Monsanto Company Petition (09-SY-194U) for Determination of Non-regulated Status of Event MON 87701

OECD Unique Identifier: MON-87701-2

Draft Environmental Assessment

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Agency Contact
Cindy Eck
Biotechnology Regulatory Services
4700 River Road
USDA, APHIS
Riverdale, MD 20737
Fax: (301) 734-8669

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ACRONYMS AND ABBREVIATIONS

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

ACRONYMS AND ABBREVIATIONS

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

1 PURPOSE AND NEED

1.1 REGULATORY AUTHORITY

"Protecting American agriculture" is the basic charge of the United States 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 (U.S.) 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 U.S. Food and Drug Administration (FDA), and the U.S. 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 (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. All food and feed derived from GE crops currently on the market in the U.S. 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* (FR) 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 (PIPs), like Cry1Ac expressing soybeans, 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.

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

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

1.2 Petition for Determination of Nonregulated Status: Monsanto 87701 Soybean

The Monsanto Company (Monsanto) of St. Louis, MO, submitted a petition (APHIS Number 09-082-01p) to APHIS in 2009 for determination of nonregulated status for Event MON 87701 soybean that expresses a Cry1Ac protein to protect it from lepidopteran insect damage. In the event of a determination of nonregulated status, the nonregulated status for MON 87707 would include MON 87701, any progeny derived from crosses between MON 87701 and conventional soybean, and crosses of MON 87701 with other biotechnology-derived soybean that has been deregulated pursuant to Part 340 and the Plant Protection Act. Event MON 87701 is currently regulated under 7

CFR part 340. Interstate movements and field trials of MON 87701 have been conducted under permits issued or notifications acknowledged by APHIS since 2002. Data resulting from these field trials are described in the Monsanto Company petition.

1.3 Purpose of Product

MON 87701 soybean expresses an insecticidal protein, Cry1Ac, and was developed for the South American soybean market. In this region, the lepidopteran pest, *Epinotia aporema*, causes severe economic damage through eating of soybean plants (Higley and Boethel, 1994). Because it bores into the stem, larvae are protected from insecticidal sprays. Control of these insects requires high levels of systemic insecticide treatment. To be effective, the application of these insecticides needs to be carefully timed (Higley and Boethel, 1994).

Cry1Ac is a lepidopteran-specific (e.g., *E. aporema*) insecticide derived from the soil bacterium, *Bacillus thuringiensis* (Bt). This protein does not affect other orders of insects or animals (van Frankenhuyzen, 2009). Although initially developed for the South American soybean market, U.S. growers may eventually adopt MON 87701 for commercial production if Monsanto obtains appropriate registrations from the EPA (Monsanto, 2010). Currently, MON 87701 has only received EPA approval for breeding and seed multiplication activities for a total of 15,000 acres in Georgia, South Carolina, North Carolina, Virginia, and Maryland with no more than 1,000 acres per county per year. This type of EPA registration precludes commercial sale of MON 87701 in the U.S.

1.4 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 GE 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 GE plants such as MON 87701 soybean. 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.

APHIS has prepared this environmental assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality's NEPA regulations (40 CFR parts 1500-1508, 7 CFR part 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 MON 87701 soybean.

1.5 Coordinated Framework Review

1.5.1 Environmental Protection Agency

The EPA regulates plant-incorporated protectants (PIPs) under FIFRA (7 U.S.C. 136 *et seq.*) and certain biological control organisms under TSCA (15 U.S.C. 53 *et seq.*). Before planting a crop containing a PIP, a company must seek an experimental use permit from EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 registration with EPA. In September 2010, Monsanto received EPA registration for MON 87701 for seed increase, only, with the following terms and conditions (US-EPA, 2010a):

1) The subject registration will automatically expire on midnight September 30, 2013.

2) The subject registration is limited to seed increase and to a total of 15,000 acres per year in the States of Georgia, South Carolina, North Carolina, Virginia, and Maryland with no more than 1,000 acres per county per year.

3) Monsanto must submit IRM monitoring and remedial action plans to EPA for approval by January 31, 2011, and reports on such annually by August 31st.

4) Monsanto must provide EPA annual reports on the acreage and States where MON 87701 has been grown by January 31st.

5) While exposure is expected to be very low in aquatic habitats, and effects on freshwater invertebrates are not expected, Monsanto must do the following to extend the expiration date of this registration. Namely, Monsanto must submit a 7-10 day freshwater invertebrate toxicity study or otherwise adequately address aquatic invertebrate issues raised by Rosi- Marshall, et al. in 2007 regarding the leaf shredding (caddis fly) trichopteran, *Lepidostoma liba* (US-EPA, 2010a).

1.5.2 Food and Drug Administration

FDA regulates GE organisms under the authority of the FFDCA (21 U.S.C. 301 *et seq.*). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those GE, in the *Federal Register* on May 29, 1992 (57 FR 22984). Under this policy, FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of bioengineered food.

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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).

MON 87701 is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced through genetic engineering. The Monsanto Company initiated the consultation process with FDA for the commercial distribution of MON 87701 and submitted a safety and nutritional assessment of food and feed derived from MON 87701 to the FDA on May 28, 2009 (BNF No. 000119) (FDA, 2010a). FDA evaluated the submission and responded to the developer by letter on August 18, 2010 (FDA, 2010b). Based on the information the Monsanto Company submitted, and as of August 5, 2010, FDA has no further questions regarding MON 87701 soybean.

1.6 Public Involvement

APHIS routinely seeks public comment on draft EAs 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 the public concerns as well as issues raised in public comments submitted for other EAs of GE organisms, concerns raised in lawsuits, as well as those issues of concern that have been raised by various stakeholders. These issues, including those regarding the agricultural production of soybeans using various production methods and the environmental and food/feed safety of GE plants were addressed to analyze the potential environmental impacts of MON 87701 soybean.

This EA, the petition submitted by Monsanto, and APHIS's PPRA 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 MON 87701 and to assist APHIS in determining whether an Environmental Impact Statement (EIS) is required prior to the determination decision of the regulated status of this soybean variety.

1.7 Issues Considered

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

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

Environmental Considerations:
- Water Resources
- Soil

- Air Quality
- Climate Change
- Animals
- Plants
- Gene Flow
- Microorganisms
- Biological Diversity

Human Health Considerations:

- Public Health
- Worker Safety

Livestock Health Considerations:

- Livestock Health/Animal Feed

Socioeconomic Considerations:

- Domestic Economic Environment
- Organic Farming
- Trade Economic Environment

2 AFFECTED ENVIRONMENT

2.1 Agricultural Production of Soybean

Soybean (*Glycine max* (L.) Merr.) is an economically important leguminous crop, providing oil and protein. Soybean plants are grown for their seed, which is further processed to yield oil and meal. Soybean is ranked number one in oil production (56 percent) among the major oil seed crops production in the world (ASA, 2011). Other expanding uses for soybeans in the U.S. include soy biodiesel, animal agriculture, exports, and edible soybean oil (USB, 2007).

2.1.1 Acreage and Area of Soybean Production

The U.S. has a land mass of about 2.3 billion acres, with approximately 440 million acres (nearly 20 percent) utilized as cropland in 2002 (Fernandez-Cornejo and Caswell, 2006). U.S. cropland use has remained relatively consistent since World War II, although it has declined over the last few decades (Lubowski et al., 2006). In general, cropland in the Atlantic Coastal states (i.e., Georgia, South Carolina, North Carolina, Virginia, and Maryland) has declined during the last half of the 20th century and this trend is likely to continue (Figure 1). It should be noted that not all cropland is used for planting crops; some is fallow and some has been converted to pasture.

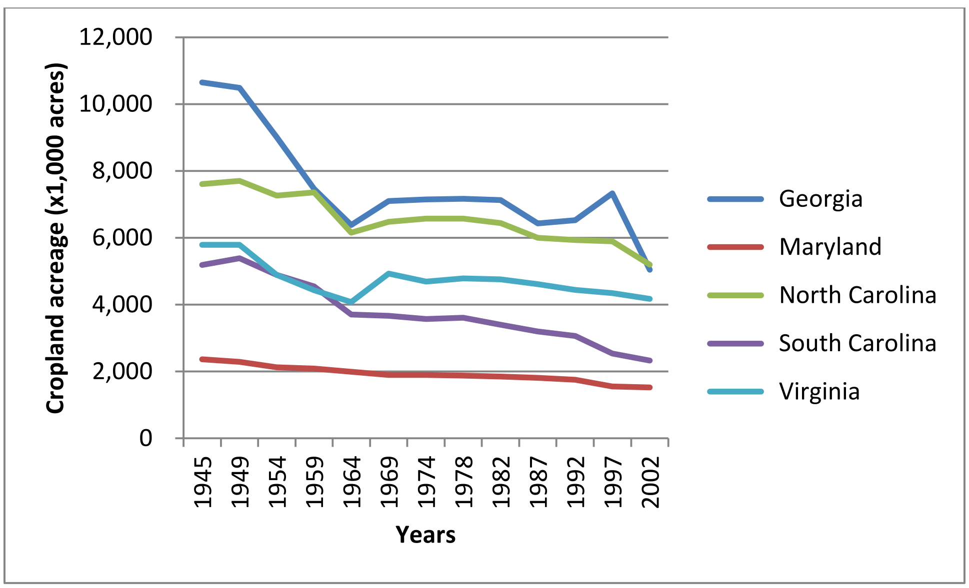

Figure 1. U.S. cropland acreage trends, 1945-2002

Source: (USDA-ERS, 2011b).

Soybean cultivation acreage has trended slightly upward over the last decade. However, there are fluctuations in the total soybean planted from year to year (USDA-NASS, 2011b). In 2010, approximately 3.3 million acres of soybeans were planted in the Atlantic Coastal states where MON 87701 has received EPA approval (Table 1).

Of these Atlantic Coastal states, North Carolina harvests the most acres of soybeans each year. Production in these states peaked in the 1980's (Figure 2). Over the past decade there has been a small upward trend in acres of soybeans harvested in these regions, although the acreage is still below the peak from the 1980's.

Table 1. Soybean production in the U.S. Atlantic Coastal states in 2010[1].

State[2]	Area harvested (x 1,000 Acres)	Production (x 1,000 bushels)	Percentage of total U.S. soybean production area[3]
Georgia	260	6,760	0.20
Maryland	465	15,810	0.47
North Carolina	1,550	40,300	1.21
South Carolina	455	10,465	0.31
Virginia	540	14,040	0.42
Total	3,270	87,375	2.62

[1]Information from (USDA-NASS, 2011b).
[2] Information obtained from (US-EPA, 2010a) (p. 39).
[3]Total U.S. production for 2010 was 3.33 billion bushels (USDA-NASS, 2011b).

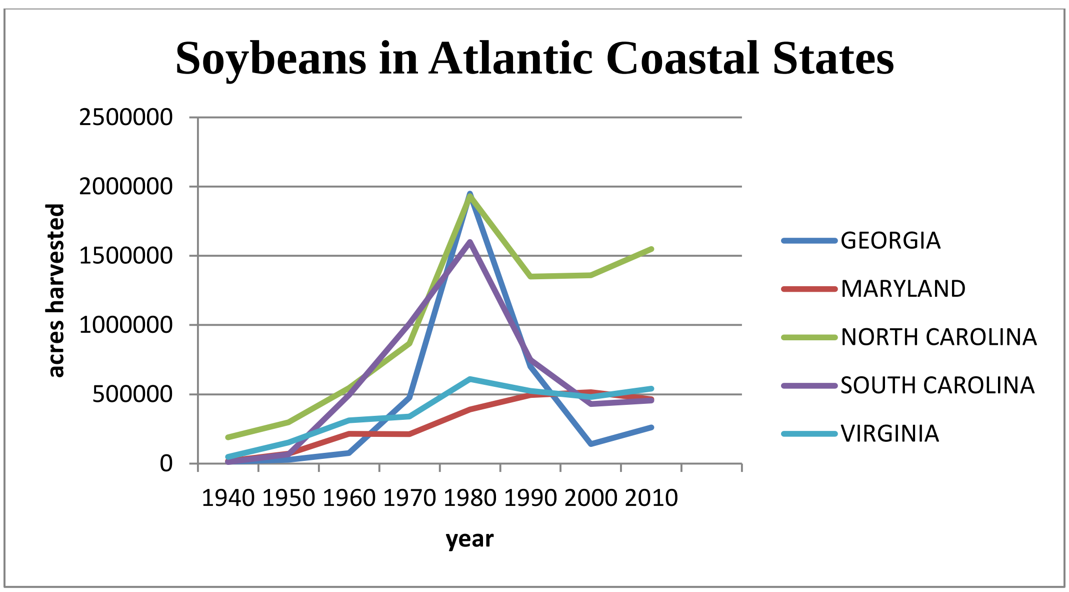

Figure 2. Annual soybean acres harvested in Atlantic Coastal states

Source: (USDA-NASS, 2011b).

2.1.2 Agronomic Practices

Conventional farming in this document includes any farming system where synthetic pesticides or fertilizers may be used. Conventional farming covers a broad scope of farming practices, ranging from farmers who only occasionally use synthetic pesticides and fertilizers to those farmers whose harvest depends on regular pesticide and fertilizer inputs. This definition of conventional farming also includes the use of genetically engineered (GE) varieties that have been deregulated pursuant to Part 340 and the Plant Protection Act by APHIS.

Prior to planting, the soil must be stripped of weeds that would otherwise compete with the crop for space, water, and light. Conservation tillage is an adopted practice that reduces soil erosion, increases plant matter content in the soil, and aids in water penetration while reducing agrochemical runoff (Heatherly et al., 2009). Conservation tillage where soybeans are irrigated may reduce water and fertilizer runoff, in part due to a greater protective plant residue on top of soil (Heatherly et al., 2009).

Soybean production typically involves the use of agronomic inputs to maximize yield. It has been documented that nitrogen fertilization of soybeans is unnecessary; it is an extra expense that may result in water contamination (Heatherly et al., 2009). Irrigation enhances soybean production, especially where rainfall is erratic or not sufficient.

Commercial soybean production may require the application of pesticides. Weeds are the most problematic aspect of soybean production and may require at least one herbicide application for effective control. According to Woodruff et al. (2010), giant ragweed, pigweed, morning glory, and smartweed are billed as the top four most troublesome weeds (Woodruff et al., 2010). Weeds are generally controlled by planting glyphosate tolerant soybean varieties, although instances of glyphosate resistant weeds have been reported, such as pigweed and morning glory (Heatherly et al., 2009; Woodruff et al., 2010). These weeds can be managed by applying herbicide combinations with different modes of action, as well as crop rotation, varying row spacing, and mechanical removal of weeds (Woodruff et al., 2010). In 2002, it was calculated that 96 percent of all planted soybeans were treated with at least one type of herbicide, ranging from 0.04 to 0.71 pounds (lbs) of product per acre. In 2006, herbicides were used on 98 percent of soybean acres (USDA-NASS, 2007).

Additionally, soybeans are susceptible to insect attack by caterpillars that feed on foliage and seeds. While a variety of lepidopteran and non-lepidopteran insects infest soybean (Musser and Catchot, 2008; Musser et al., 2009; Way, 1994), *Pseudoplusia includens* (soybean looper) is currently reported as the most important lepidopteran soybean pest in the southern U.S.

In 2006, insecticides were used on 16 percent of soybean acres. The three most common insecticides, lambda-cyhalothrin, chlorpyrifos, and esfenvalerate, were applied to 6, 5, and 3 percent of the planted acres, respectively (USDA-NASS, 2007). In addition to these three insecticides, other are recommended for use on soybeans. Table 2 shows the insecticides recommended for use on soybeans (UMD, 2009).

Table 2. Recommended insecticides for use on soybeans.

Insecticide	Rate of active ingredient per acre	Time limits: days before harvest	Class
beta-cyfluthrin	0.007-0.013 lb	grain + feeding dry vines: 45, green forage: 15	pyrethroid
cyfluthrin	0.025-0.044 lb	45	pyrethroid
gamma-cyhalothrin	0.0075-0.0125 lb	45	pyrethroid
zeta-cypermethrin	0.018-0.025 lb	21	pyrethroid
zeta-cypermethrin plus bifentrhin	0.10 lb	21	pyrethroid
bifenthrin	0.08-0.10 lb	18	pyrethroid
esfenvalerate	0.015-0.03 lb (0.03-0.05 lb bean leaf beetle)	21	pyrethroid
lambdacyhalothrin	0.015-0.025 lb	30	pyrethroid
permethrin	0.05-0.1 lb	60	pyrethroid
methomyl	0.23-0.45 lb	14	N-methyl carbamate
thiodicarb	0.25-0.75 lb	28	N-methyl carbamate
chlorpyrifos	0.5-1.0 lb	28	chlorinated organophosphate
acephate	0.73-0.97 lb	14	organophosphate
dimethoate	0.5 lb	28	organophosphate
indoxacarb	0.045-0.11 lb	21	oxadiazines
methoxyfenozide	0.06-0.12	14	diacylhydrazine

Table reproduced from (UMD, 2009).

Crop rotations between soybeans and a grain can be an effective strategy to reduce root injury from rootworm larvae (Heatherly et al., 2009). Due to the capacity of soybeans to fix atmospheric nitrogen into the soil, soybean rotation with grains (mainly corn or sorghum) has proven a positive yield return for both crops, but it has the potential of increasing soil erosion as a result of the crop rotation. Because of the capacity of soybeans to fix nitrogen, the use of variable fertilizer rate technology, which applies fertilizer only to areas where it is needed, is another adopted practice on this rotation system.

2.1.3 Soybean Seed Production

Seed quality (including genetic purity, vigor, and presence of weed seed, seed-borne diseases, and inert materials, such as dirt) is a major factor in crop yields. If natural variability in seed production is not carefully controlled, the value of a new variety or cultivar may be lost (Harlan, 1975). Genetic purity in commercial seed production is generally regulated through a system of seed certification which is intended to ensure that the desired traits in the seed are maintained throughout all stages in cultivation (Harlan, 1975).

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

Soybean seed is separated into four seed classes: 1) Breeder; 2) Foundation; 3) Registered; and 4) Certified (NCCIA, 2011). Each class of seed is identified to designate the seed generation from the original breeder source (Hartman et al., 1999) . The original Breeder seed stock is controlled by the developer of the variety (Hartman et al., 1999). The Breeder stock is used to produce Foundation seed stock (Adam, 2005). Foundation seed stock, in turn, is used to produce Registered seed for distribution to licensees, such as seed companies (Adam, 2005). Registered seed is used by seed companies to produce large quantities of Certified seed (Adam, 2005; Hartman et al., 1999). The Certified (or select) seed is then sold to growers through commercial channels (Adam, 2005; Hartman et al., 1999).

Foundation seed, Registered seed, and Certified seed production is controlled by public or private seed certification programs (AOSCA, 2009). Commercially certified soybean seed must meet state and Federal seed standards and labeling requirements. Federal Seed Act regulations are detailed in 7 CFR 201. State seed certification standards may vary slightly from state to state and can be more restrictive than the seed standards of AOSCA (Association of Official Seed Certifying Agencies) (Department, 2001; GCIA, 1988; NCCIA, 2011). The values for certified soybean seed standards from AOSCA are as follows (AOSCA, 2009):

- 98% pure seed (minimum);
- 2% inert matter (maximum);
- 0.05% weed seed (maximum; not to exceed 10 per pound (lb));
- 0.60% total of other crop seeds (maximum);
- 0.5% other varieties (maximum; includes off-colored beans and off-type seeds);
- 0.10% other crop seeds (maximum; not to exceed three per lb); and
- 80% germination and hard seed (minimum).

In addition to these specific factors, soybean certification standards identify land requirements and field practices that must be followed. Soybeans must be grown on land on which the previous crop grown was of a different type, certified seed of the same variety, or a variety having noticeable characteristic differences. In addition, for every 200 certified soybean plants, only one off-type or other variety is allowed (AOSCA, 2009). Certified seed crop is subject to field inspections by certifying agencies at harvest and other times in order to observe factors related to seed certification and determine genetic purity and identity. Harvested seeds may be inspected and sampled at any time (AOSCA, 2009).

All soybean seed sold may not be officially certified; however, commercial soybean seed sold and planted for normal soybean production is produced predominately to meet or exceed certified seed standards.

2.1.4 Organic Soybean Production

In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2010). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced.

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

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

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

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

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

Organic farming operations, as described by the NOP, are required to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods. (USDA-AMS, 2010).

Common practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields (NCAT, 2003). Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2010). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche, 2006; USDA-AMS, 2010).

For 2008, the production of organic soybeans represented approximately 0.2% of U.S. soybean production. In 2005, 122,217 acres of soybean in the U.S. were certified organic, and in 2008, 125,621 acres were similarly certified (USDA-ERS, 2010a). In the five Atlantic Coastal states where MON 87701 is registered by EPA, organic soybean acreage in 2005 and 2008 was 921 acres and 894 acres, respectively (South Carolina and Georgia did not have any certifiable organic soybean production) (USDA-ERS, 2010a). The production of organic soybeans represents about 0.13% of U.S. soybean production (USDA-NASS, 2011b). In 2008, 98,199 acres of certified or exempt organic soybean were harvested in U.S.

Organic soybean markets typically enjoy a market premium offsetting the additional production and record-keeping costs associated with this production method.

Table 3. Organic soybean production in the U.S. Coastal states in 2008.

State[1]	Area harvested organic soybean (acres)	Production (bushel)	Percentage of total state soybean production area	Percent of U.S. organic soy production area
Georgia	215	5,300	0.05	0.2
Maryland	895	21,469	0.19	0.9
North Carolina	323	10,205	0.02	0.3
South Carolina	ND	ND	--	---
Virginia	387	12,275	0.07	0.4
Total	1,820	49,249	NA	1.9

ND = no data for this crop in this state in the USDA-NASS 2008 Organic Survey

Source: (USDA-NASS, 2009)

2.2 Physical Environment

2.2.1 Water Resources

Soybean production under irrigation in the Atlantic Coastal states represent 2 percent of the total U.S. irrigated soybean area, while the cultivation of soybeans grown under dryland conditions represent 7.8 percent of the total U.S. non-irrigated soybean area (USDA-NASS, 2011b). Irrigation is generally accepted as necessary to obtain higher yields (Boerma and Specht, 2004). The high propensity for drought later in the growing season makes water less available during the essential reproductive period of the soybean, and the clay soil tends to become dry and crack (Rufty et al., 1993). Watering after planting is beneficial because it activates pre-emergence weeds immediately, therefore giving seedlings an advantage over weeds, and allows for amount of irrigation water used to depend on post-planting rainfall (Heatherly and Hodges, 1999). Although studies have shown that irrigation is most important during the reproductive period, water must also be provided during the vegetative period so plants have sufficient height to support reproduction (Boerma and Specht, 2004). Earlier-planting varieties can alleviate the stress of drought later in the season by coinciding the growing period with periods of higher rainfall (CAST, 2009a; McPherson et al., 2001).

With respect to the effects of nutrient runoff on water resources, conservation tillage and no-till practice has been shown to minimize surface water runoff and soil erosion. By improving soil quality, the resulting increase in soil organic matter promotes the binding of nutrients, as well as pesticides and herbicides, to soil and prevents their loss to surface waters and groundwater from runoff, erosion, and leaching (Leep et al., 2003).

2.2.2 Soil Quality

Land used for growing crops supports a rich and complex community of below ground microorganisms and arthropods. The interaction between the below ground community, plant root structure, and organic residues in the soil is central to a variety of dynamic soil ecological processes, including the decomposition of organic material, nutrient cycling and release, and maintenance of soil structure and composition.

Soybeans are grown on a variety of soil types, ranging from small particles (clay), medium particles (silt), and large particles (sand). Silt loam particles' medium size, good aeration, fertility, high water-holding capacity and abundance of organic matter make it the ideal soil for soybean cultivation (Hoeft et al., 2000). Care must be taken to prevent overworking of silt loam, which can result in soil hardening and nutrient deficiency. Erosion is also a concern (Hoeft et al., 2000). The ideal pH for soybean growth is 6.0, with yield declining at a pH$\leq$5.8 (Heatherly et al., 2009; Hoeft et al., 2000). Disadvantages of clay soils include their tendency to clump and impede drainage when tilled at too low or too high moisture, leading to less aeration and a tendency toward erosion (Hoeft et al., 2000).

Mutualistic relationships with beneficial microorganisms are essential to soybean growth. Beneficial microorganisms include *Rhizobium*, a gram-negative bacteria that fixes atmospheric nitrogen and makes it available to the soybean plant, and mycorrhizal fungi that attach to soybean roots and extend hyphae deep into the soil, effectively increasing soybean access to nutrients and water (Purves et al., 2004). In addition to increasing soybean access to water and nutrients, mycorrhizal hyphae also facilitates pore creation in soil through particle aggregation, an important effect in clay soils that do not aerate well (Heatherly and Hodges, 1999). Both *Rhizobium* and mycorrhizae aid plant survival during drought. Mycorrhizal-colonized non-irrigated soybeans have shown a 10 percent increase in yield compared to non-colonized non-irrigated soybeans during a drought period. These two mutualistic symbioses have been shown to occur concurrently, with mycorrhizae having a positive impact on *Rhizobium* nodulation and the nitrogen-fixing activity of nodules present on the soybean plant. These soybean plants also provided a greater yield (Heatherly and Hodges, 1999).

2.2.3 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 (N_2O) emissions from the use of nitrogen fertilizer (Aneja et al., 2009; Hoeft et al., 2000). 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 carbon dioxide (CO_2) to the atmosphere and the exposure and oxidation of soil organic matter (Baker 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, 2010c). Nitrous oxide may also be released following the use of nitrogen fertilizer (US-EPA, 2010c). 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 et al., 2008). Agriculture, including land-use changes for farming, is responsible for an estimated six percent of all human-induced GHG emissions in the U.S. N_2O emissions from agricultural soil management are a large part of this, contributing 68 percent of all U.S. N_2O emissions (US-EPA, 2010c).

2.2.4 Climate Change

Climate change represents a statistical change in climate conditions, and may be measured across both time and space. Production of agricultural commodities is interrelated with climate change on several different levels (Dale, 1997; Rosenzweig and Parry, 1994). U.S. agriculture may act influence climate change through various facets of the production process. Combustion of fossil fuels in mechanized farm equipment, fertilizer application, and decomposition of agricultural waste products may all contribute greenhouse gases to the atmosphere. Greenhouse gases collectively function as retainers of solar radiation, and agriculture-related activities are recognized as both direct (e.g., exhaust from equipment) and indirect (e.g., agricultural-related soil disturbance) sources of CO_2, methane (CH_4), and N_2O. The U.S. agricultural sector is identified as the second largest contributor to GHG emissions, ranking only behind the energy sector (i.e., electricity production, transportation, and related activities). Agricultural crop commodities may also affect dynamic geophysical soil processes, such as carbon turnover and sequestration, through tillage and cropping system practices. In general, reduced/conservation tillage practices favor more stable and increased carbon sequestration in the agro-environment (Lal and Bruce, 1999). Additionally, climate change may also affect agricultural crop production. These potential impacts on the agro-environment and individual crops may be direct, including changing patterns in precipitation, temperature, and duration of growing season, or may cause indirect impacts influencing weed and pest pressure (Rosenzweig and Parry, 1994; Schmidhuber and Tubiello, 2007).

The impacts of GE crop varieties on climate change are unclear, though it is likely dependent on cropping systems, production practices, geographic distribution of activities, and individual grower decisions. 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. The potential impact of climate change on agricultural output, however, has been examined in more detail. A recent IPCC forecast (IPCC, 2007) for aggregate North American impacts on agriculture from climate change actually projects yield increases of 5 to 20 percent for this century. The IPCC report notes 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).

2.3 Biological Resources

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

2.3.1 Animal Communities

Wildlife can be found in agricultural settings such as soybean fields. These animals may feed on soybean plants in the field and or make their homes in or near the margins of fields. White-tailed deer (USDA-APHIS, 2011b; Wallace et al., 1996) Canada geese, and other waterfowl (USDA-APHIS, 2011b) can feed on soybean, sometimes causing economic damage to the crop. In Georgia, feral hogs have also damaged soybean fields through rutting and feeding (USDA-APHIS, 2005). Rodents may also be found in soybean fields (Houtcooper, 1978). It is likely that reptiles and amphibians may also be found in soybean fields, especially if the habitat surrounding the field is suitable to support these types of animals.

Insects are considered less problematic than weeds in U.S. soybean production; nevertheless, insect injury can impact yield, plant maturity, and seed quality. Consequently, insect pests are managed during the growth and development of soybean to enhance soybean yield (Aref and Pike, 1998; Higley and Boethel, 1994). Insect injury in soybean seldom reaches levels that cause significant economic loss, as indicated by the low percentage (16%) of soybean acreage that receive insecticide treatments (USDA-NASS, 2007).

2.3.2 Plants Communities

The plant community surrounding a soybean field is dependent on geography. In certain areas, soybean fields can be bordered by other agricultural fields (including those of other soybean varieties), woodlands, or pasture and grasslands. From an agronomic perspective, the most relevant members of a surrounding plant community are those that can behave as weeds. Thus, weed pressure is also dependent on geography.

Annual weeds are perceived to be the greatest pest problem in soybean production, followed by perennial weeds (Aref and Pike, 1998). Weed control in soybean is essential to optimizing yields. Weeds compete with soybean for light, nutrients, and soil moisture. Weeds can harbor insects and diseases, and also can interfere with harvest, causing extra wear on harvest equipment (Loux et al., 2008). When weeds are left to compete with soybean for the entire growing season, yield losses can exceed 75% (Dalley et al., 2001).

Generally, the effects of competition increase with increasing weed density (Weiner et al., 2001). The time period that weeds compete with the soybean crop influences the level of yield loss. The later the weeds emerge, the less impact the weeds will have on yield. Soybean plants withstand early-season weed competition longer than corn as the soybean canopy closes earlier in soybean than in corn (Mallory-Smith and Zapiola, 2008). The extent of canopy closure regulates the availability of light to weeds and other plants that grow below the soybean.

To combat weed problems in soybean, many growers have adopted herbicide resistant soybean varieties. USDA-ERS estimated that 93% of soybean growers have adopted herbicide resistant varieties of soybeans, indicating that these crops are the main system used to manage weeds in soybean fields (USDA-ERS, 2010b).

2.3.3 Gene Flow and Weediness

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

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

Soybean is not native to the U.S. and there are no feral or weedy relatives. Soybean is a self-pollinated species, propagated by seed (OECD, 2000). Pollination typically takes place on the day the flower opens. The soybean flower stigma is receptive to pollen approximately 24 hours before anthesis (i.e., the period in which a flower is fully open and functional) and remains receptive for 48 hours after anthesis. Anthesis normally occurs in late morning, depending on the environmental conditions. The pollen usually remains viable for two to four hours, and no viable pollen can be detected by late afternoon. Natural or artificial cross-pollination can only take place during the short time when the pollen is viable. As a result, soybean is considered to be a highly self-pollinated species, with cross-pollination to adjacent plants of other soybean varieties occurring at a very low frequency (0 to 6.3 percent) (Caviness, 1966; Ray et al., 2003; USDA-APHIS, 2011b; Yoshimura et al., 2006).

2.3.4 Microorganisms

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

2.3.5 Biodiversity

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

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

Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas.

Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest result limit the diversity of plants and animals (Lovett et al., 2003).

Biodiversity can be maintained or reintroduced into agroecosystems through the use of woodlots, fencerows, hedgerows, and wetlands. Agronomic practices include intercropping (the planting of two or more crops simultaneously to occupy the same field), agroforestry, crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically for the purpose of incorporating it into the soil in order to provide nutrients and organic matter), addition of organic matter (compost, green manure, animal manure, etc.), and hedgerows and windbreaks (Altieri, 1999), as well the adoption of non-till soybean cultivation (Carpenter et al., 2002).

2.4 Human Health

Public health concerns surrounding crops genetically engineered to accumulate Bt focus primarily on human and animal consumption. 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 GE soybean 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, 2010a). FDA evaluates the submission and responds to the developer by letter BNF No. 119 (FDA, 2010b).

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

Pesticides, including herbicides and insecticides, are used on most soybean acreage in the U.S., and changes in acreage, crops, or farming practices can affect the amounts and types of pesticides used and thus the risks to workers. Common farm practices, however, can mitigate exposure to pesticides by farm workers. Choosing from less toxic groups of insecticides to control soybean insects is a good common agricultural practice. Additionally, the use of specialized equipment can also reduce farm worker exposure to pesticides. For example, the majority of large pesticide application machinery used in Arkansas and Mississippi have an enclosed cab and air conditioning and workers apply most all the applications (National Information System for the Regional IPM Centers, 2005a; National Information System for the Regional IPM Centers, 2005b). Producers are trained to use spray nozzles with the largest practical opening to minimize spray drift and mist and few injuries have occurred during the mixing, loading, or application of pesticides.

2.5 Animal Feed

Domestic animals may also be exposed to soybeans through their diet. Animal feed is the major product derived from soybean meal produced in the U.S. (USB, 2007). In 2009, approximately 39 million tons of soybean meal was produced, 27 million tons of which was marketed for animal feed, with the largest volumes consumed by poultry (48%), swine (26%), and beef (12%). In 2009, 13 million metric tons of meal was used in poultry rations, with 7.0 and 3.3 million tons in hog and beef rations, respectively (SoyStats, 2010a; SoyStats, 2010b).

Similar to the regulatory control for direct human consumption of soybean under the FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from GE soybean must comply with all applicable legal and regulatory requirements, which in turn protects human health. To help ensure compliance, GE organisms used for feed may undergo a voluntary consultation process with FDA before release onto the market, which provides the applicant with any needed direction regarding the need for additional data or analysis, and allows for interagency discussions regarding possible issues.

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, 2010a). FDA evaluates the submission and responds to the developer by letter (FDA, 2010b).

2.6 Socioeconomic

2.6.1 Domestic Economic Environment

Soybean is one of the most important crops in the U.S., being used for both animal feed and human consumption (Heatherly et al., 2009). Soybeans are an important source of protein and oil, contributing to food products such as soy milk, protein bars, and tofu (Monsanto, 2010). Once the oils have been extracted, soybean meal is used as animal feed (Monsanto, 2010). Currently, the U.S. produces approximately 38 percent of the global soybean supply (ASA, 2010). In 2010, 77.4 million acres of soybeans were planted in 31 states, with a yield of 3.33 billion bushels and a value of 38.9 million dollars (USDA-NASS, 2011a; USDA-NASS, 2011b). In the Atlantic Coastal states where soybeans are grown, yield losses from insects can sometimes reach economic thresholds. Early planting beginning in early April to control these pests, as well as avoiding the mid-summer droughts and wet falls common in Southern states, are established practices (McPherson et al., 2001).

Soybean oil is an important source of vegetable oil, while soybean protein is commonly found in foods and animal feeds. The soybean industry comprises the businesses that sell seed to growers, the growers and their operations, and those that purchase the seed and crush, process and sell the basic products of seed, oil and meal, to the next set of soybean users. The further purchasers are animal feed producers, oil users in food and industrial sectors, and manufacturers of products such as biodiesel oil.

Soybean meal is the most important product deriving from soybean seed and meal is the product that drives demand for soybean rather than oil. Oil comprises only 19 percent by weight of the soybean (Tyson et al., 2004). Soybean meal is predominantly fed to animals (98 percent of production), while about 2 percent is used for human consumption or industrial uses (USB, 2007). The total U.S. seed market is estimated to be $12 billion, with a great proportion of this (23 percent) represented by soybean seed (Roucan-Kane and Gray, 2009).

2.6.2 Trade Economic Environment

Soybeans grown in the U.S. are exported throughout the world with exports rising steadily. In 2005, U.S. exported soybean was valued at $6 billion. In 2010, the value had risen to $18 billion. The majority of the soybean exported is not for replanting, but is sold as a commodity. Soybean seed for replanting was valued at $8 million dollars in 2005 and has grown to about $27 million in 2010 (USDA-FAS, 2011). Therefore, soybean exported for replanting represents less than 1 percent (i.e., 0.15 percent) of the exported soy market.

Intermittently, some of the Atlantic Coastal states have exported soybeans to South America, ranging from $3,045 (Maryland, 2007) to more than $9 million (Georgia, 2009) (USDA-FAS, 2011). However, the database does not track whether this soybean was sold as seed for planting or for other uses.

Only a small amount of the soybean seed exported for planting is sent to South America, which is the main market for MON 87701 seed. Chile and Argentina have consistently imported the majority of this seed. Figure 3 shows the value of soybean seed exported for planting to South America between 2005 and 2010. The value of this export crop ranged from a low of $200,000 in 2006 to a high of just over $1 million in 2009. The average amount of soybean seed for planting exported to South America is approximately 460 metric tons a years. However, the amount imported varies dramatically from year to year and country to country (USDA-FAS, 2011). In most years, this seed would account for planting less than 20,000 acres of soybeans in South America. Due to the small quantities, it is likely that much of this seed is imported as seed to breed commercial seed not as seed to be planted directly for commercial use.

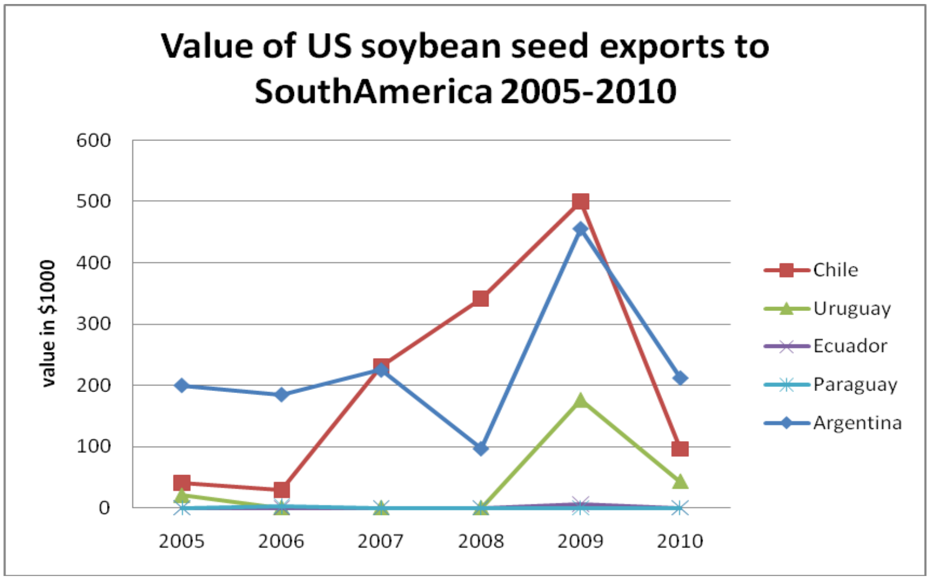

Figure 3: Value of U.S. soybean exports to South America, 2005-2010.

Source: (USDA-FAS, 2011).

Note: Currently, soybean seeds for planting are a minor part of the total U.S. soybean exports. Between 2005-2010 Chile and Argentina were the largest importers in this region of U.S. soybean seed for planting.

World-wide, U.S. soybean seed planted for export ranges from 13,000 metric tons (2005) to 32,000 metric tons (2008). The majority of soybean seed exports are to other countries in North America (see Figure 4). Exports to South America account for only about 2% of the total soybean seed for planting exports (USDA-FAS, 2011). MON 87701 is approved for importation and environmental release in Brazil (BCH, 2010). Therefore, seed could be exported to Brazil for planting.

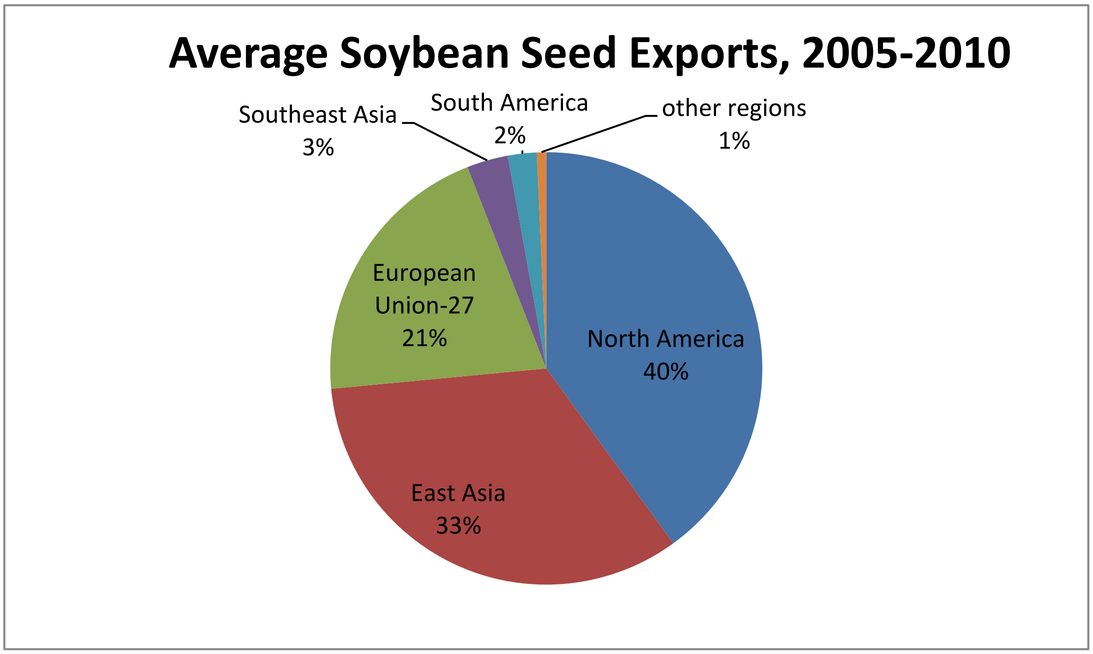

Figure 4. Average soybean seed exports, 2005-2010.

Source: (USDA-FAS, 2011).

3 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of Monsanto Company MON 87701 soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 87701 is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2011b). APHIS has concluded that MON 87701 is unlikely to pose a plant pest risk. Therefore APHIS must determine that MON 87701 is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

Two alternatives are evaluated in this EA: (1) no action and (2) determination of nonregulated status of MON 87701. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section.

3.1 No Action Alternative: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. MON 87701 soybeans and progeny derived from MON 87701 soybeans 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 MON 87701 soybeans 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 MON 87701 soybeans.

This alternative is not the Preferred Alternative because APHIS has concluded through a Plant Pest Risk Assessment that MON 87701 soybeans is unlikely to pose a plant pest risk (USDA-APHIS, 2011b). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

3.2 Preferred Alternative: Determination that MON 87701 Soybean Is No Longer a Regulated Article

Under this alternative, MON 87701 and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. MON 87701 is unlikely to pose a plant pest risk (USDA-APHIS, 2011b). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87701 and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that MON 87701 is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87701 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 MON 87701 and progeny derived from this event if the developer decides to commercialize MON 87701.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for MON 87701. 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 MON 87701. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

3.3.1 Prohibit Any MON 87701 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 MON 87701, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that MON 87701 is unlikely to pose a plant pest risk (USDA-APHIS, 2011b).

In enacting the Plant Protection Act, Congress found that

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

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

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

Based on the Plant Pest Risk Assessment (USDA-APHIS, 2011b) and the scientific data evaluated therein, APHIS concluded that MON 87701 is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87701.

3.3.2 Approve the Petition in Part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that MON 87701 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.

3.3.3 Isolation Distance between MON 87701 and Non-GE Soybean Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating MON 87701 from conventional or specialty soybean production. However, because APHIS has concluded that MON 87701 is unlikely to pose a plant pest risk (USDA-APHIS, 2011b), 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 MON 87701 to those areas where MON 87701 soybeans were allowed to be grown by EPA. EPA regulates MON 87701 soybeans under FIFRA. However, as presented in APHIS' plant pest risk assessment for MON 87701, there are no geographic differences associated with any identifiable plant pest risks for MON 87701 (USDA-APHIS, 2011b). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 87701 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.

3.3.4 Requirement of Testing for MON 87701

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing for GE products in non-GE production systems. APHIS notes there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because MON 87701 does not pose a plant pest risk (USDA-APHIS, 2011b), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for MON 87701 would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

3.4 Comparison of Alternatives

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

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

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	**No**	**Yes**
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2011b)
Management Practices		
Acreage and Areas of Soybean Production	Unlikely to influence current trends in production regions or acreage of soybean planted	Unchanged from No Action Alternative
Agronomic Practices	Cropping practices will remain the same as current practices for commercial soybean seed production	Unchanged from No Action Alternative
Pesticide Use	Pesticide use unlikely to change. May see a decrease in insecticide use on MON 87701 soy - will depend on type of insect pest. Due to limited acreage will not change national or regional pesticide use.	Unchanged from No Action Alternative
Soybean Seed Production	Unchanged	Unchanged
Organic Soybean Production	Unchanged	Unchanged
Environment		
Land Use	MON 87701 is not expected to have any effect on land use	Unchanged
Water Resources	MON 87701 is not expected to have any effect on water	Unchanged
Soil	MON 87701 is not expected to have any effect on soil	Unchanged
Air Quality	MON 87701 is not expected to have any effect on air quality	Unchanged
Climate Change	MON 87701 is not expected to have any effect on climate change	Unchanged

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

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Animals	MON 87701 is not expected to have any effect on vertebrate animals or most invertebrate animals. MON 87701 is toxic to certain lepidopteran insects. Those that feed directly on MON 87701 soybeans would be expected to die or have delayed growth. This is unlikely to affect insect populations due to the limited number acres and the patchy distribution of these fields on the landscape.	Unchanged from the No Action Alternative
Plants	MON 87701 is not expected to have any effect on plants	Unchanged
Gene Movement	MON 87701 is not expected to have any effect on vertical or horizontal gene flow.	Unchanged
Soil Microorganisms	MON 87701 is not expected to have any effect on soil microorganisms.	Unchanged
Biological Diversity	MON 87701 is not expected to have any effect on biological diversity.	Unchanged
Human and Animal Health		
Risk to Human Health	MON 87701 does not have adverse human health effects	Unchanged
Risk to Animal Feed	MON 87701 does change the nutritional qualities of animal feed.	Unchanged
Socioeconomic		
Domestic Economic Environment	Unchanged	Unchanged
Trade Economic Environment	May increase soybean seed for planting exports to some markets	May increase soybean seed for planting exports to some markets
Other Regulatory Approvals		

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

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
U.S.	FDA completed consultations, EPA tolerance exemptions and conditional pesticide registrations granted	FDA completed consultations, EPA tolerance exemptions and conditional pesticide registrations granted
South America	Brazil	Brazil
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	Fully compliant

4 ENVIRONMENTAL CONSEQUENCES

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, namely taking no action and a determination by the agency that MON 87701 does not pose a plant pest risk. Potential environmental impacts from the No Action Alternative and the Preferred Alternative for MON 87701 are described in detail throughout this section. A cumulative effects analysis is presented for each potentially affected environmental concern. Certain aspects of this product and its cultivation would be no different between the alternatives: those instances are described below.

4.1 Scope of Analysis

MON 87701 is regulated in part by FIFRA, due to characterization of the Cry1Ac protein product as a pesticide by the EPA. Currently, MON 87701 is registered by the EPA for breeding and seed increase activities in the Atlantic Coastal states of Georgia, South Carolina, North Carolina, Virginia, and Maryland (US-EPA, 2010a). This registration is limited to 15,000 total acres in the specified Atlantic Coastal states, with production limited to 1,000 acres per county. Commercial sale of MON 87701 in the U.S. is not allowed under this type of EPA registration. Thus, the scope of analysis of the EA focuses on the cultivation of MON 87701 for seed production in Georgia, South Carolina, North Carolina, Virginia, and Maryland (US-EPA, 2010a).

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for MON 87701 soybeans are described in detail throughout this section. An impact would be any change, positive or negative, from the existing (baseline) conditions of the affected environment (described for each resource area in Section 2.0). Impacts may be categorized as direct, indirect, or cumulative. A direct impact is an effect that results solely from a proposed action without intermediate steps or processes. Examples include soil disturbance, air emissions, and water use. An indirect impact may be an effect that is related to but removed from a proposed action by an intermediate step or process. Examples include surface water quality changes resulting from soil erosion due to increased tillage, and worker safety impacts resulting from an increase in herbicide use.

A cumulative effects analysis is also included for each environmental issue. A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. Examples include breeding MON 87701 with other deregulated events or the potential commercialization of MON 87701 in the U.S. beyond current EPA-approved breeding and seed multiplication activities. If there are no direct or indirect impacts identified for a resource area, then there can be no cumulative impacts. Cumulative impacts are discussed in Section 5.

Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential impacts. Certain aspects of this product and its cultivation may be no different between the alternatives; those are described below.

4.2 Agricultural Production of Soybean

4.2.1 Acreage and Area of Soybean Production

<u>No Action Alternative: Acreage and Area of Soybean Production</u>

Under the No Action Alternative, MON 87701 would continue to be regulated by APHIS. Under APHIS notification, MON 87701 seed may still be produced for export. Additionally, MON 87701 would also continue to be registered by the EPA under a seed increase registration. As dictated by the EPA seed increase registration, MON 87701 acreage is not to exceed 15,000 total cropland acres in the specified five Atlantic Coastal states, with acreage limited to 1,000 acres per county within those states.

It is expected that the 15,000 acres of MON 87701 soybeans would be planted on land currently used for agriculture. Under the No Action Alternative, cultivation of MON 87701 for seed increase activities on 15,000 acres in Atlantic Coastal states would represent 0.45 percent of the approximate 3.3 million soybean acres planted in this region (USDA-NASS, 2011a). Due to planting restrictions defined by the EPA seed increase registration, cultivation of MON 87701 would remain a small percentage of total soybean cultivation area and would have no impact on current and projected land use patterns in the Atlantic Coastal states.

<u>Preferred Alternative: Acreage and Area of Soybean Production</u>

Under the Preferred Alternative, the planting of MON 87701 would be limited by the EPA seed increase registration, but not regulated by APHIS. The restrictions placed on MON 87701 cultivation range and acreage would be unchanged compared to the No Action Alternative. Thus, the impact on current and projected acreage under the Preferred Alternative is the same as under the No Action Alternative.

4.2.2 Agronomic Practices

<u>No Acton Alternative: Agronomic Practices</u>

Under the No Action Alternative, MON 80771 could be produced under APHIS notification (7 CFR 340.3). Growers could produce soybean for seed exports in the states and counties identified by EPA in the seed increase registration. While the performance requirements in the regulations will need to be followed, these requirements are not inconsistent with the production of high quality seed. Therefore, it would be possible to raise MON 87701 soybeans on the scale allowed in the EPA registration under APHIS notification. Production of these soybeans would occur in agricultural areas where soybeans are typically cultivated.

It is expected that similar agronomic practices that are currently used for commercially available soybean seed production will also be used by growers of MON 87701. Conventional soybean methods of production including tillage, fertilizer application, cultivation, fertilization, pesticide applications, and the use of agricultural equipment would be utilized.

Planting of MON 87701 in these five Atlantic Coastal states may locally reduce the amount of insecticides applied to control lepidopteran pests. However, pesticides are only applied when insect pressures reach economic thresholds, since soybean plants tolerate large amounts of defoliation without effecting yield. In Virginia and North Carolina, 23 and 22 percent of the soybean acres received insecticide treatments, respectively (USDA-NASS, 2007). These two states were the only Atlantic Coastal states for which survey data is available. Insecticide usage on soybeans in these two states is higher than the national average. According to the Virginia Cooperative Extension, the corn earworm is the most damaging pest in Virginia soybean fields (Herbert et al., 2009). MON 87701 would likely be effective for controlling these populations in any seed field where it is planted. This could reduce the localized use of insecticides in that field. However, if other insect pest like, stink bugs, were causing damage to the soybean crop, MON 87701 would have no effect on those insects. Because the fields are not a large component of the agricultural landscape (less that 1% of the total soybean acreage), planting MON 87701 will not have an effect on pest populations or application of insecticides to control insect pests.

MON 87701 will likely be conventionally crossed with nonregulated GE herbicide resistant soybean varieties to create new varieties to target both lepidopteran and weed pressure. Ready2Yeild™ soybean (product of a MON 87701 and the nonregulated MON 89788 cross) is already approved in Brazil and may represent a similar variety that would likely be bred for the tropical and subtropical soybean market (USDA-APHIS, 2007).

There are no expected increases in pesticide use for weed or pest management, harvesting, or volunteer control compared to currently-available soybean varieties. The proportion of soybean acreage that can be dedicated to MON 87701 cultivation represents 0.04 percent of Atlantic Coastal region soybean production, suggesting that any decrease in use of insecticides targeting lepidopteran pests is also unlikely to be significant relative to the overall amounts applied in this region.

Preferred Alternative: Agronomic Practices

Under the Preferred Alternative, the planting of MON 87701 would continue to be limited by the EPA seed increase registration, but would not be regulated by APHIS. The amount and distribution of MON 87701 would be expected to remain the same as under the No Action Alternative due to the restrictions placed on MON 87701 cultivation range and acreage by the EPA seed increase registration. Therefore, there would be no change in agronomic practices under the Preferred Alternative compared to the No Action Alternative, due to similar agronomic practices that would be adopted under both alternatives.

4.2.3 Soybean Seed Production

No Acton Alternative: Soybean Seed Production

Management practices for the production of high quality seed would be used. These management practices include following AOSCA standards for the production of soybean seed of the desired class. Land use requirements and restrictions on other crops cultivated specified by AOSCA or state certifying agencies would be followed. Isolation distances beyond those needed to prevent mechanical mixing are not prescribed in the AOSCA standard (AOSCA, 2009).

<u>Preferred Alternative: Soybean Seed Production</u>

Under the Preferred Alternative, planting of MON 87701 would continue to be limited by the EPA seed increase registration, but would not be regulated by APHIS. Management practices and seed standards for production of Certified soybean seed would continue to be the same as for the No Action Alternative.

4.2.4 Organic Soybean Production

<u>No Action Alternative: Organic Soybean Production</u>

The availability of soybean seed developed for organic production is expected to remain the same under the No Action Alternative. Under this alternative, MON 87701 soybean would continue to be regulated articles under the regulations at 7 CFR part 340. Additionally, MON 87701 would still be subject to the conditions in the EPA seed increase registration. Due to these conditions, MON 87701 acreage cannot exceed 15,000 acres and is limited in planting to no more than 1,000 acres per county in Georgia, South Carolina, North Carolina, Virginia, and Maryland. Relative to the approximate 3.1 million acres of soybeans harvested in these five states, MON 87701 may represent up to 0.48 percent of total soybean acreage. The majority of the remaining soybeans (about 90 percent) are nonregulated GE soybeans (USDA-ERS, 2010b), with organic soybean production in these five states representing less than 2 percent of total organic soybean production (see Table 3, Section 2.1.4).

Due to the large proportion of GE soybean already grown in these Atlantic Coastal states and the small amount of organic soybean production present, it is unlikely that MON 87701 and the limited amount of organic soybeans grown in these states will be in proximity of each other. Additionally, as discussed in Section 2.3.3, soybean is considered to be a highly self-pollinated species, with cross-pollination to adjacent plants of other soybean varieties occurring at a very low frequency (0 to 6.3 percent) (Caviness, 1966; Ray et al., 2003; USDA-APHIS, 2011b; Yoshimura et al., 2006). Therefore, it is unlikely that MON 87701 cultivation will increase the likelihood of finding a GE off type in organic seed.

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

Preferred Alternative: Organic Soybean Production

Under the Preferred Alternative, the impact of MON 87701 deregulation on organic soybean production would not differ from the No Action Alternative. As with the No Action Alternative, MON 87701 would continue to be grown under EPA registration on limited acres in an area with little organic soybean production. Because of the limited acreage and the current high adoption rate of other GE soybean varieties, MON 87701 is not likely to impact organic soybean production any more than nonregulated GE soybeans already primarily cultivated in that region.

4.3 Physical Environment

4.3.1 Water Resources

Irrigation is the most important factor in soybean production because drought is the most damaging abiotic stress factor (CAST, 2009a). The majority of the irrigated soybean acreage occur in the western Corn Belt and mid-southern regions of the U.S. (USDA-NASS, 2011b). A recent agricultural practice aiming to reduce water stress is early planting of early-maturing soybeans groups II-V. This practice avoids a large portion of the drought period during the most sensitive reproductive stages of this crop (CAST, 2009a).

No Action Alternative: Water Resources

Under the No Action Alternative, MON 87701 production would be limited to the five Atlantic Coastal states that were approved for regulated releases by APHIS and EPA. The majority of soybean acreage in these five states is not irrigated, and the use of MON 87701 in this region under the No Action Alternative is unlikely to change any water use requirements (USDA-NASS, 2011b). This is due both to the small planted acreage of MON 87701 and the similar agronomic properties of MON 87701 and conventional soybean.

In regard to water quality, planting of MON 87701 in these five Atlantic Coastal states may locally reduce the amount of insecticides applied to control lepidopteran pests. To the extent that MON 87701 reduces the application of insecticides, it could reduce chemical runoff into surface water and groundwater. However, pesticides are only applied when insect pressures reach economic thresholds. MON 87701 would likely be effective for controlling lepidopteran pests in any seed field where it is planted and therefore could reduce the localized use of insecticides in that field. However, if other insect pest like, stink bugs, were causing damage to the soybean crop, MON 87701 would have no effect on those insects or the insecticide required to control those pests.

In addition, any benefits associated with planting of MON 87701 are limited by the relatively small permitted planting area. Because the fields are not a large component of the agricultural landscape (less that 1% of the total soybean acreage), planting MON 87701 will not have an effect on pest populations or application of insecticides to control insect pests. Therefore, there is no expected change in the impacts of insecticide use on surface or ground water quality.

Preferred Alternative: Water Resources

Under the Preferred Alternative, MON 87701 would not be regulated by APHIS. However, MON 87701 would remain subject to the EPA seed increase registration that limits cultivation to Georgia, South Carolina, North Carolina, Virginia, and Maryland. The total acreage of MON 87701 in these five states cannot exceed 15,000 acres and 1,000 acres per county across these five states. Production of MON 87701 does not require any changes to standard soybean cultivation practices. A determination of nonregulated status of MON 87701 will not change the use of irrigation practices in commercial soybean seed production. Additional volumes of water are not expected to be needed since the MON 87701 soybeans are expected to simply replace some of the area (15,000 acres) already in use for soybean production. Due to both the limited cultivated acreage of MON 87701 and the similar agronomic properties between MON 87701 and conventional soybean, the impact on water resources associated with the Preferred Alternative would be no different than those for the No Action Alternative.

Any changes in pesticide use would be restricted to local fields. MON 87701 will not change the overall pesticide use on more than 99% of the soybean acres in the allowed area. The consequences of the Preferred Alternative on water resources are the same as for the No Action Alternative.

4.3.2 Soil Quality

No Action Alternative: Soil Quality

Under the No Action Alternative, MON 87701 would remain regulated by APHIS and continue to be restricted in geographic cultivation and acreage under its EPA registration. Thus, potential environmental impacts regarding soil quality would be limited to the five Atlantic coastal states where MON 87701 is approved, including Georgia, South Carolina, North Carolina, Virginia, and Maryland.

Due to the relatively small area that MON 87701 can be cultivated on in the five Atlantic Coastal states, it is unlikely that MON 87701 would have any effect, negative or positive, on soil quality. Agronomic performance for MON 87701 and conventional soybean is similar, which suggests that agronomic practices will be no different between MON 87701 and any other conventional soybean variety. Thus, the no till/reduced tillage systems that have been adopted by soybean growers will likely continue and are likely to be used in the cultivation of MON 87701. Tillage serves a multitude of functions in soybean production such as soil compaction remediation, improvement of water movement capacity during seeding, and the incorporation of fertilizers and pesticides. Reduced tillage has been demonstrated to decrease soil erosion and these practices have also proved to save fuel costs to growers (CAST, 2009b). Non-till systems in soybeans can reduce soil erosion up to 94% while preventing water runoff and preserving this valuable resource (CAST, 2009b).

Additionally, it is unlikely under the No Action Alternative that MON 87701 will negatively affect soil microbial populations that are generally associated with conventional soybean cultivation and generally responsible for maintaining soil quality. In particular, mutual symbiotic relationships between soybean and the *Rhizobiaceae* and *Bradyrhizobiaceae* are unlikely to be negatively affected. While MON 87701 produces the insecticidal protein, Cry1Ac, presence of these toxins have been demonstrated to have no negative effect on soil microbes (Baumgarte and Tebbe, 2005; Icoz, 2008; Lawhorn et al., 2009), soil-associated fauna (Al-Deeb et al., 2003; Oliveira et al., 2007; Priestley and Brownbridge, 2009; Saxena and Stotzky, 2001; Sun et al., 2007; Zeilinger et al., 2010; Zwahlen et al., 2003) [but see (Höss et al., 2008)] or on litter decomposition processes (Zurbrügg et al., 2010).

Preferred Alternative: Soil Quality

Under the Preferred Alternative, MON 87701 would not be regulated by APHIS, but would still be subject to the current EPA registration terms and conditions. No changes to agronomic practices typically applied in the management of soybeans are required for cultivation of MON 87701. There are no expected increases in land acreage or increases in cultivation, planting, pesticide use, fertilizer use, harvesting, or volunteer control compared to what is currently planted. It is expected that similar agronomic practices that are currently used for commercially available soybean seed production will also be used by growers of MON 87701. The potential planting of MON 87701 in the Atlantic Coastal states may only cover 15,000 acres, 0.4% of the soybean acreage of these five states. The small size of these planting limits the footprint such that any effects would be local.

4.3.3 Air Quality

Air quality may be affected by a variety of agricultural-related activities, including smoke from agricultural burning, tillage, traffic and harvesting-related emissions, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizers (Aneja et al., 2009; Hoeft et al., 2000). These agricultural activities individually have potentially adverse environmental impacts on air quality. Tillage contributes to the release of GHGs because of the loss of CO_2 to the atmosphere and the exposure and oxidation of soil organic matter (Baker 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. 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 et al., 2008).

No Action: Air Quality

Under the No Action Alternative, MON 87701 would continue to be regulated by APHIS and subject to its EPA seed increase registration that limits production to no more than 1,000 acres per county and 15,000 acres total across Maryland, Virginia, Georgia, North Carolina, and South Carolina.

The agronomic practices associated with soybean cultivation would remain unchanged, as MON 87701 has agronomic properties similar to conventional soybean. At present, the majority of U.S. soybean acreage is planted with herbicide-resistant soybean varieties and have contributed to the increased adoption of reduced tillage and no-till systems (US-EPA, 2010b). Because MON 87701 will likely be conventionally crossed with nonregulated GE herbicide resistant soybean varieties, conservation tillage strategies would likely be continued to be used over the 15,000 acres where MON 87701 is planted.

Since MON 87701 expresses a lepidopteran-specific insecticidal protein, in individual fields where this soybean is planted, growers may not need to use an insecticide to control lepidopteran insect pests. However, if other orders of insect pests are present and causing economic damage to the field, growers may still need to treat with an insecticide. MON 87701 can only be planted on a small proportion of the total cropland available in the five previously mentioned Atlantic Coastal states. Therefore, the locations of MON 87701 fields will be scattered in the environment. Even if the production of MON 87701 led to insect control in an individual field, it is not likely to change the population of the pest insect within a region. Also, MON 87701 will account for less than 1 percent of the total soybean acreage in the areas where it is registered for planting. Therefore, there is likely to be no overall change in pesticide application or the corresponding effects on the air quality from pesticide use. Overall, there is not expected change to the air quality on a local, regional, or national level.

Preferred Alternative: Air Quality

Under the Preferred Alternative, planting of MON 87701 cannot exceed 15,000 acres in the five states specified under EPA registration (Georgia, South Carolina, North Carolina, Virginia, and Maryland). The distribution of MON 87701 under this alternative is expected to be similar to that under the No Action Alternative, due to the terms and conditions of its EPA registration. Cropping practices for MON 87701 are unlikely to be different than those used for conventional soybean. Thus, the environmental impact on air quality is anticipated to remain unchanged between the No Action and Preferred Alternatives.

As described above, the use of insecticides on individual fields of MON 87701 could be less than that for conventional soybeans if infestations of lepidopteran pests are above economic thresholds. Because MON 87701 plantings are likely to be scattered on the landscape, they are not expected to affect pest populations in any region. There is no expectation that overall insecticide applications would change with the production of MON 87701 seed. More than 99% of the soybeans in the five states where MON 87701 can be grown will not contain this trait. Therefore, those soybeans will likely still be treated with insecticides, and thus require the equipment necessary for insecticide application like conventional soybean. Overall impacts are similar to the No Action Alternative.

4.3.4 Climate Change

No Action Alternative: Climate Change

Under the No Action Alternative, environmental releases of MON 87701 would be under APHIS regulation. Due to the EPA registration constraints, MON 87701 can only be grown in five states (Georgia, South Carolina, North Carolina, Virginia, and Maryland) with less than 1,000 acres of this soybean grown in any one county. The maximum acreage in each county would also likely be dispersed within the county area. APHIS may choose to limit the size of individual plots to ensure that confinement is maintained.

In the U.S., there are 2.3 billion acres of land, of which, 440 million acres are cropland (19.5 percent) (USDA-ERS, 2005). Collectively, the 15,000 acres of allowed MON 87701 production represents about 3/1000 of 1 percent of the croplands in the U.S. In the five Atlantic Coastal states where MON 87701 could be grown, there are 3.3 million acres of soybeans (USDA-NASS, 2011b). Thus, the 15,000 acres where MON 87701 could be grown would account for about 0.4 percent of this soybean area.

MON 87701 soybeans would likely be managed similarly to other soybeans grown for seed. Herbicides would be used and insecticides used as needed. Some decrease in insecticide use could occur if lepidopteran pressures are high in a particular area. However, MON 87701 does not control insects like stink bugs, aphids, or beetles. So if these pests are infesting the MON 87701 field insecticides would still be used. Therefore, there is unlikely to be a measurable change in an agricultural practice that might affect climate change in these fields. Agronomic practices associated with soybean production such as tillage, cultivation, irrigation, pesticide application, fertilizer applications and use of agriculture equipment would continue on soybeans grown throughout the region. Therefore, there would be no change in agricultural activities that might contribute to climate change.

Climate change may result in shifts of herbivorous insects to higher latitudes. There is evidence that insect diversity and vegetative consumption intensity increase with increasing temperature at the same latitude in the fossil record (Bale et al., 2002). How climate change will affect individual species of pest insects will depend on their physiology, feeding behavior, and overwintering strategies (Bale et al., 2002). In cases where climate change favors the expansion of the range of soybean pests, additional soybean acres may be treated with insecticides. If these pests are controlled by Cry1Ac, fields planted with MON 87701 may suffer less insect damage without the additional application of insecticides. However, other orders of insects are not controlled by this insecticidal protein. If these increase in number, or shift their ranges north, insecticide use may be necessary to control these insects in soybeans.

Preferred Alternative: Climate Change

A determination of nonregulated status for MON 87701 is not expected to change the footprint of MON 87701 when compared to the No Action Alternative; under both alternatives, soybean production is limited to 15,000 acres per EPA's registration. The cultivation or agronomic practices, or agricultural land acreage associated with growing soybeans, is expected to have the same effect on climate change as the No Action Alternative.

4.4 Biological Resources

4.4.1 Animal Communities

<u>No Action Alternative: Animal Communities</u>

Under the No Action Alternative, MON 87701 would continue to be regulated by APHIS and subject to its EPA seed increase registration that limits production to a total of 15,000 acres per year across Georgia, South Carolina, North Carolina, Virginia, and Maryland and no more than 1,000 acres per county.

Under the No Action Alternative, conventional and GE transgenic soybean production, including the use of MON 87701, will continue while MON 87701 remains a regulated article. Soybeans are currently produced in 31 states (USDA-NASS, 2011b), and under the No Action Alternative this range of production will remain unchanged. Potential impacts of GE and non-GE soybean 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, 2005). 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.

Soybean production systems in agriculture are host to many animal species. Mammals and birds may use soybean fields and the surrounding vegetation for food and habitat throughout the year. There is ample information indicating that Cry Bt toxins do not negatively affect mammals or birds (Smirnoff and MacLeod, 1961). Invertebrates can feed on soybean plants or prey upon other insects living on soybean plants, as well as in the vegetation surrounding soybean fields. Because the Cry proteins expressed by *Bacillus thuringiensis*, such as Cry1Ac, are very specific for lepidoptera, other arthropods are not likely to be affected (van Frankenhuyzen, 2009).

<u>Preferred Alternative: Animal Communities</u>

APHIS has reviewed the data submitted by the applicant. Based on the information submitted, APHIS has concluded that the agronomic practices used to produce MON 87701 soybeans will be the same as those used to produce other conventionally grown GE and non-GE soybeans. MON 87701 soybean production does not change land acreage or any cultivation practices for conventional, transgenic, or non-transgenic soybean production.

Plants that were genetically engineered to express the Cry proteins have a history of safe use in the U.S. Since the mid-1990s, corn and cotton lines that express these proteins have been commercialized without deleterious impacts on non-target organisms (Mendelsohn et al., 2003; US-EPA, 2008b; USDA-APHIS, 2011a). The use of transgenic cotton producing the Cry1Ac protein has been shown to reduce the use of broad spectrum insecticides[2] without significant impacts on the diversity of non-target insects (Cattaneo et al., 2006; Dively, 2005; Marvier, 2007; Naranjo, 2005a; Naranjo, 2005b; Romeis et al., 2006; Torres and Ruberson, 2006; Torres and Ruberson, 2005; Whitehouse et al., 2005). MON 87701 is expected to be similar with respect to the low potential harm to the environment. Because Cry1 receptors are not present in non-target birds and mammals (Hofmann et al., 1988a; Hofmann et al., 1988b; Shimada et al., 2006a; Shimada et al., 2006b; Van Rie et al., 1990), this insecticidal protein is not expected to adversely affect non-target invertebrates (other than lepidoptera) and vertebrate organisms (US-EPA, 2008c).

Monsanto presented information about the effect that Cry1Ac has on selected non-target insects (honeybee, green lacewing, ladybird beetle and parasitic wasp (Monsanto, 2010) and provided information of peer reviewed studies that provide evidence for the lack of toxicity of Cry proteins on a variety of arthropod. Assessments 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 and Dively, 2007). The information submitted in the petition indicates that no statistically significant adverse effects were observed at the maximum test dose for a number of the tested species. Other research has also shown no direct adverse effects on insectivorous insects in field and laboratory studies with transgenic plants expressing Cry proteins (Marvier, 2007; Pilcher et al., 1997; Romeis et al., 2004; Romeis et al., 2006).

Based on the above information, APHIS concludes that MON 87701 will have no adverse effects on non-target animals. Therefore, potential impacts of MON 87701 and its associated production practices on animal species would be similar to the No Action Alternative.

4.4.2 Plant Communities

<u>No Action Alternative: Plant Communities</u>

Under the No Action Alternative, cultivation of MON 87701 would be under APHIS regulation. Plant species that typically inhabit soybean production systems will be managed through the use of mechanical, cultural, and chemical control methods. The landscape surrounding a soybean field varies depending on the region. In certain areas, soybean fields may be bordered by other soybean (or any other crop) fields or may also be surrounded by woodland, rangelands, and/or pasture/grassland areas. These plant

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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 Cry proteins are specific for a narrow range of insects, use of Cry1Ac to control plant pests is recognized as being beneficial to the survival of non-target insects US-EPA. (2008b) Biopesticides Registration Action Document Bacillus thuringiensis modified Cry1Ab (SYN-IR67B-1) and Vip3Aa19 (SYN-IR102-7) insecticidal proteins and the genetic material necessary for their production in COT102 XCOT67B cotton, U.S. Environmental Protection Agency, Office of Pesticide Programs, Biopesticides and Pollution Prevention Division, Washington, D.C. pp. 135..

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 soybeans for water, nutrients, light, and other growth factors (Hoeft et al., 2000). The types of weeds in and around a soybean field depend on the immediate area in which soybeans are planted. Those weed species will vary depending on the geographic region where soybeans are grown. According to Woodruff et al. (2010), giant ragweed, pigweed, morning glory, and smartweed are billed as the top four most troublesome weeds (Woodruff et al., 2010).

Preferred Alternative: Plant Communities

In the event of a determination of nonregulated status of MON 87701, the risks to wild plants and agricultural productivity from weedy soybean populations are low, as volunteer soybean populations can be easily managed (Carpenter et al., 2002). The effect of soybean production on plant communities is likely to be unchanged by the introduction of MON 87701. Overall impacts would be similar to the No Action Alternative.

4.4.3 Gene Flow and Weediness

No Action Alternative: Gene Flow and Weediness

Under the No Action Alternative, MON 87701 would be grown under APHIS regulatory authority. Conditions would be placed on the cultivation of MON 87701 by APHIS that would substantially limit gene movement to other soybean crops. Gene flow from current commercially available GE cultivars to non-GE soybean cultivars is expected to remain unchanged from the current conditions.

Preferred Alternative: Gene Flow and Weediness

APHIS evaluated the potential for gene introgression to occur from MON 87701 soybean to sexually compatible varieties and considered the possibility that such introgression would result in increased weediness. Monsanto provided measures of plant growth including; plant growth and development characteristics, seed germination parameters, pollen characteristics, and observations for plant-insect and plant-disease interactions and plant responses to abiotic stressors. The only significant difference between MON 87701 and the non-transformed (i.e., control) soybean was found in the percentage of hard viable seed at 20ºC (Table VIII-3 of the petition (Monsanto, 2010)). The observed variation in germination was small (0.0% for MON 87701 and 0.5% for the control soybean) and was not found under any other temperature regime that ranged between 10 to 30ºC.

A measure of the reproductive capacity of plants that are propagated by seed, such as soybeans, is the number of seeds that are produced and the germination and viability of those seeds. Overall, MON 87701 produced similar percentages of viable seed when compared to controls. These results on growth characteristics and seed production and germination, indicate that the MON 87701 is not statistically significantly different than its comparators. There is no indication that MON 87701 possesses a selective advantage that would result in increased weediness. Therefore, MON 87701 lacks the ability to persist as a troublesome weed, and there would be no direct impact on current weed management practices for soybean cultivation.

Monsanto's data found no significant difference in pollen morphology and viability from field grown MON 87701 soybean plants and other soybean varieties. The soybean is not identified as a weed in the U.S. (USDA-APHIS, 2011b). Soybeans are not frost tolerant, do not survive freezing temperatures, and do not reproduce vegetatively (OECD, 2000; USDA-APHIS, 2011b).

Based on the above information, APHIS has concluded that a determination of nonregulated status of MON 87701 soybean will not impact other soybean varieties through gene flow or introgression, nor would it present a greater risk of weediness or invasive characteristics (USDA-APHIS, 2011b). MON 87701 soybean is expected to have the same effect on gene movement as the No Action Alternative.

4.4.4 Microorganisms

No Action Alternative: Microorganisms

An essential part of soybean production is an adequate soil population of nodulation-inducing bacteria. As noted in Section 4.3.2 (Soil Quality), these bacteria must be supplied if a soybean crop has not been recently grown on the planted field. Although the bacteria persist for several years in soil, their numbers may not be sufficient to insure adequate nodulation (Bottomley, 1992). Various commercial sources of inoculants such as multiple strains of *Bradyrhizobium* can be spread in soybean fields around the time of planting, many with similar results (Beuerlein, 2005). From one season to the next, the inoculated bacteria in soil may change characteristics or phenotypes and diverge from traits expressed by the original culture (Farooq and Vessey, 2009).

GE crops that produce Bt toxins (corn and cotton) are known to produce exudates of Cry proteins that can be detected in the soil (Baumgarte and Tebbe, 2005; Dubelman et al., 2005; Icoz, 2008; Saxena and Stotzky, 2001; Saxena et al., 1999; Sun et al., 2007). The presence of these toxins, ubiquitous in the soil under normal conditions, have not shown a negative effect on soil microbes (Baumgarte and Tebbe, 2005; Blackwood and Buyer, 2004; Devare et al., 2004; Icoz, 2008; Lawhorn et al., 2009) or on litter decomposition processes (Zurbrügg et al., 2010). Therefore, the production of MON 87701 is not expected to have an effect on soil microbes.

Preferred Alternative: Microorganisms

A determination of nonregulated status of MON 87701 would not change the effects of planting MON 87701 on soil organisms when compared to the No Action Alternative. While Bt exudates can be found in the soil when GE crops that produce Bt toxins are grown, this has not had a negative effect on soil microbes in corn or cotton systems. Because soybeans have symbiotic relationships with *Rhizobiaceae* and

Bradyrhizobiaceae, the petitioner examined the effect of MON 87701 soybeans on these organisms in controlled studies. No significant differences were detected between MON 87701 and the control for each measured parameter, including nodule number, shoot total nitrogen (percent and mass), and biomass (dwt) of nodules, shoot material, and root material. (Monsanto, 2010) Therefore, the Preferred Alternative is unlikely to affect soil microorganisms including those that have symbiotic relationships with MON 87701 soybeans.

4.4.5 Biodiversity

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 crops, and Bt cotton in particular, has been the reduction of broad-spectrum insecticide use during cotton production (Fernandez-Cornejo and Caswell, 2006). The use of GE cotton producing the Cry proteins has been shown to reduce the use of broad spectrum insecticides[3] without significant impact on the diversity of non-target insects (Cattaneo et al., 2006; Dively, 2005; Marvier, 2007; Naranjo, 2005a; Naranjo, 2005b; Romeis et al., 2006; Torres and Ruberson, 2006; Torres and Ruberson, 2005; Whitehouse et al., 2005).

The presence and release of Bt toxins from the aboveground and belowground parts of Bt plants may influence microbial diversity. Bt toxin has been found to be present in every major part of Bt plants (Sivasupramaniam et al., 2008). However, the presence of Bt toxin in the soil may not influence microbial diversity or activity. Studies on the effects of Bt on non-target soil microorganisms in Bt maize and Bt cotton cultivation found that microbial biodiversity and activity were no different than that of their non-Bt counterparts (Icoz, 2008; Shen et al., 2006).

No Action Alternative: Biodiversity

Under the No Action Alternative, MON 87701 and its progeny would continue to be regulated under 7 CFR part 340. Production of MON 87701 would be restricted to 15,000 acres in five Atlantic Coastal states and no more than 1,000 acres of these soybeans could be grown in any county (US-EPA, 2010a).

As described in Section 4.2, acreage and cultivation practices associated with soybean production would not be affected. Agronomic practices associated with conventional soybean production such as tillage, cultivation, irrigation, pesticide application, fertilizer applications and use of agriculture equipment would continue. No direct or indirect adverse effects have been reported for non-target organisms since the introduction of commercial varieties of Bt cotton and corn in 1996. Bt cotton now represents 60% of the cotton planted in the U.S (James, 2009) and Bt corn is about 20% of the corn acreage (Glaser and Matten, 2003; Hutchison et al., 2010). Therefore, planting MON 87701

[3] 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 Cry proteins are specific for a narrow range of insects, use of Cry1Ac to control plant pests is recognized as being beneficial to the survival of non-target insects (EPA 2008).

soybeans is not expected to impact biodiversity.

Preferred Alternative: Biodiversity

A determination of nonregulated status of MON 87701 will not change the cultivation or agronomic practices, or agricultural land acreage associated with growing soybeans. Potential impacts associated with Cry proteins are expected to be similar to the no action alternative. Therefore, this alternative will have the same effect on biological diversity as the No Action Alternative.

4.5 Human Health

4.5.1 No Action Alternative: Human Health

Under the No Action Alternative, consumers are not expected to be exposed to MON 87701 because it is not registered by EPA for commercial scale planting in the U.S. The EPA registration limits the production to breeding and seed increase activities to support export of MON 87701 to tropical and subtropical regions outside the U.S. and its territories (US-EPA, 2010a).

MON 87701 is compositionally similar to currently available soybeans on the market with the exception of the Cry1Ac protein. Cry1Ac has an existing exemption from the requirement of a tolerance in food and feed commodities granted by EPA in 1997. The Cry1Ac has a history of safe use in cotton and corn products, is not toxic to humans, and is not likely to be an allergen (US-EPA, 1997; US-EPA, 2010a). Compositional tests conducted by the petitioner indicate that MON 87701 is compositionally similar to other commercially available soybeans (Monsanto, 2010). Fifteen analytes: alanine, 22:0 behenic acid, carbohydrates, daidzein, glycine, histidine, isoleucine, leucine, lysine, protein, serine, threonine, trypsin inhibitor, valine, and vitamin E were statistically different from the control varieties used in the study. The values for these analytes all fell within the range of commercially available soybean varieties (Monsanto, 2010). Therefore, MON 87701 is nutritionally indistinguishable from commercial soybeans. The consumption of this soybean variety will not affect human health differently than other soybean varieties. Soy typically contains about 50 percent protein by dry weight, and is the most important product of soybean production. A relatively small proportion of the soybean crop is consumed directly by humans and most domestic soybean meal is consumed by livestock.

The Monsanto Company initiated the consultation process with FDA for the commercial distribution of MON 87701 and submitted a safety and nutritional assessment of food and feed derived from MON 87701 to the FDA on May 28, 2009 (BNF No. 000119) (FDA, 2010a). FDA evaluated the submission and responded to the developer by letter on August 18, 2010 (FDA, 2010b). Based on the information the Monsanto Company submitted, and as of August 5, 2010, FDA has no further questions regarding MON 87701 soybean.

Based on the FDA's consultation, laboratory data and scientific literature provided by Monsanto (Monsanto, 2010), and safety data available on other Cry1Ac products, APHIS has concluded that MON 87701 would have no significant impacts on human health.

As discussed in the agronomic practices section, most soybean fields are not treated with insecticides. Soybeans can tolerate large amounts of defoliation without affecting yield (UMD, 2009). Therefore, the number of acres treated for insects varies from year to year and may vary from state to state. The NASS chemical use survey from 2006 indicates that 16 percent of soybeans planted were treated with insecticides, with treated acres varying from 75 percent in Louisiana to 4 percent in Ohio (USDA-NASS, 2007). MON 87701 soybeans only control lepidopteran pests, so treatments to control, thrips, stink bugs, and beetles would still need to be applied. MON 87701 only controls lepidopteran insects that feed on the plant directly. Soybeans in neighboring fields would still need to be treated if a lepidopteran pest had reached economic levels. Under the No Action Alternative, because the number of production acres is limited, very little change in current insecticide use patterns is expected, and, as a result, there is no expected change in farm worker exposure or health.

4.5.2 Preferred Alternative: Human Health

Under the Preferred Alternative, a determination of nonregulated status of MON 87701 by APHIS would not result in any differences in exposure to MON 87701 by consumers when compared to the No Action Alternative. Because MON 87701 and its progeny would continue to be regulated by EPA under 7 CFR part 340 for seed production, only, it is not expected that consumers will be exposed to this variety through food sources.

APHIS considers the FDA regulatory assessment in making its determination of the potential impacts of deregulation of the new agricultural product. The Monsanto Company initiated the consultation process with FDA for the commercial distribution of MON 87701 and submitted a safety and nutritional assessment of food and feed derived from MON 87701 to the FDA on May 28, 2009 (BNF No. 000119) (FDA, 2010a). FDA evaluated the submission and responded to the developer by letter on August 18, 2010 (FDA, 2010b). Based on the information the Monsanto Company submitted, and as of August 5, 2010, FDA has no further questions regarding MON 87701 soybean.

For the reasons described, above, in the No Action Alternative, there is no expected change to worker health and safety from a determination of nonregulated status of MON 87701. Based on the FDA's consultation, laboratory data and scientific literature provided by Monsanto (Monsanto, 2010), and safety data available on other Cry1Ac products, APHIS has concluded that a determination of nonregulated status of MON 87701 would have no significant impacts on human health.

4.6 Animal Feed

The majority of the soybean cultivated in the U.S. is grown for animal feed, and is usually fed as soybean meal (USB, 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 MON 87701 soybean 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.

The FDA has completed a consultation on the MON 87701 soybean. Monsanto submitted a summary of its safety and nutritional assessment of MON 87701 soybean to FDA on May 28, 2009 (FDA, 2010a). Monsanto has provided the FDA with information on the identity, function, and characterization of the genes, including expression of the gene products in MON 87701 soybean.

Monsanto analyzed the composition of forage and seed from the MON 87701 soybean and compared it to a non-transgenic soybean control variety, A5547 (control), which has a genetic background similar to MON 87701. Monsanto also evaluated the composition of forage and seed from a total of twenty commercial non-transgenic soybean varieties ("reference varieties") grown under the same field conditions as MON 87701 and control soybeans. Monsanto used the data derived from the reference varieties to generate a 99% tolerance interval for each analyte. Monsanto states that these data illustrate the natural variability in commercially grown soybean varieties grown under similar field conditions. The compositional analysis included key nutrients and anti-nutrients (Monsanto, 2010).

No Action Alternative: Animal Feed

For the No Action Alternative, MON 87701 would be registered by EPA for seed production only. There would be no commercial scale planting of MON 87701 in the U.S., and MON 87701 soybean would not be used in animal feed. As a result, there would be no additional risks or benefits to livestock feed safety from MON 87701 under the No Action Alternative.

Preferred Alternative: Animal Feed

Under the Preferred Alternative, the planting of MON 87701 would be limited by the EPA seed increase registration, but not regulated by APHIS. Thus, the restrictions placed on the MON 87701 cultivation range and acreage would be unchanged compared to the No Action Alternative. There would be no commercial planting of MON 87701. Therefore, animals feed would not include MON 87701 and animals would not be exposed to this variety through food sources.

APHIS considers the FDA regulatory assessment in making its determination of the potential impacts of deregulation of the new agricultural product. The FDA has completed its consultation on the MON 87701 soybean (FDA, 2010b). Based on a review of composition and nutritional characteristics of MON 87701 soybean, the FDA has concluded that MON 87701 is not materially different in any respect relevant to feed safety compared to soybean varieties already on the market (FDA, 2010b).

Based on this information APHIS has concluded that a determination of nonregulated status of MON 87701 soybean would have no significant impacts on animal feed or animal health. Overall impacts are similar to the No Action Alternative.

4.7 Socioeconomic Impacts

4.7.1 Domestic Economic Environment

No Action Alternative: Domestic Economic Environment

MON 87701 is registered by EPA only for seed production in five Atlantic Coastal states (Georgia, South Carolina, North Carolina, Virginia, and Maryland). It is not registered for large scale commercial planting. Given that it is not being grown for commodity use in the U.S., it will not have an effect on the U.S. domestic soybean market.

Preferred Alternative: Domestic Economic Environment

Under the Preferred Alternative, MON 87701 is not expected to have any different impacts from the No Action Alternative on the domestic soybean market. Although APHIS would not require permits or notification for the movement or release into the environment of this soybean under this alternative, its production is limited by its EPA registration.

4.7.2 Trade Economic Environment

No Action Alternative: Trade Economic Environment

The majority of exported soybean seed for planting is sold to other countries in North America. Only about 2 percent of this current market or about 460 metric tons are exported to South American countries. Growing MON 87701 on 15,000 acres could result in approximately 16,000 metric tons[4] of seed for export. This is a 35-fold increase in potential exports to this market. Brazil has already approved MON 87701 for import and planting. Based on the GATS database, soybean seed for planting is not currently exported to Brazil, so this could be a new market for soybean seed exports. Argentina and Chile, the countries that currently import the most soybean seed for planting, have not yet approved MON 87701. Because MON 87701 represents such a small portion of the total soybean seed production in the U.S., it will not impact the availability of other seed varieties that meet the current export needs.

Preferred Alternative: Trade Economic Environment

MON 87701 was developed for insect control in some South American markets. These countries have their own regulatory systems. To the extent that regulatory approval in the country of origin facilitates regulatory approvals in destination markets, a determination of nonregulated status of MON 87701 could increase seed exports to some countries. Exports to South America are a minor part (2 percent) of the current soybean seed export market (see discussion in Section 2.4.2). Increases in exports to South

[4] 15,000 acres with an average yield of 40 bushels an acre University of Missouri Extension. (1993) Table 1, Weights per bushel, Tables for Weights and Measurement: Crops, William J. Murphy, Department of Agronomy. and 60 lbs of soy per bushel UK Cooperative Extension Service. (2005) Estimating Soybean Yield, Estimating Soybean Yield, University of Kentucky - College of Agriculture. pp. 2.. Using 2204.623 lbs/ metric ton.

American markets as the result of a determination of nonregulated status of MON 87701 are not likely to change the current export amounts to other regions although it could increase the overall export of soybean seed. Soybean seed for planting is a minor part of the overall soybean export market. Even with the potential addition of new export markets, the contribution of MON 87701 to the overall soy export market is minor.

5 CUMULATIVE IMPACTS

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

5.1 Assumptions Used for Cumulative Imptacts Analysis

MON 87701 soybean is currently registered for use by the EPA in five Atlantic Coastal states, including Georgia, South Carolina, North Carolina, Virginia, and Maryland, with production being limited to a total of 15,000 acres and 1,000 acres or less per county in each of these states. The EPA registration is for seed increase, only, and does not include the commercial sale of MON 87701 soybeans in the U.S. According to the petition, the intended use of this soybean seed is for export to South American markets (Monsanto, 2010). However, the petition does mention the potential for future plans of Monsanto to expand that market into the U.S. (Monsanto, 2010). Before selling MON 87701 seed in the U.S., Monsanto would be required to obtain a new registration from EPA to sell MON 87701 for commercial use in the U.S. If the developer decides to apply for an EPA Section 3 registration, which permits wide-scale commercial planting, EPA will determine the data requirements at that time. EPA has stated in the Biopesticide Registration Action Document (BRAD) that additional information on pest biology, dose, simulation modeling, and cross resistance would be necessary to assess the risks for an unlimited commercial registration of MON 87701 (US-EPA, 2010a).

In the event APHIS reaches a determination of nonregulated status of MON 87701 (Preferred Alternative), APHIS would no longer have regulatory authority over these soybeans. The petitioner has indicated the future possibility of applying for an EPA registration that would expand the acreage of MON 87701 soybeans beyond the currently allowable 15,000 acres. Therefore, the potential future expansion of MON 87701 acreage in the U.S. is being considered as part of the cumulative impacts analysis.

GE soybeans currently are planted on the majority of soybean acres in the U.S. (93% of acreage in 2010) (USDA-ERS, 2010b). All these GE soybean varieties are herbicide resistant. As a result, the use of herbicide resistant soybean systems is the most common method in the U.S. for management of weeds in soybean fields. Based on this information, it is reasonable to foresee that MON 87701 would be combined with one or more of these APHIS deregulated herbicide resistant events in the future (USDA-APHIS, 2011a). It also should be noted that because these commercially available herbicide resistant varieties of soybeans are no longer APHIS regulated, stacking of traits with MON 87701 may be done under either the No Action or Preferred Alternatives. Therefore, throughout the cumulative impacts section, APHIS will assume that MON 87701 will be combined with a commercially available herbicide resistant variety through conventional breeding methods.

5.2 Cumulative Impacts: Acreage and Area of Soybean Production

If MON 87701 were to remain registered by the EPA for breeding and seed increase activities under the current terms and conditions, there would be no cumulative effect on current and projected land use patterns in those states. In the future, Monsanto may apply for an EPA commercial use registration for MON 87701. If approved by the EPA, MON 87701 cultivation would not be restricted in the U.S. and could be expanded from 15,000 acres to more than 75 million acres, assuming that MON 87701 is broadly adopted throughout the U.S (USDA-NASS, 2010).

It is likely that MON 87701 may be conventionally crossed with other GE soybean varieties that have been deregulated pursuant to Part 340 and the Plant Protection Act, since 93 percent of commercially planted soybeans in 2010 were genetically engineered to be herbicide resistant (USDA-ERS, 2010b). For example, Ready2Yeild™ soybean (product of a MON 87701 and the nonregulated MON 89788 cross) is already approved in Brazil and may represent a similar variety that would be commercialized in the U.S in areas where soybean experience both lepidopteran and weed pressure (USDA-APHIS, 2007).

Neither the EPA approval of MON 87701 under a commercial use registration nor the crossing of MON 87701 with an herbicide-resistant soybean variety is likely to expand the range of soybeans or change land use patterns beyond what is already observed for soybean cultivation in the U.S. MON 87701 is still a domesticated crop that cannot be cultivated outside areas of current agronomic management due to agricultural input requirements. Additionally, displacement of all currently adopted soybean varieties by MON 87701 and MON 87701 progeny is unlikely. At present, insecticides are used on only about 16 percent of soybean acres planted in the U.S. (USDA-NASS, 2007). Only a portion of these acres are managed for lepidopteran insect pests that MON 87701 protects against. Thrips, beetles, and stink bugs are also pests of soybeans (UMD, 2009) for which MON 87701 would not be effective against. Because soybeans can tolerate a large amount of defoliation, growers monitor fields and make management decisions based on the type of insect and the damage to the crop (Gouge et al., 2011). For many growers, in most years, they may not need to treat fields with insecticides at all. Therefore, these growers are not likely to adopt MON 87701 unless the cost difference between it and other varieties is negligible.

Because of the high adoption rate of herbicide resistant soybeans already in the market place, it is unlikely that combining MON 87701 with these herbicide resistant varieties will result in increased adoption of herbicide resistant varieties, even if MON 87701 is marketed in the U.S. in the future.

Consequently, the cumulative effect on land use is likely to be minimal if commercial use registration of MON 87701 and conventional crossing with nonregulated GE soybean varieties were to occur, as these actions are unlikely to increase U.S. soybean acreage and the small proportion of U.S. soybean acres that is under significant lepidopteran insect pressure.

5.3 Cumulative Impacts: Agronomic Practices

If MON 87701 were to remain registered by the EPA for breeding and seed increase activities in the five Atlantic Coastal states, there would be no expected cumulative effects on soybean agronomic practices, as cultivation of MON 87701 does not require any unique agronomic practices.

There are two potential foreseeable future activities related to MON 87701 cultivation. First, Monsanto may apply for and be approved for an EPA commercial use registration for MON 87701. In contrast to the current MON 87701 seed increase registration, commercial use registration approval would permit MON 87701 to be commercially produced and sold across the U.S. Secondly, Monsanto may also cross MON 87701 with other commercially-available GE soybean varieties for commercialization in the U.S. An example would be the production of a soybean variety containing both nonregulated Bt and herbicide resistance traits, such as Ready2Yeild™ soybean (product of a MON 87701 and MON 89788 cross).

The potential approval of MON 87701 under a commercial use registration by EPA and generation of soybean varieties stacked with the MON 87701 and herbicide resistant events are unlikely to result in any cumulative effects on soybean agronomic practices. This is due to similar agronomic requirements between MON 87701 and conventional soybean and the reduced likelihood that MON 87701 will be adopted across all U.S. soybean acres. Currently, insecticides are used on only about 16% of the soybean acres planted in the U.S. (USDA-NASS, 2007) Only a portion of these acres are managed for lepidopteran insect pests. Thrips, beetles, and stink bugs are also pests of soybeans. Because soybeans can tolerate a large amount of defoliation, growers monitor fields and make management decisions based on the type of insect and the damage to the crop. For many growers, in most years, they may not need to treat fields at all. Therefore, these growers are not likely to adopt MON 87701 unless the cost difference between it and other varieties is negligible.

Certain areas experience much higher insect pressure than others. For example, in Louisiana in 2006, 75 percent of the soybean fields were treated with insecticides (USDA-NASS, 2007). Growers in soybean areas where lepidopteran pests result in the majority of insect damage may choose to adopt MON 87701. Adopters of this technology may reduce insecticide applications to MON 87701 soybean fields, when lepidopteran insect pressure is high. However, these growers will still need to monitor fields for insect damage and apply other insecticides, due to the presence of insect pests not affected by Cry1Ac that may cause damage to soybean.

The states that might adopt MON 87701 due to lepidopteran insect pressure include Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Texas, and Virginia (Leonard, 2011). Together these states account for about 15 percent of the total soybean acres of the U.S. It is unlikely that all of these acres would be converted to MON 87701 soybeans, because insect pressure is not uniform in all areas of a state. Therefore, it is likely that if MON 87701 were to become available in the U.S. in the future, the adoption rate would be less than 15 percent of the total U.S. soybean production. The adoption rate would be driven by the price of MON 87701 seed, the cost of insecticides, the likelihood of damage levels from lepidopteran pests that reach economic thresholds, and the price of soybeans.

5.4 Cumulative Impacts: Soybean Seed Production

There would likely be no cumulative effect on seed production, as the management practices for the production of high quality seed would be the same under the No Action and Preferred Alternatives. These management practices include following AOSCA or state standards for the production of soybean seed of the desired class.

5.5 Cumulative Impacts: Organic Soybean Production

If MON 87701 were to remain as currently registered by the EPA for breeding and seed increase activities, there would be no cumulative impacts on organic soybean production. Although MON 87701 could be bred with other nonregulated GE soybean varieties to produce a stacked variety (e.g., Bt and herbicide resistant soybean) under both APHIS regulated and nonregulated status, there would be no cumulative impacts to organic soybean production due to the limited production acreage specified under the current EPA permit conditions.

On a broader scale, if MON 87701 were to be granted a commercial use registration by EPA and if MON 87701 were to be stacked with other traits, such as herbicide resistance, then it is possible for MON 87701 to increase acreage beyond the previously approved cultivation area. However, as described before, it is unlikely that MON 87701 would be adopted and displace all of the currently-adopted soybean varieties. The states that might adopt MON 87701 due to lepidopteran insect pressure include Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Texas, and Virginia (Leonard, 2011). Soybean cultivation area in these states totals 18,829,000 acres, with organic soybean production totaling 19,301 acres or 0.13 percent of total soybean cultivation (USDA-ERS, 2010a). Due to the small proportion of organic soybean production in the states likely to adopt MON 87701 if it were to become available commercially, it is unlikely that there would be any cumulative impacts from a determination of nonregulated status of MON 87701 by APHIS (Preferred Alternative) and any changes in its EPA registration.

5.6 Cumulative Impacts: Water Resources

If MON 87701 were to remain registered by the EPA for breeding and seed increase activities in the five Atlantic Coastal states, there would likely be no cumulative effect on water resources, as the impact of the No Action Alternative and the Preferred Alternative is similar across the five state region dictated by the EPA seed increase registration for MON 87701.

The potential approval of MON 87701 under a commercial use registration by EPA and generation of soybean varieties stacked with the MON 87701 and herbicide resistant events is also unlikely to have a cumulative effect on water resources over a larger range of cultivation beyond the five Atlantic coastal states previously described. It also does not result in a change in production practices that may indirectly affect water use or water runoff from agricultural fields. As discussed above, there may be a reduction in insecticide use on MON 87701 fields. However, it is not likely to change the effects of agricultural chemicals on surface or ground water because the individual fields will be dispersed among the larger landscape. In the future it is possible that the developer may seek an EPA registration that would allow planting on a larger area. As discussed above this area is likely to be in the southern U.S. were lepidopteran insect pressure reaches economic levels. It is possible that adoption of MON 87701 could result in fewer insecticide applications in these areas. However, it is unlikely that the magnitude of this change would impact surface or groundwater resources both because other insect pressure may still require insecticide applications and because insect pressure varies from year to year and location to location. Currently, insecticides are applied to few soybean acres, so the overall change in insecticide applications will be small. Therefore, there are no cumulative effects on water resources from the preferred alternative.

5.7 Cumulative Impacts: Soil Quality

If use of MON 87701 were to remain as currently specified under EPA registration (i.e., for breeding and seed increase activities in the five Atlantic Coastal states, only), there would likely be no cumulative effect on soil quality, as the impact of the No Action Alternative and the Preferred Alternative is similar across the five state region dictated by the EPA seed increase registration for MON 87701.

If, in the future, MON 87701 is granted a commercial use registration by the EPA, it may be cultivated across a larger area than the 15,000 Atlantic Coastal state acres where it is presently approved. Substitution of currently adopted soybean varieties with MON 87701 is unlikely across large swaths of soybean cultivation area due to the lack of lepidopteran insect pressure resulting in significant economic effects. Additionally, as discussed in Section 4.2.2, there are no anticipated changes in soil, as the use of tillage, agriculture equipment, irrigation, and fertilizer applications would not likely change as a result of a determination of nonregulated status of MON 87701. Therefore, even if MON 87701 were to be commercialized in the future, the Preferred Alternative is not expected to contribute to increases of soil loss or degradation in comparison to the No Action Alternative, and, as a result, there are no expected cumulative impacts.

5.8 Cumulative Impacts: Air Quality

If MON 87701 were to remain as currently registered by the EPA for breeding and seed increase activities in the specified five Atlantic Coastal states, there is no expected cumulative effect on air quality resulting from a determination of nonregulated status, as the impact of the No Action Alternative and the Preferred Alternative would be the same across this five state region.

If in the future MON 87701 is granted a commercial use registration by the EPA, it may be cultivated across a larger area than the 15,000 Atlantic Coastal state acres where it is presently approved. However, adoption of MON 87701 across the entire U.S. soybean cultivation range is unlikely, as there may be a lack of large economic effect resulting from significant lepidopteran insect pressure. As previously discussed, the region most likely to adopt a soybean variety containing MON 87701 is the southern U.S. where lepidopteran insect pressure can reach economic levels. It is possible that adoption of MON 87701 could result in fewer insecticide applications in these areas. However, it is unlikely that the magnitude of this change would impact air quality, both because other insect pressure may still require insecticide applications and because insect pressure varies from year to year and location to location. Currently, insecticides are applied to few soybean acres, so the overall change in insecticide applications is expected to be small.

MON 87701 may be combined with nonregulated herbicide resistance traits, producing a soybean variety containing both traits. GE herbicide resistant soybeans already account for a majority of soybean acres in the U.S. (93% of acreage in 2010) (USDA-ERS, 2010b). Stacking MON 87701 with GE herbicide resistant traits would not result in any changes to agronomic practices already used for currently cultivated soybeans. By combining the MON 87701 event with a nonregulated herbicide resistant trait, it is possible to continue adoption and utilization of reduced- or no till strategies in soybean cultivation, effectively mitigating the cumulative impact of this agronomic practice on air quality. Therefore, there are no cumulative effects on air quality from the Preferred Alternative.

5.9 Cumulative Impacts: Climate Change

As discussed in Section 4.3.4, the Preferred Alternative will not result in any effects on climate change as compared to the No Action Alternative. While some agricultural practices can contribute to climate change through greenhouse gas emissions, these will not change as a result of a determination of nonregulated status of MON 87701 soybeans. Thus, if MON 87701 were granted an EPA commercial use registration that effectively permits an expansion in range or if MON 87701 were stacked with other nonregulated soybean varieties, there is unlikely to be a cumulative impact to climate change because of the lack of significant effects between the No Action Alternative and the Preferred Alternative.

As discussed in Section 4.3.4, climate change could contribute to changes in insect pressure in agricultural systems. To the extent that climate change results in more lepidopteran insect pressure, there may be an increased need to manage lepidoteran pests with insecticides. If this were to occur, a market for MON 87701 soybeans in the U.S. could result in the developer seeking a registration from EPA to allow for commercial use of MON 87701.

5.10 Cumulative Impacts: Animal Communities

Under EPA registration, MON 87701 is restricted to 15,000 acres in five Atlantic Coastal states (Georgia, South Carolina, North Carolina, Virginia, and Maryland). However, Cry1Ac is also expressed in commercially available cotton products either alone or in combination with other insecticidal proteins (Bio, 2011). As discussed in Section 4.4.1

MON 87701 is not toxic to vertebrate animals. It expresses a protein, Cry1Ac that is toxic to certain lepidopteran species. Caterpillars that eat Cry1Ac plants die or, at lower exposures, have delayed development. Other orders of insects are not affected by the Cry1Ac endotoxin and would not be affected by MON 87701. Because of the limited amount of MON 87701 allowed on the landscape, it would not contribute to the total number of crop acres that express the Cry1Ac protein. There are about 10.5 million acres of cotton planted in the U.S., with approximately 1.7 million of those acres located in states were MON 87701 is registered for use for seed increase by EPA.

The petitioner has indicated that in the future, MON 87701 could be made available to commercial soybean growers in the U.S. Before this could occur, the developer would need to request an EPA registration for this use. The predicted adoption areas, based on current insect pressures, could be as many as 9 million acres of soybeans. In the states that also grow cotton, the number of soybean acres is about 2 million. It is unlikely that all of these acres would adopt MON 87701 because insecticides are not currently used on all soybean acres in this area, because not all soybean acres are subject to lepidopteran pressure. Those growers that consistently use insecticides to control lepidopteran pests in soybeans are the most likely adopters. In these same areas, about 5.4 million acres of cotton are grown. Therefore, in cotton growing areas, MON 87701 soybeans could increase the acreage of Cry1Ac by about 35 percent. This could increase the exposure of animals to Cry1Ac in the environment. Vertebrate animals are not affected by Cry1Ac (see discussion in Section 4.4.1), so the change in exposure will not impact these animals. Insect populations that feed on both cotton and soy could experience greater exposure. As a result, there could be a reduction in these populations in areas where both cotton and soybeans are grown (Hutchison et al., 2010). It is important to recognize that these insects are the intended target for the insecticidal properties in these crops.

Non-target invertebrates could also experience greater exposure to the Cry1Ac endotoxin. As described in Section 4.4.1, non-target invertebrate populations are not likely to be effected by the Cry1Ac endotoxin, so the increase in exposure would not change the effects on these populations compared to the current situation.

In cotton, a decrease in insecticide use as a result of the use of Bt cottons has been seen. The same reductions may not occur with the adoption of Bt soybeans because the majority of soybeans are not treated with insecticides and many of the pests of soybeans are not susceptible to Cry1Ac. So, while in cotton there may be an observed benefit to beneficial insects, in soybeans there is not likely to be the same benefit.

Target Insect Resistance

Insect resistance management is often required as part of the EPA registration for Bt crops. Because of the limited acreage allowed for MON 87701, specific refuge requirements are not part of its EPA registration. However, the EPA permit for MON 87701 has a monitoring requirement, a remedial action plan, and required sales reporting.

If the cultivation range was to expand in the future, a new EPA registration application may require specific refuge requirements (US-EPA, 2010a). Some insects that are controlled by MON 87701 are also pest insects of cotton. The current natural refuge for cotton in the areas where MON 87701 would most likely be adopted include soybean acreage as part of the natural refuge (US-EPA, 2010a). The adoption of MON 87701 in these areas with high rates of lepidopteran pests could increase the overall acreage of plants expressing this protein. Insects, like soybean loopers can attack both cotton and soybean so there is a potential for greater exposure of that population to this protein in these areas. This could contribute to driving resistance in these populations. However, since numerous plant species have been reported as hosts for this pest (Harding 1976), these plants may act as a breeding area (i.e., refuge) where this pest can reproduce without pressure of Bt-expressing plants and/or Bt-based insecticide sprays.

Any future action to change the area where MON 87701 is EPA registered to be grown would take into account the other Bt crops in the area as well as any natural refuge in designing resistance management plan.

5.11 Cumulative Impacts: Plant Communities

APHIS has not identified any different effect from the cultivation of MON 87701 soybeans than from other available soybean varieties. MON 87701 is similar in all respects to other soybeans except for the expression of Cry1Ac. This Cry protein is toxic to certain lepidopteran insects; it does not have any effect on plants. Therefore, APHIS has not identified any cumulative impacts on plants from the cultivation of MON 87701 soybeans.

5.12 Cumulative Impacts: Gene Flow and Weediness

The soybean industry has identity protection measures in place to restrict pollen movement and gene flow between soybean fields through the use of isolation distances, border and barrier rows, the staggering of planting dates and various seed handling and transportation procedures (Bradford, 2006; NCAT, 2003; Sundstrom et al., 2002). MON 87701 soybean that is cultivated for seed will be grown using these practices. In addition, there is no evidence that horizontal gene transfer and expression of DNA occurs between soybean and soil bacteria or unrelated plant species under natural field conditions, and even if this did occur, proteins corresponding to the transgenes are not likely to be produced. Gene movement between sexually compatible soybean varieties is no greater for MON 87701 soybean than it is for other non-GE or GE cultivars. Based on the scientific evidence, APHIS has not identified any cumulative effects on gene movement that would occur from a determination of nonregulated status to MON 87701 soybeans.

5.13 Cumulative Impacts: Microorganisms

Bt from root exudates do occur in soils where GE Bt crops are planted. As discussed in Section 4.3.2, these exudates do not affect soil quality. Therefore, the production of MON 87701, even in rotation with other Bt crops, will not cumulatively impact soil quality or microorganisms when compared to the No Action Alternative.

5.14 Cumulative Impacts: 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 MON 87701 is planted.

MON 87701 is similar in all respects to other soybeans except for the expression of Cry1Ac. This Cry protein is toxic to certain lepidopteran insects. APHIS has evaluated the effects of these soybeans on nontarget organisms and determined that there is no effect (see section 4.4.5) on nontarget organisms. MON 87701 could be grown in areas where other GE crops expressing Bt proteins are grown and add to total interaction of GE Bt expressing plants and the environment. Under the current EPA registration this addition is minimal. However, in the future, if the registration is changed, larger acreage of MON 87701 could be cultivated. It is unlikely that this incremental increase in Bt crops will have a cumulative effect on biodiversity because the GE Bt expressing crops have been cultivated 1996 without adverse impacts on biodiversity in the areas of cultivation.

5.15 Cumulative Impacts: Human Health

MON 87701 soybeans express a protein, Cry1Ac, which is toxic to certain lepidopteran species. This protein is not toxic to vertebrate animals, including humans, and has no similarities to known allergens (see discussion in Section 4.5). This protein has an exemption from tolerance from the EPA. There are no effects on human health from the consumption of this protein. The Monsanto Company initiated the consultation process with FDA for the commercial distribution of MON 87701 and submitted a safety and nutritional assessment of food and feed derived from MON 87701 to the FDA on May 28, 2009 (BNF No. 000119) (FDA, 2010a). FDA evaluated the submission and responded to the developer by letter on August 18, 2010 (FDA, 2010b). Based on the information the Monsanto Company submitted, and as of August 5, 2010, FDA has no further questions regarding MON 87701 soybean. Therefore, a determination of nonregulated status of MON 87701 will not result in any cumulative effects to human health of consumers.

MON 87701 soybeans could result in lower use of insecticides on fields that may be treated for lepidoteran insect damage. This could reduce exposure of workers to insecticides if the number of applications of insecticide were reduced due to the adoption of this product. Under the current EPA registration, the limited number of acres of MON 87701 soybeans would reduce the likelihood that there would be any measurable reduction in pesticide use in any area. Individual workers may be exposed to fewer insecticide applications, but, as a group, worker exposure would not change.

If MON 87701 were EPA registered in the future for use in the U.S. on a greater number of acres there is a possibility that regional adoption of MON 87701 could reduce worker exposure to insecticides used on soybeans in certain areas. However, this reduction would only occur in areas where lepidopteran pressure is high and other insects are not of economic importance. Expression of the same Bt protein in cotton resulted in a reduction in insecticide use on cotton. However, this may not occur in soybeans because most soybean acres are not treated for insects. As discussed above in Section 4.7.3, southern states would be most likely to adopt this technology if it were available. Soybean acreage in these states accounts for about 15 percent of the total soybean acreage in the U.S. Adoption is likely to vary by location even in these southern states. The overall change in pesticide use may be measurable locally, but is unlikely to change significantly with respect to overall insecticide use on soybeans. Therefore, the potential for some reduction in insecticide use on soybean fields as the result of a possible future change in EPA registration of MON 87701 is not likely to result in cumulative impacts to worker health when compared to current soybean agricultural practices.

5.16 Cumulative Impacts: Animal Feed

A determination of nonregulated status of MON 87701 will not change the current EPA restrictions on cultivation of MON 87701 for seed increase, only. Under the current EPA permit restrictions, there would be no cumulative impacts to animal feed and livestock health associated with MON 87701 soybean seed.

The petitioner has indicated that in the future MON 87701 could be made available to commercial soybean growers in the U.S. Before this could occur, the developer would need to request an EPA registration for this use.

As with human health, the Cry1Ac protein expressed in MON 87701 soybeans, which is toxic to certain lepidopteran species, is not toxic to vertebrate animals, including livestock, and has no similarities to known allergens (see discussion in Section 4.5). This protein has an exemption from tolerance from the EPA. There are no anticipated effects on livestock health from the consumption of this protein.

The FDA has completed its consultation on MON 87701 (FDA, 2010a). Based on a review of composition and nutritional characteristics of MON 87701 soybean, the FDA has concluded that MON 87701 soybean is not materially different in any respect relevant to feed safety compared to soybean varieties already on the market (FDA, 2010b). If a determination of nonregulated status of MON 87705 soybean is made and commercial cultivation of MON 87701 is permitted by EPA in the future, no cumulative effects would be anticipated.

5.17 Cumulative Impacts: Domestic Economic Environment

Under both the No Action and Preferred Alternatives, cultivation of MON 87701 would be restricted to the five Atlantic Coastal states specified in the current EPA registration, limiting the overall number of acres to 15,000 and 1,000 acres per county in these states. Also, planting of MON 87701 would remain limited to breeding and seeds increase activities and will not be available for domestic use. A determination of nonregulated status of MON 87701 will not change the distribution or limits on the acreage of these soybeans because the current EPA registration sets those restrictions. Under these current permit conditions, there would be no cumulative impacts to the domestic soybean market associated with MON 87701 soybean seed.

The petitioner has indicated that in the future a registration that allows for planting this soybean domestically may be sought from EPA. As previously discussed, these soybeans would only likely be adopted in soybean production areas of southern states with high lepidopteran pest pressure (i.e., Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Texas, and Virginia (Leonard, 2011). In 2010, in these states, GE soybeans with GE herbicide-tolerant traits (the only GE traits available in soybeans) account for approximately 90 to 98 percent of all soybeans planted in those states. If approved for commercial production, the market penetration would be determined by the price of soybeans, the cost of the product, and the cost effectiveness of other pesticides for controlling insect pests. Since soybean acreage in these states accounts for about 15 percent of the total soybean acreage in the U.S., the total market penetration is unlikely to exceed 15 percent of the domestic soybean market.

5.18 Cumulative Impacts: Trade Economic Environment

MON 87701 was engineered to control lepidoptran pests of soybeans. These pests are more economically important in tropical and semi-tropical areas of the world than in temperate climates. MON 87701 soybean is EPA-registered for seed increase in the U.S. so that it can be exported for planting in other markets. MON 87701 will likely be conventionally crossed with nonregulated GE herbicide resistant soybean varieties to create new varieties to target both lepidopteran and weed pressure. Ready2Yeild™ soybean (product of a MON 87701 and the nonregulated MON 89788 cross) is already approved in Brazil and may represent a similar variety that would likely be bred for the tropical and subtropical soybean market (USDA-APHIS, 2007).

Soybean seed exports for crop cultivation are a minor part of the current soybean export market. Table 5 illustrates the worldwide trends for soybean exports over the next ten years. Trends for increasing overseas markets coupled with greater production and export from the target markets for this seed could increase the market for soybean seed exported for planting from the southern U.S. states. The contribution to the overall soybean export market will be insignificant because most soybean seed is exported for processing not planting. The increase in seed exports that may result from a determination of nonregulated status of MON 87701 is small compared to the total export market. Therefore, for the Preferred Alternative, there are no expected cumulative impacts on soybean exports.

In the future, if the EPA registration is changed to allow commercial production of MON 87701 in the U.S., a larger acreage of MON 87701 could be cultivated. MON 87701 would likely be stacked with other nonregulated soybean varieties, particularly GE herbicide resistant soybean varieties, to create new varieties to target both lepidopteran and weed pressure. However, as stated previously, adoption of a soybean variety containing MON 87701 is most likely to occur only in the southern U.S. where lepidopteran insect pressure can reach economic levels. The states that might adopt MON

87701 due to lepidopteran insect pressure include Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Texas, and Virginia (Leonard, 2011). Together these states account for about 15 percent of the total soybean acres of the U.S. It is unlikely that all of these acres would be converted to MON 87701 soybeans, because insect pressure is not uniform in all areas of a state. Therefore, it is likely that if MON 87701 were to become available in the U.S. in the future, the adoption rate would be less than 15 percent of the total U.S. soybean production. Additionally, since MON 87701 is expected to be crossed with already available GE soybean, it is unlikely that any additional soybean acreage would be cultivated in these areas as a result of the availability of MON 87701 on a commercial scale. Given this small percentage of potential total soybean acres planted with MON 87701 and the prediction of a declining share of worldwide soybean exports for the U.S. (Table 5), any contribution of MON 87701-containing soybean varieties to future trade exports would be insignificant. No cumulative impacts on the trade economic environment are anticipated.

_Table 5. Soybean trade long-term projections.

	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21
Importers	*Imports, million metric tons*											
European Union[1]	12.9	13.5	13.5	13.1	12.9	12.7	12.5	12.3	12.1	11.9	11.7	11.5
Japan	3.4	3.5	3.6	3.4	3.3	3.3	3.3	3.2	3.2	3.1	3.1	3.0
South Korea	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3
Taiwan	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Mexico	3.5	3.6	3.7	3.8	3.9	4.0	4.1	4.1	4.2	4.3	4.4	4.5
Former Soviet Union[2]	1.0	1.2	1.2	1.3	1.4	1.4	1.5	1.5	1.6	1.6	1.6	1.7
Other Europe	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
China	50.3	57.0	60.7	64.0	66.9	70.1	73.2	76.4	79.4	82.4	85.4	88.3
Malaysia	0.6	0.6	0.6	0.6	0.6	0.6	0.7	0.7	0.7	0.7	0.7	0.7
Indonesia	1.6	1.6	1.7	1.7	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0
Other	15.2	11.9	12.1	12.4	12.8	13.1	13.5	13.9	14.2	14.6	15.0	15.3
Total imports	92.7	97.2	101.4	104.5	107.8	111.3	114.7	118.3	121.6	124.9	128.3	131.5
Exporters	*Exports, million metric tons*											
Argentina	13.0	13.0	13.7	14.8	15.1	15.6	16.1	16.7	17.1	17.5	17.5	17.9
Brazil	28.6	31.4	33.6	34.5	36.2	37.9	40.0	41.9	43.9	45.9	48.0	49.5
Other South America	7.3	6.4	7.2	7.4	7.8	8.0	8.5	8.9	9.4	9.9	10.5	11.1
China	0.2	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Other foreign	2.8	3.2	3.6	3.6	3.7	3.8	3.9	3.9	4.1	4.2	4.3	4.4
United States	40.9	42.7	42.9	43.7	44.5	45.4	45.9	46.4	46.7	47.1	47.5	48.0
Total exports	92.7	97.2	101.4	104.5	107.8	111.3	114.7	118.3	121.6	124.9	128.3	131.5
	Percent											
U.S. trade share	44.1	44.0	42.3	41.8	41.3	40.8	40.0	39.2	38.4	37.7	37.0	36.5

[1] Covers EU-27, excludes intra-EU trade.
[2] Covers FSU-12. Includes intra-FSU trade.
Source: (USDA-ERS, 2011a). Projections completed in November 2010.

6 THREATENED AND ENDANGERED SPECIES

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

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

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

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

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or critical habitat. This process is used by APHIS to assist the program in fulfilling their obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

As part the environmental review process, APHIS thoroughly reviews GE product information and data to inform the ESA effects analysis and, if necessary, the biological assessment. For each transgene(s)/transgenic plant the following information, data, and questions are considered by APHIS:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;

- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;

- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;

- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;

- Determination of the concentrations of known plant toxicants (if any are known in the plant); and

- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES.

There are no known wild *Glycine* species related to cultivated soybean present in North America. Additionally, soybean is a highly self-pollinated species, with cross pollination to other soybean varieties occurring at very low frequencies (0.04 to 3.62 percent) in adjacent plants (Caviness, 1966). The probability of gene flow and introgression of MON 87701 into other species in the U.S. is essentially zero (Stewart et al., 2003). Therefore, it is unlikely that any outcrossing of MON 87701 with sexually compatible species, including threatened or endangered plant species, could occur in the U.S. No impact to any threatened or endangered plant species is expected.

APHIS' evaluation focused on the likelihood of whether TES species would be exposed to the toxin expressed in MON 87701 soybean. Exposure of TES species to Cry1Ac is only likely if the species occur in the areas where soybean is grown, because soybean plant parts (seeds, pollen, crop debris) are not readily transported long distances without human intervention.

The only listed TES animal found in habitat likely to include soybean fields in the area where MON 87701 may be cultivated and that might feed on soybean is the Federally Endangered Delmarva Peninsula Fox Squirrel, found in areas of the mid-Atlantic Eastern seaboard (*Sciurus niger cinereus*) (http://ecos.fws.gov/tess_public/SpeciesReport.do). The squirrel forages for food in woodlots and openings, such as farm fields, with a diet that mainly includes acorns, nuts/seeds of hickory, beech, walnut, and loblolly pine. They also feed on tree buds and flowers, fungi, insects, fruit, and seeds in the spring and mature, green pine cones in the summer and early fall (USF&WS, 1999). Considering these factors along with the lack of noted adverse effects on mice and other non-target organisms, it is expected that MON 87701 soybean will not have an adverse effect on the Delmarva Peninsula Fox Squirrel.

The use of transgenic cotton producing the Cry1Ac, the same protein expressed by MON 87701, has been shown to reduce the use broad spectrum insecticides without significant impacts on diversity of non-target insects (Cattaneo et al., 2006; Dively, 2005; Marvier, 2007; Naranjo, 2005a; Naranjo, 2005b; Romeis et al., 2006; Torres and Ruberson, 2006;

Torres and Ruberson, 2005; Whitehouse et al., 2005). 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; Romeis et al., 2008; Sanvido et al., 2007; US-EPA, 2008a). Cry1Ab and Cry2Ae proteins are highly specific to Lepidoptera. The specificity of Bt crystalline proteins to lepidopteran insect larvae, but not for other insects, birds, and mammals results from the highly specific receptors for these proteins in the larvae midgut (Arora et al., 2007). Once activated by insect-specific proteases in the insect midgut, Cry proteins bind to receptors in the midgut. Such binding leads to the formation of pores in the midgut membranes and ultimately to cell lysis and death. The specific binding of Bt-based Cry proteins to midgut membrane receptors is a key determinant of pest specificity (Showalter et al., 2009). Accordingly, the APHIS review of the potential impacts is focused on Federally listed threatened and endangered lepidopterans in the soybean growing regions of the U.S. where MON 87701 potentially could be grown.

APHIS has thoroughly examined all listed and proposed threatened and endangered Lepidoptera and compared their habitats to counties where soybeans of this petition could be grown. APHIS has determined that the breeding habitats of listed Lepidoptera do not overlap soybean growing areas. Therefore, it is highly unlikely that these species can be exposed to Bt soybeans. Threatened and endangered Lepidoptera in the U.S. have very restrictive habitat ranges; and their larvae typically feed on specific host plants, none of which includes soybeans, or plants likely to be found in soybeans fields. There are lepidoptera species that are Federally listed TES in the U.S. (FWS, 2010). The Mitchell's satyr butterfly (*Neonympha mitchellii mitchelli*) occurs in Virginia and the St. Francis's Satyr butterfly (*Neonympha mitchellii fransisci*) in North Carolina. Both species are classified as 'endangered' by the U.S. Fish & Wildlife Service (FWS, 2010). The Dakota skipper (*Hesperia dacotae*) and the Karner blue butterfly (*Lycaeides melissa samuelis*) are also listed as threatened, endangered, proposed, or candidate species (FWS, 2010), but they do not occur in the Coastal Atlantic states, as defined in this petition. The habitat of the endangered Saint Francis' satyr butterfly "consists primarily of "*wide, wet meadows dominated by a high diversity of sedges and other wetland graminoids.*" (FWS, 2010) There are no Federally endangered or threatened lepidopteran species present in Georgia, Maryland, or South Carolina (FWS, 2010). These three species are not known to feed on soybeans (The Xerces Society for Invertebrate Conservation).

Based on the above information, APHIS has determined that the Preferred Alternative, deregulating MON 87701 soybeans, would have no effect on Federally listed TES and species proposed for listing, or on designated critical habitat or habitat proposed for designation. Consequently, a written concurrence or formal consultation with the US FWS is not required for this action

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

7.1.1 Executive Orders with Domestic Implications

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

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

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

Each alternative was analyzed with respect to EO 12898 and 13045. Neither alternative is expected to have a disproportionate adverse effect on minorities, low-income populations, or children. As presented in the Environmental Consequences section, no significant impacts were identified in the analyses conducted on human health or the physical environment.

MON 87701 has been shown to be no difference in compositional and nutritional quality compared to conventional soybean, apart from the presence of the Cry1Ac protein. The inserted gene (*cry1Ac*) and protein (Cry1Ac) expressed in MON 87701 are not expected to be allergenic, toxic, or pathogenic in mammals. The Cry1Ac protein has a history of safe consumption in the context of other food and feeds (FDA, 2010c). This information establishes the safety of MON 87701 and its products to humans, including minorities and low income populations 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 a determination of nonregulated status of MON 87701 are expected to have a disproportionate adverse effect on minorities and low income populations. MON 87701 is genetically engineered to express an insecticidal protein, Cry1Ac. MON 87701 may potentially be stacked with currently available nonregulated herbicide tolerant traits. Thus, pesticide application practices and usage associated with a determination of nonregulated status of MON 87701 are not expected to change from the current trends for existing nonregulated GE soybeans.

MON 87701 has been shown to be no difference in compositional and nutritional quality compared to conventional soybean, apart from the presence of the Cry1Ac protein. The inserted gene (*cry1Ac*) and protein (Cry1Ac) expressed in MON 87701 are not expected to be allergenic, toxic, or pathogenic in mammals. The Cry1Ac protein has a history of safe consumption in the context of other food and feeds (FDA, 2010c). This information establishes the safety of MON 87701 and its products to humans, including 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 a determination of nonregulated status of MON 87701 are expected to have a disproportionate adverse effect on children. MON 87701 is genetically engineered to express an insecticidal protein, Cry1Ac. MON 87701 may potentially be stacked with currently available nonregulated herbicide tolerant traits. Thus, pesticide application practices and usage associated with a determination of nonregulated status of MON 87701 are not expected to change from the current trends for existing nonregulated GE soybeans.

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

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

All soybean varieties, including MON 87701, require human assistance to persist beyond a first generation of soybean plants that may arise from spilled seed; they do not establish self-propagating populations. Soybean does not possess traits that are characteristic of invasive species (Baker, 1965).

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

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

MON 87701 has been shown to be no difference in compositional and nutritional quality compared to conventional soybean, apart from the presence of the Cry1Ac protein. The inserted gene (*cry1Ac*) and protein (Cry1Ac) expressed in MON 87701 are not expected to be allergenic, toxic, or pathogenic in mammals. The Cry1Ac protein has a history of safe consumption in the context of other food and feeds (FDA, 2010c). Based on APHIS' assessment of MON 87701, it is unlikely that a determination of nonregulated status of MON 87701 will have a negative effect on migratory bird populations.

7.1.2 International Implications

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

APHIS has given this EO careful consideration and does not expect a significant environmental impact outside the U.S. in the event of a determination of nonregulated status of MON 87701. All existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new soybean cultivars internationally apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340.

Any international trade of MON 87701 subsequent to a determination of nonregulated status of the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC, 2010). The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC, 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

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

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

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

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

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

7.1.3 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the changes in soybean production due to the unrestricted use of MON 87701. Cultivation of MON 87701 is not expected to lead to the increased production of soybean in U.S. agriculture.

There is no expected change in water use and quality due to the cultivation of MON 87701 compared with current soybean production. Also, there is no expected change in air quality associated with the cultivation of MON 87701.

Based on this review, APHIS concludes that the cultivation of MON 87701 would comply with the Clean Water Act and the Clean Air Act.

7.1.4 Impacts on Unique Characteristics of Geographic Areas

A determination of nonregulated status of MON 87701 is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

The common agricultural practices that would be carried out in the cultivation of MON 87701 are not expected to deviate from current practices. The product is expected to be deployed on agricultural land currently suitable for production of soybean and replace existing varieties, and is not expected to increase the acreage of soybean production.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of MON 87701. 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 MON 87701, including the use of EPA registered pesticides.

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

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

APHIS' proposed action, a determination of nonregulated status of MON 87701 is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

APHIS' Preferred Alternative would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of significant scientific, cultural, or historical resources.

APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for increased noise on the use and enjoyment of a historic property during the operation of tractors and other mechanical equipment close to such sites. Nevertheless, it is expected that this noise would only be temporary and short-term. The cultivation of MON 87701 is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

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