NATIONAL ENVIRONMENTAL POLICY ACT DECISION

AND

FINDING OF NO SIGNIFICANT IMPACT

Monsanto Company

Lepidopteran-Protected Soybean MON 87751

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.

Monsanto Company (hereafter referred to as Monsanto) submitted a request (APHIS Number 13-337-01p) to APHIS in December 2013 for extension of a determination of nonregulated status under 7 CFR 340 for a genetically engineered (GE) lepidopteran-resistant soybean event MON 87751. 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 and the regulations at 7 CFR 340. A person may request that APHIS extend a determination of nonregulated status to other organisms under §340.6(e)(2) of the regulations. Such a request shall include information to establish the similarity of the antecedent organism and the regulated articles in question. 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 reviewed and analyzed the information submitted in the extension request by Monsanto (Monsanto, 2013) and has concluded that MON 87751 is similar to the antecedent organism, MON 87701, and therefore, based on its Plant Pest Risk Assessment for MON 87701 soybean (USDA-APHIS, 2011c), APHIS has concluded that MON 87751 soybean is unlikely to pose a plant pest risk (*see* Appendix A).

The petition for MON 87701 soybean (09-082-01p) received a determination of non-regulated status from APHIS on October 12, 2011 (76 FR 63279-63280). MON 87701 soybean is a lepidopteran-resistant soybean developed through *Agrobacterium*-mediated transformation of soybean meristem tissue utilizing transformation vector, PV-GMIR9, of soybean variety A5547, a type V maturity group soybean (Company, 2009). MON 87701 soybean expresses an

insecticidal protein, Cry1Ac, and was developed for the South American soybean market (Company, 2009). In accordance with § 340.6(e)(2), Monsanto requests this determination of nonregulated status of MON 87701 soybean from APHIS be extended to MON 87751 and any progeny derived from crosses of MON 87751 with conventional soybean, and any progeny derived from crosses of MON 87751 soybean with other transgenic soybean varieties that have received a determination of nonregulated status, no longer be considered regulated articles under 7 CFR Part 340. MON 87751 is currently regulated under 7 CFR part 340. Interstate movements and field trials of MON 87751 have been conducted under notification or permits acknowledged by APHIS from 2009 through 2013 in 17 states: Alabama, Arkansas, Georgia, Iowa, Illinois, Indiana, Kansas, Louisiana, Missouri, Mississippi, North Carolina, Nebraska, Ohio, Pennsylvania, South Carolina, Tennessee, and Wisconsin; and Puerto Rico. Data resulting from these field trials are described in the request for extension (Monsanto, 2013).

MON 87751 soybean produces CrylA.105 and Cry2Ab2 insecticidal (Cry) proteins. Cry1A.105 is a modified Cry1A protein derived from *Bacillus thuringiensis*. Cry2Ab2 is derived from *B. thuringiensis* subsp. *kurstaki*. The CrylA.105 and Cry2Ab2 proteins provide protection from feeding damage caused by targeted lepidopteran insect pests. MON 87751 soybean is expected to provide benefits to growers similar to those obtained by use of other lepidopteran-protected crop varieties, including reduced use of broad spectrum insecticides, increased yield protection and increased worker safety.

Similar to the antecedent organism, MON 87701 soybean, MON 87751 soybean is currently targeted for South American markets. If MON 87751 is grown commercially in the U.S., it would be subject to all U.S. Environmental Protection Agency (U.S. EPA) commercial planting registration requirements.

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS completed an Environmental Assessment (EA) and NEPA Decision/FONSI that analyzed the potential impacts to the human environment from a determination on the regulated status of a petition request (APHIS-2011-0038) by Monsanto for their genetically engineered MON 87701 soybean in 2011 (76 FR 63279-63280). The EA assessed alternatives to a determination of nonregulated status under 7 CFR 340 of MON 87701 soybean and analyzed the potential environmental effects that result from the proposed action and the alternatives. APHIS has carefully examined the existing NEPA documentation completed for MON 87701 soybean and has concluded that the Monsanto extension request for a determination of nonregulated status of MON 87751 soybean encompasses the same scope of environmental analysis as MON 87701 soybean. This conclusion is based on:

- MON 87751 soybean expresses the same Cry proteins as MON 87701 soybean and MON 89034 corn, and MON 15985 cotton;
- MON 87751 expresses the same resistance to lepidopteran pests as MON 87701 soybean, plus resistance to fall armyworm (*Spodoptera frugiperda*);
- Mon 87751 does not exhibit any additional traits beyond what is expressed in MON 87701 soybean;

- the extension request for MON 87751 encompasses the same regulatory action as MON 87701 soybean, that is a determination of nonregulated status under 7 CFR part 340;
- the affected environment, issues and alternatives described and analyzed in the existing NEPA documentation for MON 87701 soybean are applicable to the extension request of MON 87751 soybean;
- no new alternatives have been identified that are relevant to this regulatory action;
- no substantive new environmental or social issues and impacts have been identified that are relevant to this regulatory action; and
- APHIS is not aware of any substantive new information that would warrant alteration of the existing NEPA documentation for MON 87751 soybean, including the proposed action or analysis of impacts in the EA;

Based on its similarity to the antecedent organism event MON 87701 soybean, the Monsanto extension request for MON 87751 soybean has been subject to the previous NEPA review completed for MON 87701 soybean. Therefore, the existing NEPA documentation completed for MON 87701 soybean is being used to evaluate and determine if there are any potentially significant impacts to the human environment from APHIS' response to Monsanto's extension request for a determination of nonregulated status under 7 CFR 340 of MON 87751 soybean.

Regulatory Authority

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

Since 1986, the United States government has regulated 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 provisions 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.

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

The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetics 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 Services' (BRS) mission is to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the Federal Plant Pest Act, and further consolidated under 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 and 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 does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest risk provisions of the Plant Protection Act and 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 risk provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS' Response to Application for an Extension of Nonregulated Status Under 7 CFR 340

Under the authority of the plant pest provisions of the Plant Protection Act (PPA) and 7 CFR Part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as MON 87751 soybean. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is similar to an antecedent organism which has previously been determined is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) of the antecedent organism that the genetically engineered organism identified in the extension request 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 request to APHIS to extend a determination of nonregulated status to a lepidopteran-resistant MON 87751 soybean. In accordance with §340.6(e)(2), Monsanto requests APHIS' determination of nonregulated status for MON 87701 soybean be extended to MON 87751Soybean and any progeny derived from crosses of MON 87751 soybean with conventional soybean, and any progeny derived from crosses of MON 87751 soybean with other transgenic soybean varieties that have received a determination of nonregulated status, no longer considered regulated articles under regulations at 7 CFR Part 340. The antecedent organism identified in the extension request for MON 87751 soybean is MON 87701 soybean. The petition for MON 87701 soybean (09-082-01p) received a determination of nonregulated status from APHIS on October 12, 2011 (76 FR 63279-63280).

MON 87751 Soybean

Monsanto has developed MON 87751 soybean as a lepidopteran-resistant soybean. MON 87751 soybean and the antecedent organism, MON 87701 soybean, as described in petition 09-082-01p (Company, 2009), were generated through *Agrobacterium tumefaciens*-mediated transformation of conventional soybean. PV-GMIR13196 was the plasmid vector for MON 87751. PV-

GMIR13196 contains two separate T-DNAs that are each delineated by left and right border regions. The first T-DNA, designated as T-DNA I, contains the *crylA.105* and *cry2Ab2* expression cassettes. A comparison of characteristics of MON 87701 soybean and MON 87751 soybean is summarized in Appendix A of this document.

MON 87701 soybean expresses an insecticidal protein, CrylAc, and was developed for the South American soybean market. Cry1Ac is an insecticide derived from the soil bacterium, *Bacillus thuringiensis* (*Bt*) (USDA-APHIS, 2011b).

MON 87751 soybean expresses CrylA.105 and Cry2Ab2 insecticidal (Cry) proteins. Cry1A.105 is a modified Cry1A protein derived from *Bacillus thuringiensis*. Cry2Ab2 is derived from *B. thuringiensis* subsp. *kurstaki*. The CrylA.105 and Cry2Ab2 proteins provide protection from feeding damage caused by targeted lepidopteran insect pests. Studies conducted with MON 87751 soybean demonstrated efficacy against key soybean pests, including *Crocidosema aporema* (bean shoot moth), *Rachiplusia nu* (sunflower looper) and *Spodoptera frugiperda* (fall armyworm), *Anticarsia gemmatalis* (velvetbean caterpillar), *Chrysodeixis includens* (soybean looper) and *Helicoverpa zea* (corn earworm). The season-long expression pattern of Cry1A.105 and Cry2Ab2 in MON 87751 is expected to control target insects that are heterozygous for resistance genes specific to one of the proteins and provide an effective tool in managing potential insect resistance, thus prolonging the durability of this product. MON 87751 is expected to provide benefits to growers similar to those obtained by use of other lepidopteran-protected crop varieties, including reduced use of broad spectrum insecticides, increased yield protection and increased worker safety (Monsanto, 2013).

The southeastern states within the U.S. are consistently affected by lepidopteran pests but represent a small portion of total U.S. soybean production. Lepidopteran pressure is greater in South America and accordingly, as with MON 87701 soybean, the initial commercial cultivation of MON 87751 soybean is currently targeted for South America. If MON 87751 is to be grown commercially in the U.S., it would be subject to all U.S. Environmental Protection Agency (U.S. EPA) commercial planting registration requirements.

Coordinated Framework Review

Food and Drug Administration

Similar to the antecedent organism MON 87701 soybean, MON 87751 soybean is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced by genetic engineering. In June 2006, FDA published recommendations in "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use" (FDA, 2006) for establishing voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including bioengineered

plants. Early food safety evaluations help make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with FDA, but the information may be used later in the biotechnology consultation.

On November 25, 2013, Monsanto submitted a safety and nutritional assessment summary of food and feed derived from MON 87751 to the FDA (US-FDA Docket Number BNF 000144). FDA is currently evaluating the submission. No questions have been raised thus far pursuant to §408(d) of the Federal Food, Drug, and Cosmetic Act. Monsanto has concluded that soybean derived from events MON 87701 and MON 8751 and the foods and feeds obtained from these events are as safe as conventional soybean varieties, and with the exception of the plant-incorporated protectant proteins, are not materially different in composition or any other relevant parameter from other soybean varieties now grown, marketed, and consumed in the U.S. EPA is the primary authority for the review of plant-incorporated protectants.

Environmental Protection Agency

As described in Subsection 2.4, Human Health, under FIFRA, all pesticides (including herbicides) sold or distributed in the U.S. must be registered by the EPA (US-EPA, 2011). Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. All pesticides registered prior to November 1, 1984 must also be reregistered to ensure that they meet the current, more stringent standards and should have a reregistration review every 15 years (US-EPA, 2011). Before a pesticide can be used on a food or feed crop, the EPA must establish the tolerance value, which is the maximum amount of pesticide residue that can remain on the crop or in foods or feed processed from that crop (US-EPA, 2011).

The EPA regulates plant-incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain biological control organisms under the Toxic Substances Control Act (TSCA). The EPA is responsible for regulating the sale, distribution and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology.

Both Cry1A.105 and Cry2Ab2 are present in lepidopteran-protected MON 89034 maize and both proteins have tolerance exemptions from U.S. EPA in maize. The Cry1A.105 and Cry2Ab2 proteins from MON 87751 share greater than 99% and 97% amino acid identity, respectively, with the Cry1A.105 and Cry2Ab2 proteins expressed in MON 89034. Hence, the consumption of the Cry1A.105 and Cry2Ab2 proteins from MON 87751 or its progeny poses no meaningful risk to human and animal health or an increased plant pest risk. Similar data submitted to USDA-APHIS in petition 09-082-01p for the antecedent organism, MON 87701, supported the same safety conclusions for Cry1Ac."

Pursuant to §408(d) of the Federal Food Drug and Cosmetic Act [21 U.S.C. 346 a(d)], Monsanto will petition U.S. EPA for an exemption from the requirement of a tolerance for Cry1A.105 and Cry2Ab2 in or on soybean. On July 2, 2008, U.S. EPA established an exemption from the requirement of a tolerance for residues of the plant-incorporated protectant Cry2Ab2 in maize and cotton (40 CFR 174.519). On July 16, 2008, U.S. EPA established an exemption from the requirement of a tolerance for residues of the plant-incorporated protectant Cry1A.105 in maize (40 CFR 174.502).

In February 2014, Monsanto applied to U.S. EPA for a Section 3 seed increase registration for Cry1A.105 and Cry2Ab2, and the genetic material (vector PV-GMIR13196) necessary for its production in soybean to allow seed production activities in the U.S. to support markets in South America.

Scope of the Environmental Analysis

Based on its similarity to the antecedent organism event MON 87701soybean, APHIS has concluded that the Monsanto extension request for a determination on the regulated status for MON 87751 encompasses the same scope of environmental analysis as MON 87701 soybean. APHIS reviewed and analyzed the information submitted in the extension request by Monsanto (Monsanto, 2013) and has concluded that MON 87751 soybean is similar to the antecedent organism, MON 87701 soybean, and, therefore, based on its Plant Pest Risk Assessment for MON 87701 soybean (USDA-APHIS, 2011c), APHIS has concluded that MON 87751 soybean is unlikely to pose a plant pest risk (*see* Appendix A). Although a determination of nonregulated status under 7 CFR 340 of MON 87751 soybean would allow for new plantings of MON 87751 soybean anywhere in the U.S., APHIS primarily focused the environmental analysis on those geographic areas that currently support soybean production. Similar to the antecedent organism MON 87701 soybean, a determination of nonregulated status of MON 87751 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. To determine areas of soybean production, APHIS used data from the National Agricultural Statistics Service (USDA-NASS, 2014a) to determine where soybean is produced in the U.S. Soybean is primarily produced throughout the Midwest U.S., with crop production concentrated in Illinois and Iowa (Commodities, 2013) .

Public Involvement

APHIS is not aware of any substantive new information that would warrant alteration of the existing NEPA documentation for MON 87701 soybean, including the proposed action or analysis of impacts in the EA since the completion of the public involvement process for MON 87701 soybean. APHIS has not received any additional information or comments from the public specifically directed at the MON 87701 soybean petition, PPRA or NEPA documentation since a determination of non-regulated status was announced on October 12, 2011 (76 FR 63279-63280).

In preparing this NEPA decision/FONSI for MON 87751 soybean, APHIS carefully reviewed and took into consideration all public input that was received during the public involvement process that was completed for Monsanto petition 09-082-01p. On June 28, 2011, APHIS published a notice in the Federal Register (76 FR 3770-3771, Docket no. APHIS-2011-0038) announcing the availability of the Monsanto petition (09-082-01p), 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 2 issues were raised by individuals during the comment period. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. The two comments expressed opposition to a determination of nonregulated status of MON 87701 soybean because of concerns over impact on bees and on groundwater, but did not change the analysis provided in the PPRA or draft EA. Comment documents may be viewed at http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=APHIS-2011-0038

On August 28, 2014, APHIS published a notice in the Federal Register (79 FR 51297-51299, Docket No. APHIS-2014-0055) announcing the availability of the draft Monsanto MON 87751 Extension Request Finding of No Significant Impact (FONSI) for a 30-day public review and comment period. Comments were required to be submitted by September 29, 2014. A total of three public comments were received subsequent to the draft FONSI publication. The commenters expressed disagreement with GE crops in general, but did not include any further information. The docket folder containing the comments may be located at: http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0055

Major Issues Addressed in the FONSI

APHIS has concluded that the Monsanto extension request for a determination of nonregulated status under 7 CFR 340 of MON 87751 soybean encompasses the same scope of environmental analysis as MON 87701 soybean. APHIS is not aware of any substantive new environmental or social issues associated with MON 87751 soybean that were not considered in the previous NEPA analysis completed for a determination on the regulated status of a petition request for MON 87701 soybean. Therefore, APHIS is using the same issues identified and analyzed in the existing NEPA documentation for MON 87701 soybean to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of an extension request by Monsanto for MON 87751 soybean.

The issues considered in the MON 87701 soybean analysis 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 for 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 food/feed safety of genetically engineered plants were addressed to analyze the potential environmental impacts of MON 87751 soybean.

The list of resource areas considered were developed by APHIS through experience in considering public concerns and issues raised in public comments submitted for other EAs of GE organisms. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25). These same issues have been determined by APHIS to be relevant to APHIS' authority actions associated with MON 87701 soybean. These resource areas 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

Alternatives that were analyzed

APHIS has concluded that the Monsanto extension request for a determination of nonregulated status of MON 87751 soybean encompasses the same scope of environmental analysis and regulatory decision as MON 87701 soybean; that is, a determination of nonregulated status under 7 CFR part 340. APHIS reviewed and analyzed the information submitted in the extension request by Monsanto (Monsanto, 2013), and has concluded that MON 87751 soybean is similar to the antecedent organism, MON 87701 soybean, and therefore, based on its Plant Pest Risk Assessment for MON 87701 soybean (USDA-APHIS, 2011c), APHIS has concluded that MON 87751 soybean is unlikely to pose a plant pest risk (*see* Appendix A). The comparison of characteristics of MON 87751 soybean to the antecedent organism, MON 87701 soybean, indicates that MON 87751 soybean expresses similar Cry proteins as MON 87701 soybean; MON 87751 soybean expresses the same resistance to lepidopteran pests as MON 87701 soybean, as well as to *Spodoptera frugiperda*; and MON 87751 soybean does not exhibit any additional traits beyond what is expressed in MON 87701 soybean. Therefore, the proposed action identified in the existing NEPA documentation completed for MON 87701 soybean is being used to evaluate APHIS' action associated with a determination of nonregulated status of MON 87751 soybean.

Based on the similarity to the antecedent organism event MON 87701 soybean, APHIS has concluded that all the alternatives identified in the MON 87701 soybean EA to be relevant to APHIS' regulatory actions associated with MON 87751 soybean, and therefore, are being used in their entirety. APHIS is not aware of any new alternatives that are relevant to APHIS' decision on the regulatory status of MON 87751 soybean that were not considered in the previous NEPA analysis for MON 87701 soybean. Therefore, APHIS is using the same alternatives, including the proposed action, identified and analyzed in the existing NEPA documentation completed for MON 87701 soybean to evaluate and determine if there are any potentially significant impacts to the human environment from a determination of nonregulated status under 7 CFR 340 of MON 87751.

Alternatives described in existing MON 87701 Soybean EA

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, 2011c), 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 or notifications acknowledged by APHIS would still be required for introductions of MON 87751 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, 2011c) indicating this alternative would not satisfy the purpose and need for 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, 2011c). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87701 soybean and progeny derived from this event. The Preferred Alternative, i.e., a determination of nonregulated status of MON 87701 soybean, is not expected to increase soybean production, either by its availability alone or associated with other factors, or result in an increase in overall acreage of GE soybean. Potential impacts would be similar to the No Action Alternative. 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.

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

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 health risk (USDA-APHIS, 2011c).

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 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 mandate of each agency"

Based on the PPRA (USDA-APHIS, 2011c), and the scientific data evaluated therein, APHIS 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 (USDA-APHIS, 2011c), 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 Production and Geographical Restrictions

Because APHIS has concluded that MON 87701 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2011c), 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.

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. APHIS also considered geographically restricting the production of MON 87701 soybean based on the location of production of non-GE soybean in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' 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, 2011c). 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. However, individuals might choose on their own to geographically isolate their non-GE soybean production systems from MON 87701 soybean or to use isolation distances and other management practices to minimize gene movement between MON 87701 soybean and non-GE soybean fields. Information to assist growers in making informed management decisions for MON 87701 soybean is available from the Association of Official Seed Certifying Agencies (AOSCA, 2010).

Requirement of Testing for MON 87701 Soybean

During the comment periods for other petitions for nonregulated status, some commenters requested that USDA require and provide testing for GE products in non-GE production systems. APHIS notes that there are no nationally–established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because MON 87701 soybean does not pose a plant pest risk (USDA-APHIS, 2011c), 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 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

Based on the similarity of the antecedent organism event MON 87701 soybean to MON 87751 soybean (*see* Appendix A), APHIS has concluded that the previous analysis of impacts completed for MON 87701 soybean to be relevant to APHIS' regulatory actions associated with responding to the Monsanto extension request for MON 87751 soybean. The potential impacts of MON 87751 soybean on agricultural production of soybean, physical environment, animal and plant communities, public health, animal feed, socioeconomics, and threatened and endangered species are identical to those presented in the Final EA and FONSI for MON 87701 soybean and therefore are being used in their entirety to evaluate APHIS' action associated with a determination of nonregulated status of MON 87751 soybean. The MON 87701 soybean EA (USDA-APHIS, 2011a) 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 (reference)
Management Practices		
Acreage and Areas of Soybean Production	Unlikely to change current production areas or acreage of soybean planted.	Unchanged from No Action Alternative.
Agronomic Practices	Agronomic practices will remain the same as current practices for commercial soybean production.	Unchanged from No Action Alternative.
Pesticide Use	Pesticide usage unlikely to change.	Unchanged from No Action Alternative.
Soybean Seed Production	Unchanged.	Unchanged from No Action Alternative.
Organic Soybean Production	Unchanged.	Unchanged from No Action Alternative.
Environment		
Land Use	Not expected to have any effect on land use.	Unchanged from No Action Alternative.
Water Resources	Not expected to have any effects on water resources.	Unchanged from No Action Alternative.
Soil	Not expected to have any effects on soil.	Unchanged from No Action Alternative.
Air Quality	Not expected to have any effects on air quality.	Unchanged from No Action Alternative.
Climate Change	Not expected to have any effects on climate change.	Unchanged from No Action Alternative.
Animals and Plants		
Animals	MON 87701 will remain regulated, and will not affect any organisms other than targeted lepidopteran insects.	Unchanged from No Action Alternative.
Plants	Not expected to have any effect on plants.	Unchanged from No Action Alternative.

Gene Movement	Not expected to have any effect on horizontal or vertical gene flow.	Unchanged from No Action Alternative.
Soil Microorganisms	Not expected to have any effect on soil organisms.	Unchanged from No Action Alternative.
Biological Diversity	Not expected to have any effect on biological diversity.	Unchanged from No Action Alternative.
Human and Animal Health		
Risk to Human Health	Not expected to have any effects on human health.	Unchanged from No Action Alternative.
Risk to Animal Feed	Not expected to have any effects on animal feed.	Unchanged from No Action Alternative.
Socioeconomic		
Domestic and Economic Environment	Unchanged.	Unchanged from No Action Alternative.
Trade Economic Environment	Unchanged.	Unchanged from No Action Alternative.
Other Regulatory Approvals	Unchanged for existing nonregulated GE organisms.	FDA consultation is ongoing; EPA evaluating section 3 seed increase.
Compliance with Other Laws		
CWA, CAA, Eos	Fully compliant	Fully compliant

Finding of No Significant Impact

Based on the analysis of impacts in the existing MON 87701 soybean EA (USDA-APHIS, 2011a) and the similarity of MON 87751 soybean to the antecedent organism MON 87701 soybean, a determination of nonregulated status under 7 CFR 340 of MON 87751 soybean will not have a significant impact, individually or cumulatively, on the quality of the human environment. I agree with this conclusion and therefore find that an environmental impact statement 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.

In the 2013 production year, soybean was harvested in the United States on approximately 76.5 million acres, producing 3.3 billion bushels of soybean (43.3 bushels/acre) with a value of $41.84 billion ($12.70/bushel) (USDA-NASS, 2014a). These data represent increases from 2011 totals of 73.8 million harvested acres, producing 3.1 billion bushels (41.9 bushels/acre) with a value of $38.5 billion ($12.50/bushel) (USDA-NASS, 2014b).

Over the past 60 years, soybean yield per unit area has almost tripled (Soyatech, 2008). This increase is attributed to the introduction of improved soybean germplasm, development of new

varieties, the availability of better field equipment, and the use of herbicide and other pesticides that have greatly reduced crop losses caused by weeds and pests (Soyatech, 2008).

The U.S. is the largest producer of soybeans in the world, followed by Brazil, Argentina, China, India, Paraguay and Canada, and these countries account for approximately 95% of all soybean production worldwide (Association, 2012; Commodities, 2013).

In 2011, the U.S. exported 34.7 MT of soybeans, approximately 37% of the global supply (Association, 2012). Major importers of American soybeans in 2013 were Mexico, China, Japan, Indonesia, and Germany (Board, 2013).

A determination of nonregulated status of MON 87751 Soybean is not expected to directly cause an increase in agricultural acreage devoted to soybean production. The availability of MON 87751 soybean will not change cultivation areas for soybean production in the U.S. and there are no anticipated changes to the availability of GE soybean varieties on the market.

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

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

   A determination of nonregulated status under 7 CFR 340 of MON 87751 soybean will have no significant environmental impact in relation to the availability of GE, conventional, organic or specialty soybean varieties. Based on the discussions in Chapter 4 of the MON 87701 soybean EA (USDA-APHIS, 2011a) and its similarity to the antecedent organism event, a determination of nonregulated status of Event MON 87751 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 87751 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 87751 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 or specialty systems.

   Based on data provided by Monsanto for MON 87751 soybean (Monsanto, 2013), APHIS has concluded that the availability of MON 87751 soybean would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE soybean seed production. A determination of nonregulated status of MON 87751 soybean will not require a change to seed production practices, nor current production practices.

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

A determination of nonregulated status of MON 87751 soybean would have no significant impacts on human or animal health. As discussed in Chapter 4 of the MON 87701 soybean EA (USDA-APHIS, 2011a), similar products were no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 beginning in 1996 with the introduction of *Bt* products. In each case, FDA and EPA reviews and approvals determined that the products met the agency's review criteria for approval. The cultivation of these existing crop products would not change under either alternative. Both characteristics have been successfully cultivated in multiple crops in the ensuing years with no evidence of human health impacts.

Public health concerns associated with the use of GE soybean, such as MON 87751 soybean, and GE soybean products focus primarily on human and animal (livestock) consumption of GE food and feed commodities.

Non-GE soybean varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for human food or animal feed safety prior to release in the market. Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and labeled properly. As a GE product, however, food and feed derived from MON 87751 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 have wished to commercialize a GE variety that would be included in the food supply have completed a consultation with the FDA. In such 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. This process includes: 1) an evaluation of the amino acid sequence introduced into the food crop to confirm whether the protein is related to known toxins and allergens; 2) an assessment of the protein's potential for digestion; and 3) an evaluation of the history of safe use in food (Hammond and Jez, 2011). FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require. Several international agencies also review food safety associated with GE-derived food items, including the European Food Safety Agency (EFSA) and the Australia and New Zealand Food Standards Agency (ANZFS). Monsanto provided the FDA with information on the identity, function, and characterization of the genes for MON 87751 soybean, including expression of the gene products, on date. The FDA is currently reviewing Monsanto's submission.

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 under 7 CFR 340 of MON 87751 soybean. Similar to the antecedent organism 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, 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 87751 soybean. The product will be deployed on agricultural land currently suitable for production of soybean, will replace existing varieties, and is not expected to increase the acreage of soybean production. This action would not convert land to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 87751 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 87751 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 under 7 CFR 340 of MON 87751 soybean are not highly controversial. Although there is some opposition to a determination of nonregulated status of MON 87751 soybean, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment. As discussed in Chapter 4 of the MON 87701 soybean EA (USDA-APHIS, 2011a), a determination of nonregulated status is not expected to directly cause an increase in agricultural acreage devoted to soybean production, or those acres devoted to GE soybean cultivation. The availability of MON 87751 soybean will not change cultivation areas for soybean production in the U.S., and there are no anticipated changes to the availability of soybean varieties on the market. A determination of nonregulated status of MON 87751 soybean could add another soybean variety to the soybean market and is not expected to change the market demands for soybeans produced using organic methods. A determination of nonregulated status of MON 87751 soybean will not result in changes in the current practices of planting,

tillage, fertilizer application/use, cultivation, pesticide application use/volunteer control. Management practices and seed standards for production of certified soybean seed would not change. The effect of MON 87751 soybean on wildlife or biodiversity is not different than that of crops currently used in agriculture, or other soybean produced in conventional agriculture in the U.S.

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

   Based on the analysis documented in the MON 87701 soybean EA (USDA-APHIS, 2011a) and its similarity to the antecedent MON 87701 soybean, the possible effects on the human environment from a determination of nonregulated status under 7 CFR 340 of MON 87751 soybean are well understood. The effects of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. As discussed in Chapter 4 of the MON 87701 soybean EA (USDA-APHIS, 2011a), a determination of nonregulated status of MON 87751 soybean is not expected to directly cause an increase in agricultural acreage devoted to soybean, or those acres devoted to GE soybean cultivation. A determination of nonregulated status of MON 87751 soybean will not result in changes in the current practices of planting, tillage, fertilizer application/use, and volunteer control. Management practices and seed standards for production of certified soybean seed would not change. The effect of MON 87751 soybean on wildlife or biodiversity is no different than that from other crops currently used in agriculture, or other soybean produced in conventional agriculture in the U.S. As described in Chapter 2 of the MON 87701 soybean EA (USDA-APHIS, 2011a), 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 varieties, MON 87751 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. 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 87751 soybean.

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

   A determination of nonregulated status for MON 87751 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 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 87751 soybean. When a request for an extension of nonregulated status is submitted, APHIS must make a determination if the GE organism is similar to an antecedent organism which has previously been determined to be unlikely to pose a plant pest risk. If APHIS determines, based on its Plant Pest Risk Assessment of the antecedent organism, that the genetically engineered organism identified in the extension request 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. 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 87751 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 enough information to determine if the GE organism is unlikely to pose a plant pest risk. A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act and the regulations at 7 CFR part 340. The petitioner is required to provide information under §340.6(c) (4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A person may also request that APHIS extend a determination of nonregulated status to other organisms under §340.6(e)(2). Such a request shall include information to establish the similarity of the antecedent organism and the regulated articles in question. 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.*

   Based on the similarity of the antecedent organism MON 87701 soybean to MON 87751 soybean, no significant cumulative effects were identified through this assessment. The MON 87701 soybean EA (USDA-APHIS, 2011a) 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 included for each environmental issue analyzed in Chapter 4 of the MON 87701 soybean EA (USDA-APHIS, 2011a). In the event APHIS reaches a determination of nonregulated status of MON 87751 Soybean, APHIS would no longer have regulatory authority over this soybean. In the event of a determination of nonregulated status of MON 87751 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 87751 soybean when added to past, present, and reasonably foreseeable future actions.

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

   Based on the similarity of the antecedent organism MON 87701 soybean to MON 87751 soybean, a determination of nonregulated status under 7 CFR 340 of MON 87751 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 87751 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 historic resources. This action is limited to a determination of nonregulated status of MON 87751 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 87751 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 use and enjoyment of a historic property when common agricultural activities take place. For example, for MON 87751, 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 87751 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 the endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*

   As described in Chapter 4 of the MON 87701 EA (USDA-APHIS, 2011a), APHIS has analyzed the potential for effects from a determination of nonregulated status under 7 CFR 340 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 87751 soybean, APHIS has determined that a determination of nonregulated status of MON 87751 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 87751 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87751 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. 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 existing NEPA documentation completed for MON 87701 soybean, including input from the public involvement process. Based on APHIS' conclusion that

MON 87751 soybean encompasses the same scope of environmental analysis and regulatory decision as MON 87701 soybean; that is, a determination of nonregulated status under 7 CFR part 340, I believe the issues identified and analyzed in the existing NEPA documentation for MON 87701 soybean are relevant to this regulatory action and best addressed by extending a determination of nonregulated status to MON 87751. This regulatory action 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 and under 7 CFR 340.

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 (a determination of nonregulated status of MON 87751 soybean) has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, this Alternative 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 87751 soybean, the continued regulated status of MON 87751 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 87751 soybean will not have any significant environmental effects.

M. J. Firko

Michael Firko, Ph.D.

Deputy Administrator

Biotechnology Regulatory Services

16 Oct 2014

Date

AOSCA (2010) "General IP Protocols Standards." The Association of Official Seed Certifying Agencies. http://www.identitypreserved.com/handbook/aosca-general.htm >.

Association, AS (2012) "Soy stats 2012." American Soybean Association. Last Accessed: June 06, 2011 < http://www.soystats.com/2012/page_02.htm >.

Board, US (2013) "U.S. Soy Exports Set New Record." http://www.unitedsoybean.org/article/u-s-soy-exports-set-new-record/ >.

Commodities, S (2013) "Soybeans-World Supply and Demand Summary." http://www.spectrumcommodities.com/education/commodity/statistics/soybeans.html >.

Company, M (2009) "Petition for the Determination of Non-Regulated Status for MON 87701." Monsanto. http://www.aphis.usda.gov/brs/aphisdocs/09_08201p.pdf >.

FDA (2006) "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use." http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096156.htm >.

Hammond, BG and Jez, JM (2011) "Impact of food processing on the safety assessment for proteins introduced into biotechnology-derived soybean and corn crops." *Food and chemical toxicology : an international journal published for the British Industrial Biological Research Association.* 49 (4): p 711-21. http://www.ncbi.nlm.nih.gov/pubmed/21167896 >.

Monsanto (2013) "Request for an Extension of Determination of Nonregulated Status for Lepidopteran-Protected Soybean " Monsanto Company

Soyatech (2008) "Statistics." *2008 Soya and Oilseed Bluebook*. Southwest Harbor, Maine: Soyatech, Inc. p 343-89.

US-EPA (2011) "Pesticides: Registration Review." U.S. Environmental Protection Agency. http://www.epa.gov/oppsrrd1/registration_review/ >.

USDA-APHIS (2011a) "Monsanto Company Petition (09-SY-194U) for Determination of Non-Regulated Status of Event MON 87701: Final Environmental Assessment." USDA-APHIS. http://www.aphis.usda.gov/brs/aphisdocs/09_08201p_fea.pdf >.

USDA-APHIS (2011b) "National Environmental Policy Act Decision and Finding of No Significant Impact: Monsanto Company Event 87701 Soybean." http://www.aphis.usda.gov/brs/aphisdocs/09_08201p_fonsi_rtc.pdf >.

USDA-APHIS (2011c) "Plant Pest Risk Assessment for Monsanto MON 87701 Soybeans." USDA-APHIS. http://www.aphis.usda.gov/brs/aphisdocs/09_08201p_fpra.pdf >.

USDA-NASS (2014a) "Quick stats: 2013 US total - Acreage, Yield, Production and Price for Soybeans." Last Accessed: May 25, 2011 < http://www.nass.usda.gov/Quick_Stats/Lite/result.php?9CF79235-C090-3838-8811-077B8BC4CA2F >.

USDA-NASS (2014b) "Quick Stats: Acreage, Yield, Production and Price for Soybeans." http://www.nass.usda.gov/Quick_Stats/Lite/result.php?3DD85A8D-5F4B-3EDC-8D1A-9C4F262BDB10 >.

Appendix A

Determination of Nonregulated Status for Lepidopteran-Protected Soybean MON 87751 (*Glycine max*)

In response to an application for an extension of the determination of nonregulated status for insect-resistant soybean (13-337-01p) from Monsanto Company (hereafter referred to as Monsanto), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that MON 87751 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 87751 soybean is unlikely to pose a plant pest risk, APHIS will approve the application for an extension of the determination for nonregulated status of MON 87751 soybean. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation under those regulations will no longer be required for MON 87751 soybean and its progeny. Importation of MON 87751 soybean 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.

Monsanto developed the transgenic MON 87751 soybean through *Agrobacterium tumefaciens*-mediated transformation of the conventional soybean A3555. MON 87511 has been engineered to express two *Bacillus thuringiensis* proteins (Cry1A.105 and Cry2Ab2) that confer resistance to certain lepidopteran pests of soybeans. Based upon the similarity of MON 87751 to another soybean (MON87701) deregulated by APHIS in October 2011 that expresses the *Bt* protein Cry1Ac, the attached table was constructed to reflect key similarities and differences between MON87751 and MON87701:

	Antecedent (MON 87701[1])	Extension (MON 87751)
Description		
Organism	**Soy**	**Soy**
Phenotype	Resistant to lepidopteran insect pests (velvetbean caterpillar, soybean looper, soybean axil borer, sunflower looper)	Resistant to the same lepidopteran insect pest complex, including the fall armyworm.
Genotype	Cry1Ac	Cry1A.105 (present in MON 89034 corn[2]), Cry2Ab2 (present in MON 89034 corn[2] and MON 15985 cotton[3])
Other Construct Info	Constitutive promoter (RBPC-SS 1A)	Constitutive promoter (RBPC-SS 1A; Actin2)
Method of Transformation	*Agro* -mediated	*Agro* -mediated
Insert Copy	Single intact insertion	Single intact insertion
Compositional Analysis	Within range of soy	Within range of soy
Plant Pest Risk		
Disease and pest susceptibilities	Unlikely to pose plant pest risk	Likely to pose similar risk as antecedent
Impacts on Beneficial Non-Targets	Unlikely to pose plant pest risk	Likely to pose similar risk as antecedent
Enhanced Weediness	EPA (MON 87701): no adverse effects to nontargets	EPA (MON 89034): no adverse effects to nontargets
Enhanced Weedness of Relatives	Unlikely to pose plant pest risk	Likely to pose similar risk as antecedent
Changes to Agriculture or Cultivation Practices	Unlikely to pose plant pest risk	Likely to pose similar risk as antecedent
Horizontal Gene Transfer	Unlikely to pose plant pest risk	Likely to pose similar risk as antecedent

[1] 09-082-01p: granted nonregulated status 12Oct11

[2] 06-298-01p: granted nonregulated status 24Jul08

[3] 00-342-01p: granted nonregulated status 22Nov02

Both MON87751 and MON87701 are resistant to the velvetbean caterpillar, soybean looper, soybean axil borer, and sunflower looper, but MON 87751 also includes resistance to fall armyworm. Monsanto has indicated that both MON87751 and MON87701 were developed primarily for South American markets (due to pest pressures there) and will only have limited commercialization in the United States. The only difference of significance between MON 87751 and MON 87701 that relates to plant pest risk is the difference in activity spectra of the proteins expressed. This difference is unlikely to affect any of the risk assessment categories that APHIS examines in its plant pest risk assessments (also summarized in attached table), with the sole exception of a possible difference in impacts to non-target organisms beneficial to agriculture. APHIS has never assessed the risk to beneficial non-targets of the Cry1A.105 and Cry2Ab2 proteins when expressed in soybeans. APHIS has, however, assessed the risks of the two proteins when expressed in corn (Cry1A.105 and Cry2Ab2) and cotton (Cry2Ab2) and concluded that the organisms did not pose a plant pest risk. Furthermore, EPA reviewed the safety of Cry1A.105 and Cry2Ab2 in corn and concluded that "adverse effects will not occur to nontarget organisms." This evidence together suggests that Cry1A.105 and Cry2Ab2 in MON 87751 are unlikely to pose a plant pest risk; nor is MON 87751 likely to pose a different plant pest risk than MON87701.

MON 87751 soybean encompasses the same scope of environmental analysis and regulatory decision as MON 87701 soybean; that is, a determination of nonregulated status under 7 CFR part 340, I believe the issues identified and analyzed in the existing NEPA documentation for MON 87701 soybean are relevant to this regulatory action and best addressed by extending a determination of nonregulated status to MON 87751. This regulatory action 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 and under 7 CFR 340.

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 (a determination of nonregulated status of MON 87751 soybean) has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, this Alternative 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 87751 soybean, the continued regulated status of MON 87751 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 87751 soybean will not have any significant environmental effects.

M. J. Firko

Michael Firko, Ph.D.

Deputy Administrator

Biotechnology Regulatory Services

16 Oct 2014

Date