COT67B cotton will not change cultivation areas for cotton production in the U.S. Because changes in the agronomic practices and locations for cotton seed production using COT67B cotton are not expected, no cumulative effects have been identified for this issue.

Organic Farming

Certified organic cotton acreage is a small percentage of overall cotton production. Acreage in the year 2000 and 2008 are approximately the same at slightly over 15,000 acres (USDA-ERS 2010c). Organic cotton acreage represented 0.11% of total U.S. cotton acreage in the year 2000 and was 0.16% of total planted U.S. cotton acreage in 2008 (USDA-ERS 2009b). Bayer CropScience FM 958 and ADF 2485 were the predominate varieties planted in 2009 by organic cotton producers (USDA-AMS 2009).

APHIS recognizes that producers of non-GE cotton, particularly producers who sell their products to markets sensitive to genetically engineered traits (e.g., organic or some export markets) can be reasonably assumed to be using practices on their farm to protect their crop from unwanted substances and maintain their price premium. For example, the NOP has recognized the practicality of protecting organically-produced crops, and the investment farmers put into their production practices, by requiring that organic production plans include methods to protect organically-produced crops. “Organic crops must be protected from contamination by prohibited substances used on adjoining lands (for example, drifting pesticides, fertilizer-laden runoff water, and pollen drift from genetically engineered...)” (NCAT 2003).

Typically, there is more than one method for farms under organic practices to prevent unwanted material from entering their fields including: isolation of the farm, physical barriers or buffer zones between organic production and non-organic production, as well as formal communications between neighboring farms (NCAT 2003). The organic plan used as the basis for organic certification should include a description of practices used to prevent or reduce the likelihood of unwanted substances, like GE pollen or seed, at each step in the farming operation, such as planting, harvesting, storing, and transporting the crop (Riddle 2004;

Krueger 2007; Kuepper, Born et al. 2007). Organic plans should also include mechanisms to monitor the risk of GE pollen or seed co-mingling with the organic crop (Kuepper, Born et al. 2007). Farmers using organic methods are requested to let neighboring farmers know that they are using organic production practices and request that the neighbors also help the organic farmer reduce contamination events (NCAT 2003; Krueger 2007). Thus, commonly used production practices for cotton, and the practical methods typically used by cotton farmers using organic methods currently provide many measures that greatly reduce the likelihood of accidental gene flow between COT67B cotton and non-GE cotton fields. These practices protect organic crops and thus maximize profits and price premiums accorded to cotton under organic production. APHIS will assume that farmers are already using, or have the ability to use, these common practices as APHIS's baseline for the analyses of the following alternatives below. Recommended organic production practices for cotton are also readily available (Kuepper 2002). Historically, organic cotton production represents a small percentage of total U.S. cotton acreage (USDA-ERS 2010c). It will likely remain small regardless of whether new varieties of GE or non-GE cotton varieties, including COT67B cotton, become available for commercial cotton production.

No Action: Organic Farming

Current availability of seed for conventional (both GE and non-GE) cotton varieties, and those cotton varieties that are developed for organic production, are expected to remain the same under the No Action Alternative. Commercial production of conventional and organic cotton is not expected to change and will likely remain the same under the No Action Alternative. Planting and production of GE, non-GE and organic cotton will continue to fluctuate with market demands as it has over the last 10 years, and these markets are likely to continue to fluctuate under the No Action Alternative (USDA-NASS 2010b; USDA-NASS 2010c).

Preferred Alternative: Organic Farming

It is not likely that organic farmers, or other farmers who choose not to plant transgenic varieties or sell transgenic seed, will be substantially impacted by the expected commercial use of COT67B cotton. Transgenic cotton lines including those that are resistant to lepidopteran insects are already in widespread use by farmers. COT67B cotton should not present any new and different issues and impacts for organic and other specialty cotton producers and consumers. According to the petition, agronomic trials conducted in 2005 and 2006 in a variety of locations in the U.S. demonstrated that COT67B cotton is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterpart (USDA-APHIS 2008). No differences were observed in pollen diameter, weight, and viability. Therefore, COT67B cotton is not expected to have an increased ability to cross pollinate other cotton varieties.

Commonly used production practices for cotton and the practical methods typically used by cotton farmers using organic methods to protect their crop under organic production (NCAT 2003) provide many measures that greatly reduce the likelihood of accidental gene flow between COT67B cotton and non-GE cotton fields. The trend in the use of GE cotton varieties, non-GE varieties, and the use of organic cotton production systems is likely to remain the same as the No Action Alternative.

Cumulative Effects: Organic Farming

A determination of nonregulated status of COT67B cotton is not expected to change the market demands for GE cotton or cotton produced using organic methods. A determination of nonregulated status of COT67B cotton could add another GE cotton variety to the conventional cotton market. Based upon recent trend information, adding GE varieties to the market is not related to the ability of organic production systems to maintain their market share. Between 2000 and 2008, although 12 GE cotton events or lines were deregulated pursuant to Part 340 and the Plant Protection Act , the acreage associated with the organic production of cotton remained at slightly above 15,000 acres (USDA-ERS 2009b).

Specialty Cotton Systems

In addition to the specialization adopted across the industry to enable varietal seed production for upland cotton, which represents 98% of U.S. cotton production, a number of other specialty cottons are produced (USDA-NASS 2010a). These include ELS varieties of Pima and Acala which represented less than 2% of total U.S. cotton planted in 2009 (USDA-NASS 2010a). Historically, ELS cotton acreage has ranged from a low of 63,000 acres in 1983 to a high of 377,000 acres in 1989 (National Cotton Council of America 2010). This represented 0.83% and 3.5% of the total cotton acreage planted for those years, respectively. The most recently available data for certified organic cotton production was 15,377 acres in 2008 (USDA-ERS 2010c). Naturally colored cotton acreage was reported to be 4,000 acres in 1992 (Dickerson, Lane et al. 1999) and between 5,000 and 7,000 acres in 1995 (Lee 1996). In 2006, there were at least six companies offering organic and/or colored cottonseed in the U.S. in Massachusetts, Texas, Virginia, Arizona, and North Carolina (Reed and Stone 2007). Similar to the production of conventional seed, industry quality standards for specialty crop products have led these seed producers and growers to employ a variety of techniques to ensure that their products are not pollinated by or commingled with conventional or genetically engineered crops (Bradford 2006). In general, the conventional management practices used for conventional seed production are generally sufficient to meet standards for the production of specialty crop seed (Bradford 2006).

No Action: Specialty Systems

Current availability of seed for specialty cotton varieties are expected to remain the same under the No Action Alternative. Commercial production of specialty cotton is not expected to change and will likely remain the same under the No Action Alternative. Cotton producers practice effective methods of maintaining genetic purity and mechanisms are in place to protect the genetic diversity of cotton. Cultivation of specialty cotton requires genetic purity procedures and cotton growers have utilized these methods effectively to prevent undesired gene flow.

Preferred Alternative: Specialty Systems

It is not likely that specialty system farmers, or other farmers who choose not to plant transgenic varieties or sell transgenic seed, will be substantially impacted by the expected commercial use of COT67B cotton. Transgenic cotton lines including those that are resistant to lepidopteran insects are already in widespread use by farmers. COT67B cotton should not present any new and different issues and impacts for specialty cotton producers and consumers. According to the petition, agronomic trials conducted in 2005 and 2006 in a variety of locations in the U.S. demonstrated that COT67B cotton is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterpart (USDA-APHIS 2008). No differences were observed in pollen diameter, weight, and viability. Therefore, COT67B cotton is not expected to have an increased ability to cross-pollinate other cotton varieties.

A determination of nonregulated status of COT67B cotton under the Preferred Alternative would not change the availability and genetic purity of seed for specialty cotton varieties. Conventional management practices and procedures, as described previously for cotton seed production, proper seed handling, protection of wild relatives of cotton, and organic cotton farming, are in place to maintain the genetic diversity of cotton. Cotton growers have utilized these methods effectively to meet the standards for the production of specialty crop seed. Impacts would be similar to the No Action Alternative.

Cumulative Effects: Specialty Systems

A determination of nonregulated status of COT67B cotton is not expected to change the market demands for GE cotton or cotton produced using specialty systems. A determination of nonregulated status of COT67B cotton could add another GE cotton variety to the conventional cotton market. Between 2000 and 2009, 12 GE cotton events or lines were deregulated pursuant to Part 340 and the Plant Protection Act. Based on demonstrated agronomic characteristics and cultivation practices, and since the market share of specialty cotton varieties is unlikely to change by the introduction of COT67B cotton, APHIS has determined that there are no past, present, or reasonably foreseeable changes that would impact specialty cotton producers and consumers.

Physical Environment

Water Use

Cotton plant water use varies according to the environment it is growing in. Cotton grown in the desert southwestern U.S. requires about 40 inches of water per acre per year (Hunsaker 1999). Cotton grown in humid regions of the southeastern U.S. can require as little as 18 inches of water per acre per year (Bednarz, Ritchie et al. 2002). Much of the cotton grown from central Texas east is without supplemental irrigation (Cotton Incorporated 2010a). Where irrigation water is needed (approximately 35% of the U.S. cotton grown), cotton yields are also much higher (Cotton Incorporated 2010a). Despite high production levels in irrigated areas, the amount of cotton produced in California, Arizona, and New Mexico has been steadily declining for the last decade because of a lack of affordable irrigation water, the planting of higher value crops, and other land uses (Cotton Incorporated 2010a).

Water quality is also preserved in modern cotton productions systems. The increase in conservation tillage practices has resulted in a reduction of runoff from agricultural lands, decreasing non-point source pollution of fertilizer, and pesticides. Intensive local monitoring of surface water and sub-soils has demonstrated the benefits of no-till cotton in protecting both ground and surface water resources (University of Tennessee Agricultural Extension Service 2010). Better nutrient management and precision technologies are ensuring inputs are used by the crop and are not entering ground or surface waters (Cotton Incorporated 2010b).

No Action: Water Use

Under the No Action Alternative, COT67B cotton interactions with water would be limited to the areas that were approved for regulated releases by APHIS. Land acreage and agronomic practices associated with cotton production would not be affected. In 2009, GE insect-resistant cotton occupied 65% of the cotton acreage (USDA-ERS 2009b). Conventional and GE cotton production occurs on land that is dedicated to crop production and most cotton is planted in fields that have been in crop production for years. There would be no change in irrigation practices associated with cotton production including the irrigation of cotton in drought prone areas.

Preferred Alternative: Water Use

Impacts would be similar to the No Action Alternative. COT67B cotton does not change cultivation practices for cotton production, nor would it increase the total acres and range of U.S. cotton production areas. A determination of nonregulated status of COT67B cotton will not change the use of irrigation practices in commercial cotton production. Since the COT67B cotton is expected to simply replace GE and non-GE cotton varieties already in use, the consequences of the Preferred Action Alternative on commercial cotton production are the same as the No Action Alternative.

Cumulative Effect: Water Use

No cumulative effects have been identified for a determination of nonregulated status of COT67B cotton. A determination of nonregulated status of COT67B cotton would not change the water use and irrigation practices used in commercial cotton production.

Soil

According to the USDA National Resource Conservation Service, there have been significant reductions in the loss of soil from croplands in the U.S. (USDA-NRCS 2006). Total soil loss on highly erodible croplands and non-highly erodible cropland decreased by 39.2% from 1982 to 2003. These reductions are due to a combination of effective conservation practices and the decrease in number of acres of highly erodible cropland (USDA-NRCS 2006). Over the last 10 years, cotton has contributed to this reduction in soil loss through a shift towards conservation tillage and the use of cover crops (Cotton Incorporated 2010a). In the U.S., conservation tillage in cotton has increased from 0.5 million acres in 1990 to about 2.75 million acres in 2004 (Cotton Incorporated 2010a). Benefits of conservation tillage practices include maintenance of soil organic matter and beneficial insects, increased soil water-holding capacity, less soil and nutrient loss from the field, reduced soil compaction, and less time and labor required to prepare the field for planting (NCSU 2001). The use of herbicide-resistant cotton has allowed cotton growers to more readily adopt soil conservation practices because it provides an economical, effective means of controlling weeds in post-plant cotton (McClelland, Barrentine et al. 2000; Cotton Incorporated 2010a).

Soil quality benefits of Bt cotton may also be realized by reducing the risks associated with environmental spills or misapplications of chemical insecticides to the soil. Reduced insecticide applications also mean a reduction in the number of trips across the field with heavy farm equipment which contributes to soil compaction, especially when the soil is wet. The number of acre-treatments per year of budworm/bollworm insecticides declined from over 10 million to less than 3 million between the years 1996 and 2007 (USDA-NASS 2008). This is attributed to the widespread adoption of Bt cotton, introduced commercially in 1996, which increased from 1.73 million acres of cotton planted to 7.6 million acres in the U.S. during the same time period (Benbrook 2009).

No Action: Soil

COT67B cotton interactions with the soil would be limited to the areas that are approved by APHIS for regulated releases. Land acreage and agronomic practices associated with cotton production would not be affected. In 2009, GE insect-resistant cotton occupied 65% of the cotton acreage (USDA-ERS 2009b). Conventional and GE cotton production occurs on land that is dedicated to crop production and most cotton is planted in fields that have been in crop production for years. The soil environment would be modified by cotton roots and crop soils would be affected by the agronomic practices associated with conventional methods of cotton production including tillage, cultivation, fertilization, pesticide applications, fertilizer applications, and the use of agricultural equipment.

Preferred Alternative: Soil

No changes to agronomic practices typically applied in the management of conventional cotton, including other commercially available Bt cotton varieties, are required for COT67B cotton. There are no expected increases in land acreage. Syngenta conducted comprehensive field trials in eight geographical locations within the Cotton Belt during the 2004, 2005, and 2006 growing seasons (Reed and Stone 2007). Phenotypic, agronomic, and ecological assessments for COT67B cotton were the same when compared to its nontransgenic isoline COT67B(-) and the cultivar Coker 312. No increases in fertilizers and pesticides were required, nor were any changes in cultivation, planting, harvesting, and volunteer control required (Reed and Stone 2007). It is expected that similar agronomic practices that are currently used for commercially available Bt cotton will also be used by growers of COT67B cotton. If COT67B cotton is adopted and replaces non-Bt cotton varieties, soils currently under non-BT cotton production may benefit from the use of COT67B cotton due to a reduction in the use of budworm/bollworm insecticides applications and the number of acre-treatments per year required using heavy farm equipment.

Cumulative Effects: Soil

APHIS has not identified any cumulative effects for this issue. Comprehensive phenotypic, agronomic, and ecological assessments conducted by the petitioner for COT67B cotton failed to identify a consistent trend of difference between COT67B cotton and control cottons for these characteristics (Reed and Stone 2007). The few differences that were identified were typically small, site specific, and unlikely to be biologically meaningful. Event COT67B cotton required the same soil, fertilizer, water and pest management practices (except for lepidopteran pest control) as non-GE cotton (Reed and Stone 2007). Consequently, the phenotypic, agronomic, and ecological data presented by Syngenta (Reed and Stone 2007) support the conclusion by APHIS that COT67B cotton will not result in any significant impact to the soil that is not already found in conventional cotton production practices.

Based on these findings, and since the amount of cotton grown in the U.S. is unlikely to change by the introduction of COT67B cotton, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would impact soil. The consequences of the Preferred Action Alternative on commercial cotton production are the same as for the No Action Alternative.

Air Quality

Many agricultural activities affect air quality including smoke from agricultural burning, tillage, traffic and harvest emissions, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizer (Hoeft, Nafziger et al. 2000; Aneja, Schlesinger et al. 2009). These agricultural activities individually have potentially adverse environmental impacts on air quality. Tillage contributes to the release of GHG because of the loss of CO_2 to the atmosphere and the exposure and oxidation of soil organic matter (Baker, Southard et al. 2005). Emissions released from agricultural equipment (e.g., irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (US-EPA 2010). Nitrous oxide may also be released following the use of nitrogen fertilizer (US-EPA 2010). Aerial application of pesticides may cause impacts from drift and diffusion. Pesticides may volatilize after application to soil or plant surfaces and move following wind erosion (Vogel, Majewski et al. 2008). Agriculture, including land-use changes for farming, is responsible for an estimated 6% of all human-induced GHG emissions in the U.S. and N2O emissions from agricultural soil management are a large part of this—68% of all U.S. N20 emissions (US-EPA 2010).

No Action: Air Quality

Under the No Action Alternative, COT67B cotton interactions with the air would be limited to the areas that were approved for regulated releases by APHIS. Land acreage and cultivation practices associated with cotton production would not be affected. In 2009, GE insect-resistant cotton occupied 65% of the cotton acreage (USDA-ERS 2009b). Conventional and GE cotton production occurs on land that is dedicated to crop production and most cotton is planted in fields that have been in cotton production for at least 5 years (USDA-NASS 2009). Air quality would be affected by agronomic practices associated with conventional methods of cotton production such as tillage, cultivation, pesticide and fertilizer applications, and the use of agricultural equipment.

Preferred Alternative: Air Quality

COT67B cotton production does not change land acreage or any cultivation practices for conventional, transgenic, or non-transgenic cotton production. There are no expected increases in cultivation, planting, pesticide use, fertilizer use, harvesting, or volunteer control compared to currently available GE and non-GE cotton cultivars. It is expected that similar agronomic practices that are currently used for commercially available Bt cotton will also be used by growers of COT67B cotton. If COT67B cotton is adopted and replaces non-Bt cotton varieties, air quality issues associated with pesticide application and use in non-BT cotton production may benefit from the use of COT67B cotton due to a reduction in the use of budworm/bollworm insecticides applications and the number of acre-treatments per year required using heavy farm equipment. The comprehensive phenotypic, agronomic, and ecological assessment conducted for COT67B cotton during the 2004, 2005, and 2006 growing season failed to identify a consistent trend of difference between COT67B cotton and control cotton for any of the phenotypic and agronomic characteristics measured (Reed and Stone 2007). The few differences identified were typically small, site specific, and unlikely to be biologically meaningful. The evaluation of ecological interactions at the same locations, based on monitoring of specific insect, disease, and abiotic stressors such as heat and drought again failed to identify trends for differences in susceptibility to pests or environmental stress. Consequently, these phenotypic, agronomic, and ecological data demonstrate that COT67B cotton does not require increased agricultural inputs for commercial cultivation, including weed and pest management. Based on this information, APHIS concludes that the production of COT67B cotton would not increase agricultural production effects on air quality. Overall impacts are similar to the No Action Alternative.

Cumulative Effects: Air Quality

Based on the findings described above, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have a negative impact on air quality. The consequences of the Preferred Action Alternative on commercial cotton production are the same as for the No Action Alternative.

Climate Change

Production of agricultural commodities is one of the many human activities that could possibly contribute GHG that affect climate (see discussion in Affected Area, Physical Environment). CO_2, NO_2, and CH_4 may be produced through the combustion of fossil fuels to run farm equipment, the use of fertilizers, or the decomposition of agricultural waste products including crop residues and animal wastes. Classes of crops planted are relevant to climate change, as are the locations and the soil types in which they are planted. Climate change itself may force changes to agricultural practices by extending the ranges of weeds and pests of agriculture (IPCC 2007). Indirect effects of new crops will be determined by the traits engineered into organisms and the management strategies used in the production of these organisms.

No Action: Climate Change

Under the No Action Alternative, environmental releases of COT67B cotton would be under APHIS regulation. Due to the limited size of these field trials, there would be no measurable effect on climate change from these confined environmental releases. Land acreage and cultivation practices associated with cotton production would not be affected. In 2009, GE insect-resistant cotton occupied 65% of the cotton acreage (USDA-ERS 2009b). Conventional and GE cotton production occurs on land that is dedicated to crop production and most cotton is planted in fields that have been in crop production for years. Agronomic practices associated with conventional cotton production such as tillage, cultivation, irrigation, pesticide application, fertilizer applications, and use of agriculture equipment would continue.

Preferred Alternative: Climate Change

A determination of nonregulated status of COT67B cotton would not change the cultivation or agronomic practices, or agricultural land acreage associated with growing cotton, and thus is expected to have the same effect on climate change as the No Action Alternative.

Cumulative Effects Climate Change

APHIS has not identified any cumulative effects for this issue. The use of COT67B cotton in commercial cotton production is expected to have no cumulative effect on climate change because APHIS does not anticipate any changes in cotton production practices or an expansion of cotton acreage as a result of COT67B cotton deregulation. The consequences of the Preferred Action Alternative on commercial cotton production and acreage are the same as for the No Action Alternative.

Animal and Plant Communities

Animals

Cotton production systems in agriculture are host to many animal species. Mammals and birds may use cotton fields and the surrounding vegetation for food and habitat throughout the year. Invertebrates can feed on cotton plants or prey upon other insects living on cotton plants as well as in the vegetation surrounding cotton fields. The cumulative effects analysis for this issue is found below at “Cumulative Effects: Plants, Animals, Biodiversity.”

No Action: Animals

Under the No Action Alternative, conventional and GE transgenic cotton production, including the use of Bt cotton varieties, will continue while COT67B cotton remains a regulated article. Cotton is currently produced in 17 states (USDA-NASS 2009), and under the No Action Alternative this range of production will remain unchanged. Potential impacts of GE and non-GE cotton production practices on non-target species would be unchanged. The use of insecticides, other than Bt crops, may affect non-target organisms including honey bees, soil invertebrates, or culturable microbial flora (US-EPA 2008). A notable advantage of GE insecticidal (Bt) crops over conventional insecticides is the high specificity of the Bt toxins, which minimize the potential toxic effects on non-target insects (Sanvido, Romeis et al. 2007; US-EPA 2008). In addition, because Bt crops help reduce the use of insecticides, risks to the environment and effects on non-target and beneficial organisms are reduced.

Preferred Alternative: Animals

APHIS has reviewed the mammalian and non-target safety assessment and the data submitted by the applicant, and FDA has completed its consultation process for cotton event COT67B cotton which is engineered to express the FLCry1Ab[3] protein (Appendix A). The agronomic practices used to produce COT67B cotton will be the same as those used to produce other conventionally grown GE and non-GE cotton. COT67B cotton production does not change land acreage or any cultivation practices for conventional, transgenic, or non-transgenic cotton production. In 2009, Bt cotton occupied 65% of the cotton acreage in the U.S. (USDA-ERS 2009b). COT67B cotton would be an additional Bt cotton variety for growers to use. Therefore, the discussion of effects on animals of COT67B cotton will focus solely on the introduced FLCry1Ab protein in Bt cotton.

Plants that were genetically engineered to express the Cry1Ab protein have a history of safe use in the U.S. Since the mid-1990s, corn and cotton lines that express this protein have been commercialized without substantiated reports of significant deleterious impacts on non-target organisms (Mendelsohn, Kough et al. 2003; OECD 2007; US-EPA 2008; USDA-APHIS 2009). The use of transgenic cotton producing the Cry1Ab proteins has been shown to reduce the use of broad spectrum insecticides[4] without significant impacts on the diversity of non-target insects (Dively 2005; Torres and Ruberson 2005; Whitehouse, Wilson et al. 2005; Naranjo 2005a; Naranjo 2005b; Cattaneo, Yafuso et al. 2006; Romeis, Meissle et al. 2006; Torres and Ruberson 2006; Marvier, McCreedy et al. 2007). COT67B cotton is expected to be similar with respect to the low potential harm to the environment (Reed and Stone 2007). Because Cry1Ab receptors are not present in non-target birds and mammals (Hofmann, Luthy et al. 1988a; Hofmann, Vanderbruggen et al. 1988b; Van Rie, Jansens et al. 1989; Van Rie, Jansens et al. 1990; Shimada, Murata et al. 2006a; Shimada, Miyamoto et al. 2006b), these insecticidal proteins are not expected to adversely affect non-target invertebrate and vertebrate organisms (US-EPA 2008).

Syngenta submitted data from laboratory and field studies on non-target representative species, and other peer reviewed studies that provide evidence for the lack of toxicity of FLCry1Ab (US-EPA 2008). Assessment of insecticidal transgenic crops include laboratory tests with indicator test species to determine potential toxicity at toxin doses higher than would be anticipated under field conditions (Rose, Dively et al. 2007). Selection of representative indicator test species was based upon the potential for exposure to FLCry1Ab. Syngenta submitted non-target data for two above-ground arthropods (insidious flower bug (*Orius insidiosus*) and spotted ladybird beetle (*Coleomegilla maculate*)); two soil dwelling arthropods (rove beetle (*Aleochara bilineata*) and springtail (*Folsomia candida*)); a pollinator (honeybee (*Apis mellifera*)); a bird (Bobwhite quail (*Colinus virginianus*)); a mammal (mouse (*Mus musculus*)); an aquatic invertebrate (water flea (*Daphnia magna*)); and a fish (catfish (*Ictalurus punctatus*)). The data submitted in the petition indicate that no significant adverse effects were observed at the maximum test dose for any of

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[3] In FDA documents, the protein is referred to as FLCry1Ab protein rather than Cry1Ab. This is to indicate that the full length of the protein was inserted.

[4] Broad spectrum insecticides are chemical insecticides which kill insects that are causing injury to plants and also kill other insects that are not causing injury to the plant. Insects that are inadvertently killed by the application of insecticide are called “non-target” insects. Because the Cry1Ab protein is specific for a narrow range of insects, use of Cry1Ab to control plant pests is recognized as being beneficial to the survival of non-target insects (EPA 2008).

the tested species. Other research has also shown no direct adverse effects on insectivorous insects in field and laboratory studies with transgenic plants expressing Cry1Ab (Pilcher, Obrycki et al. 1997; Romeis, Dutton et al. 2004; Romeis, Meissle et al. 2006; Marvier, McCreedy et al. 2007). Exposure of aquatic organisms is likely very low because cotton pollen is large, sticky, and is not transported long distances by the wind (Hartman, Flocker et al. 1981). Seed and plant debris are not expected to be readily transported via overland runoff or wind to aquatic habitats (USDA-APHIS 2009).

Based on the above information, APHIS concludes that COT67B cotton will have no adverse effects on non-target animals.

Overall, potential impacts of COT67B cotton and associated production practices on animal species would be similar to the No Action Alternative.

Plants

The landscape surrounding a cotton field varies depending on the region. In certain areas, cotton fields may be bordered by other cotton (or any other crop) fields or may also be surrounded by woodland, rangelands, and/or pasture/grassland areas. These plant communities may be natural or managed plant habitats for the control of soil and wind erosion and/or serve as wildlife habitats.

Some plants are weeds and compete with cotton for water, nutrients, light, and other growth factors (USDA-APHIS 2008). The types of weeds in and around a cotton field depend on the immediate area in which the cotton is planted. Those weed species will vary depending on the geographic region where the cotton is grown. Common weeds in cotton include annual and perennial grasses (monocots), broad-leaf weeds (dicots), and sedges (*Cyperus* spp.). The cumulative effects analysis for this issue is found below at “Cumulative Effects: Plants, Animals, Biodiversity.”

No Action: Plants

Under the No Action Alternative, environmental releases of COT67B cotton would be under APHIS regulation. Plant species that typically inhabit cotton production systems will be managed through the use of mechanical, cultural, and chemical control methods.

Preferred Alternative: Plants

In the event of a determination of nonregulated status of COT67B cotton, the risks to wild plants and agricultural productivity from weedy cotton populations are low; volunteer cotton populations are easily managed and feral populations occur rarely in the U.S. Cotton Belt (Wozniak 2002). *G. hirsutum* does have sexually compatible wild or self-sustaining feral populations of cotton in Hawaii and parts of southern Florida (US-EPA 2008). As a result, the US-EPA has banned the sale or distribution of Bt cotton in these areas in order to prevent the movement of the Bt endotoxin into these wild or feral populations (US-EPA 2008).

Agronomic studies conducted by Syngenta tested the hypothesis that the weediness potential of COT67B cotton is unchanged with respect to conventional cotton (Reed and Stone 2007). No differences were detected between COT67B cotton and nontransgenic cotton in growth, reproduction, or interactions with pests and diseases, other than the intended effect of protection from lepidopteran pests. The main natural controls on feral populations of cotton are poor seed dispersal, poor seed germination, competition from other plants, and a high requirement for moisture (US-EPA 2001). Therefore, the incorporation of the insect resistance trait is unlikely to appreciably improve seedling establishment and increase weediness potential. In addition, cultivation of COT67B cotton does not require different fertilizer or herbicide application, tillage, planting, or harvesting from existing commercial cotton varieties, including Bt cotton varieties. The effect of cotton production on plant communities is likely to be unchanged by the introduction of COT67B cotton. Overall impacts would be similar to the No Action Alternative.

Biological Diversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Vandermeer and Perfecto 1995). Biodiversity provides valuable genetic resources for crop improvement (Harlan 1975) and also provides other functions beyond food, fiber, fuel, and income. These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri 1999). The loss of biodiversity results in a need for costly external inputs in order to provide these functions to the crop (Altieri 1999).

Biodiversity can be maintained or reintroduced into agroecosystems through the use of woodlots, fencerows, hedgerows, and wetlands. Agronomic practices include intercropping (the planting of two or more crops simultaneously to occupy the same field), agroforestry, crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically for the purpose of incorporating it into the soil in order to provide nutrients and organic matter), addition of organic matter (compost, green manure, animal manure, etc.), and hedgerows and windbreaks (Altieri 1999). To some degree these practices are being utilized by cotton growers to increase biodiversity (Cotton Incorporated 2010a).

The use of broad-spectrum insecticides is one of the most severe constraints for biological diversity in crops (Croft 1990). One of the benefits of Bt cotton has been the reduction of broad-spectrum insecticide use during cotton production (Fernandez-Cornejo and Caswell 2006). However, there is concern over the non-target effects of transgenic cotton, especially Bt cotton, on beneficial insects and non-target pests. The use of transgenic cotton producing the Cry1Ab proteins has been shown to reduce the use of broad spectrum insecticides[5] without significant impact on the diversity of non-target insects (Dively 2005; Torres and Ruberson 2005; Whitehouse, Wilson et al. 2005; Naranjo 2005a; Naranjo 2005b; Cattaneo, Yafuso et al. 2006;

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[5] Broad-spectrum insecticides are chemical insecticides which kill insects that are causing injury to plants and also kill other insects that are not causing injury to the plant. Insects that are inadvertently killed by the application of insecticide are called “non-target” insects. Because the Cry1Ab protein is specific for a narrow range of insects, use of Cry1Ab to control plant pests is recognized as being beneficial to the survival of non-target insects (EPA 2008).

Romeis, Meissle et al. 2006; Torres and Ruberson 2006; Marvier, McCreedy et al. 2007). COT67B cotton is expected to be similar with respect to the low potential harm to the environment (US-EPA 2008). Research in Arizona has shown that Bt cotton has a minimal effect on both the number and function of foliar-dwelling arthropod natural enemies, ants, and beetles (Naranjo 2005a; Naranjo 2005b; Cattaneo, Yafuso et al. 2006). On the other hand, broad-spectrum insecticide use causes a significant reduction in natural enemy insect populations in cotton fields (Naranjo 2005a; Naranjo 2005b).

Little is known about how the presence and release of Bt toxins from the aboveground and belowground parts of Bt cotton influence microbial diversity. Bt toxin has been found to be present in every major part of Bt cotton plants (leaves, stems, and roots) (Vadakattu and Watson 2004). Bt cotton roots also release the Bt protein into the soil (Vadakattu and Watson 2004). However, the presence of Bt toxin in the soil may not influence microbial diversity or activity. The effects of Bt on non-target soil microorganisms in Bt maize and Bt cotton cultivation found that microbial biodiversity and activity was no different than that of their non-Bt counterparts (Shen, Cai et al. 2006; Icoz, Saxena et al. 2008).

No Action: Biological Diversity

Under the No Action Alternative, COT67B cotton and its progeny would continue to be regulated articles under the regulations at 7 CFR part 340. Growers and other parties who are involved in production, handling, processing, or consumption of cotton would continue to have access to existing deregulated GE lepidopteran-resistant (Bt) cotton products as well as conventional cotton varieties.

Land acreage and cultivation practices associated with cotton production would not be affected. In 2009, GE insect-resistant cotton occupied 65% of the cotton acreage (USDA-ERS 2009b). Conventional and GE cotton production occurs on land that is dedicated to crop production and most cotton is planted in fields that have been in crop production for years. Agronomic practices associated with conventional cotton production such as tillage, cultivation, irrigation, pesticide application, fertilizer applications, and use of agriculture equipment would continue.

Preferred Alternative: Biological Diversity

No direct or indirect adverse effects have been reported for non-target organisms since the introduction of commercial varieties of Bt cotton in 1995. Bt cotton now represents 65% of the cotton planted in the U.S. (USDA-ERS 2010a). In addition, broad-spectrum insecticides, which are considered to be one of the largest impediments to agroecosystem biodiversity, have been reduced by the commercial use of Bt cotton (Croft 1990; USDA-NASS 2008; Benbrook 2009). Therefore, the deregulation of COT67B cotton for the control of lepidopteran pests is highly unlikely to have any direct toxic effects on non-target organisms and is likely to be neutral or beneficial to animal and plant biodiversity compared to non-transgenic cotton managed with conventional broad-spectrum insecticides.

A determination of nonregulated status of COT67B cotton will not change the cultivation or agronomic practices, or agricultural land acreage associated with growing cotton. COT67B cotton would be an additional Bt cotton variety for growers to use and therefore is expected to have the same effect on biological diversity as the No Action Alternative.

Cumulative Effects: Animals, Plants, Biodiversity

APHIS has determined that there are no impacts from past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to create cumulative impacts or reduce the long-term productivity or sustainability of any of the resources associated with the ecosystem in which COT67B cotton is planted. Based on scientific evidence, the diversity and abundance of non-target organisms in lepidopteran-resistant cotton is at least as high as in conventional cotton, and in many studies higher biodiversity is associated with transgenic cotton (Head, Moar et al. 2005; Torres and Ruberson 2005; Whitehouse, Wilson et al. 2005; Naranjo 2005a; Naranjo 2005b; Cattaneo, Yafuso et al. 2006; Torres and Ruberson 2006). Control of lepidopteran pests by COT67B cotton is highly unlikely to have direct toxic effects on non-target organisms and is likely to be neutral or beneficial to biodiversity compared with conventionally managed cotton. Therefore, the likelihood of adverse cumulative effects on non-target organisms and biodiversity following the introduction of COT67B cotton is minimal.

Gene Movement

G. hirsutum is a perennial plant that is cultivated as an annual in the U.S. where it is grown from Virginia southward and westward to California (McGregor 1976; USDA-NASS 2009). The cotton flower is perfect, containing both male and female parts, and can self- or cross-pollinate (Hartman, Flocker et al. 1981). However, the flowers of most cotton species, including *G. hirsutum*, are generally considered to be self-pollinating (Hartman, Flocker et al. 1981). Cross-pollination due to wind is considered insignificant because cotton pollen is sticky and heavy (Khan and Afzal 1950; Thies 1953). Some insect cross-pollination of cotton can occur if suitable insects are present and in large enough numbers (McGregor 1976; Fryxell 1979). The primary pollinators of cotton are bumble bees (*Bombus spp.*), black bees (*Melissodes spp.*), and honey bees (*Apis mellifera*) (McGregor 1976). However, pollen movement by insects is considered to be low. McGregor (1976) reported that a cotton field surrounded by a large number of honey bee colonies showed less than 2% movement of fluorescent tracer particles by insects at 150 to 200 feet from the source. A majority of field-based research with cotton shows an outcrossing rate of 10% or less within one meter of the pollen source (Andersson and Carmen de Vicente 2010). Historic literature suggests that differences in flowering patterns and pollinators presented barriers to cross pollination between *G. tomentosum* and either *G. hirsutum* or *G. barbadense* (Fryxell 1979; Wozniak 2002). Recent field and laboratory studies contradict this historic literature, demonstrating that these three species share common pollinators, and further that differences in flower structure and flowering habits do not serve as barriers to cross pollination (Pleasants and Wendel 2010).

There are no published reports of naturally occurring hybrids between these two species (Andersson and Carmen de Vicente 2010). In assessing the risk of gene introgression from COT67B cotton to its sexually compatible relatives, APHIS considered two primary issues: 1) the potential for gene flow and introgression and 2) the potential impact of introgression.

Although most of the cultivated cotton grown in the U.S. is *G. hirsutum*, *G. barbadense* (Pima cotton) is also grown (USDA-NASS 2009). In addition to these cultivated species, *G. thurberi* and *G. tomentosum* are found in the mountains of southern Arizona and in Hawaii, respectively. None of the above are listed (or proposed) as endangered or threatened under federal (US-FWS 2011) or state listings (Hawaii 2001; Arizona 2009) with the exception of *G. hirsutum*. The State of Florida has listed wild populations of *G. hirsutum* as an endangered species (Coile and Garland 2003). However, in Florida, wild *G. hirsutum* is not present in the northwestern panhandle where cotton cultivation occurs (Coile and Garland 2003; USDA-NASS 2009; Wunderlin and Hansen 2010). Additionally, the terms and conditions of EPA's conditional registration for FLCry1Ab in cotton prohibits commercial cultivation south of Route 60 near Tampa (US-EPA 2008). COT67B cotton is neither expected to be planted commercially in the areas of Florida where wild populations of *G. hirsutum* occur nor would they likely be impacted by COT67B cotton planted north of Route 60. Therefore, because they are not likely to be present in close proximity, cultivated *G. hirsutum* is not likely to cross with wild populations of *G. hirsutum*.

G. tomentosum is native to the Hawaiian Islands, occurring primarily in arid, rock, or clay coastal plains (Wagner, Herbst et al. 1999). In laboratory and greenhouse breeding programs with hand pollination, *G. tomentosum* and *G. hirsutum* are sexually compatible and form viable progeny. However, DNA marker analyses have not found evidence of genes from *G. hirsutum* occurring in native populations of *G. tomentosum* (DeJoode and Wendel 1992). It is possible that the lack of evidence of movement of *G. hirsutum* genes into *G. tomentosum* is the result of lack of opportunity because cotton has not been grown commercially in Hawaii for at least the last 45 years (USDA-NASS 2009). *G. tomentosum* is not known to be weedy or to have invasive characteristics (Holm, Plucknett et al. 1977; Holm, Doll et al. 1997; University of Hawaii at Manoa 2001), and is considered a rare plant in Hawaii (University of Hawaii at Manoa 2001). Because *G. tomentosum* is not a weedy plant, even if FLCry1Ab did introgress into *G. tomentosum* it is not likely to become weedy or invasive. Finally, EPA's conditional registration for FLCry1Ab prohibits commercial use of COT67B cotton in Hawaii (US-EPA 2008), therefore it would not be planted in Hawaii and the probability of outcrossing would not exist.

The difference in chromosome numbers precludes sexual compatibility of *G. hirsutum* with *G. thurberi* (OECD 2008). Outcrossing of genes from COT67B cotton to *G. thurberi* is unlikely to occur because *G. thurberi* contains only the D genome whereas *G. hirsutum* contains both the A and D genome. In addition, in Arizona, *G. thurberi* was eradicated near cotton growing areas as part of the cotton boll weevil control program (Kearney and Peebles 1960; Benson and Darrow 1981).

Horizontal gene transfer and expression of DNA from a plant species to bacteria is unlikely to occur (Keese 2008). First, many bacteria (or parts thereof) that are closely associated with plants have been sequenced, including *Agrobacterium* and *Rhizobium* (Kaneko, Nakamura et al. 2000; Wood, Setubal et al. 2001; Kaneko, Nakamura et al. 2002). There is no evidence that these organisms contain genes derived from plants. Second, in cases where review of sequence data implied that horizontal gene transfer occurred, these events are inferred to occur on an evolutionary time scale in the order of millions of years (Koonin, Makarova et al. 2001; Brown 2003). Third, transgene DNA promoters and coding sequences are optimized for plant expression, not bacterial expression (Reed and Stone 2007). Thus, even if horizontal gene transfer occurred, proteins corresponding to the transgenes are not likely to be produced.

No Action: Gene Movement

Under the No Action Alternative, conventional and GE transgenic cotton production, including the use of Bt cotton varieties, will continue while COT67B cotton will remain a regulated article. Cotton land acreage and cultivation practices for both Bt and non-Bt cotton varieties will remain the same. In 2009 Bt cotton varieties occupied 65% of the cotton acreage (USDA-ERS 2009b). Gene flow from current commercially available Bt cultivars to non-Bt cotton cultivars, feral cotton populations, wild sexually compatible relatives and other non-target organisms, such as soil bacteria, will remain unchanged.

Preferred Alternative: Gene Movement

Under this alternative, COT67B cotton would be available to growers. A potential environmental impact to be considered as a result of planting this cotton, as with any other commercially-available cotton, is the potential impact arising from gene introgression of COT67B cotton with other sexually compatible related species.

The US-EPA (2001) acknowledges the potential for gene transfer of the Bt endotoxin from Bt cotton to other cultivated cotton varieties in close proximity. However, commercially available cotton cultivars are generally considered to be self-pollinated (Hartmann, Flocker et al. 1981). Wind pollination is considered unimportant because cotton pollen is heavy and sticky and is not transported easily by the wind. Some insect cross-pollination can occur if suitable insects are present and in large enough numbers (Fryxell 1956; McGregor 1976). However, pollen movement by insects is considered to be low (McGregor 1976). A majority of field-based research with cotton shows an outcrossing rate of 10% or less within 1 meter of the pollen source (Anderson, Carmen de Vicente 2010). Based on these factors, APHIS believes that maintenance of adequate isolation distances between GE and non-GE cotton fields, the planting of border or barrier rows to intercept pollen, employing natural barriers to pollen movement such as tree lines, and staggering planting dates could preclude the likelihood of cotton pollen movement from one field to another.

Gene flow from Bt cotton to wild or feral populations of cotton is possible in limited geographic locations within Hawaii and Florida (USDA-APHIS 2008). In Hawaii the US-EPA (2001) has restricted the sale and distribution of Bt cotton for commercial planting where it could outcross with the wild cotton species *G. tomentosum.* These restrictions in Hawaii also apply to Bt cotton test plots and breeding nurseries. The US-EPA (2001) also prohibits the planting of Bt cotton (either *G. hirsutum* or *G. barbadense*) in southern Florida where it could outcross with feral populations of *G. hirsutum*. Because of these restrictions, gene flow from Bt cotton to wild or feral populations is extremely unlikely.

APHIS evaluated the potential for gene introgression to occur from COT67B cotton to sexually compatible wild relatives and considered whether such introgression would result in increased weediness. Based on the plant pest risk assessment, APHIS has concluded that COT67B cotton is not a plant pest and that gene flow between this product and wild or feral relatives will not occur in the U.S. (USDA-APHIS 2009).

Based on the above information, APHIS has concluded that a determination of nonregulated status of COT67B cotton will not impact sexually compatible relatives, nor would it increase the weedy or invasive characteristics of weedy or wild relatives if gene flow or introgression were to occur (USDA-APHIS 2008). COT67B cotton would be an additional Bt cotton variety for growers to use and is expected to have the same effect on gene movement as the No Action Alternative.

Cumulative Effect: Gene Movement

Based on the scientific evidence, APHIS has not identified any cumulative effects on gene movement that would occur from a determination of nonregulated status of COT67B cotton.

Gene movement between sexually compatible cotton species is no greater for COT67B cotton than it is for other non-GE or GE cultivars. Many factors limit the likelihood of gene movement between cotton species. These include: cotton is considered to be a self-pollinating crop with a very low frequency of outcrossing from insect pollinators or wind; the FLCry1Ab gene in COT67B cotton and other Bt cottons imparts no agronomic advantages resulting in a greater potential for weediness or invasiveness should introgression occur; neither GE or non-GE cotton cultivars form self-sustaining populations outside of cultivation because of limitations in seed dispersal, germination, and high moisture requirements. Where there is a potential for GE cotton to introgress into wild or feral populations of cotton, the US-EPA has placed restrictions on GE cotton breeding, testing and production. In addition, there is no evidence that horizontal gene transfer and expression of DNA occurs between cotton and soil bacteria under natural field conditions, and even if this did occur, proteins corresponding to the transgenes are not likely to be produced.

Public Heath

Human Health

Under FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from COT67B cotton must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market.

The basic premise relied on for mammalian toxicology assessment is the fact that all the Bt plant-incorporated protectants are proteins. Proteins are commonly found in the diet and, except for a few well described phenomena, present little risk as a mammalian hazard (US-EPA 2001). In addition, for the majority of Bt proteins currently registered, the source bacterium has been a registered microbial pesticide, which has been approved for use on food crops without specific restrictions. Because of their use as microbial pesticides, a long history of safe use is associated with many Bt products (US-EPA 2001).

Several types of data are required by the US-EPA for the Bt plant-incorporated protectants to provide a reasonable certainty that no harm will result from the aggregate exposure to these proteins. The information is intended to show that the Bt protein behaves as would be expected of a dietary protein, is not structurally related to any known food allergen or protein toxin, and does not display any oral toxicity when administered at high doses (US-EPA 2001). These data consist of an *in vitro* digestion assay, amino acid sequence homology comparisons, and an acute oral toxicity test. The acute oral toxicity test is done at a maximum hazard dose using purified protein of the plant-incorporated protectant as a test substance. Due to limitations of obtaining sufficient quantities of pure protein test substance from the plant itself, an alternative production source of the protein is often used such as the *Bacillus thuringiensis* source organism or an industrial fermentation microbe (US-EPA 2001).

US-EPA holds that protein instability in digestive fluids and the lack of adverse effects using the maximum hazard dose approach in general eliminate the need for longer-term testing of Bt protein plant-incorporated protectants. Dosing of these animals with the maximum hazard dose, along with the product characterization data should identify potential toxins and allergens, and provide an effective means to determine the safety of these proteins (US-EPA 2001). The adequacy of the current testing requirements was discussed at the June 7, 2000 Scientific Advisory Panel (SAP) meeting. In their final report, the SAP agreed in principle with the methods used by EPA to assess the toxicity of proteins expressed in plants, especially the maximum hazard dose approach (US-EPA 2001).

No Action: Human Health

The food/feed nutritional and safety assessment for COT67B cotton has been reviewed by the FDA. Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from COT67B cotton must be in compliance with all applicable legal and regulatory requirements. FDA completed their consultation on COT67B cotton on February 13, 2009 and concluded that it had “no further questions concerning food and feed derived from cotton event COT67B” (US-FDA BNF No. 0112). The FDA considers Syngenta’s consultation on COT67B cotton and its expression of FLCry1Ab to be complete (Appendix A).

The Cry1Ab protein is also present in a number of *B. thuringiensis* cotton plant incorporated protectants registered by the US-EPA since 1996 and re-registered in 2001 and 2006. The FDA completed food and feed safety consultations for these products and the EPA, through its statutory authority under the Federal Food Drug and Cosmetic Act, established a permanent exemption from the requirement of a tolerance for the FLCry1Ab protein and the genetic material necessary for its production in all plants (40 CFR 180.1173). The health and safety of children and minorities were also considered in the establishment of this exemption from the requirement of a tolerance.

Preferred Alternative: Human Health

Similar to the No Action Alternative, the FDA considers Syngenta’s consultation on COT67B cotton and its expression of FLCry1Ab to be complete (Appendix A). The Cry1Ab protein is also present in a number of *B. thuringiensis* cotton plant incorporated protectants registered by the

US-EPA since 1996 and re-registered in 2001 and 2006. The FDA completed food and feed safety consultations for these products and the EPA, through its statutory authority under the Federal Food Drug and Cosmetic Act, established a permanent exemption from the requirement of a tolerance for the FLCry1Ab protein and the genetic material necessary for its production in all plants (40 CFR 180.1173).

The primary food uses of cotton are refined cottonseed oil and cottonseed "linters." Refined cottonseed oil is highly processed using heat, solvent, and alkali treatments. Linters consist of essentially 100% pure cellulose fibers and are subjected to heat and solvent extraction (Reed and Stone 2007). Given the relatively low levels of FLCry1Ab in processed cottonseed fractions and the fact that refined cottonseed oil and cotton fiber contain little to no protein of any kind, the potential for human exposure to FLCry1Ab from food products containing COT67B cotton by-products is expected to be minimal (Reed and Stone 2007).

As with Bt cotton products previously deregulated and commercialized, COT67B cotton is expected to be used throughout cotton producing areas of the country. Based on the analysis of field and laboratory data and scientific literature provided by Syngenta (Reed and Stone 2007), and safety data available on earlier insect-resistant GE cotton, along with the completion of the consultation process with FDA, APHIS has concluded that a determination of nonregulated status of COT67B cotton would have no significant impacts on human or animal health. Overall impacts are similar to the No Action Alternative.

Cumulative Effects: Human Health

There are no significant impacts on human or animal health related to the No Action Alternative or a determination of nonregulated status of COT67B cotton, and no cumulative effects have been identified.

Worker Safety

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.

No Action: Worker Safety

During agricultural production of cotton, agricultural workers and pesticide applicators may be exposed to a variety of EPA registered pesticides (US-EPA 2001). Under the No Action Alternative, agricultural workers and pesticide applicators may be exposed to these agricultural chemicals during cotton production.

Preferred Alternative: Worker Safety

Before the introduction of Bt cotton varieties in 1996, chemical pesticides were widely used to control lepidopteran pests of cotton. Organophosphate, carbamate, and pyrethroid products accounted for a substantial percentage of the insecticides used (USDA-NASS 2008). However, these three classes of pesticides require numerous safety warnings and extensive use restrictions, which raise concerns for worker safety (US-EPA 2001). Bt cotton varieties have offered a very effective and environmentally benign alternative to chemical insecticides for lepidopteran insect pest control. As a result, Bt cotton varieties have been extensively adopted by cotton farmers and now represent 65% of the commercial cotton planted (USDA-ERS 2010a).

Similar to the No Action Alternative, it is expected that EPA registered pesticides that are currently used for cotton production will continue to be used growers. If COT67B cotton is adopted, agricultural workers and pesticide applicators may benefit from the use of COT67B cotton due to a reduction in the use of budworm/bollworm insecticides applications and the number of acre-treatments per year.

Cumulative Effects: Worker Safety

A determination of nonregulated status of COT67B cotton is not expected to increase the total acreage of cotton production or the use of Bt cotton. Syngenta anticipates that COT67B cotton will primarily replace some of the Bt cotton cultivars already on the market today. As a result, worker safety issues related to the use of EPA registered pesticides during conventional and Bt cotton production should remain the same. However, if a grower replaces a non-Bt cotton variety with COT67B cotton then it would be expected that there would be a reduction in the use of budworm/bollworm insecticides. This has been the case with the adoption of other Bt cotton cultivars (Benbrook 2009). A reduction in pesticide use and exposure should positively benefit worker safety.

Animal Feed

Cotton is grown primarily for its lint, but the seed residue, called cottonseed meal, provides a valuable animal feed (Hartman, Flocker et al. 1981). Cotton seed meal animal feed provides protein, fat, and energy (Reed and Stone 2007). Under FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from COT67B cotton must be in compliance with all applicable legal and regulatory requirements. GE organisms for feed may undergo a voluntary consultation process with the FDA prior to release onto the market.

No Action: Animal Feed

The food/feed nutritional and safety assessment for COT67B cotton has been reviewed by the FDA. Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from COT67B cotton must be in compliance with all applicable legal and regulatory requirements. FDA completed their consultation on COT67B cotton on February 13, 2009 and concluded that it had “no further questions concerning food and feed derived from cotton event COT67B” (US-FDA BNF No.

0112). The FDA considers Syngenta's consultation on COT67B cotton and its expression of FLCry1Ab to be complete (Appendix A).

The Cry1Ab protein is also present in a number of *B. thuringiensis* cotton plant incorporated protectants registered by the US-EPA since 1996 and re-registered in 2001 and 2006. The FDA completed food and feed safety consultations for these products and the EPA, through its statutory authority under the Federal Food Drug and Cosmetic Act, established a permanent exemption from the requirement of a tolerance for the FLCry1Ab protein and the genetic material necessary for its production in all plants (40 CFR 180.1173).

Preferred Alternative: Animal Feed

COT67B cotton is genetically engineered via recombinant DNA techniques to produce a FLCry1Ab protein originally derived from *Bacillus thuringiensis* subsp. *kurstaki* HD-1. COT67B cotton was produced through the introduction of the DNA into the cotton cultivar "Coker." The protein has activity against several important lepidopteran pest species of cotton including, but not limited to, cotton bollworm, tobacco budworm, pink bollworm, and cabbage looper. The Cry1Ab protein is also present in a number of cotton plant incorporated protectants registered by the US-EPA in 1996, 2001, and 2006. The FDA, through its statutory authority under the Federal Food Drug and Cosmetic Act, has established a permanent exemption from the requirement of a tolerance for the FLCry1Ab and the genetic material necessary for its production in plants (40 CFR 180.1173. Three Bt Cry1 endotoxin protein-based cotton plant incorporated protectants have been deregulated by the USDA and registered by the EPA under FIFRA. These are Bollgard, Bollgard II, and WideStrike (Reed and Stone 2007).

Syngenta has submitted compositional and nutritional characteristics of COT67B cotton seed to APHIS (Reed and Stone 2007). The nutritional components that were analyzed included proximates, amino acids, fatty acids, and minerals. In addition, cottonseed also contains anti-nutrients which limit the amount of cottonseed that can be used in feed rations (OECD 2004). These anti-nutrients, gossypol, and cyclopropenoid fatty acids (malvalic, sterculic, and dihydrosterculic acid) were also analyzed. Gossypol protects plants from insect and disease pests, but can cause toxicity in non-ruminant animals and young cattle. The cyclopropenoid fatty acids interfere with stearic acid metabolism in humans and animals. The analysis of these 41 key nutritional and anti-nutritional components revealed that 35 were not statistically different for COT67B cotton when compared to the nontransgenic cotton variety Coker 312. All the analytes measured fell within the normal range of natural variation in cotton (OECD 2004; ILSI 2008).

The FDA considers Syngenta's consultation on COT67B cotton to be complete (Appendix A). Syngenta also submitted information on identity, function, characterization of genes, expression levels of gene products, as well as information on the potential allergenicity and toxicity of the expressed proteins to APHIS. APHIS's assessment of the safety of this product for animals focuses on plant pest risk (USDA-NASS 2009) and effects on wildlife and threatened and endangered species (section on Animals and Threatened and Endangered Species), and those analyses are based on the comparison of the GE-cotton to its non-GE counterpart. No new issues appear to be associated with the FLCry1Ab protein in COT67B cotton.

Based on the assessment of laboratory data provided by Syngenta in the submitted petition and an analysis of the scientific literature (USDA-APHIS 2009), along with the completion of the consultation process with FDA regarding FLCry1Ab protein expression in COT67B cotton (Appendix A), APHIS has concluded that a determination of nonregulated status of COT67B cotton would have no significant impacts on animal feed, nor on animal health. Overall impacts are similar to the No Action Alternative.

Cumulative Effects: Animal Feed

There are no significant impacts on animal health related to the No Action Alternative or a determination of nonregulated status of COT67B cotton, and no cumulative effects have been identified.

Socioeconomic Issues

Domestic Economic Environment at Risk

The U.S. cotton industry generates about 200,000 jobs among the various sectors from farm to textile mills and accounts for more than $25 billion in products and services annually (USDA-ERS 2009a). Cotton sales from U.S. farms was valued at $4.9 billion in 2007 which was an increase from 2002 despite a decrease of about two million acres in harvested cotton acres (USDA-NASS 2009). Cotton is produced in 17 states, but the major concentrations of cotton production are Texas, California, Arkansas, Georgia, and Mississippi (USDA-NASS 2009). The predominant type of cotton grown in the U.S. is American upland cotton (*G. hirsutum*), which accounts for about 97% of the annual U.S. cotton crop. U.S. cotton production represents 14% of world cotton production (USDA-ERS 2009a).

According to the Census of Agriculture, U.S. cotton farms numbered 18,605 in 2007, down from 24,805 in 2002 (USDA-ERS 2009a). While the number has fallen, cotton acreage per farm has risen, averaging 564 acres per farm in 2007 compared with 502 acres in 2002 (USDA-ERS 2009a). The percentage of large cotton farms (over 1,000 acres) has continued to increase while the share of small cotton farms (under 100 acres) declines (USDA-ERS 2009a). The value of U.S. farm sales of cotton has increased despite the decrease in total number of farms and total cotton acreage (USDA-ERS 2009a).

Cotton producers in the U.S. are among the most technically advanced in the world, annually harvesting about 17 million bales or 7.2 billion pounds of cotton (US-EPA 2009). By the adoption of new technologies, including agronomic traits delivered through biotechnology, the yields of cotton lint per acre in the U.S. ranks among the highest in the world (Reed and Stone 2007). Since the introduction of GE insect-resistant and herbicide-tolerant cotton, transgenic varieties have been widely adopted by U.S. cotton farmers (Fernandez-Cornejo and Caswell 2006). These varieties offer excellent protection from the damage incurred by insect pests, as well as an economical alternative to broad-spectrum insecticides (Reed and Stone 2007).

Despite the wide adoption of Bt cotton varieties to control lepidopteran insects, these same species continue to be the most economically important pests of the crop. In 2007, it was estimated that the Heliothine complex of *H. virescens* and *H. zea* infested 6.7 million acres of cotton and reduced yields across the Cotton Belt by 229,186 bales (Williams 2008). Total 2007 cost and loss estimates for arthropod cotton pests were $877 million dollars (Williams 2008).

No Action: Domestic Economic Environment

Under the No Action Alternative, COT67B cotton and its progeny would continue to be regulated articles under the regulations at 7 CFR part 340. Growers and other parties who are involved in production, handling, processing, or consumption of cotton would not have access to COT67B cotton and its progeny, but would continue to have access to existing deregulated GE lepidopteran-resistant cotton products as well as other deregulated GE and conventional cotton varieties. Syngenta anticipates that COT67B cotton and its progeny would replace currently available Bt cotton varieties and would not increase Bt cotton production or cotton acreage. Domestic growers will continue to utilize currently available Bt cotton varieties or other deregulated varieties based upon availability and market demand.

Preferred Alternative: Domestic Economic Environment

In its review and analysis of the public interest documents submitted to support current Bt cotton products, US-EPA determined that economic value would result from the sale and use of these products (US-EPA 2001). Other studies have reached the same conclusions. For example, based on an analysis of biotechnology-derived crops planted in 2004, the National Center For Food and Agricultural Policy estimated that products providing protection against cotton bollworm, tobacco budworm, and pink bollworm increased cotton production by almost 600 million pounds, improved farm income by almost $300 million, and reduced chemical pesticide use by more than 1.6 million pounds (Sankula, Marmon et al. 2005). Numerous other studies have estimated the economic benefits from the adoption of transgenic cotton. Fernandez-Cornejo and Caswell (2006) provide a summary of many of these studies that characterize effects on yield, pesticide use, and grower returns. In a summary table from this report, grower returns and yields are consistently reported as increased due to planting Bt cotton products.

Syngenta considers the major benefits resulting from the introduction of COT67B cotton and its progeny to be additional grower choice, increased competition, and extended useful life of Bt cotton technology. Syngenta intends to conventionally breed COT67B and COT102, to be named VipCot™ (Reed and Stone 2007). The resulting progeny will have the plant incorporated insect resistant proteins FLCry1Ab and Vip3A. COT102 has nonregulated status from USDA-APHIS (USDA-APHIS 2005b). The Vip3A protein has a unique mode of action that is different from FLCry1Ab. Because of these different modes of action, Syngenta claims that combining these two traits into one cotton variety will reduce the likelihood of lepidopteran resistance to Bt cotton (Reed and Stone 2007). Additionally, stacking of FLCry1Ab with Vip3A could provide a higher level of suppression of more cotton lepidopteran pest species than in Bt varieties expressing these endotoxins alone (Reed and Stone 2007). Syngenta projects an additional economic benefit to the net income of U.S. cotton producer's of $83 million accrued over an 8-year adoption period of VipCot™ (Reed and Stone 2007). VipCot™, according to Syngenta projections, would accrue $42 million dollars through the replacement of inferior cultivars and an additional $41 million dollars from added competition and grower choice (Reed and Stone 2007). This equates to an average increase of $558 per year in net income for cotton producing farms (USDA-NASS 2009). Farms specializing in cotton production (roughly one-half of the farms that produce cotton) would be expected to see a greater increase in net income because they account for about 70% of annual U.S. cotton sales (USDA-NASS 2009). However, not all of this cotton is planted to Bt cotton. Only 65% of cotton acreage was planted to Bt varieties in 2007 (USDA-ERS 2010a) and the net income of cotton producers just growing Bt cotton varieties is not available (USDA-NASS 2009). No such assertions are made for the deregulation of COT67B cotton because Syngenta anticipates that COT67B cotton by itself would only replace existing Bt cotton varieties and not result in increased cotton acreage resulting in impacts similar to the no action alternative.

Cumulative Effects: Domestic Economic Environment

Based on the information described above, APHIS concludes that a determination of non-regulated status of COT67B cotton in itself will have no foreseeable domestic economic environmental effects. COT67B cotton would simply replace existing Bt and non-Bt cotton varieties that are already available on the market. COT67B cotton would not lead to an expansion of U.S. cotton acreage or the production of Bt cotton varieties. APHIS does acknowledge that a determination of nonregulated status of COT67B cotton could result in the creation of the new Syngenta variety VipCot™. This new variety, according to Syngenta economic projections, could increase the net income of cotton producers by $83 million dollars when accrued over an eight year period. This increase in net income would occur through the replacement of inferior cotton varieties, added competition, and more grower choice.

Trade Economic Environment at Risk

Cotton is the single most important textile fiber in the world, accounting for about 40% of all fibers produced. On average, the U.S. produces 20% of the global cotton production, and is the leading supplier in the international market (USDA-ERS 2007). However, the U.S. cotton sector has faced a number of challenges as it shifts from a domestic-oriented market to one focused largely on the global marketplace. Domestic mill demand has declined significantly (in the U.S.) from only a decade ago as competition from imported textile and apparel products has risen dramatically. Meanwhile, export demand has increased rapidly with the recent expansion of global textile production (USDA-ERS 2007).

Structural change has altered the market for U.S. cotton since the 1990s. Shifts in textile trade policy, combined with significant liberalization of China’s cotton production policies, have overturned longstanding global consumption and trade patterns. The result has been to shift the U.S. into a nearly unprecedented dependence on global markets. While about 60% of U.S. cotton was consumed domestically for the last 60 years of the 20th century, exports have significantly surpassed the use of cotton within the U.S. since 2001/02. As a result, U.S. cotton prices are no longer determined solely by domestic supplies and stocks (Isengildina-Massa and MacDonald 2009).

Research using a multi-region computable general equilibrium model assessed the impacts of international Bt cotton adoption on cotton and related sectors of regional economies (Frisvold and Reeves 2007). Productivity gain estimates were based on 2005 adoption rates for Bt cotton in seven countries. Global economic benefits were nearly $1.4 billion, while U.S. benefits were over $200 million. Increased production from Bt cotton adoption led to a 3% reduction in the world cotton price. Employment and trade balances in the textile and apparel sectors increased for China and India, but generally declined elsewhere. Individual countries obtained greater economic welfare gains if they adopted Bt cotton than if they did not adopt it. Non-adopting regions lost cotton market share to adopting regions.

U.S. cotton production reached consecutive records in 2004 and 2005 seasons, with rising global cotton demand providing a home for much of the increased output. However, the growing use of better crop production technologies overseas may narrow the gap between foreign production and mill use, constraining growth in foreign import demand and U.S. cotton exports (USDA-ERS 2007). Meanwhile, debate over trade policy and the sustainability of current farm programs are a source of uncertainty for U.S. agricultural commodities in general and the cotton sector in particular (USDA-ERS 2007).

World cotton production and mill use have soared to record highs in recent years. As yield-enhancing technology has helped reduce the cost of producing cotton around the globe, rising petroleum prices have further shifted relative fiber prices to favor cotton versus polyester. With yield prospects higher than in the past, farmers around the world have been more willing to devote area to cotton, further easing the ability of the global cotton sector to meet growing world demand for textiles (USDA-ERS 2007).

Around the world, new technology has made cotton more attractive to farmers in many countries, while policy reforms in other countries have increased farmers' willingness to plant cotton (USDA-ERS 2007). Outside the U.S., the spread of Bt cotton has recently revolutionized India's cotton sector just as China's adoption has run its course. The cost savings of Bt cotton brought millions of hectares back into cotton production in eastern China and has also helped India's cotton area rebound by more than 1 million hectares (USDA-ERS 2007). Bt cotton has also been adopted in smaller producing countries like Australia, Argentina, Mexico, and South Africa (USDA-ERS 2007).

With technology sustaining global cotton area and improving yields, world cotton production has reached new heights. The world's four largest cotton-producing countries are China, the United States, India, and Pakistan, together accounting for nearly 70% of world production over the last three years (USDA-ERS 2007).

No Action: Trade Economic Environment

The cropping and marketing decisions made by cotton growers are unlikely to be influenced by the selection of this alternative and it is expected that approximately 65% of the cotton produced will continue to be planted with the currently available biotech Bt cotton (USDA-ERS 2010a). U.S. cotton will continue to play a role in global cotton production, and will continue to be a supplier in the international market. How and where that cotton will be used will be subject to global market conditions.

Preferred Alternative: Trade Economic Environment

Syngenta's stewardship agreements with growers will include a term requiring growers to divert COT67B cotton products away from export markets where COT67B cotton seed or its products have not yet received regulatory approval for import ("channeling") (Reed and Stone 2007). Syngenta will communicate these requirements to growers using a wide-ranging grower education campaign. To date, food products derived from COT67B cotton have been assessed as safe by Food Standards Australia-New Zealand (FSANZ 2008). This assessment was re-affirmed in 2009 (FSANZ 2009). Syngenta COT102, which is proposed to be crossed with COT67B cotton to produce the stacked VipCot™ line, has also been assessed as safe for food products in Australia and New Zealand (FSANZ 2006) and for food and feed in Mexico (CERA 2010). Syngenta is also seeking import and production clearances in Japan and Canada (FSANZ 2008).

Global economic benefits from the adoption of Bt cotton were nearly $1.4 billion dollars for the U.S., China, India, Australia, Mexico, Argentina, and South Africa (Frisvold and Reeves 2007). U.S. benefits were over $200 million (Frisvold and Reeves 2007). The adoption of Bt cotton technology has brought millions of hectares of cotton land back into production in China and has revolutionized India's cotton industry (USDA-ERS 2007). Increased global production of Bt cotton adoption led to a 3% reduction in the world cotton price (Frisvold and Reeves 2007). This research also showed that individual countries obtained greater economic gains by adopting Bt cotton technology than if they did not adopt it. Their research also found non-adopting regions to lose cotton market share to the adopting regions. Economic evidence shows that international trade and productivity is enhanced by the adoption of Bt cotton and that these products can be channeled into suitable export markets. A determination of nonregulated status of COT67B cotton will not adversely impact the trade economic environment and could potentially enhance it through the subsequent development and global adoption of the VipCot™ (COT102 x COT67B) line which could provide another lepidopteran insect resistance management choice for growers.

Cumulative Effects: Trade Economic Environment

Current and historic economic evidence indicate that Bt cotton technology enhances international cotton trade and production. Based on the information described above, APHIS has determined that there are no past, present, or reasonable foreseeable actions that in aggregate with effects of the proposed action would negatively impact the trade economic environment.

Social Environment at Risk

U.S. cotton farms and their operators are similar in many respects to those of other crops, but are very different in some key areas. According to data from the 2003 Agricultural Resource Management Survey (ARMS), farms growing cotton tend to be larger than those growing other crops, with above average gross farm incomes, government payments, farm expenses, net incomes, farm asset values, and debt-to-asset ratios (USDA-ERS 2007).

Large farm operations are more likely to be organized into partnerships, and cotton farms are no exception. Partnerships allow operators to pool their resources to achieve economies of scale and to combine their talents in managing the farm operation (USDA-ERS 2007). Cotton farm operators are also more likely to list farming as their occupation and to have completed high school and college compared with other farm operators (USDA-ERS 2007).

Cotton farms in 2003 generated an average net cash income of $127,354 per farm, far more than the average of $11,568 for non-cotton farms in the cotton production regions (USDA-ERS 2007). The higher average income generated on cotton farms is mainly due to their larger farm operations. Cotton farms averaged 1,199 acres per farm, compared with 376 acres for non-cotton farms (USDA-ERS 2007). Cotton farms' average ratio of cash expenses to gross cash income was 71%, compared with 91% for non-cotton farms (USDA-ERS 2007). This means that cotton farms could generate $100 of gross income with less expenditures (i.e., cotton farms can earn $100 of gross income for each $71 of cash expense compared to $91 of cash expense for a non-cotton farm). Larger farms can achieve economies of scale by spreading management, labor, and machinery costs over more units of output, thus gaining an advantage over smaller farms (USDA-ERS 2007).

The household income for cotton producers averaged $142,463 in 2003. In comparison, the household income for non-cotton farms in cotton-producing states averaged $71,447 (USDA-ERS 2007). For most farm households, income from off-farm sources exceeds income from the farm operation. However, cotton producers derive the majority of their family income from the farm. 11% of cotton producers listed nonfarm jobs or businesses as their main occupation, compared with 48% of non-cotton farm operators (USDA-ERS 2007).

No Action: Social Environment

Under the No Action Alternative, there would be no direct impact on the social environment surrounding cotton farming. The cropping and marketing decisions made by cotton growers are unlikely to be influenced by the selection of this alternative.

Preferred Alternative: Social Environment

In 2009, GE insect-resistant cotton occupied 65% of the U.S. cotton acreage (USDA-ERS 2009b). Conventional and GE cotton production occurs on land that is dedicated to crop production and most cotton is planted in fields that have been in crop production for years. The introduced lepidopteran-resistant trait in COT67B cotton is not intended to confer any competitive advantage in terms of weediness or to extend the range of cultivation outside of existing cultivation areas. A determination of nonregulated status of COT67B cotton by APHIS and registration of VipCot™ by EPA is not expected to significantly expand the number of Bt cotton acres, and cotton acreage is expected to remain relatively stable. Overall impacts are similar to the No Action Alternative.

Cumulative Effects: Social Environment

Based on the information described above, APHIS has determined that there are no past, present, or reasonably foreseeable actions that in aggregate with effects of the proposed action would impact the social environment surrounding cotton farming.

Other Cumulative Effects

The potential cumulative effects regarding specific issues have been analyzed and addressed above. No further potential cumulative effects have been identified. Stacked varieties, those crop varieties that may contain more than one trait, are currently found in the marketplace and in agricultural production. In the event of a determination of nonregulated status, COT67B cotton may be combined with non-GE and GE cotton varieties by traditional breeding techniques, resulting in a plant that, for example, may also be resistant to herbicides, but may also have progeny with no transgenes at all. To date, none of the GE cotton varieties that have been deregulated pursuant to Part 340 and the Plant Protection Act and used for commercial cotton production or cotton breeding programs have been subsequently found to pose a plant pest risk. APHIS regulations at 7 CFR part 340 do not provide for Agency oversight of these GE cotton varieties previously deregulated pursuant to Part 340 and the Plant Protection Act, nor over stacked varieties combining deregulated GE varieties unless it can be positively shown that such stacked varieties somehow posed a likely plant pest risk. Further, there is no guarantee that COT67B cotton will be stacked with any particular deregulated GE variety, as company plans and market demands play a significant role in those business decisions. Moreover, COT67B cotton could even be combined with non-GE cotton varieties. Thus, predicting all potential combinations of stacked varieties that could be created using both deregulated GE cotton varieties and also non-GE cotton varieties is hypothetical and purely speculative.

Threatened and Endangered Species

Whether Cry1Ab is sprayed on the plant surface or expressed inside the plant, it is significantly less harmful to non-target organisms than broad-spectrum insecticides (Glare and O'Callaghan 2000; Dively 2005; Head, Moar et al. 2005; Naranjo 2005a; Naranjo 2005b; Romeis, Meissle et al. 2006; Sisterson, Biggs et al. 2007). Bt toxins expressed in transgenic plants for pest management are generally regarded as safe due to their mode of action, specificity, and fast degradation in the environment (Glare and O'Callaghan 2000; Sanvido, Romeis et al. 2007; Romeis, Shelton et al. 2008; US-EPA 2008). The specificity of Bt proteins for certain insect larvae, but not for other insects, birds, and mammals is because of the lack of highly specific receptors for the protein in the midgut (Lemaux 2009). Bt or Cry toxins are toxic when ingested by susceptible larvae (Lemaux 2009). This specifically means that those Cry proteins toxic to lepidopteran insect larvae will have no effects on coleopteran insect (beetle) larvae (Lemaux 2009). The Cry1 proteins are specific for Lepidoptera; Cry2 proteins for Lepidoptera/Diptera; Cry3 proteins for Coleoptera; and Cry4 proteins for Diptera (Reed and Stone 2007).

Research has established that the specific activity of the Cry1 and Cry2 class of insecticidal proteins is dependent upon their binding to specific receptors present in the larval insect midgut (Hofmann, Luthy et al. 1988a; Hofmann, Vanderbruggen et al. 1988b; Lambert, Buysse et al. 1996). The FLCry1Ab protein as expressed in COT67B cotton is not expected to adversely affect other invertebrate or vertebrate organisms, including non-target birds, mammals, and humans based on acute oral toxicity studies (Reed and Stone 2007). APHIS evaluated the laboratory and field studies submitted by Syngenta on representative species that support these expectations (Reed and Stone 2007). The toxicity and specificity of the lepidopteran-specific Cry1Ab protein is associated with their solubilization and proteolytic activation in the larval insect midgut, and their binding to specific cell membrane receptors in the brush border membrane vesicles present in the midgut of susceptible lepidopteran insect larvae. These specific receptors are not present in other insects, birds, mammals, and humans (Sacchi, Parenti et al. 1986; Hofmann, Luthy et al. 1988a; Hofmann, Vanderbruggen et al. 1988b; Van Rie, Jansens et al. 1989; Van Rie, Jansens et al. 1990; Lambert, Buysse et al. 1996; Shimada, Murata et al. 2006a; Shimada, Miyamoto et al. 2006b).

APHIS obtained and reviewed the USFWS Federal List of listed (or proposed) Threatened and Endangered Species (TES) and considered the potential impacts of a determination of nonregulated status of COT67B cotton on these TES organisms (Appendix C). There are currently 21 species of butterflies, moths, and skippers on this list (US-FWS 2011). Since it is not possible to use TES species to quantify sensitivity to FLCry1Ab, APHIS' evaluation focused on the likelihood of whether TES species would be exposed to the toxin expressed in COT67B cotton. Exposure of TES species to FLCry1Ab is only likely if the species occur in the areas where cotton is grown, because cotton plant parts (seeds, pollen, crop debris) are not readily transported long distances without human intervention.

APHIS has thoroughly examined all listed and proposed threatened and endangered lepidopterans and compared their habitats to counties where cotton is grown. APHIS has determined that the breeding habitats of listed Lepidoptera do not overlap cotton growing areas. Therefore it is highly unlikely that these species can be exposed to Bt cotton. Threatened and endangered lepidopterans in the U.S. have very restrictive habitat ranges; and their larvae typically feed on specific host plants, none of which includes cotton, or plants likely to be found in cotton fields. In the states where cotton is cultivated, only California, Florida, and North Carolina have lepidopteran species that are on the Federal TES list (US-FWS 2011), Appendix C: Threatened and Endangered Species). Of these listed species, only the Quino Checkerspot butterfly (*Euphydryas editha quino*), the Kern primrose sphinx moth (*Euproserpinus euterpe*), and the St. Francis' satyr (*Neonympha mitchellii francisci*) are known to occur in counties were cotton is grown. The US-EPA (2002) has already concluded that the habitats of these species do not overlap with cotton fields and their larvae do not feed on cotton and will not be exposed to Cry protein in cotton pollen. The US-EPA (2002) has also concluded that the amounts of cotton pollen that might be deposited on host plants would be negligible, or perhaps none at all, and have no impact. In addition, the amount of pollen that would drift from these cotton plants onto plants fed upon by endangered/threatened species would be very small compared to the levels fed to test species (US-EPA 2002). Syngenta submitted non-target data for test species following incorporation of the FLCry1Ab protein into an artificial diet or through a single high dosage given via gavage (Reed and Stone 2007). The test species included two above-ground arthropods (insidious flower bug (*Orius insidious*) and spotted ladybird beetle (*Coleomegilla maculate*)), two soil dwelling arthropods (rove beetle (*Aleochara bilineata*) and springtail (*Folsomia candida*)), a pollinator (honeybee (*Apis mellifera*)), a bird (Bobwhite quail (*Colinus virginianus*)), a mammal (mouse (*Mus musculus*)), an aquatic invertebrate (water flea (*Daphnia magna*)), and a fish (catfish (*Ictalurus punctatus*)). The data submitted in the petition indicate that no significant adverse effects were observed at the maximum test dose for any of the tested species (Reed and Stone 2007). The three endangered/threatened lepidopteran species known to be found in counties where cotton is grown are discussed below:

- The Quino Checkerspot butterfly is found in coastal sage scrub, open chaparral, juniper woodland, and native grassland (US-FWS 2003). Its primary host plants include: the dwarf plantain (*Plantago erecta*) that occurs in southern California within annual scrub, grassland, and open chaparral plant communities; the wooly plantain (*Plantago patagonica*) that overlaps in distribution with *P. erecta* at lower elevations; the white snapdragon (*Antirrhinum coulterianum*) that appears to be a facultative fire-follower in non-desert areas and in desert plant communities often growing between shrubs; the thread-leaved bird's beak (*Cordylanthus rigidus*), a partially parasitic plant often found at high densities in disturbed areas open slopes and flats of foothill woodlands, chaparral margins, and coniferous forests (US-FWS 2003). Areas where cotton is grown are likely to have been used in agricultural production for many years and thus would not change the habitat that is already unsuitable for the Quino Checkerspot butterfly.

- The Kern Primrose Sphinx moth is also found in California. This moth may occupy habitat near cotton cultivation, known to occur in Kern, Santa Barbara, San Luis Obispo, and Ventura counties, CA (Jump, Longcore et al. 2006; US-FWS 2007a). The larvae feed primarily on their essential host plant *Camissonia* sp. (certain primrose and sun cup species). The host plant evening primrose is found along sandy washes with young alluvial sandy soils that are prone to regular flooding (Jump, Longcore et al. 2006). Since listing, the primary threats to the Kern primrose sphinx moth are agricultural land use practices that degrade the moth habitat, particularly cattle grazing, disking, using pesticides and herbicides, and development. Many agricultural pesticides are specifically designed to target insect larvae (caterpillars) as well as adult moths (US-FWS 2007a). All Kern primrose sphinx moth populations are potentially at risk from this effect. Kern primrose sphinx moth exposure to agricultural pesticides could occur when cotton is grown in and around sandy washes with sandy alluvial soil where moths perform morning basking and where the food plant *Camissonia campestris* or *contorta* (field primrose and evening primrose, respectively) is supported. The potential route of Kern primrose sphinx moth exposure to the Bt protein contained in CO67B would be in the form of pollen deposited on the evening primrose, where the endangered caterpillars feed. Because cotton pollen is heavy and will not be dispersed much from the field (Thies 1953; Hartman, Flocker et al. 1981), it is not likely that the larvae of the Kern primrose sphinx moth will be exposed to the FLCry1Ab protein. Any pollen produced by COT67B cotton plants is not expected to drift onto larval host plants.

- The Saint Francis' satyr is known only in the sand hills of North Carolina, in Cumberland and Hoke Counties (US-FWS 2010a). The species is known only to be located on the government land (Fort Bragg U.S. Army installation). The habitat occupied by this satyr consists primarily of wide, wet meadows dominated by a high diversity of sedges (*Carex*) and other wetland graminoids. Saint Francis' satyr has also been observed in pitcher plant (*Sarracenia flava*) swales, with cane (*Arundinaria tecta*), rough-leaved loosestrife (*Lysimachia asperulaefolia*) and pocosin lily (*Lilium iridollai*). It is unknown whether satyr uses such habitat for reproduction or simply as a dispersal corridor. Adult food habits are not really known, but larva probably feed on *Carex* but this has not been established. Oviposition has been observed on small *Panicum* grass. Areas in Hoke and Cumberland County where cotton is grown are likely to have been used in agricultural production for many years and would be unsuitable habitat for the St. Francis' satyr.

Based on the above information, a determination of nonregulated status of COT67B cotton would have no effect on federally listed threatened or endangered species and species proposed for listing, or on designated critical habitat or habitat proposed for designation. Consequently, a written concurrence or formal consultation with the USFWS is not required for this action.

Consideration of Executive Orders, Standards, and Treaties relating to environmental impacts

Executive Order (EO) 12898 (US-NARA 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," requires federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects. ***EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks,"*** acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) requires each federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

Each alternative was analyzed with respect to EO 12898 and 13045. None of the alternatives are expected to have a disproportionate adverse effect on minorities, low-income populations, or children. Collectively, the available mammalian toxicity, along with the history of safe use of microbial Bt products and other cotton varieties expressing Bt proteins, establishes the safety of cotton line COT67B and its products to humans, including minorities, low income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken. None of the impacts on agricultural practices expected to be associated with deregulation of cotton line COT67B described above are expected to have a disproportionate adverse effect on minorities, low income populations, or children. As noted above, the cultivation of previously deregulated cotton varieties with similar insect-resistant traits has been associated with a decrease and/or shift in pesticide applications for those who adopt these varieties that is either favorable or neutral with respect to environmental and human toxicity. If pesticide applications are reduced, there may be a beneficial effect on children and low income populations that might be exposed to the chemicals. These populations might include migrant farm workers and their families, and other rural dwelling individuals who are exposed to pesticides through ground-water contamination or other means of exposure. It is expected that US-EPA and USDA Economic Research Service would monitor the use of this product to determine impacts on agricultural practices such as chemical use as they have done previously for Bt products.

EO 1311 (US-NARA 2010), "Invasive Species," states that federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause. Non-engineered cotton as well as other Bt and herbicide-tolerant cotton varieties are widely grown in the U.S. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by APHIS, COT67B cotton plants are sufficiently similar in fitness characteristics to other cotton varieties currently grown and are not expected to become weedy or invasive (USDA-APHIS 2009).

EO 13186 (US-NARA 2010), "Responsibilities of Federal Agencies to Protect Migratory Birds," states that federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations. Data submitted by the applicant has shown no difference in compositional and nutritional quality of COT67B cotton compared to other Bt cotton or non-Bt cotton, apart from the presence of FLCry1Ab protein. The migratory birds that occasionally forage in cotton fields are unlikely to ingest high amounts of COT67B cotton seed as cotton seed is limited by harvest. The introduction of Bt cotton has had a positive effect on bird counts in North American cotton fields. Comparing bird populations from 1991 to 1995 and 1996 to 2000 showed that bird counts increased and were positively correlated with Bt cotton adoption, the reduction in insecticide use and the relative presence of the species in cotton fields prior to the introduction of Bt cotton (US-EPA 2001). Broad-spectrum insecticides, which are considered to be one of the largest impediments to agroecosystem biodiversity, have been reduced by the commercial use of Bt cotton (Croft 1990; USDA-NASS 2008; Benbrook 2009). Since the introduction of Bt cotton there has been a two thirds decrease for the most toxic insecticides products to birds and fish, and a one third decrease for the most toxic products to humans (US-EPA 2001). Additionally, there have been no reported adverse effects of Bt cotton on non-target insects which can serve as a food source for birds. Collectively, the weight of considerable field studies with Bt crops, including Bt cotton, have consistently demonstrated that Bt crops have only minor effects, if any, on a large number of non-target insect taxa which is very small in comparison to the use of broad-spectrum insecticides (Naranjo 2009).

Based on APHIS' assessment of COT67B cotton it is unlikely that a determination of nonregulated status of this cotton variety will have a negative effect on migratory bird populations.

International Implications

EO 12114 (US-NARA 2010), "Environmental Effects Abroad of Major Federal Actions" requires federal officials to take into consideration any potential environmental effects outside the U.S., its territories, and possessions that result from actions being taken. APHIS has given this careful consideration and does not expect a significant environmental impact outside the U.S.in the event of a determination of nonregulated status of COT67B cotton. It should be noted that all the considerable, existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new cotton cultivars internationally, apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340. Any international trade of COT67B cotton subsequent to a determination of nonregulated status of the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the ***International Plant Protection Convention*** (IPPC 2010).

The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds. The IPPC set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (172 countries as of March 2010). In April 2004, a standard for pest risk analysis (PRA) of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The Cartagena Protocol on Biosafety is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which includes those modified through biotechnology. The Protocol came into force on September 11, 2003, and 157 countries are Parties to it as of March, 2010 (CBD 2010). Although the U.S. is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with domestic regulations that importing countries that are Parties to the Protocol have put in place to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol, and the required documentation.

LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (NBII 2010). These data will be available to the Biosafety Clearinghouse. APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the Organization for Economic Cooperation and Development. NAPPO has completed three modules of a standard titled, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO 2009).

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

Compliance with Clean Water Act and Clean Air Act

This Environmental Assessment evaluated the changes in cotton production due to the unrestricted use of COT67B cotton. COT67B cotton will not lead to the increased production of cotton in U.S. agriculture. There is no expected change in water use due to the production of COT67B cotton compared to current cotton seed and cotton production regimes, nor is it expected that air quality will change because of production of COT67B cotton.

Impacts on Unique Characteristics of Geographic 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 COT67B cotton. 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; do not cause any alterations of 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 non regulated status of COT67B cotton. The product will be deployed on agricultural land currently suitable for production of cotton, will replace existing varieties, and is not expected to increase the acreage of cotton production. Progeny of this variety that express the identified traits of the COT67B cotton will be retained by Syngenta or licensed users. This action would not convert land use 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 COT67B cotton 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 non regulated status of COT67B cotton, 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 cotton production sites.

National Historic Preservation Act (NHPA) of 1966 as amended. The NHPA of 1966, and its implementing regulations (36 CFR 800), requires federal agencies to: 1) determine whether activities they propose constitute "undertakings" that has the potential to cause effects on historic properties and, 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e. State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate. This action will not adversely impact cultural resources on tribal properties. Any farming activity 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.

This action 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 historical resources. This action is limited to a determination of non regulated status of COT67B cotton. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants 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. This action 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. There is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices such as the use of tractors and other mechanical equipment are in close proximity 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.

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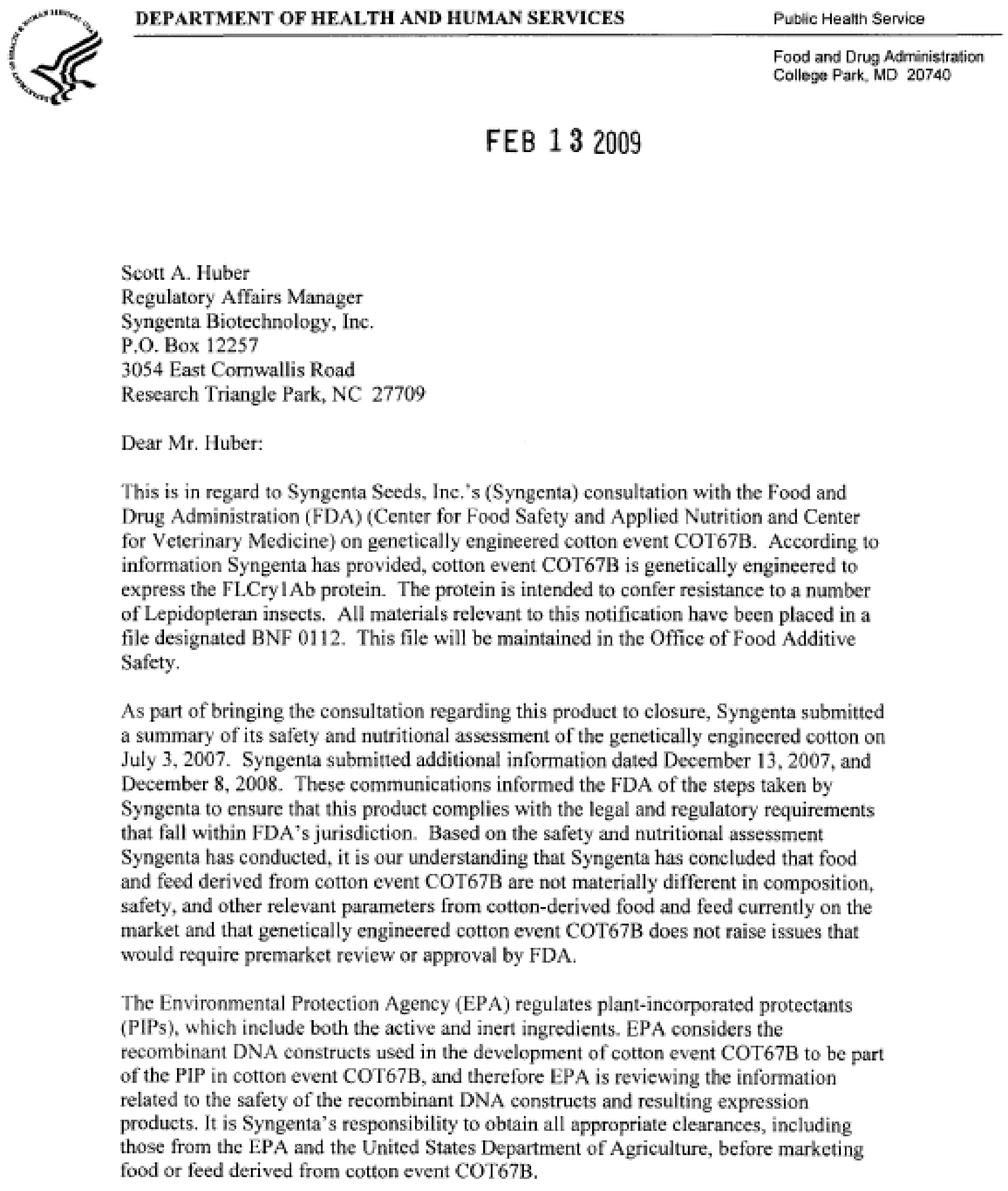
Appendix A: BNF 0112



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD 20740

FEB 13 2009

Scott A. Huber
Regulatory Affairs Manager
Syngenta Biotechnology, Inc.
P.O. Box 12257
3054 East Cornwallis Road
Research Triangle Park, NC 27709

Dear Mr. Huber:

This is in regard to Syngenta Seeds, Inc.'s (Syngenta) consultation with the Food and Drug Administration (FDA) (Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine) on genetically engineered cotton event COT67B. According to information Syngenta has provided, cotton event COT67B is genetically engineered to express the FLCry1Ab protein. The protein is intended to confer resistance to a number of Lepidopteran insects. All materials relevant to this notification have been placed in a file designated BNF 0112. This file will be maintained in the Office of Food Additive Safety.

As part of bringing the consultation regarding this product to closure, Syngenta submitted a summary of its safety and nutritional assessment of the genetically engineered cotton on July 3, 2007. Syngenta submitted additional information dated December 13, 2007, and December 8, 2008. These communications informed the FDA of the steps taken by Syngenta to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Syngenta has conducted, it is our understanding that Syngenta has concluded that food and feed derived from cotton event COT67B are not materially different in composition, safety, and other relevant parameters from cotton-derived food and feed currently on the market and that genetically engineered cotton event COT67B does not raise issues that would require premarket review or approval by FDA.

The Environmental Protection Agency (EPA) regulates plant-incorporated protectants (PIPs), which include both the active and inert ingredients. EPA considers the recombinant DNA constructs used in the development of cotton event COT67B to be part of the PIP in cotton event COT67B, and therefore EPA is reviewing the information related to the safety of the recombinant DNA constructs and resulting expression products. It is Syngenta's responsibility to obtain all appropriate clearances, including those from the EPA and the United States Department of Agriculture, before marketing food or feed derived from cotton event COT67B.

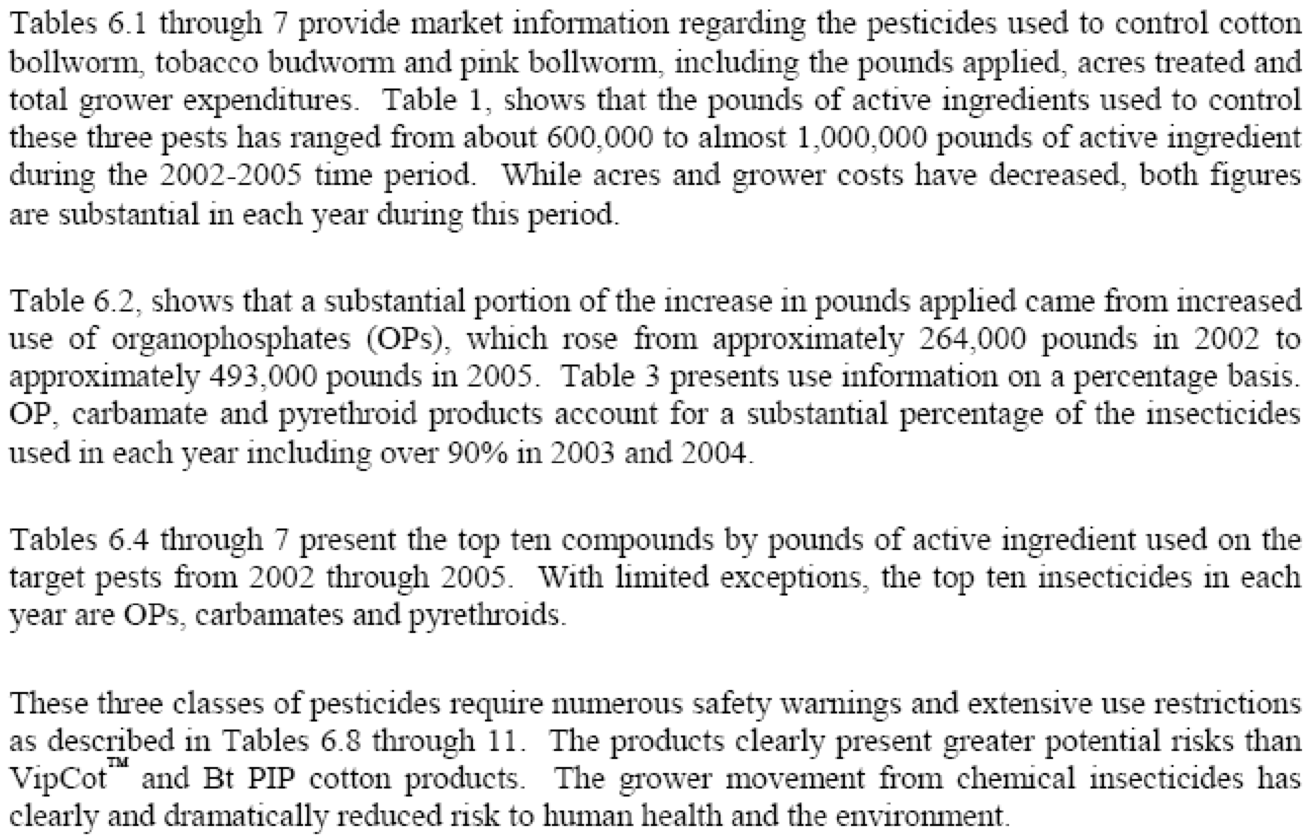
Based on the information Syngenta has presented to FDA, we have no further questions concerning food and feed derived from cotton event COT67B at this time. However, as you are aware, it is Syngenta's continued responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

Laura M Tarantino

Laura M. Tarantino, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

Appendix B: Pesticide Usage to Treat Cotton Bollworm, Tobacco Budworm, and Pink Bollworm (Submitted by Syngenta in the petition, pages 310-314)



Tables 6.1 through 7 provide market information regarding the pesticides used to control cotton bollworm, tobacco budworm and pink bollworm, including the pounds applied, acres treated and total grower expenditures. Table 1, shows that the pounds of active ingredients used to control these three pests has ranged from about 600,000 to almost 1,000,000 pounds of active ingredient during the 2002-2005 time period. While acres and grower costs have decreased, both figures are substantial in each year during this period.

Table 6.2, shows that a substantial portion of the increase in pounds applied came from increased use of organophosphates (OPs), which rose from approximately 264,000 pounds in 2002 to approximately 493,000 pounds in 2005. Table 3 presents use information on a percentage basis. OP, carbamate and pyrethroid products account for a substantial percentage of the insecticides used in each year including over 90% in 2003 and 2004.

Tables 6.4 through 7 present the top ten compounds by pounds of active ingredient used on the target pests from 2002 through 2005. With limited exceptions, the top ten insecticides in each year are OPs, carbamates and pyrethroids.

These three classes of pesticides require numerous safety warnings and extensive use restrictions as described in Tables 6.8 through 11. The products clearly present greater potential risks than VipCot™ and Bt PIP cotton products. The grower movement from chemical insecticides has clearly and dramatically reduced risk to human health and the environment.

TABLE 6.1

USAGE INFORMATION FOR PESTICIDES USED TO TREAT COTTON BOLLWORM, TOBACCO BUDWORM, AND PINK BOLLWORM

Year	**Pounds**	**Acres Treated**	**Expenditure**
2002	724,737	9,626,617	$56,113,616
2003	592,575	5,277,667	$26,675,567
2004	596,876	6,090,454	$31,966,188
2005	966,611	4,456,605	$24,667,171

TABLE 6.2

USE BY CHEMICAL CLASS FOR PESTICIDES USED TO TREAT COTTON BOLLWORM, TOBACCO BUDWORM, AND PINK BOLLWORM

Chemical Class	**2002**		**2003**		**2004**		**2005**	
	Pounds AI	**Acres Treated**	Pounds AI	**Acres Treated**	Pounds AI	**Acres Treated**	Pounds AI	**Acres Treated**
OP	264,021	511,685	394,775	742,145	285,866	723,093	493,513	816,657
Carbamate	98,892	199,121	37,586	136,959	95,445	180,273	30,768	86,644
Pyrethroid	241,174	6,924,048	135,302	3,962,964	180,726	4,445,635	106,999	2,870,133
Other	120,650	1,991,763	24,912	435,599	34,839	741,453	335,331	683,171
Grand Total	**724,737**	**9,626,617**	**592,575**	**5,277,667**	**596,876**	**6,090,454**	**966,611**	**4,456,605**

TABLE 6.3

PERCENT OF USE BY CHEMICAL CLASS FOR PESTICIDES USED TO TREAT BOLLWORM, BUDWORM, AND PINK BOLLWORM

Chemical Class	2002		2003		2004		2005	
	Pounds AI	Acres Treated	Pounds AI	Acres Treated	Pounds AI	Acres Treated	Pounds AI	Acres Treated
OP	36%	5%	67%	14%	48%	12%	51%	18%
Carbamate	14%	2%	6%	3%	16%	3%	3%	2%
Pyrethroid	33%	72%	23%	75%	30%	73%	11%	64%
Other	17%	21%	4%	8%	6%	12%	35%	15%
Grand Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**

TABLE 6.4

MAJOR COTTON BOLLWORM, TOBACCO BUDWORM, AND PINK BOLLWORM PESTICIDES BY POUNDS OF ACTIVE INGREDIENT – 2002

Compound	Chemical Class	Pounds	Acres Treated	Expenditures
Spinosyn	Other	97,659	1,693,144	$16,500,447
Acephate	OP	91,305	209,811	$998,332
Profenofos	OP	67,051	109,321	$948,109
Cyfluthrin	Pyrethroid	59,525	1,828,023	$9,731,280
Zeta-cypermethrin	Pyrethroid	55,005	1,440,416	$5,946,676
Cyhalothrin-lambda	Pyrethroid	52,726	1,687,917	$8,505,838
Aldicarb	Carbamate	41,805	52,933	$840,543
Disulfoton	OP	35,612	59,354	$265,907
Phorate	OP	28,250	19,425	$296,622
Cypermethrin	Pyrethroid	27,664	476,407	$1,748,985
Total		**556,602**	**7,576,751**	**45,782,739**

TABLE 6.5

MAJOR COTTON BOLLWORM, TOBACCO BUDWORM, AND PINK BOLLWORM PESTICIDES BY POUNDS OF ACTIVE INGREDIENT – 2003

Compound	Chemical Class	Pounds	Acres Treated	Expenditures
Acephate	OP	142,993	346,118	$1,441,128
Profenofos	OP	121,691	137,277	$1,305,772
Cyhalothrin-lambda	Pyrethroid	44,845	1,494,299	$7,282,063
Methyl parathion	OP	44,377	57,101	$248,292
Chlorpyrifos	OP	34,482	41,523	$445,435
Azinphos-methyl	OP	31,246	98,687	$488,836
Cyfluthrin	Pyrethroid	30,793	926,580	$4,779,941
Cypermethrin	Pyrethroid	24,560	478,520	$1,369,898
Zeta-cypermethrin	Pyrethroid	21,885	633,855	$2,957,471
Oxamyl	Carbamate	17,587	92,394	$331,095
Total		**514,459**	**4,306,354**	**20,649,931**

TABLE 6.6

MAJOR COTTON BOLLWORM, TOBACCO BUDWORM, AND PINK BOLLWORM PESTICIDES BY POUNDS OF ACTIVE INGREDIENT – 2004

Compound	Chemical Class	Pounds	Acres Treated	Expenditures
Dicrotophos	OP	148,436	361,654	$1,550,591
Acephate	OP	109,598	289,974	$1,287,601
Cypermethrin	Pyrethroid	82,301	1,072,143	$4,678,681
Aldicarb	Carbamate	59,635	72,413	$1,169,880
Cyfluthrin	Pyrethroid	40,042	1,229,031	$6,534,719
Cyhalothrin-lambda	Pyrethroid	38,803	1,253,028	$6,100,081
Oxamyl	Carbamate	21,524	69,237	$409,896
Zeta-cypermethrin	Pyrethroid	12,147	533,481	$2,268,945
Thiodicarb	Carbamate	11,357	28,699	$141,963
Profenofos	OP	10,451	33,515	$107,518
Total		**534,294**	**4,943,175**	**24,249,875**

TABLE 6.7

MAJOR COTTON BOLLWORM, TOBACCO BUDWORM, AND PINK BOLLWORM PESTICIDES BY POUNDS OF ACTIVE INGREDIENT – 2005

Compound	Chemical Class	Pounds	Acres Treated	Expenditures
Acephate	OP	298,338	443,523	$3,654,391
Dichloropropene	Other	250,749	10,156	$255,715
Malathion	OP	91,955	74,663	$255,973
Dicrotophos	OP	62,333	209,482	$692,486
Chloropicrin	Other	53,014	10,156	$79,429
Cypermethrin	Pyrethroid	41,712	653,834	$2,804,910
Aldicarb	Carbamate	27,937	63,161	$564,487
Cyhalothrin-lambda	Pyrethroid	23,894	793,507	$3,877,601
Cyfluthrin	Pyrethroid	21,369	611,304	$3,100,233
Methyl parathion	OP	15,234	30,468	$104,732
Total		**886,535**	**2,900,254**	**15,389,957**

Appendix C: Threatened and Endangered Species

Distribution, habitat, and food sources of threatened and endangered Lepidoptera (US-FWS 2010a)

Given the specificity of activity of the Cry1A proteins, species outside the insect order Lepidoptera should not be affected (Glare and O'Callaghan 2000). APHIS has thoroughly examined all FWS threatened and endangered lepidopteran species to determine if there could be possible effects from the proteins found in COT67B cotton. Threatened and endangered lepidopterans in the U.S. have restrictive habitats; and their larvae typically feed on specific host plants, none of which includes cotton or its sexually compatible relatives, or plants expected to be found in cultivated agricultural land. Furthermore, an examination of county distribution of endangered lepidopterans shows that most are not known to occur in counties where cotton is grown, with the exception of the Kern primrose sphinx moth, the Quino Checkerspot butterfly and the Saint Francis satyr butterfly. The US-EPA (2002) has already concluded that the habitats of these species do not overlap with cotton fields and their larvae do not feed on cotton. Pollen dispersal due to wind is considered insignificant because cotton pollen is sticky and heavy (Khan and Afzal 1950; Thies 1953). The US-EPA (2002) has concluded that the amounts of cotton pollen that might be deposited on host plants of these species would be negligible, or perhaps none at all, and have no impact. If pollen were to deposit on host plants, the amount of pollen that would drift from these cotton plants onto plants fed upon by endangered/threatened species, would be very small compared to the levels fed to test species (US-EPA 2002; Reed and Stone 2007; USDA-APHIS 2009).

Butterfly, bay checkerspot *Euphydryas editha bayensis*	The Bay checkerspot butterfly (*Euphydryas editha bayensis*) is restricted to serpentine outcrops near San Francisco Bay, in Santa Clara and San Matao, CA. The primary constituent elements of the habitat for the bay checkerspot are one or more of the following: stands of *Plantago erecta*, *Castilleja exserta*, or *Castilleja densiflora*; spring flowers providing nectar; pollinators of the bay checkerspot's food and nectar plants; soils derived from serpentinic rock; and space for dispersal between habitable areas (US-FWS 2001a; NatureServe 2010a).
Butterfly, Behren's silverspot *Speyeria zerene behrensii*	Currently inhabits one site in southern Mendocino County, CA. The Behren's silverspot butterfly inhabits coastal prairie habitat that contains *Viola adunca* (early blue violet), the larval host plant, adult nectar sources, and adult courtship areas (US-FWS 2004; NatureServe 2010b).
Butterfly, callippe silverspot *Speyeria callippe callippe*	Is found in native grassland and associated habitats in the San Francisco Bay area, CA. The females lay their eggs on the dry remains of the larvae foodplant, Johnny jump-up (*Viola pedunculata*), or on the surrounding debris (US-FWS 2010b).
Butterfly, El Segundo blue *Euphilotes battoides allyni*	Now limited to one 302-acre parcel (owned by the Los Angeles Airport) and one 2-acre parcel (owned by the Standard Oil Company of California) in El Segundo Dunes, Los Angeles County, CA in sand dunes with its larval and adult host plant *Eriogonum parvifolium* (US-FWS 2007b; NatureServe 2010c).

Butterfly, Fender's blue *Icaricia icarioides fenderi*	Restricted primarily to the Willamette Valley of Oregon, in upland prairies in Douglas, Benton, Lane, Linn, Polk, and Yamhill Counties, OR and Lewis County, WA. Dry, fescue prairies make up the majority of habitat. Larvae feed exclusively on certain lupine, mainly *Lupinus sulphereus* var. *kincaid* occasionally *L. laxiflorus* and *albicauliss* (US-FWS 2000a; NatureServe 2010d).
Butterfly, Karner blue *Lycaeides melissa samuelis*	Requires the wild lupine (*Lupinus perennis*) that occurs in Illinois, Indiana, Michigan, Minnesota, New Hampshire, New York, Ohio, and Wisconsin to deposit eggs for larval food. In eastern New York and New Hampshire, habitat typically is in sandplain communities, such as grassy openings within very dry, sandy pitch pine/scrub oak barrens. In the Midwest, the habitat is also dry and sandy, including oak savanna and jack pine barrens, and less often dune communities. Within the overall community remnant inhabited by a metapopulation, any patch of foodplant in open to semi-shaded setting is likely to be used. Females lay eggs on or near wild lupine plants, and main requirement seems to be thousands of stems of lupine in the short term (NatureServe 2010e).
Butterfly, Lange's metalmark *Apodemia mormo langei*	Is currently found only at Antioch Sand Dunes in Contra Costa County, CA, as part of the Antioch Dunes National Wildlife Refuge. The larvae are known to feed only on buckwheat (*Eriogonum nudum* ssp. *auriculatum*) (US-FWS 2008).
Butterfly, lotis blue *Lycaeides argyrognomon lotis*	Is found only in Mendocino County, CA in a sphagnum-willow bog of about five acres in size. Larvae probably feed on *Lotus formosissimus*; if not then presumably some other legume such as *Lathyrus vestitus bolanderi*. If not a legume, some species of Ericaceae would seem most likely (NatureServe 2010f).
Butterfly, mission blue *Icaricia icarioides missionensis*	Restricted to a few sites in about three populations, including San Bruno Mountain in San Mateo County, Twin Peaks in San Francisco, and the vicinity of Skyline College in San Mateo County, CA. Limited to grasslands, with its larval hosts, *Lupinus albifrons*, *L. varicolor*, and *L. formosus* (NatureServe 2010g).
Butterfly, Mitchell's satyr *Neonympha mitchellii mitchellii*	Known to occur in Indiana, Michigan, and Ohio in northern limestone wetlands. Females oviposit on a variety of small forbs and sedges (e.g., *Thelypeteris palustris*, and *Carex* sp.) seedlings and individuals do not move great distances (US-FWS 1997; Szymanski, Shuey et al. 2004; Barton and Bach 2005; US-FWS 2010c).
Butterfly, Myrtle's silverspot *Speyeria zerene myrtleae*	Marin, San Mateo, and Sonoma, CA. Myrtle’s silverspot inhabits coastal dunes, coastal prairie, and coastal scrub at elevations ranging from sea level to 300 meters (1,000 feet), and as far as 5 kilometers (3 miles) inland. The larval food plant is *Viola adunca* and possibly other *Viola* species (US-FWS 1998).

Butterfly, Oregon silverspot *Speyeria zerene hippolyta*	Known to occur in Del Norte County, CA; in Clatsop, Lane, Lincoln, Tillamook and Counties, OR and Pacific County, WA in salt-spray meadows with its host *Viola adunca* (US-FWS 2001b).
Butterfly, Palos Verdes blue *Glaucopsyche lygdamus palosverdesensis*	Occurs only in Los Angeles County, CA, confined to coastal sage scrub community and is dependent on two known host plants, locoweed (*Astragalus trichopodus* var. *lonchus*, also known as Santa Barbara milkvetch) and common deerweed (*Lotus scoparius*) (US-FWS 1980; Butterfly Conservation Initiative 2006a).
Butterfly, Quino checkerspot *Euphydryas editha quino (=E. e. wrighti)*	Is known to occur in the San Diego National Wildlife Refuge, in Riverside and San Diego Counties, CA, in Chaparral, coastal sage scrub, with primary host plants: dwarf plantain (*Plantago erecta*), wooly plantain (*Plantago patagonica*), the white snapdragon (*Antirrhinum coulterianum*), thread-leaved bird's beak (*Cordylanthus rigidus*) (US-FWS 2003; US-FWS 2010d).
Butterfly, Saint Francis' satyr *Neonympha mitchellii francisci*	Located in one site in NC sandhills, may be restricted to artillery impact areas at Fort Bragg, military installation in North Carolina. Known only from a few sedge wetlands (NatureServe 2010h).
Butterfly, San Bruno elfin *Callophrys mossii bayensis*	Restricted to Contra Costa, Marin and San Mateo Counties, CA. The San Bruno elfin is found in coastal mountains near San Francisco Bay, in the fog-belt of steep north facing slopes that receive little direct sunlight. It lives near prolific growths of the larval food plant, stonecrop (*Sedum spathulifolium*), which is a low-growing succulent. Stonecrop is associated with rocky outcrops that occur at 900-1075 feet elevation (Butterfly Conservation Initiative 2006b; US-FWS 2010e; NatureServe 2010i).
Butterfly, Schaus swallowtail *Heraclides aristodemus ponceanus*	Restricted to Dade and Monroe Counties, FL. Habitat is tropical hardwood hammocks and their edges with the larval foodplant which is torchwood *Amyris elemifera*. Adults do stray into other nearby areas. Larvae feed mainly on *Amyris elemifera* and occasionally on other Rutaceae (US-FWS 1999b; NatureServe 2010j).
Butterfly, Smith's blue *Euphilotes enoptes smithi*	Restricted to Monterey, Santa Cruz, and San Mateo counties, CA. Coastal and inland sand dunes and steep slopes along the coast where coastal sand dune strand vegetation dominates. One population found in chaparral-woodland dominated area. Also has been found in serpentine grassland area. Area must contain seacliff and coastal buckwheat. An undescribed ecotype of *E. latifolium* (coastal buckwheat) is used by the females for oviposition as well as providing food for the larvae (NatureServe 2010k).
Butterfly, Uncompahgre fritillary *Boloria acrocnema*	Restricted to: Gunnison, Hinsdale, and Chaffee counties in CO; isolated alpine habitats in the San Juan Mountains of southwestern Colorado. Habitat is moist alpine slopes above 12,000 feet with extensive snow willow (*Salix nivalis)* (US-FWS 1994; NatureServe 2010l).
Moth, Blackburn's sphinx *Manduca blackburni*	Tod , Maui and is more or less restricted to tracts of dry forest. Inhabits mostly lowland dry forests and shrub lands

	where the larvae feed on native and a few introduced SOLANACEAE (tobacco family). However, adults do wander and larvae have turned up on cultivated Solanaceae. Larvae of Blackburn's sphinx moth feed on plants in the nightshade family (Solanaceae). The natural host plants are native shrubs in the genus Solanum (popolo), and the native tree, Nothocestrum latifolium (`aiea), on which the larvae consume leaves, stems, flowers, and buds. However, many of the host plants recorded for this species are not native to the Hawaiian Islands, and include *Nicotiana tabacum* (commercial tobacco), Nicotiana glauca (tree tobacco), *Solanum melongena* (eggplant), *Lycopersicon esculentum* (tomato), and possibly *Datura stramonium* (Jimson weed) (US-FWS 2000b; US-FWS 2010f; NatureServe 2010m).
Moth, Kern primrose sphinx *Euproserpinus euterpe*	Found in Kern, San Luis Obispo, Santa Barbara, and Ventura Counties, CA. The most important habitat factor is presence of the larval foodplant, which is *Camissonia* sp. Some of the habitat has been disked, and some roads and development are within the population areas. Sheep grazing has contributed to habitat destruction (US-FWS 2007a).