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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