NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

Monsanto Company
Event MON 87701 Soybean

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

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

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS Number 09-082-01p) by Monsanto Company (Monsanto) for their genetically engineered Event MON 87701 Soybean (hereafter referred to as MON 87701 Soybean) that expresses a Cry1Ac protein to protect soybean plants from lepidopteran insect damage. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from approving the petition seeking nonregulated status for MON 87701 Soybean. The EA assesses alternatives to a determination of nonregulated status of MON 87701 Soybean and analyzes the potential environmental and social effects that result from the proposed action and the alternatives.

Since releasing the draft EA for public comment on June 28, 2011, EPA approved a label change that allows MON 87701 Soybean to be grown in Illinois, Arkansas, and the Commonwealth of Puerto Rico (U.S. EPA, 2011). This label change only modified the locations where MON 87701 Soybean breeding and seed multiplication activities can be carried out under the EPA label and did not expand the total acreage approved for planting. Total EPA approved acreage remains at 15,000 acres. Relevant information and environmental impacts associated with this EPA label change has been incorporated into the final EA and this NEPA decision document.

Regulatory Authority

"Protecting American agriculture" is the basic charge of APHIS. APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of

[1] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §508.14).

genetically engineered (GE) varieties) can provide benefits to the environment, consumers, and farm income.

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

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

APHIS is responsible for regulating GE organisms and plants under the plant pest provision in the Plant Protection Act of 2000, 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 United States have successfully completed this consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food.

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

Regulated Organisms

The APHIS Biotechnology Regulatory 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.

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 who request a determination of the regulated status of GE organisms, including GE plants such as MON 87701 Soybean. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

Monsanto has submitted a petition (APHIS Number 09-082-01p) to APHIS seeking a determination that their genetically engineered MON 87701 Soybean is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR Part 340.

MON 87701 Soybean

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 Soybean for commercial production if Monsanto obtains appropriate registrations from the EPA (Monsanto, 2010). Currently, MON 87701 Soybean 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, Maryland, Illinois, Arkansas, and the Commonwealth of Puerto Rico with no more than 1,000 acres per county (municipio) per year except for Illinois and Arkansas where only 300 acres can be grown in each state (U.S. EPA, 2011). This type of EPA registration precludes commercial sale of MON 87701 Soybean in the U.S.

Coordinated Framework Review

Food and Drug Administration

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

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 Soybean for seed increase, only, with the following terms and conditions (US-EPA, 2010):

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 Soybean 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, 2010).

On June 9, 2011 EPA approved a label change that allows MON 87701 Soybean to be grown in Illinois, Arkansas, and the Commonwealth of Puerto Rico. The label permits up to 300 acres in Arkansas or Illinois, and up to 100 acres per municipio in Puerto Rico. There is still a limit of total 15,000 acres in the allowed areas (U.S. EPA, 2011).

Scope of the Environmental Analysis

Although a determination of nonregulated status of MON 87701 Soybean would allow for new plantings of MON 87701 Soybean to occur anywhere in the U.S., APHIS primarily focused the environmental analysis to those geographic areas where MON 87701 Soybean could be grown. MON 87701 Soybean is regulated in part by FIFRA, due to characterization of the Cry1Ac protein product as a pesticide by the EPA. Currently, MON 87701 Soybean 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, 2010) as well as Illinois, Arkansas, and the Commonwealth of Puerto Rico (U.S. EPA, 2011). This registration is limited to 15,000 total acres in the specified states and Puerto Rico, with production limited to 1,000 acres per county (municipio) except in Arkansas and Illinois were production is limited to 300 acres for each state. Commercial sale of MON 87701 Soybean 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 Soybean for seed production in Georgia, South Carolina, North Carolina, Virginia, and Maryland (US-EPA, 2010) as well as Illinois, Arkansas , and the Commonwealth of Puerto Rico (U.S. EPA, 2011).

Public Involvement

On June 28, 2011, APHIS published a notice in the Federal Register (76 FR 37770-37771, Docket no. APHIS-2011-0038) announcing the availability of the Monsanto petition, and the APHIS PPRA and draft EA for a 60-day public review and comment period. Comments were required to be received on or before August 29, 2011. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of four comments were received from individuals during the comment period. Comment documents may be viewed at http://www.regulations.gov/#!searchResults;rpp=10;po=0;s=aphis-2011-0038. Two public comments referenced a different soybean line; these were outside the scope of the action being considered by the Agency in this docket. These comments were referred to the docket of the referenced soybean line. One comment expressed opposition to a determination of nonregulated status of MON 87701 Soybean, but did not change the analysis provided in the PPRA or draft EA. This individual did not mention a specific disagreement with APHIS' analyses of MON 87701 Soybean detailed in the EA or the PPRA(USDA-APHIS, 2011a); rather, the comment made general statements about unknowns associated with the use of genetically modified organisms (GMOs) or GE crops. The second comment suggests that APHIS should analyze the impacts of MON 87701 Soybean on bees and groundwater. Impacts to non-target insects and impacts on water are both addressed in the EA. The author of the comment did not offer any new information or mention any specific disagreement with APHIS' analyses of MON 87701 Soybean detailed in the EA or the PPRA(USDA-APHIS, 2011a). No new issues, alternatives or

substantive new information were identified in any of the comments received by APHIS. Responses to substantive comments are included as an attachment to this Finding of No Significant Impact.

Major Issues Addressed in the EA

The issues considered in the EA were developed based on APHIS' determination that certain genetically engineered organisms are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status of MON 87701 Soybean. Issues discussed in the EA were developed by considering public concerns as well as issues raised in public comments submitted for other environmental assessments of genetically engineered organisms, concerns raised in lawsuits, as well as those issues that have been raised by various stakeholders. These issues, including those regarding the agricultural production of soybean using various production methods, and the environmental and food/feed safety of genetically engineered plants were addressed to analyze the potential environmental impacts of MON 87701 Soybean.

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

Agricultural Production Considerations:

- Acreage and Areas of 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

Alternatives that were fully analyzed
The EA analyzes the potential environmental consequences of a determination of nonregulated status of MON 87701 Soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 87701 Soybean is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS, 2011b), APHIS has concluded that MON 87701 Soybean is unlikely to pose a plant pest risk. Therefore, APHIS must determine that MON 87701 Soybean is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of MON 87701 Soybean. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section of the EA.

No Action: Continuation as a Regulated Article
Under the No Action Alternative, APHIS would deny the petition. MON 87701 Soybean and progeny derived from MON 87701 Soybean 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 Soybean 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 Soybean.

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

Preferred Alternative: Determination that MON 87701 Soybean is No Longer a Regulated Article
Under this alternative, MON 87701 Soybean and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. MON 87701 Soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2011a). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87701 Soybean 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 Soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87701 Soybean 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 Soybean and progeny derived from this event if the developer decides to commercialize MON 87701 Soybean.

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

Prohibit any MON 87701 Soybean 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 Soybean, 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 Soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2011a).

In enacting the Plant Protection Act, Congress found that

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

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

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

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

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

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

Requirement of Testing For MON 87701 Soybean

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

Environmental Consequences of APHIS' Selected Action

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

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	**No**	**Yes**
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2011a)
Management Practices		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
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
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	Unchanged from the No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	unlikely to affect insect populations due to the limited number acres and the patchy distribution of these fields on the landscape.	
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		
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

Finding of No Significant Impact

The analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. I

agree with this conclusion and therefore find that an EIS need not be prepared. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27):

Context – The term "context" recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. This action has potential to affect conventional and organic soybean production systems, including surrounding environments and agricultural workers; human food and animal feed production systems; and foreign and domestic commodity markets. MON 87701 Soybean is regulated in part by FIFRA, due to characterization of the Cry1Ac protein product as a pesticide by the EPA. Currently, MON 87701 Soybean 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, 2010) and Illinois, Arkansas, and the Commonwealth of Puerto Rico (U.S. EPA, 2011). This registration is limited to 15,000 total acres in the specified states and Puerto Rico. Production is limited to 1,000 acres per county or municipio, except in Illinois and Arkansas were it is limited to 300 acres in each state. Commercial sale of MON 87701 Soybean in the U.S. is not allowed under this type of EPA registration. 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). If approved by the EPA for commercial sale, MON 87701 Soybean 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 Soybean is broadly adopted throughout the U.S (USDA-NASS, 2010). Therefore, the potential future expansion of MON 87701Soybean acreage in the U.S. is considered as part of the cumulative impacts analysis. However, potential adoption of MON 87701 Soybean by soybean growers in the U.S. is limited. MON 87701 Soybean expresses a Cry1Ac protein to protect soybean plants from lepidopteran insect damage. 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. The states that might adopt MON 87701 Soybean 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 Soybean, because insect pressure is not uniform in all areas of a state. Therefore, it is likely that if MON 87701 Soybean 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 Soybean seed, the cost of insecticides, the likelihood of damage levels from lepidopteran pests that reach economic thresholds, and the price of soybeans.

A determination of nonregulated status of MON 87701 Soybean is not expected to directly cause an increase in agricultural acreage devoted to soybean production, or those soybean acres devoted to GE soybean cultivation. The availability of MON 87701 Soybean will not change cultivation areas for soybean production in the U.S. and there are no anticipated changes to the availability of GE and non-GE soybean varieties on the market. Due to planting restrictions defined by the EPA seed increase registration, cultivation of MON 87701 Soybean 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 and Illinois, Arkansas, and

the Commonwealth of Puerto Rico. Cultivation of MON 87701 Soybean for seed increase activities on 15,000 acres in the allowed states would represent 0.09 percent of the approximate 15.5 million soybean acres planted in this region (USDA-NASS, 2011). Additionally, neither the EPA approval of MON 87701 Soybean under a commercial use registration nor the crossing of MON 87701 Soybean 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 Soybean is still a domesticated crop that cannot be cultivated outside areas of current agronomic management due to agricultural input requirements. GE soybeans currently are planted on the majority of soybean acres in the U.S. (93% of acreage in 2010) (USDA-ERS, 2010a). 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 Soybean would be combined with one or more of these herbicide resistant events that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 in the future (USDA-APHIS, 2011b).

Although a determination of nonregulated status of MON 87701 Soybean would allow for new plantings of MON 87701 Soybean to occur anywhere in the U.S., APHIS primarily focused the environmental analysis to those geographic areas where MON 87701 Soybean could be grown. A determination of nonregulated status of MON 87701 Soybean is not expected to increase soybean production, either by its availability alone or accompanied by other factors, or cause an increase in overall GE soybean acreage.

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

1. *Impacts that may be both beneficial and adverse.*
   A determination of nonregulated status of MON 87701 Soybean will have no significant environmental impact in relation to the availability of GE, conventional or organic soybean varieties. As discussed in Chapters 4 and 5 of the EA, a determination of nonregulated status of MON 87701 Soybean is not expected to directly cause an increase in agricultural acreage devoted to soybean production, or those soybean acres devoted to GE soybean cultivation. The availability of MON 87701 Soybean will not change cultivation areas for soybean production in the U.S. and there are no anticipated changes to the availability of GE and non-GE soybean varieties on the market. A determination of nonregulated status of MON 87701 Soybean could add another GE soybean variety to the conventional soybean market and is not expected to change the market demands for GE soybean or soybean produced using organic methods. GE and organic soybeans are planted on about 93% and 0.13% of soybean acres in the U.S., respectively (USDA-ERS, 2010a). All of the 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 Soybean would be combined with one or more of these herbicide resistant events that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 in the future (USDA-APHIS, 2011b). Currently, MON 87701 Soybean is registered by the EPA for breeding and seed increase activities in the states of Georgia, South Carolina, North Carolina, Virginia, and

Maryland (US-EPA, 2010) as well as Illinois, Arkansas, and the Commonwealth of Puerto Rico. This registration is limited to 15,000 total acres in the specified states (and Puerto Rico), with production limited to 1,000 acres per county (municipio) except for Arkansas and Illinois where it is limited to 300 acres in each state (U.S. EPA, 2011). Relative to the approximate 5.5 million acres of soybeans harvested in these seven states, MON 87701 Soybean may represent up to 0.09 percent of total soybean acreage. The majority of the remaining soybeans (about 90 percent) are nonregulated GE soybeans (USDA-ERS, 2010a), with organic soybean production in these six states representing less than 2 percent of total organic soybean production. Illinois has about 6.5 percent of the national organic soybean production (see Table 3, Section 2.1.4). However, acreage is limited to 300 acres in the whole state, or less than 3/1000th of 1percent of the soybeans grown in this state. On a broader scale, if MON 87701 Soybean were to be granted a commercial use registration by EPA, the states that might adopt MON 87701 Soybean 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 approximately 18.8 million acres, with organic soybean production totaling 0.13 percent of total soybean cultivation (USDA-ERS, 2010b). A determination of nonregulated status of MON 87701 Soybean will not result in changes in the current practices of planting, tillage, fertilizer application/use, cultivation, pesticide application/use and volunteer control. Planting of MON 87701 Soybean may locally reduce the amount of insecticides applied to control lepidopteran pests when insect pressures reach economic thresholds. Management practices and seed standards for production of Certified soybean seed would not change. MON 87701 Soybean is EPA-registered for seed increase in the U.S. so that it can be exported for planting in other markets. The increase in seed exports that may result from a determination of nonregulated status of MON 87701 Soybean is small compared to the total export market. Soybean seed exports for crop cultivation are a minor part of the current soybean export market. Soybean exported for replanting represents less than 1 percent (i.e., 0.15 percent) of the exported soy market.

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

A determination of nonregulated status of MON 87701 Soybean would have no significant impacts on human or animal health. MON 87701 Soybean 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, 2010). Compositional tests conducted by the petitioner indicate that MON 87701 Soybean is compositionally similar to other commercially available soybeans (Monsanto, 2010). Monsanto initiated the consultation process with FDA for the commercial distribution of MON 87701 Soybean and submitted a safety and nutritional assessment of food and feed derived from MON 87701 Soybean to the FDA on May 28, 2009 (BNF No. 000119) (FDA, 2010b). FDA evaluated the submission and responded to the developer by letter on August 18, 2010 (FDA, 2010a). Based on the information Monsanto 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 Soybean would have no significant impacts on human or animal health.

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

There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status of MON 87701 Soybean. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property; do not cause any alterations of property, wildlife habitat, or landscapes; and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of MON 87701 Soybean. The product will be deployed on agricultural land currently suitable for production of soybeans, will replace existing varieties, and is not expected to increase the acreage of soybean production. 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 Soybean including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of MON 87701 Soybean, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to soybean production sites.

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

The effects on the quality of the human environment from a determination of nonregulated status of MON 87701 Soybean are not highly controversial. Although there is some opposition to a determination of nonregulated status of MON 87701 Soybean, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment. As discussed in Chapters 4 and 5 of the EA, a determination of nonregulated status of MON 87701 Soybean is not expected to directly cause an increase in agricultural acreage devoted to soybean production, or those soybean acres devoted to GE soybean cultivation. The availability of MON 87701 Soybean will not change cultivation areas for soybean production in the U.S. and there are no anticipated changes to the availability of GE and non-GE soybean varieties on the market. A determination of nonregulated status of MON 87701 Soybean could add another GE soybean variety to the conventional soybean market and is not expected to change the market demands for GE soybean or soybean produced using organic methods. Currently, MON 87701 Soybean 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, 2010) and Illinois, Arkansas, and the Commonwealth of Puerto Rico (U.S. EPA, 2011). This registration is limited to 15,000 total acres in the specified seven states and Puerto Rico, with production limited to 1,000 acres per county (municipio), except for Illinois and Arkansas where it is limited to 300 acres in each state. On a broader scale, if

MON 87701 Soybean were to be granted a commercial use registration by EPA, the states that might adopt MON 87701 Soybean 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 (approximately 18.8 million acres) of the total soybean acres of the U.S. (75 million acres) (USDA-ERS, 2010a; USDA-NASS, 2010). A determination of nonregulated status of MON 87701 Soybean will not result in changes in the current practices of planting, tillage, fertilizer application/use, cultivation, pesticide application/use and volunteer control. Management practices and seed standards for production of Certified soybean seed would not change. The effect of MON 87701 Soybean on wildlife or biodiversity is no different than that of other Bt crops currently used in agriculture, or other GE or non-GE soybean produced in conventional agriculture in the U.S. During the public comment period, APHIS received comments opposing a determination of nonregulated status of MON 87701 Soybean. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. One individual expressed a general opposition to genetically modified organisms (GMOs) or GE crops. The comment did not mention a specific disagreement with APHIS' analyses of MON 87701 Soybean detailed in the EA or the PPRA (USDA-APHIS, 2011b); rather it suggests that GE soybean and GE plants generally have a negative effect on human health and environmental safety. The comment did not provide any supporting evidence for its claims. A second comment requested that APHIS analyze the impacts of MON 87701 Soybean on honey bees and groundwater. APHIS addressed impacts to non-target insects and water quality in the EA. APHIS has addressed substantive comments in the response to public comments document attached to this FONSI based on scientific evidence found in peer-reviewed, scholarly, and scientific journals.

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

Based on the analysis documented in the EA the possible effects on the human environment are well understood. The effects of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. As discussed in Chapters 4 and 5 of the EA, a determination of nonregulated status of MON 87701 Soybean is not expected to directly cause an increase in agricultural acreage devoted to soybean production, or those soybean acres devoted to GE soybean cultivation. A determination of nonregulated status of MON 87701 Soybean will not result in changes in the current practices of planting, tillage, fertilizer application/use, cultivation, pesticide application/use and volunteer control. Management practices and seed standards for production of Certified soybean seed would not change. The effect of MON 87701 Soybean on wildlife or biodiversity is no different than that of other Bt crops currently used in agriculture, or other GE or non-GE soybean produced in conventional agriculture in the U.S. As described in Chapter 2 of the EA, well established management practices, production controls, and production practices (GE, conventional, and organic) are currently being used in soybean production systems (commercial and seed production) in the U.S. Therefore, it is reasonable to assume that farmers, who produce conventional soybean (GE and non-GE varieties), MON 87701 Soybean, or produce soybean using organic methods, will continue to use these

reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural soybean production. Additionally, GE soybeans currently are planted on the majority of soybean acres in the U.S. (93% of acreage in 2010) (USDA-ERS, 2010a). Based upon historic trends, conventional production practices that use GE varieties will likely continue to dominate in terms of acreage with or without a determination of nonregulated status of MON 87701 Soybean. Given the extensive experience that APHIS, stakeholders, and growers have in dealing with the use of GE soybean products and Bt agricultural crops, the possible effects to the human environment from the release of a an additional GE soybean product are already well known and understood. Therefore the impacts are not highly uncertain, and do not involve unique or unknown risks.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*
A determination of nonregulated status of MON 87701 Soybean would not establish a precedent for future actions with significant effects or represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based upon an independent determination on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340. Each petition that APHIS receives is specific to a particular GE organism and undergoes this independent review to determine if the regulated article poses a plant pest risk. Under the authority of the plant pest provisions of the 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 who request a determination of the regulated status of GE organisms, including GE plants such as MON 87701 Soybean. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340. APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is 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.

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

No significant cumulative effects were identified through this assessment. The EA discussed cumulative effects on soybean management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative effects analysis is provided in Chapter 5 of the EA, including the potential future expansion of MON 87701Soybean acreage in the U.S. and the assumption that MON 87701 Soybean will be stacked with a commercially available herbicide resistant soybean variety. In the event APHIS reaches a determination of nonregulated status of MON 87701 Soybean, 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 Soybean beyond the currently allowable 15,000 acres. GE soybeans currently are planted on the majority of soybean acres in the U.S. (93% of acreage in 2010) (USDA-ERS, 2010a). 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 Soybean would be stacked (combined) with one or more of these herbicide resistant events that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 in the future (USDA-APHIS, 2011b). 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). However, there is no guarantee that MON 87701 Soybean will be stacked with any particular nonregulated GE variety, as company plans and market demands play a significant role in those business decisions. Moreover, MON 87701 Soybean could even be combined with non-GE soybean varieties. Thus, predicting all potential combinations of stacked varieties that could be created using both GE soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 and also non-GE soybean varieties is hypothetical and purely speculative. In the event of a determination of nonregulated status of MON 87701 Soybean, APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of MON 87701 Soybean when added to other past, present, and reasonably foreseeable future actions.

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

A determination of nonregulated status of MON 87701 Soybean will not adversely impact cultural resources on tribal properties. Any farming activities that may be taken by farmers on tribal lands are only conducted at the tribe's request; thus, the tribes have control over any potential conflict with cultural resources on tribal properties. A determination of nonregulated status of MON 87701 Soybean would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the

National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of nonregulated status of MON 87701 Soybean. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of MON 87701 Soybean is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the soybean production regions. The cultivation of MON 87701 Soybean does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

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

As described in Chapter 6 of the EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of MON 87701 Soybean on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. After reviewing possible effects of a determination of nonregulated status of MON 87701 Soybean, APHIS has determined that a determination of nonregulated status of MON 87701 Soybean, would have no effect on Federally listed TES and species proposed for listing, or on designated critical habitat or habitat proposed for designation.

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

The proposed action would be in compliance with all federal, state, and local laws. Because the agency has concluded that MON 87701 Soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87701 Soybean is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. Monsanto initiated the consultation process with FDA for the commercial distribution of MON 87701 Soybean and submitted a safety and nutritional assessment of food and feed derived from MON 87701 Soybean to the FDA on May 28, 2009 (BNF No. 000119) (FDA, 2010b). FDA evaluated the submission and responded to the developer by letter on August 18, 2010 (FDA, 2010a). Based on the information Monsanto submitted, and as of August 5, 2010, FDA has no further questions regarding MON 87701 Soybean.

MON 87701 Soybean 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, 2010). The EPA regulates 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 Soybean for breeding and seed increase activities in the Atlantic Coastal states of Georgia, South Carolina, North Carolina, Virginia, and Maryland (US-EPA, 2010). In June of 2011 the label was changed to include Illinois, Arkansas, and the Commonwealth of Puerto Rico (U.S. EPA, 2011). There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

NEPA Decision and Rationale

I have carefully reviewed the EA prepared for this NEPA determination and the input from the public involvement process. I believe that the issues identified in the EA are best addressed by selecting Alternative 2 (Determination that MON 87701 Soybean is No Longer a Regulated Article). This alternative meets APHIS' purpose and need to allow the safe development and use of genetically engineered organisms consistent with the plant pest provisions of the Plant Protection Act.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative 2 is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with MON 87701 Soybean, the continued regulated status of MON 87701 Soybean would be inconsistent with the plant pest provisions of the PPA, the regulations codified at 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status of MON 87701 Soybean will not have any significant environmental effects.

Michael C. Gregoire — 9/22/2011

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services

Date:

Animal and Plant Health Inspection Services
U.S. Department of Agriculture

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Attachment
Finding of No Significant Impact
Response to Comments
Petition 09-082-01p

On June 28, 2011, APHIS published a notice in the Federal Register (76 FR 37770- 37771 - 27303, Docket no APHIS–2011–0038) announcing the availability of the Monsanto petition, and the APHIS PPRA and draft EA for a 60-day public review and comment period. Comments were required to be received on or before August 29, 2011. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of four comments were received from individuals during the comment period. Two public comments referenced a different soybean line; these were outside the scope of the action being considered by the Agency in this docket. These comments were referred to the docket of the referenced soybean line. One comment expressed opposition to a determination of nonregulated status of MON 87701 Soybean, but did not change the analysis provided in the PPRA or draft EA. These individuals did not mention their specific disagreement with APHIS' analyses of MON 87701 Soybean detailed in the EA or the PPRA(USDA-APHIS, 2011a); rather, they made general statements about unknowns associated with the use of genetically modified organisms (GMOs) or GE crops. The second comment suggests that APHIS should analyze the impacts of MON 87701 Soybean on bees and groundwater. Impacts to non-target insects and impacts on water are both addressed in the EA. The author of the comment did not offer any new information or mention any specific disagreement with APHIS' analyses of MON 87701 Soybean detailed in the EA or the PPRA(USDA-APHIS, 2011a). No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS.

Comment: The soybean is claimed, in the backup documents, to be self-pollinating. In spite of that statement, bees, in their natural course of existence should be considered. With the fragility of bees and Colony Collapse Disorder, why risk any crop to future destruction by genetically engineered crops or herbicides. Any studies would have to involve decades of research and monitoring with impacts on crops, insects, plants, wildlife and birds across the board and with sufficient radius to determine effects.

Response: As discussed in Section IV of the EA, potential impacts of GE and non-GE soybean production practices on non-target species would be unchanged when compared to current soybean production practices. 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, including honey bees, are not likely to be affected (van Frankenhuyzen, 2009).

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, 2008a; USDA-APHIS, 2011b). 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 Soybean 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, 2008b).

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 Soybean will have no adverse effects on non-target animals.

Comment: Groundwater and any NPDES discharge would need to be studied, monitoring and analyzed. Downstream analysis would be needed. Any future assessment of or use of taxpayer funds including cleanup and oversight of contamination would need to be considered as an impact.

Response: APHIS considered the impacts on water of approving the petition for nonregulated status for MON 87701 Soybean. As discussed in section IV of the EA, planting of MON 87701 Soybean in these seven states and Puerto Rico may locally reduce the amount of insecticides applied to control lepidopteran pests. To the extent that MON 87701 Soybean 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 Soybean 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

[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, 2008a).

87701 Soybean 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 Soybean are limited by the relatively small permitted planting area. Because the fields are not a large component of the agricultural landscape (less that 0.1% of the total soybean acreage), planting MON 87701 Soybean 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.

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Plant Pest Risk Assessment for Monsanto MON 87701 Soybeans

Monsanto Company (referred to hereafter as Monsanto) has petitioned APHIS (APHIS number 09-082-01p) for a determination that genetically engineered (GE) soybean (*Glycine max*) event MON 87701 is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under APHIS' 7 Code of Federal Regulations (CFR) part 340. APHIS administers 7 CFR part 340 under the authority of the plant pest provisions of the Plant Protection Act of 2000[1]. This plant pest risk assessment was conducted to determine if MON 87701 is unlikely to pose a plant pest risk.

MON 87701 was produced by using *Agrobacterium*-mediated transformation (Monsanto, 2010). Because *Agrobacterium tumefaciens* is a plant pest, this soybean has been considered a regulated article under APHIS regulations at 7 CFR part 340.

Potential impacts to be addressed in this risk assessment are those that pertain to the use of MON 87701 and its progeny in the absence of confinement. APHIS utilizes data and information submitted by the applicant, in addition to current literature, to determine if MON 87701 is unlikely to pose a plant pest risk. If APHIS determines that a GE organism is unlikely to pose a plant pest risk, then APHIS has no regulatory authority over that organism.

Potential impacts in this Plant Pest Risk Assessment are those that pertain to plant pest risk characteristics. APHIS regulation 7 CFR 340.6(c) specifies the information needed for consideration in a petition for nonregulated status. APHIS will evaluate information submitted by the applicant related to plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, any impacts on the weediness of any other plant with which it can interbreed, and transfer of genetic information to organisms with which it cannot interbreed.

The Environmental Assessment (EA) for this petition considered whether agricultural or cultivation practices for MON 87701 may result in impacts on the environment. A thorough assessment of the effects of the determination on non-target and beneficial organisms, and threatened and endangered species is included in the EA.

Development of Lepidopteran Resistant Soybean Event MON 87701

MON 87701 soybean expresses an insecticidal protein, Cry1Ac, and was developed for the South American soybean market (Monsanto, 2010). 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

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[1] Section 403 (14) of the Plant Protection Act (7USC Sec 7702(14) defines plant pest as:
"Plant Pest - The term "plant pest" means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: (A) A protozoan. (B) A nonhuman animal. (C) A parasitic plant. (D) A bacterium. (E) A fungus. (F) A virus or viroid. (G) An infectious agent or other pathogen. (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs."

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, United States (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 U.S. Environmental Protection Agency (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. (US-EPA, 2010).

Soybean growers in the U.S., the world's largest exporter of this commodity, suffer 0.001% yield loss due to insect pests (Heatherly et al., 2009). Insect pests in the U.S. that could be controlled by MON87701 include: soybean looper (*Pseudoplusia includens)*, corn earworm / bollworm (*Helicoverpa zea*), fall armyworm (*Spodoptera frugiperda*), green cloverworm (*Plathypena scabra*), velvetbean caterpillar (*Anticarsia gemmatalis*), lesser cornstalk borer (*Elasmopalpus lignosellus*), beet armyworm (*Spodoptera exigua*), and yellow stripe armyworm (*S. ornithogalli*) (Way, 1994)

Crystal (Cry) proteins derived from *Bacillus thuringiensis* (*Bt*) have a long history of safe use without adverse human health or environmental effects, and provide an option for the control of lepidopteran insect pests (Ferré and Van Rie, 2002). *Bt*-expressing soybean is a new commodity not commercially registered in the U.S. However, *Bt*-cotton and *Bt*-corn, that also express Cry proteins, have a long history of safe use without adverse human health or environmental effects and provide an option for the control of lepidopteran insect pests (Glare and O'Callaghan, 2000; NAS, 2004; Romeis et al., 2008).

As additional information, tolerance exemptions and conditional pesticide registrations have been granted for the plant-incorporated protectant Cry1Ac in Bollgard® and Bollgard II® cottons, GE crops that express 100% amino acid sequence identity as MON 87701 (Monsanto, 2010). MON 87701 is within the scope of the U.S. Food and Drug Administration (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.

Description of the Modification

MON 87701 was developed through *Agrobacterium*-mediated transformation of soybean meristem tissue utilizing transformation vector, PV-GMIR9 (Monsanto, 2010 page 38) of soybean variety A5547, a type V maturity group soybean (Monsanto, 2010 page 37). The PV-GMIR9 vector used for the transformation of soybean to produce MON 87701 is approximately 15.5 kb and contains two T-DNAs. Each of the two T-DNAs contains a single expression cassette. The first TDNA (designated as T-DNA I) contains the *cry1Ac* expression cassette, which results in the expression of Cry1Ac protein. The *cry1Ac* expression cassette contains the *cry1Ac* coding sequence under the regulation of the *RbcS4* promoter and leader, *CTP1* chloroplast targeting sequence, and the *7S'* 3' non-translated sequence. The second TDNA (designated as T-DNA II) contains the *cp4 epsps* gene expression cassette. The *cp4epsps* expression cassette contains the *cp4 epsps* coding sequence under the regulation of the *FMV* promoter, the *shkG* leader, the *CTP2* chloroplast targeting sequence and the *E9* 3' non-translated sequence.

The backbone region outside of the T-DNAs contains two origins of replication for maintenance of plasmid in bacteria (*ori V, ori-pBR322*), a bacterial selectable marker gene (*aadA*), and a coding sequence for repressor of primer protein for maintenance of plasmid copy number in *E. coli* (*rop*). A description of the genetic elements in PV-GMIR9 is provided in Table IV-1 of the petition.

Transformed plants were self-pollinated. The unlinked insertions of T-DNA I (*cry1Ac* gene expression cassette) and T-DNA II (*cp4 epsps* gene expression cassette) segregated in the resulting progeny. A non-lethal dose of glyphosate herbicide was applied to these plants. The plants with minor injury were selected for further analyses, whereas plants showing no injury, i.e., containing T-DNA II (*cp4 epsps* gene expression cassette), were eliminated from subsequent development. Subsequently, plants containing only a single T-DNA I (*cry1Ac* gene cassette) were identified and selected by a combination of analytical techniques, including ELISA and TaqMan PCR analysis. MON 87701 was selected from these plants. (See section III of Monsanto, 2010 for a more detailed description.)

MON 87701 has been genetically engineered to contain one transgene construct[2]: a *RbcS4* promoter, a full-length *cry1Ac* gene, a *CTP*1 chloroplast targeting sequence, and a 7S α' 3' non-translated region.

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[2] The *cp4 epsps* gene from *Arabidopsis thaliana* (Monsanto, 2010, page 45), encoding for the selectable marker glyphosate tolerance, was also incorporated as part of the initial transformation process. However, the transformation process resulted in the introduction of the *cry1Ac* gene and the *cp4 epsps* gene into two different loci. The presence of the *cp4 epsps* gene allowed for selection of transformed cells containing *cry1Ac* gene in the presence of glyphosate. As part of the breeding process to develop MON 87701, the *cp4 epsps* gene was bred out, and is not present in MON 87701 (Monsanto, 2010 Figure IV-1 and table IV-1).

- The *RbcS4* promoter and 5' non-translated region from the ribulose 1,5-bisphosphate carboxylase small subunit 1A transit peptide of *Arabidopsis thaliana* (Krebbers et al., 1988).
- *CTP*1 targeting sequence encoding the transit peptide of the Arabidopsis RbcS4 encoding small subunit 1A transit peptide, from Arabidopsis thaliana, present to direct the cry1Ac protein to the chloroplast (Krebbers et al., 1988).
- *cry1Ac*, a codon-modified coding sequence of the Cry1Ac protein of *Bacillus thuringiensis* (Fischhoff and Perlak, 1996) [3]. The Cry1Ac protein is toxic to certain lepidopteran species.
- 7Sα', the 3' region of the *Sphas*1 gene of Glycine max encoding the 7S α' seed storage protein, b-conglycinin, including 35 nucleotides of the carboxyl terminal b-conglycinin coding region with the termination codon and the polyadenylation sequence (Schuler et al., 1982). The element functions to terminate transcription and direct polyadenylation of the mRNA.
- The right and left border regions of T-DNA from *Agrobacterium tumefaciens* nopaline Ti-plasmid.
- Intervening sequence used for cloning.

Data from Southern analyses demonstrate that MON 87701 plants contain: (1) a single copy of *cry1Ac* (Monsanto, 2010, Figures V-2 to V-7, pages 58-65); (2) no sequences from the transformation plasmid (PV-GMIR9) (Monsanto, 2010) (*i.e.*'backbone sequences'); (3) no sequences from T-DNA II. (Monsanto, 2010, Figure V-7). Analysis of DNA sequences of MON 87701 confirmed that the overall integrity of the intended insert and the contiguousness of the functional elements have been maintained (Monsanto, 2010, Response Appendix 1). Statistical analyses over multiple generations confirm that the *cry1Ac* gene is stably integrated and is inherited over generations in the expected fashion (Monsanto, 2010, Figures V-8 and V-9).

Potential of MON 87701 to Become Invasive and/or a Weed

Soybeans are not considered a weed in the U.S. (Holm, 1977; Holm, 1997; Muenscher, 1980.; Reed and Hughes, 1977), and are not listed as a Federal noxious weed (7 CFR part 360[4]). APHIS assessed whether MON 87701 is any more likely to become a weed than the nontransgenic comparator, or other cultivated soybeans. The assessment encompassed a thorough consideration of the basic biology of soybeans and an evaluation of the unique

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[3]-MON 87701 expresses the Cry1Ac protein, an insecticidal protein from *Bacillus thuringiensis* subsp. *kurstaki*, which provides resistance to certain lepidopteran pests. The Cry1Ac protein expressed in MON 87701 shares >99% amino acid identity with Cry1Ac from *B. thuringiensis* (Bt) subsp. *kurstaki* and 100% amino acid sequence identity with the Cry1Ac protein present in Bollgard cotton, with the exception of four additional amino acids at the N-terminus of the MON 87701-produced Cry1Ac protein. These four amino acids are derived from the chloroplast targeting sequence.

[4] http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/weedlist2006.pdf

characteristics of MON 87701. APHIS analyzed the field test reports and other data included in the petition, as well as data from scientific literature on the establishment, reproduction, and dispersal processes of soybeans as measures of invasiveness and weediness and the effectiveness of Cry1Ac-expressing soybeans.

Monsanto provided measures of plant growth (Monsanto, 2010, pages 92-108) 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 (Monsanto, 2010, Tables VIII-3, VIII-5, VIII-6, and VIII-7 and Appendix F, G, H, and I). The only significant difference between MON 87701 and the non-transformed soybean was found between the percentage of hard viable seed at 20ºC (Monsanto, 2010, Table VIII-3). The observed variation in germination was small (0.0% for MON 87701 and 0.5% for A5547), not found under any other temperature regime that ranged between 10 to 30 ºC (Monsanto, 2010 Page 99).

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 or slightly higher (not significant) percentages of viable seed when compared to A5547 or the null isoline (Monsanto, 2010, Table VIII-3). Interestingly, the tests conducted in Mississippi had a consistent and significant lower germination than the other locations (Monsanto, 2010 Table F-2).

These results on growth characteristics and seed production and germination, indicate that the MON 87701 is not 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.

Potential for Gene Flow and Gene Introgression from MON 87701 into its Sexually-Compatible Relatives

Glycine max is cultivated as an annual crop in the U.S. in 43 states(USDA NASS (National Agricultural Statistics Service), 2007). *Glycine max* is generally self-pollinating, (Caviness, 1966; Free, 1970; Monsanto, 2010; Ray et al., 2003). In assessing the risk of gene introgression from MON 87701 to its sexually compatible relatives, APHIS considered two primary issues: 1) the potential for gene flow and introgression, and 2) the potential impact of introgression. Due to the fact that *G. max* lacks wild and cultivated plants with which freely interbreeds, the USDA has determined that any adverse consequences of gene flow from MON 87701 to wild or weedy species in the U.S. are highly unlikely.

Potential for Transfer of Genetic Information to Organisms with which MON 87701 Cannot Interbreed

APHIS assessed whether horizontal gene transfer might occur between MON 87701 and inserted genes with other organisms. However, such transfer and expression of DNA

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

Potential for MON 87701 to have Altered Disease and Pest Susceptibilities

APHIS assessed whether MON 87701 is likely to have significantly altered disease and pest susceptibility. This assessment encompassed a thorough consideration of the introduced trait and disease and pest susceptibility data from MON 87701 field trials.

The applicant on Table G-6 (Monsanto, 2010) provided a summary of disease susceptibility evaluated in 131 occasions in 11 different sites, finding no differences between MON 87701 and the control line. Data submitted by Monsanto indicate that there are no significant differences for disease susceptibility between MON 87701 and its comparators (Monsanto, 2010 Field trials summary, Table G-6). However, seed diseases caused by *Cercospora kikuchii* and *Phomopsis* spp. were observed in seeds produced in Mississippi and North Carolina trials (Monsanto, 2010, pages 96 and 104).

Susceptibility to arthropods was also evaluated in 11 sites in 133 occasions finding no differences in pest susceptibility of 20 taxa, except for four species, three of them in the order Lepidoptera (*Plathypena scabra*, *Pseudoplusia includes* and *Anticarsia gemmatalis*), which is commonly affected by Cry1A proteins, and one species that should not be affected by Cry1 toxins (*Cerotoma trifurcate*, Coleoptera: Chrysomelidae) (Monsanto, 2010, page 295).

MON 87701 was grown during 2007 in 17 locations encompassing the range of geographical and environmental conditions (Monsanto, 2010) where it is anticipated that it will be grown for the intended purpose in the U.S. These field trials included two soybean comparators: MON 87701 and A5547, the comparator. MON 87701 plants were examined for changes in the types of plant pests that were observed and the relative pest damage that those plants incurred (field test summaries submitted for MON 87701 (Monsanto, 2010)) and published information (McPherson et al., 2001; McPherson and MacRae, 2009; Miklos et al., 2007; Walker et al., 2000). When expressed in MON 87701, the Cry1Ac protein provides greater protection from the feeding damage incurred by several important lepidopteran pests of soybeans.

Soybean is not a plant pest in the United States[5], and the introduced DNA in MON 87701 is unlikely to pose a plant pest risk. Based on the analysis of genetic modifications and their functions and field testing data submitted by petitioner, APHIS concludes that there are no significant differences between MON 87701 soybeans and the non-transgenic counterparts relative to pest and disease susceptibility.

Potential Impacts of MON 87701 on Target and Non-target Organisms, Including Beneficial Organisms

For decades, microbial products containing *Bacillus thuringiensis* (the organism that produces the Cry1A protein) have been used to control insect pests on a commercial scale and for home garden applications (Glare and O'Callaghan, 2000; OMRI, 2009; Shelton et al., 2002). Plants that are 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 have been commercialized without substantiated reports of significant deleterious impacts on non-target organisms (Mendelsohn et al., 2003; OECD, 2007; US-EPA, 2008). The use of transgenic crops producing Cry1A proteins has been shown to reduce the use broad spectrum insecticides[6] without significant impacts on diversity of non-target insects (Cattaneo et al., 2006; Dively, 2005; Marvier, 2007; Naranjo, 2005; Romeis et al., 2006; Torres and Ruberson, 2005; Torres and Ruberson, 2007; Whitehouse et al., 2005). MON 87701 is expected to be similar with respect to the low potential harm to the environment (Monsanto, 2010). Because Cry receptors are not present in non-target birds and mammals (Glare and O'Callaghan, 2000; Hofmann et al., 1988a; Hofmann et al., 1988b; Shimada et al., 2006a; Shimada et al., 2006b; Van Rie et al., 1989; Van Rie et al., 1990), these insecticidal proteins are not expected to adversely affect non-target invertebrate and vertebrate organisms (Glare and O'Callaghan, 2000; US-EPA, 2008).

In addition to the 21 references that the petitioner provided (Monsanto, 2010), other information has been reviewed by APHIS (Carrière et al., 2009; Chen et al., 2009; de Vaufleury et al., 2007; Ferry et al., 2007; Ferry et al., 2006; Ludy and Lang, 2006; Obrist et al., 2006; Rauschen et al., 2009; Schoenly et al., 2003; Sharma and Pampapathy, 2006; Torres and Ruberson, 2008; Vercesi et al., 2006; Zeilinger et al., 2010; Zwahlen and Andow, 2005) that describes the non-effects of Bt crops or toxins in non-target

---

[5] http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/weedlist2006.pdf

[6] 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 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. (2008) 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..

organisms, except minor and unclear results found by Zwahlen et al.(2007) using Bt corn (Cry1Ab) as a model.

Based on the above information, APHIS believes that a determination of nonregulated status for MON 87701 will have no adverse effects on non-target organisms. Another consideration by APHIS was the potential that additional 15,000 acres of Cry1Ac-expressing crops may have on the development of Bt resistance in important lepidopteran pests.

Conclusion

APHIS has prepared this plant pest risk assessment in order to determine if event MON 87701 is unlikely to pose a plant pest risk. Based on the information provided by the applicant and the lack of plant pest risk from the inserted genetic material, weedy characteristics, atypical responses to disease or plant pests in the field, effects on non-targets or beneficial organisms in the agro-ecosystem, and horizontal gene transfer, APHIS has concluded that event MON 87701 is unlikely to pose a plant pest risk.

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

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Final Environmental Assessment

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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 provision 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 United States have successfully completed this consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other

regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food.

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

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 are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340. 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, Puerto Rico, South Carolina, North Carolina, Virginia, Illinois, Arkansas, and Maryland with no more than 1,000 acres per county per year (300 total in the states Illinois or Arkansas). 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 a determination on nonregulated status 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 Soybean 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 Soybean 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).

On June 9, 2011 EPA approved a label change that allows MON 87701 Soybean to be grown in Illinois, Arkansas, and the Commonwealth of Puerto Rico. The label permits up to 300 acres in Arkansas or Illinois, and up to 100 acres per municipio in Puerto Rico. There is still a limit of total 15,000 acres in the allowed areas (U.S. EPA, 2011).

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

[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).

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.

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, 2010b). FDA evaluated the submission and responded to the developer by letter on August 18, 2010 (FDA, 2010a). 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 for nonregulated status 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 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). In the states of Illinois and Arkansas it has remained relatively constant, with the expectation that land use will remain the same. (Data was not available for Puerto Rico). It should be noted that not all cropland is used for planting crops; some is fallow and some has been converted to pasture.

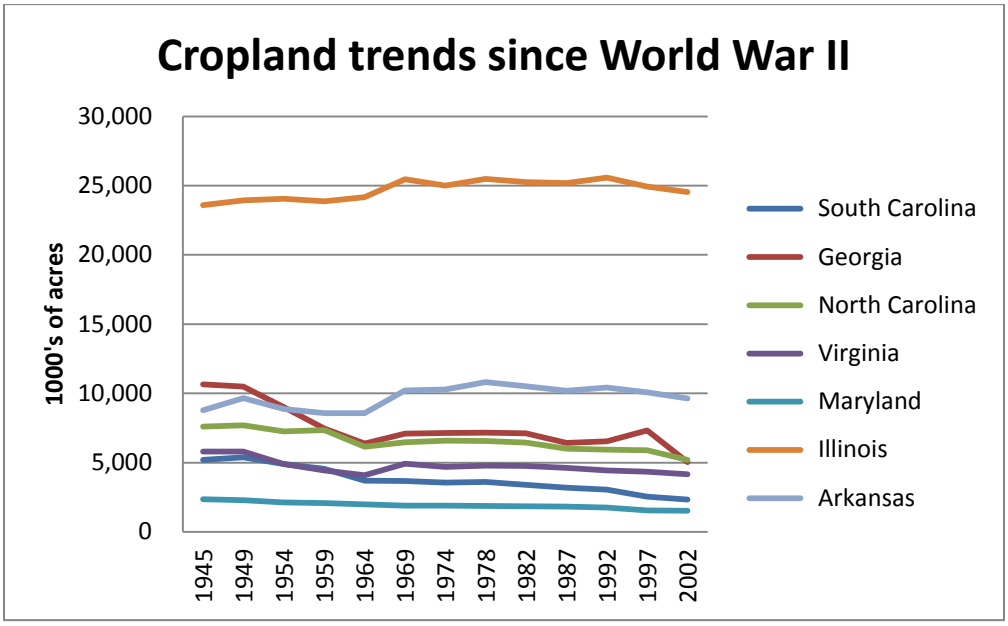

Figure 1. U.S. cropland acreage trends, 1945-2002

Source:(Lubowski et al., 2006).

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 15.5 million acres of soybeans were planted in the states where MON 87701 has received EPA approval (Table 1). This data does not include soybean production in Puerto Rico. Soybean production is not listed in Puerto Rico in the 2007 Census of Agriculture. However, soybean winter nurseries for breeding programs do operate in Puerto Rico. The extent of the total soybean nursery acreage is not known, but is likely to be small when compared to other crop production in the commonwealth.

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 Atlantic Coastal States, although the acreage is still below the peak from the 1980's. Similarly in Arkansas soybean production appears to have peaked in the 1980's. Illinois produces far more soybeans than any of the other states where Mon 87701 can be grown. Production in this state has generally trended upward; however in more recently it has declined slightly (Figure 2).

Table 1. Soybean production in 2010[1] in the states where Mon 87701 is labeled for use.

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
Illinois	9,100	466,075	14.1
Arkansas	3,150	110,250	3.34
Total	15,520	663,700	20.1

[1]Information from (USDA-NASS, 2011b). No data was available for Puerto Rico
[2] Information obtained from (U.S. EPA, 2011; US-EPA, 2010a).
[3]Total U.S. production for 2010 was 3.33 billion bushels (USDA-NASS, 2011b).

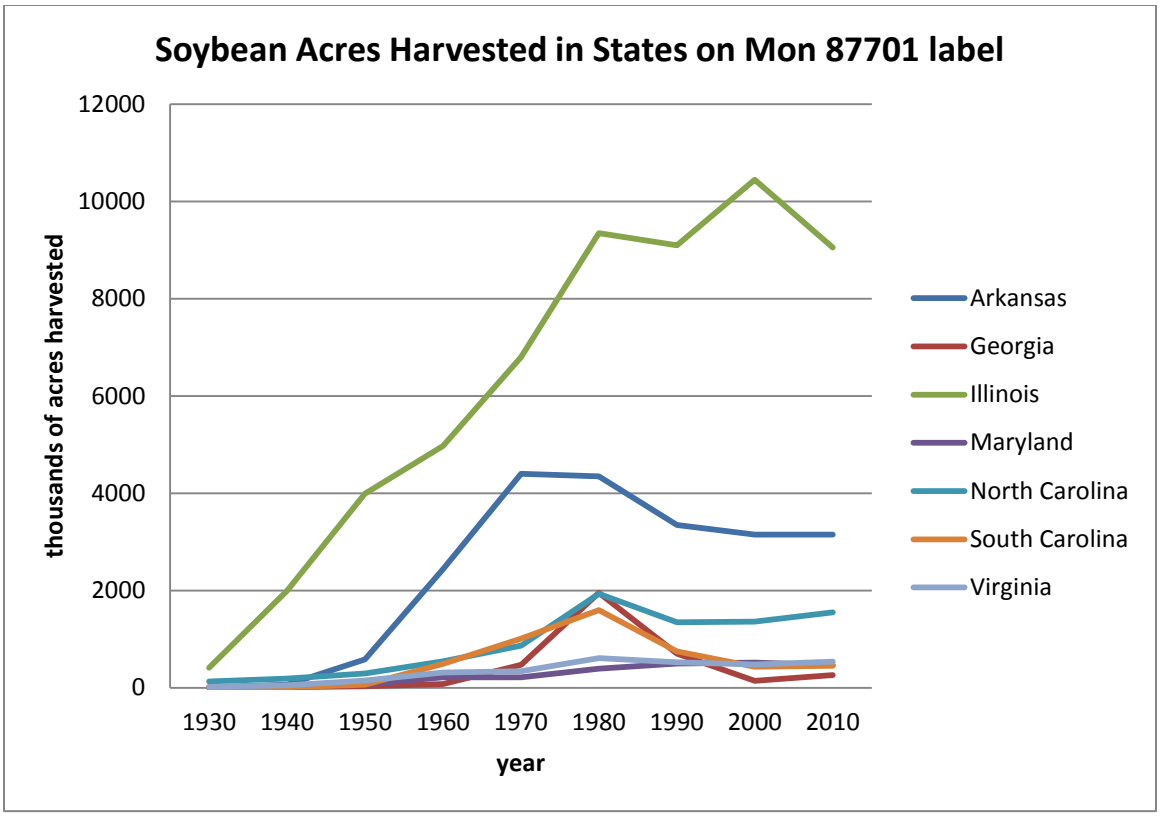

Figure 2. Annual soybean acres harvested in states where Mon 87701 is labeled for use

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 are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

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, 1999) . The original Breeder seed stock is controlled by the developer of the variety (Hartman, 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, 1999). The Certified (or select) seed is then sold to growers through commercial channels (Adam, 2005; Hartman, 1999).

Foundation seed, Registered seed, and Certified seed production is controlled by public or private seed certification programs (AOSCA Moline, 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 Moline, 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 Moline, 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 Moline, 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, 2010b). 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, 2010b). 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 seven U.S. 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
Arkansas	D	D	--	--
Illinois	6,342	210,952	0.07	6.5
Total	1,820	49,249	NA	8.3

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

D= data not disclosed in in the USDA-NASS 2008 Organic Survey to protect individuals privacy

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. Illinois represents about 2 percent of the irrigated soybeans in the U.S. and Arkansas accounts for 30 percent of the irrigated soybeans in the U.S.(USDA-NASS, 2007). 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, 2009; 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*, gram-negative bacteria that fix atmospheric nitrogen and make 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, 2010b). Nitrous oxide may also be released following the use of nitrogen fertilizer (US-EPA, 2010b). 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, 2010b).

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, 2011a; Wallace et al., 1996) Canada geese, and other waterfowl (USDA-APHIS, 2011a) 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, 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, 2010a).

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 (. 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, 2011a; 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, 2010b). FDA evaluates the submission and responds to the developer by letter BNF No. 119 (FDA, 2010a).

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

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, 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. Illinois and Arkansas export more soybean to South America than the Atlantic Coastal states. Illinois has a high of nearly $7 million in 2008 with most of that exported to Columbia, and Arkansas exported about $300 thousand in 2009, with the majority of that soy being exported to Argentina. Again this is total soybean exports to South America from these states it is not possible to determine the quantity used for planting.

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.

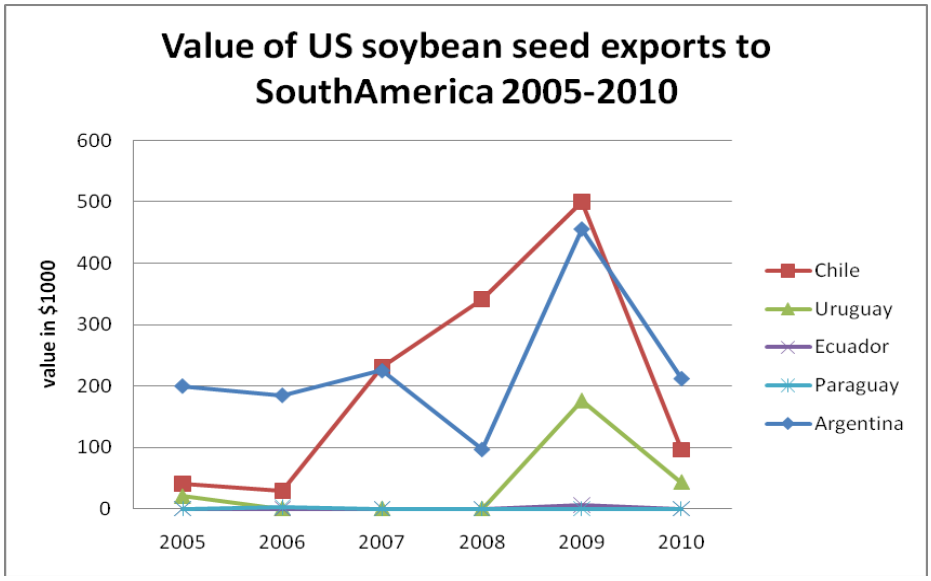

Figure 3: Value of U.S. soybean exports to South America, 2005-2010.

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.

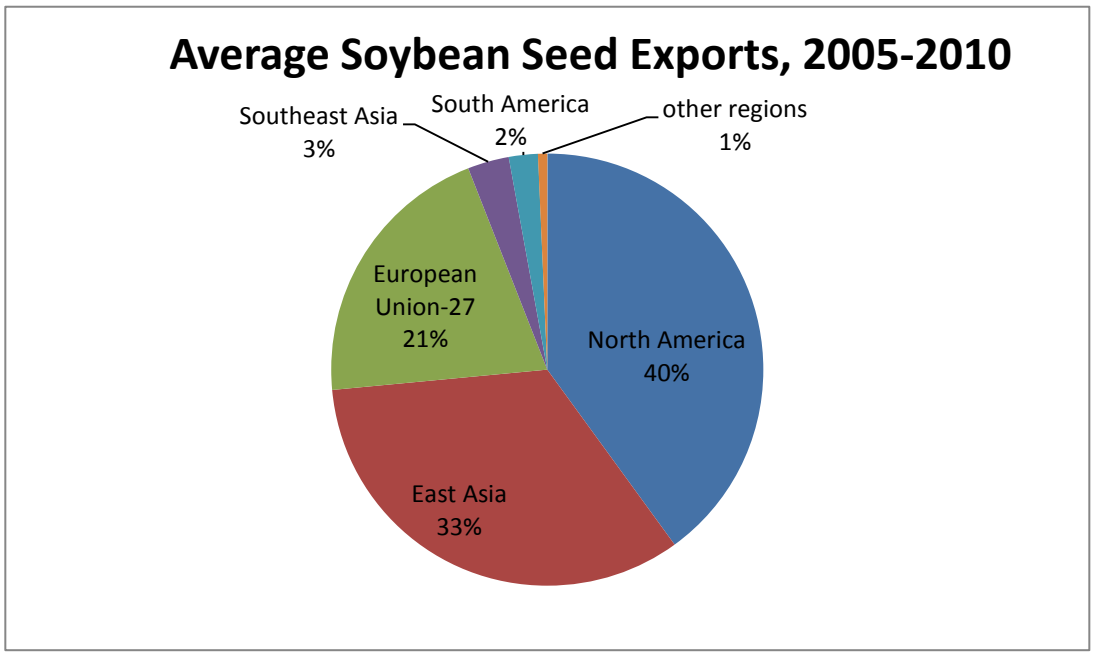

Figure 4. Average soybean seed exports, 2005-2010.

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, 2011a), 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, 2011a). 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, 2011a). 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, 2011a).

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, 2011a) 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, 2011a), 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, 2011a). 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, 2011a), 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, 2011a)
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 states of Georgia, South Carolina, North Carolina, Virginia, Maryland (US-EPA, 2010a) Illinois, Arkansas and the Commonwealth of Puerto Rico (U.S. EPA, 2011). This registration is limited to 15,000 total acres in the specified Atlantic Coastal states, with production limited to 1,000 acres per county. In Illinois and Arkansas production is limited to 300 acres in each state. In the Commonwealth of Puerto Rico, the acreage is limited to 1000 acres in each municipio. 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) as well as Illinois, Arkansas and the Commonwealth of Puerto Rico (U.S. EPA, 2011).

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 events that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 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

No Action Alternative: Acreage and Area of Soybean Production

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, as well as the Commonwealth of Puerto Rico, with acreage limited to 1,000 acres per county within those states or municipio in Puerto Rico. Additionally, part of the 15,000 acres could include 300 acres grown each in Arkansas and Illinois.

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 the allowed states would represent 0.09 percent of the approximate 15.5 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 areas where it is labeled for use.

Preferred Alternative: Acreage and Area of Soybean Production

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

No Acton Alternative: Agronomic Practices

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 seven states and Puerto Rico 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. In Arkansas 7 percent and in Illinois 2 percent of the soybean acres received insecticide treatments. Insecticide usage on soybeans in these North Carolina and Virginia are 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 0.1 percent of soybean production in states where this product can be grown, 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 Moline, 2009).

Preferred Alternative: Soybean Seed Production

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

No Action Alternative: Organic Soybean Production

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, Maryland and Puerto Rico (municipio). As part of the 15,000 acres 300 acres may be planted in both Arkansas and Illinois. Relative to the approximate 15.5 million acres of soybeans harvested in these seven states and Puerto Rico, MON 87701 may represent up to 0.09 percent of total soybean acreage. The majority of the remaining soybeans (about 90 percent) are nonregulated GE soybeans (USDA-ERS, 2010a), with organic soybean production in these six states representing less than 2 percent of total organic soybean production. Illinois has about 6.5 percent of the national organic soybean production (see Table 3, Section 2.1.4). However, acreage is limited to 300 acres in the whole state, or less than 3/1000th of 1percent of the soybeans grown in this state.

Due to the large proportion of GE soybean already grown in these 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, 2011a; 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 a determination of nonregulated status of MON 87701 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, 2009). 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, 2009).

No Action Alternative: Water Resources

Under the No Action Alternative, MON 87701 production would be limited to the seven states and Puerto Rico where it is approved for regulated releases by APHIS and EPA. The majority of soybean acreage in these six of the seven 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 seven states and Puerto Rico 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 0.1% 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 seven states and Puerto Rico. The total acreage of MON 87701 in these seven states cannot exceed 15,000 acres and 1,000 acres per county across these five states and Puerto Rico. Illinois and Arkansas are each limited to 300 acres for the whole state. 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 areas where MON 87701 is approved.

Due to the relatively small area that MON 87701 can be cultivated on in the seven states and Puerto Rico, 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 (. 2007). Non-till systems in soybeans can reduce soil erosion up to 94% while preventing water runoff and preserving this valuable resource (. 2007).

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).

<u>Preferred Alternative: Soil Quality</u>

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 seven states and Puerto Rico may only cover 15,000 acres, 0.09% of the soybean acreage of these areas. 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 15,000 acres total in seven states and Puerto Rico.

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, 2010c). 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 0.1 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 as specified under EPA registration. 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 seven states (and Puerto Rico) 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 seven states (Georgia, South Carolina, North Carolina, Virginia, Illinois, Arkansas,and Maryland) and Puerto Rico. The maximum acreage allowed in each county, municipio, or state would also likely be dispersed within the political boundry. 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 seven states (and Puerto Rico) where MON 87701 could be grown, there are 15.5 million acres of soybeans (USDA-NASS, 2011b). Thus, the 15,000 acres where MON 87701 could be grown would account for about 0.09 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

No Action Alternative: Animal Communities

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 in seven states and Puerto Rico.

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 (with no data for Puerto Rico) (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).

Preferred Alternative: Animal Communities

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, 2008a; USDA-APHIS, 2011b). 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, 2005; 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, 1988; Hofmann et al., 1988; 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,

[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, 2008a).

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 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, 2011a). Soybeans are not frost tolerant, do not survive freezing temperatures, and do not reproduce vegetatively (. 2000; USDA-APHIS, 2011a).

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, 2011a). 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, 2005.; Icoz, 2008; Saxena et al., 1999; Saxena and Stotzky, 2001; 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, 2005; 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).

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

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

[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).

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 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, 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, 2010b). FDA evaluated the submission and responded to the developer by letter on August 18, 2010 (FDA, 2010a). 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 a determination on nonregulated status 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, 2010b). 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).

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

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.

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

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 a determination of nonregulated status of the new agricultural product. The FDA has completed its consultation on the MON 87701 soybean (FDA, 2010a). 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, 2010a).

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 seven states (Georgia, South Carolina, North Carolina, Virginia, Illinois, Arkansas, and Maryland) and Puerto Rico. 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

[4] 15,000 acres with an average yield of 40 bushels an acre (University of Missouri Extension, 1993) and 60 lbs of soy per bushel (UK Cooperative Extension Service, 2005). Using 2204.623 lbs/ metric ton.

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 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 approval of nonregulated status for a GE crop in combination with the future production of crop seeds with multiple approved 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 Impacts Analysis

MON 87701 soybean is currently registered for use by the EPA in five Atlantic Coastal states, Georgia, South Carolina, North Carolina, Virginia, and Maryland, with production being limited to a total of 15,000 acres in total. EPA further limits Mon 87701 to 1,000 acres or less per county in each of these states. The current label also includes Puerto Rico with no more than 1000 acres per municipio, as well as Illinois and Arkansas both of which have limits of 300 in each state. 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, 2010a). 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 nonregulated herbicide resistant events in the future (USDA-APHIS, 2011b). 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 are not regulated 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, 2010a). 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 seven states and Puerto Rico, 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, 2010b). 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 seven statesand Puerto Rico, 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 seven states and Puerto Rico 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, 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 areas 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 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, 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 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, 2010a). 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 seven states and Puerto Rico. 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 1.9 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, 2010b). FDA evaluated the submission and responded to the developer by letter on August 18, 2010 (FDA, 2010a). 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, 2010b). 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, 2010a). 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 seven states and Puerto Rico as specified in the current EPA registration, limiting the overall number of acres to 15,000. 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, 2011). 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. To facilitate APHIS' ESA consultation process, APHIS met with the USFWS to discuss factors relevant to their effects analysis for petitions for nonregulated status and developed a process for conducting an effects determination (Appendix A). 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 effect to any threatened or endangered plant species is expected from outcrossing.

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, 2005; 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, 2008b). 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 and municipios 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, Arkansas, Illinois, South Carolina, or Puerto Rico (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, a determination of nonregulated status of 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 and Academic Press, 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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APPENDIX A - APHIS THREATENED AND ENDANGERED SPECIES DECISION TREE FOR FWS CONSULTATIONS

DECISION TREE ON WHETHER SECTION 7 CONSULTATION WITH FWS IS TRIGGERED FOR PETITIONS OF TRANSGENIC PLANTS

This decision tree document is based on the phenotypes (traits) that have been permitted for environmental releases under APHIS oversight (for a list of approved notifications and environmental releases, visit Information Systems for Biotechnology, at http://isb.vt.edu.) APHIS will re-evaluate and update this decision document as it receives new applications for environmental releases of new traits that are genetically engineered into plants.

BACKGROUND

For each transgene(s)/transgenic plant the following information, data, and questions will be addressed by APHIS, and the EAs on each petition will be publicly available. APHIS review will encompass:

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

FDA published a policy in 1992 on foods derived from new plant varieties, including those derived from transgenic plants (http://vm.cfsan.fda.gov/~lrd/fr92529b.html and http://vm.cfsan.fda.gov/~lrd/consulpr.html). The FDA's policy requires that genetically engineered foods meet the same rigorous safety standards as is required of all other foods. Many of the food crops currently being developed using biotechnology do not contain substances that are significantly different from those already consumed by human and thus do not require pre-market approval. Consistent with its 1992 policy, FDA expects developers to consult with the agency on safety and regulatory questions. A list of consultations is available at http://vm.cfsan.fda.gov/~lrd/biocon.html . APHIS considers the status and conclusion of the FDA consultations in its EAs.
Below is a description of our review process to whether a consultation with U.S. Fish and Wildlife Service is necessary.

If the answer to any of the questions 1-4 below is yes, APHIS will contact FWS to determine if a consultation is required:

Is the transgenic plant sexually compatible with a TE plant[5] without human intervention?

1. Are naturally occurring plant toxins (toxicants) or allelochemicals increased over the normal concentration range in parental plant species?
2. Does the transgene product or its metabolites have any significant similarities to known toxins[6]?
3. Will the new phenotype(s) imparted to the transgenic plant allow the plant to be grown or employed in new habitats (e.g., outside agro-ecosystem)[7].
4. Does the pest resistance[8] gene act by one of the mechanisms listed below? If the answer is YES then a consultation with U.S. Fish and Wildlife Service is NOT necessary.

A. The transgene acts only in one or more of the following ways:

i. As a structural barrier to either the attachment of the pest to the host, to penetration of the host by the pest, to the spread of the pest in the host plant (e.g., the production of lignin, callose, thickened cuticles);
ii. In the plant by inactivating or resisting toxins or other disease causing substances produced by the pest;
iii. By creating a deficiency in the host of a component required for growth of the pest (such as with fungi and bacteria);
iv. By initiating, enhancing, or potentiating the endogenous host hypersensitive disease resistance response found in the plant;
v. In an indirect manner that does not result in killing or interfering with normal growth, development, or behavior of the pest;

B. A pest derived transgene is expressed in the plant to confer resistance to that pest (such as with coat protein, replicase, and pathogen virulence genes).

For the biotechnologist:

[5] APHIS will provide FWS a draft EA that will address the impacts, if any, of gene movement to the TES plant
[6] Via a comparison of the amino acid sequence of the transgene's protein with those found in the protein databases like PIR, Swiss-Prot and HIV amino acid data bases.
[7] Such phenotypes might include tolerance to environmental stresses such as drought, salt, frost, aluminum or heavy metals.
[8] Pest resistance would include any toxin or allelochemical that prevents, destroys, repels or mitigates a pest or effects any vertebrate or invertebrate animal, plant, or microorganism.

Depending on the outcome of the decision tree, initial the appropriate decision below and incorporate its language into the EA. Retain a hard copy of this decision document in the petition's file.

_____ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS has reached a determination that the release following a determination of non-regulated status would have no effects on listed threatened or endangered species and consequently, a written concurrence or formal consultation with the Fish and Wildlife Service is not required for this EA.

_____ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of non-regulated status is not likely to adversely affect any listed threatened or endangered species and consequently obtained written concurrence from the Fish and Wildlife Service.

_____ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of non-regulated status is likely to affect adversely one or more listed threatened or endangered species and has initiated a formal consultation with the Fish and Wildlife Service.

Determination of Nonregulated Status for Monsanto MON 87701 soybeans

In response to petition 09-082-01p from Monsanto Company, the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that event MON 87701 soybean and progeny derived from it are unlikely to pose plant pest risks and are no longer to be considered regulated articles under APHIS' Biotechnology Regulations (Title 7 of Code of Federal Regulations (CFR), part 340). Since APHIS has determined that MON 87701 soybeans are unlikely to pose plant pest risks, APHIS will approve the petition for nonregulated status of MON 87701 soybeans. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental release, importation, or interstate movement under those regulations will no longer be required for event MON 87701 soybeans and its progeny. Importation of MON 87701 soybeans seeds and other propagative material would still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and the Federal Seed Act regulations at 7 CFR part 201.

This determination for MON 87701 is based on APHIS' analysis of field, greenhouse and laboratory data submitted by Monsanto, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for MON 87701.

The Plant Pest Risk Assessment conducted on MON 87701 concluded that it is unlikely to pose plant pest risks and should no longer be subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 for the following reasons: (1) it exhibits no characteristics that would cause it to be weedier than the non-genetically engineered parent soybean line or any other cultivated soybeans; (2) gene introgression from event MON 87701 soybeans into wild relatives in the United States and its territories is extremely unlikely and is not likely to increase the weediness potential of any resulting progeny nor adversely affect genetic diversity of related plants any more than would introgression from traditional soybean varieties; (3) horizontal gene transfer is unlikely to occur between MON 87701 soybeans and organisms with which it cannot interbreed; (4) disease and insect susceptibilities are similar to other soybean cultivars grown in the U.S. ; (5) it does not pose a risk to non-target organisms, including beneficial organisms, and (6) compositional profiles of MON 87701 soybeans are similar to those of its parent line and other soybean cultivars grown in the U.S, therefore no direct or indirect plant pest effects on raw or processed plant commodities are expected.

In addition to our finding that event MON 87701 is unlikely to pose a plant pest risk, APHIS has completed a Final Environmental Assessment (EA) and FONSI for this action and has determined that a determination of nonregulated status for MON 87701 and its progeny would have no significant impacts, individually or collectively, on the quality of the human environment and will have no effect on federally listed threatened or endangered species, species proposed for listing, or their designated or proposed critical

habitats (http://www.aphis.usda.gov/brs/not reg.html). APHIS also concludes in its PPRA that new varieties derived from MON 87701 are unlikely to exhibit new plant pest properties that are substantially different from the ones observed for MON 87701 soybeans, or those observed for other soybean varieties not considered regulated articles under 7 CFR part 340.

Based on my full and complete review and consideration of all of the scientific and environmental data, analyses, information, and conclusions of the PPRA, the Final EA, the agency's Response to Public Comments received in reference to the Draft EA, the FONSI, and my knowledge and experience as the Deputy Administrator of APHIS Biotechnology Regulatory Services, I have determined and decided that this determination of nonregulated status of MON 87701 soybeans is the most scientifically sound and appropriate regulatory decision.

Michael C. Gregoire

9/22/2011

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Date