

**NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT**

Monsanto Company
MON 87712-4 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 11-202-01p) by Monsanto Company (hereafter referred to as Monsanto) for their genetically engineered MON 87712-4 soybean (hereafter referred to as MON 87712 soybean) that potentially increases soybean yield through a single-gene strategy. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment that may result from approving the petition seeking nonregulated status for MON 87712 soybean. The EA assesses alternatives to a determination of nonregulated status of MON 87712 soybean and analyzes the potential environmental and social effects that result from the proposed action and the alternatives.

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 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. 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 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 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 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 risk 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 87712 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 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 11-202-01p) to APHIS seeking a determination that their genetically engineered MON 87712 soybean is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at & CFR Part 340.

MON 87712 Soybean

Monsanto has submitted a petition (APHIS Number 11-202-01p) to APHIS in 2011 for determination of nonregulated status of MON 87712 soybean that expresses the *BBX32* gene from *Arabidopsis thaliana*. This gene results in production of a protein that interacts with one or more endogenous transcription factors to regulate the plant's day/night physiological processes. This results in increased availability of assimilates, an extended period of photosynthetic activity, changes in diurnal metabolism during the reproductive phase of the soybean plant, and significantly increased yield compared to control plants ((Holtan et al., 2011); (Monsanto, 2011).

The purpose of MON 87712 soybean is to provide another soybean option that potentially increases yield. Increased soybean productivity in the United States has been accomplished by both increasing the area under cultivation and through yield increases per unit area such as with MON 87712 soybean. U.S. soybean yield increases can be attributed to genetic and agronomic innovations and better control of pests and diseases that provide producers better tools to meet production demands (Specht et al., 1999), depending also on continuing infusions of genetic resources for yield stability and growth (USDA-ERS, 2006a). The potential commercial use of MON 87712 soybean would offer farmers an additional choice of a potentially higher yielding soybean.

Monsanto has conducted field trials of MON 87712 soybean in the United States since 2006 in order to evaluate phenotypic characteristics comparing MON 87712 with the non-transgenic variety A3525 lacking the *BBX32* gene. Agronomic data were collected in 2009 in 19 locations that represented a diverse range of environmental conditions where MON 87712 soybean is expected to be grown. No statistically significant differences were observed for germination, emergence, seedling vigor, days to flower, plant height, lodging, pod shattering, grain moisture and weight (Monsanto 2011, p. 130), disease incidence and insect damage ((Monsanto, 2011), Appendix H). No qualitative or quantitative observations indicated any biologically meaningful

differences from the comparator A3525 and the control lines or differences outside the range of conventional soybean norms. Field trials of MON 87712 soybean were conducted within selected soybean growing areas in the U.S., including Illinois, Indiana, Ohio, Iowa, Kansas, Nebraska, Missouri, Texas, Florida and Kentucky. Data resulting from these field trials are described in the MON 87712 soybean petition (Monsanto, 2011; Pioneer, 2011) and analyzed for plant pest risk in the USDA-APHIS Plant Pest Risk Assessment (PPRA)(USDA-APHIS, 2011).

Coordinated Framework Review

Food and Drug Administration

MON 87712 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” (US-FDA, 2011) 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.

Monsanto initiated a food safety consultation with the FDA on the *BBX32* protein, and received questions from FDA on July 18, 2012, and responded to those on August 9, 2012. When complete, the decision memo will be published as BNF-000131. Monsanto has received no additional questions from FDA pursuant to §408(d) of the Federal Food, Drug, and Cosmetic Act as of September 11, 2013, and FDA’s evaluation has not yet been completed (Phillion, 2013).

Environmental Protection Agency

The U.S. 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.). EPA has authority under FIFRA to establish pesticide use restrictions. These use restrictions are presented on pesticide labels which are prepared during the pesticide registration process. MON 87712 soybean does not express a pesticidal property, and, accordingly, is not regulated by the U.S. EPA.

Scope of the Environmental Analysis

Although approving the petition for nonregulated status of MON 87712 soybean would allow for new plantings of MON 87712 soybean anywhere in the U.S., APHIS primarily focused the environmental analysis to those geographic areas that current support soybean production. Approving the petition for nonregulated status of MON 87712 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, 2010) to determine where soybean is produced in the U.S. (USDA-NASS, 2010). The majority of soybeans produced in the United States are grown in 31 states. The top producing states are Iowa, Illinois, Minnesota, Indiana, and Nebraska, commonly growing soybean in rotation with corn (Soyatech, 2011). U.S. soybean acreage is concentrated where soybean yields are highest, namely the Midwest (USDA-ERS, 2006b). More recently, soybean acreage has expanded to the

northern and western parts of the country due to stagnant yields in wheat and improvements in better yielding short-season soybeans adapted to the climate in these areas (USDA-ERS, 2010), increasing the overall acreage devoted to soybean production in the U.S.

Over the last 20 years, soybean production has increased 35.6%, from nearly 2.2 billion bushels (59.88 million metric tons[MT]) in 1992 to approximately 3.0 billion bushels (81.7 million MT) in 2012 (USDA-NASS, 2012d). From 1991 to 2011, average yield increased approximately 17.6% from 34.2 bushels per acre in 1991 to 41.5 bushels per acre in 2011, but declined nationally in 2012 to 39.3 bushels per acre compared to 2011 average yields (USDA-NASS, 2012d).

Public Involvement

APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. APHIS does this through a notice published in the *Federal Register*. On March 6, 2012, APHIS published a notice¹ in the *Federal Register* advising the public that APHIS is implementing changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for GE organisms to allow for early public involvement in the process. As identified in this notice, APHIS will publish two separate notices in the *Federal Register* for petitions for which APHIS prepares an EA. The first notice will announce the availability of the petition, and the second notice will announce the availability of APHIS' decision making documents. As part of the new process, with each of the two notices published in the *Federal Register*, there will be an opportunity for public involvement:

2.1.1 First Opportunity for Public Involvement

Once APHIS deems a petition complete, the petition is made available for public comment for 60 days, providing the public an opportunity to raise issues regarding the petition itself and give input that will be considered by the Agency as it develops its EA and PPRA. APHIS publishes a notice in the *Federal Register* to inform the public that APHIS will accept written comments regarding a petition for a determination of nonregulated status for a period of 60 days from the date of the notice. This availability of the petition for public comment will be announced in a *Federal Register* notice.

Second Opportunity for Public Involvement

Assuming an EA is sufficient, the EA and PPRA are developed and a notice of their availability is published in a second *Federal Register* notice. This second notice follows one of two approaches for public participation based on whether or not APHIS decides the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues:

Approach 1: GE organisms that do not raise substantive new issues. This approach for public participation is used when APHIS decides, based on the review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition, that the petition involves a GE organism that *does not raise new biological, cultural, or*

¹ This notice can be accessed at: <http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf>

ecological issues because of the nature of the modification or APHIS' familiarity with the recipient organism. After developing its EA, finding of no significant impact (FONSI), and PPRA, APHIS publishes a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the EA, FONSI, and PPRA for a 30-day public review period.

If APHIS determines that no substantive information has been received that would warrant APHIS altering its preliminary regulatory determination or FONSI, substantially changing the proposed action identified in the EA, or substantially changing the analysis of impacts in the EA, APHIS' preliminary regulatory determination becomes final and effective upon public notification through an announcement on its website. No further *Federal Register* notice is published announcing the final regulatory determination.

Approach 2. For GE organisms that raise substantive new issues not previously reviewed by APHIS. A second approach for public participation is used when APHIS determines that the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues. This could include petitions involving a recipient organism that has not previously been determined by APHIS to have nonregulated status or when APHIS determines that gene modifications raise substantive biological, cultural, or ecological issues not previously analyzed by APHIS. Substantive issues are identified by APHIS based on our review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition.

APHIS solicits comments on its draft EA and draft PPRA for 30 days through the publication of a *Federal Register* notice. APHIS reviews and evaluates comments and other relevant information, then revises the PPRA as necessary and prepares a final EA. Following preparation of these documents, APHIS approves or denies the petition, announcing in the *Federal Register* the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, National Environmental Policy (NEPA) decision document (either a FONSI or NOI to prepare an EIS), and regulatory determination.

Enhancements to public input are described in more detail in the *Federal Register* notice² that was published on March 6, 2012.

APHIS has determined that this EA will follow Approach 2 following an APHIS-BRS decision tree, in this case because the trait is a new one, and not previously determined as nonregulated. The issues discussed in this EA were developed by considering the public concerns, including public comments received in response to the *Federal Register* notice (77 F.R. 41354-6) announcing the availability of the petition (i.e., the first opportunity for public involvement previously described in this document), as well as issues noted in public comments submitted for other EAs of GE organisms, and concerns described in lawsuits and expressed 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 GE plants, were addressed to analyze the potential environmental impacts of MON 87712 soybean.

² This notice can be accessed at: <http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf>

The public comment period for MON 87712 soybean petition closed on September 11, 2012. At its closing, the docket file contained a total of 4,665 public comments. Some of the submissions to the docket contained multiple attached comments gathered by organizations from their members. The majority of the comments expressed a general dislike of the use of GE organisms or were form letters sent to all of the dockets which were open at the time that this docket was open. The form letter expressed a concern that there were too many dockets published on the same day. It also referenced other open dockets and potential effects from the use of the subjects of those petitions. These issues are outside the scope of this EA. The issues that were raised in the public comments which were related to the Monsanto 87712 soybean petition included:

- Outcrossing with other soybean lines that are nontransgenic can negatively impact their salability and also consumer choice in GE-sensitive markets.
- Food and feed impacts are conducted and evaluated by the seed developer and need peer review along with FDA review.
- Increased yield will result in increased supply and lower prices to both US and foreign soybean producers.
- Concerns that there are economic impacts of cross pollination from MON 87712 soybean to organic soybeans for some organic growers. According to the comment organic growers have experienced rejection rates of 0.25%.
- Concerns that MON 87712 soybean is not approved in all export markets, and if this variety arrived at a market without specific approval, trade disruptions and economic losses could occur. The developer needs binding stewardship mechanisms in place to prevent potential trade economic impacts as well as compensation mechanisms if these mechanisms fail to be observed.

In the EA, APHIS evaluated these comments and other documents submitted and has included a discussion of these and other related issues with relevant documentation and citations where appropriate.

The Draft EA, and Draft PPRA were made available for public comment during a 30-day comment period beginning on August 5, 2013. One comment was received, and was carefully analyzed to identify new issues, alternatives, or information. The public comments in response to the petition, and a public comment in response to the EA and the attached documents may be viewed at the federal website, [regulations.gov](http://www.regulations.gov)³.

The single public comment that was received from a citizen did not offer an opinion about granting nonregulated status to MON 87712 soybean, but questioned APHIS' authority to regulate GE plants and challenged the Agency's NEPA process. See Addendum I for the APHIS response¹.

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 for MON 87712 soybean. Issues discussed in the EA were

³ <http://www.regulations.gov/#!searchResults;rpp=50;so=ASC;sb=docId;po=0;s=APHIS-2012-0046>

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 87712 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 resource areas considered also address concerns raised in previous and unrelated lawsuits, as well as issues that have been raised by various stakeholders in the past. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25). These resource areas can be categorized as follows:

Agricultural Production Considerations:

- Acreage and Area of Soybean Production
- Agronomic Practices
- Soybean Seed Production
- Organic Soybean Production

Environmental Considerations:

- Soil Quality
- Water Resources
- Air Quality
- Climate Change
- Animal Communities
- Plant Communities
- Gene Flow and Weediness
- Microorganisms
- Biodiversity

Human Health Considerations:

- Consumer Health
- Occupational Health and Safety

Livestock Health Considerations:

- Animal Feed

Socioeconomic Considerations:

- Domestic Economic Environment
- Trade Economic Environment

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of a determination of nonregulated status of MON 87712 soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 87712 soybean is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS, 2011), APHIS has concluded that MON 87712 soybean is unlikely to pose a plant pest risk. Therefore, APHIS must determine that MON 87712 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 87712 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 87712 soybean and progeny derived from MON 87712 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 87712 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 87712 soybean.

This alternative is not the preferred alternative because APHIS has concluded through a Plant Pest Risk Assessment that MON 87712 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2011). 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 87712 soybean is No Longer a Regulated Article

Under this alternative, MON 87712 soybean and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. MON 87712 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2011). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87712 soybean and progeny derived from this event. The Preferred Alternative, i.e., a determination of nonregulated status of MON 87712 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 87712 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87712 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 87712 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 87712 soybean. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

1. Prohibit any MON 87712 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 87712 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 87712 soybean is unlikely to pose a plant health risk (USDA-APHIS, 2011; 2012).

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, 2011), and the scientific data evaluated therein, APHIS concluded that MON 87712 soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87712 soybean.

2. Approve the petition in part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may “approve the petition in whole or in part.” For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that MON 87712 soybean is unlikely to pose a plant pest risk, (USDA-APHIS, 2011), there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3. Isolation Distance between MON 87712 soybean and Non-GE soybean Production and Geographical Restrictions

APHIS has concluded that MON 87712 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2011); therefor 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 87712 soybean from conventional soybean production. APHIS also considered geographically restricting the production of MON 87712 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 87712 soybean, there are no geographic differences associated with any identifiable plant pest risks for MON 87712 soybean (USDA-APHIS, 2011). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 87712 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 87712 soybean or to use isolation distances and other management practices to minimize gene movement between MON 87712 soybean and non-GE soybean fields. Information to assist growers in making informed management decisions for MON 87712 soybean is available from the Association of Official Seed Certifying Agencies (AOSCA, 2010).

4. Requirement of Testing for MON 87712 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 87712 soybean does not pose a plant pest risk (USDA-APHIS, 2011), 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 87712 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, 2011)
Management Practices		
Acreage and Areas of soybean Production	Current trends in cultivation and the proportion of crop acreage planted with soybean would continue. The majority of soybean produced in the United States would be in the same 31 states as today. The trend of planting primarily GE soybeans would likely continue. Average U.S. soybean yield is expected to continue to increase without expansion of soybean acreage.	The acreage and area of production would remain unchanged from that of the No Action Alternative. There are no substantial agronomic or phenotypic differences between MON 87712 soybean and its comparators and it is subject to the same variables that influence yield in other varieties. The increased yields are the result of changes during the reproductive growth stages that lead to an increased number of seeds and seed weight. soybean acreage is expected to remain relatively stable through 2021/2022 while soybean yield is expected to increase by about 11% over the same period.
Agronomic Practices	soybean management practices and methods that increase yield such as tillage methods, fertilization, crop rotation, irrigation, pest management, and plant residue management would be expected to continue.	Testing indicates the agronomic characteristics and cultivation practices used for the production of MON 87712 soybean are essentially the same as those used for the cultivation of other commercially available soybean and would remain unchanged from the No Action Alternative. MON 87712 soybean does deplete higher amounts of potassium and phosphorus from the soil, yet these levels are similar to other high-yield varieties or from a production strategy designed to maximize yields utilizing lower yielding conventional or GE varieties.
Pesticide Use	Pest management practices would continue to rely on the use of pesticides and fungicides to control insect, fungal, and weed pests. It is expected the use of glyphosate on glyphosate-resistant soybeans would remain the principle	Testing shows MON 87712 soybean is vulnerable to the same pests that effect other commercially available conventional and GE soybean varieties and as such pest management practices would not change from those used under the No Action Alternative.

	method for weed management	
soybean Seed Production	The production of foundation, registered, certified, or quality control seed would still require biological, technical, and quality control factors to ensure varietal purity.	Practices to ensure varietal purity would remain the same as those of the No Action Alternative. Tests would be available and easily accomplished to determine the presence of the gene which conveys the increased yield traits of MON 87712 soybean.
Organic soybean Production	The methods applied in certified seed production systems designed to maintain soybean seed identity and meet National Organic Standards as established by the NOP would continue to be practiced by farmers producing organic soybean. The availability of GE soybean is unrelated to proportion of organic soybean market share.	Measures used by organic soybean producers to manage, identify, and preserve organic production systems would not change. Similar to other commercially available GE soybean varieties, MON 87712 soybean does not present any new or different issues or impacts for organic soybean producers or consumers.
Environment		
Water Resources	Agronomic practices that could impact water resources (e.g., irrigation, tillage practices, and the application of pesticides and fertilizers) would be expected to continue. The use of pesticides in accordance with EPA-approved label directions assure no unreasonable risks to water quality from their use. The historic trend of increased soybean yields on existing cropland would likely continue, minimizing potential impacts to water resources from expanding cultivation.	The production of MON 87712 soybean is not expected to change current agronomic practices, acreage, or range of production that may impact water resources.
Soil	Cropping practices that impact soil such as tillage, contouring, cover crops; agricultural chemical management, and crop rotation would continue. The fertility of some U.S. cropland is declining as a result of increasing crop yields without proper fertilization.	Production of MON 87712 soybean is not expected to change cropping practices. Root exudates from MON 87712 soybean are not expected to change soil physicochemical characteristics. Similar to current high yield production strategies, increased depletion of nutrients such as phosphorus and potassium

		from the production of MON 87712 soybean can be mitigated through the common practices of regular testing of soil fertility and application of nutrients as needed.
Air Quality	Soybean agronomic practices having potential to impact air quality such as tillage, the application of pesticides and fertilizer, and use of emitting agricultural equipment would continue. The use of pesticides in accordance with EPA-approved labels minimizes drift and reduces environmental impacts. Conservation tillage or no-till practices associated with the adoption of herbicide-resistant soybean is expected to continue.	No changes to agronomic practices for the production of MON 87712 soybean are expected that would impact air quality. The application of pesticides and use of conservation tillage and no-till practices would likely be similar to the No Action Alternative.
Climate Change	Agronomic practices having the potential to impact climate change, such as the release of CO ₂ to the atmosphere from tillage, machinery powered by fossil fuel, and NO ₂ emissions associated with nitrogen fertilizers would continue. The trend towards conservation tillage practices that contribute to carbon sequestration and application of more phosphorous and potassium associated with high yield soybean production would also likely continue.	The production of MON 87712 soybean is not expected to change current soybean cropping practices that may impact GHG emissions. The potential increased application of phosphorus and potassium associated with the production of high yield soybean would not impact climate change.
Animals and Plants		
Animals	Conventional and nonregulated GE soybean have been determined to have no allergenic or toxicity to animal communities. Soybean agronomic practices such as such as tillage, cultivation, pesticide, herbicide and fertilizer applications, and the use of agricultural equipment	Testing demonstrates consumption of MON 87712 soybean poses no allergenic or toxicity risk to animal communities. As field trials demonstrate growth and disease characteristics of MON 87712 soybean are similar to other conventional soybean, no change to soybean agronomic practices potentially impacting animal

	would continue to impact animal communities. The use of EPA-registered pesticides and herbicides in accordance with EPA-approved labels minimize potential impacts to animal communities.	communities would be needed to cultivate MON 87712 soybean.
Plants	The majority of soybean acres would likely continue to be planted with GE varieties. Plant species typically competing with soybean production would be managed through the use of mechanical, cultural, and chemical control methods. Multiple herbicides would likely continue to be used for weed control in soybean fields and glyphosate would continue to be the primary herbicide applied in the near term; however, diversification of herbicide use and agronomic measures to deter development of herbicide-resistant weeds would likely increase. Herbicide use in accordance with EPA-approved labels containing measures to reduce herbicide drift and volatilization potentially impacting plant communities minimize potential adverse impacts to plant communities. Soybean volunteers would continue to be controlled with mechanical and herbicidal practices.	No changes to agronomic practices potentially impacting plant communities would be needed to cultivate MON 87712 soybean. Field trials and laboratory analyses show no differences between MON 87712 soybean and other GE and non-GE soybean in growth, reproduction, or interactions with pests and diseases that may impact plant communities. Volunteers of MON 87712 soybean would be managed similar to other nonregulated soybean varieties.
Gene Movement	MON 87712 soybean would continue to be cultivated only under regulated conditions. The availability of GE, non-GE and organic soybeans would not change as a result of the continued regulation of MON 87712 soybean. Because soybean is highly self-pollinated and its pollination rate	Field and laboratory tests demonstrate no significant differences among the parameters that may lead to an increased potential for gene flow or weediness between MON 87712 soybean and the conventional control. MON 87712 soybean would not persist in unmanaged environments and does not demonstrate a competitive

	<p>significantly decreases with distance, it is not frost tolerant, does not reproduce vegetatively, its seed is not easily dispersed, any volunteers that persist in warmer U.S. climates can be easily controlled with common agronomic practices, and there are no wild soybean species or near relatives in the U.S., gene flow and introgression from soybean to wild or weedy species are highly unlikely.</p>	<p>advantage compared to conventional soybean. The trait for increased yield is not expected to contribute to increased weediness without changes in a combination of other characteristics associated with weediness. Nonregulated MON 87712 soybean would not present a plant pest risk.</p>
<p>Soil Microorganisms</p>	<p>MON 87712 soybean would remain under APHIS regulation. The availability of GE, non-GE and organic soybeans would not change as a result of the continued regulation of MON 87712 soybean. Agronomic practices used for soybean production, such as soil inoculation, tillage and the application of agricultural chemicals (pesticides and fertilizers) that potentially impact microorganisms would continue.</p>	<p>Nonregulated status of MON 87712 soybean is not expected to result in changes in current soybean cropping practices that may impact microorganisms. Field and greenhouse tests show no significant differences from other nonregulated soybean varieties in the parameters measured to assess the symbiotic relationship of MON 87712 soybean and rhizobia or its responses to abiotic stressors, suggesting no different impact to the microbial community.</p>
<p>Biological Diversity</p>	<p>MON 87712 soybean would remain under APHIS regulation; the availability of GE, non-GE and organic soybeans would not change. Agronomic practices used for soybean production and yield optimization, such as tillage, the application of agricultural chemicals (pesticides and fertilizers), timing of planting, row spacing, and scouting would be expected to continue. Agronomic practices that benefit biodiversity both on cropland (e.g., intercropping, agroforestry, crop rotations, cover crops, and no-tillage) and</p>	<p>Nonregulated status of MON 87712 soybean would not cause changes in current soybean cropping practices that may impact biodiversity as field and laboratory testing demonstrate its growth, reproduction, and interactions with pests and diseases are similar to other nonregulated varieties. MON 87712 soybean poses no potential for naturally occurring, pollen-mediated gene flow and transgene introgression and as such is not expected to affect genetic diversity.</p>

	on adjacent non-cropland (e.g., woodlots, fencerows, hedgerows, and wetlands) would continue.	
Human and Animal Health		
Risk to Human Health	<p>MON 87712 soybean would remain under APHIS regulation and no change to human exposure to existing GE and non-GE soybean varieties would occur. Compositional and nutritional characteristics of nonregulated GE soybean varieties have been determined to pose no risk to human health. A variety of EPA-approved pesticides would continue to be used for pest management in both GE and non-GE soybean cultivation. Use of registered pesticides in accordance with EPA-approved labels protects human health and worker safety. EPA also establishes tolerances for pesticide residue that give a reasonable certainty of no harm to the general population and any subgroup from the use of pesticides at the approved levels and methods of application.</p>	<p>Testing shows the MON 87712 soybean BBX32 protein has no amino acid sequence similar to known allergens, lacks toxic potential to mammals, and was degraded rapidly and completely in simulated gastric fluid. Monsanto has initiated a food/feed safety consultation on MON 87712 soybean with the FDA and a final decision from FDA is pending. Laboratory and field testing also demonstrate no biologically meaningful differences for compositional and nutritional characteristics between the MON 87712 soybean and conventional soybean varieties. Field testing shows MON 87712 soybean is similar in growth and habit to other conventional soybean and no change to agronomic practices would be required for its cultivation. No change to human health or worker safety would occur from determining MON 87712 soybean nonregulated.</p>
Risk to Animal Feed	<p>MON 87712 soybean would remain regulated and not be allowed for distribution to the animal feed market. Soybean-based animal feed would still be available from currently cultivated soybean crops, including both GE and non-GE soybean varieties. Nonregulated GE soybean varieties used as animal feed have been previously determined to not pose any risk to animal health.</p>	<p>Safety testing of MON 87712 soybean BBX32 protein shows it has no amino acid sequence similar to known allergens, lacks toxic potential to mammals, and was degraded rapidly and completely in simulated gastric fluid, indicating no potential risk for its use as animal feed. Monsanto has initiated a food/feed safety consultation on MON 87712 soybean with the FDA and a final decision from FDA is pending. Testing shows compositional and nutritional</p>

		characteristics of MON 87712 soybean grain and forage are similar to currently available soybean varieties and no adverse impacts to animal feed would occur upon its nonregulated status. Impacts to animal feed safety would therefore be similar to the No Action Alternative.
Socioeconomic		
Domestic Economic Environment	MON 87712 soybean would remain regulated by APHIS. Domestic growers would continue to utilize GE and non-GE soybean varieties based upon availability and market demand. U.S. soybeans would likely continue to be used oil or fresh consumption. Agronomic practices and conventional breeding techniques using GE herbicide- and pest-resistant cultivars currently used to optimize yield and reduce production costs would be expected to continue. Average soybean yield is expected to continue to increase without expansion of soybean acreage while grower net returns are estimated to increase domestically for animal feed, with lesser amounts and byproducts used for	Field tests show the performance and composition of MON 87712 soybean is not substantially different from that of other conventional soybean reference varieties and although yield potential is increased, it would be similar to other commercially available soybean varieties and subject to the same variables affecting agronomic practices and yields as other varieties. MON 87712 soybean would likely replace other varieties of GE soybean on existing cropland and not impact organic soybean production or markets. As MON 87712 soybean is another GE soybean variety potentially increasing farm productivity without altering soybean's nutritional value, potential allergenicity, or toxicity, no change to U.S. consumer attitudes towards GE crops is expected. No adverse impact to the domestic economic environment would occur under this alternative.
Trade Economic Environment	U.S. soybeans will continue to play a role in global soybean production, and the United States will continue to be a supplier in the international market if MON 87712 soybean remains regulated by APHIS. Although U.S. global exports are expected to increase overall, increasing competition is expected to reduce U.S. export	A determination of nonregulated status of MON 87712 soybean is not expected to adversely impact the current trends affecting the trade economic environment and may have a negligible impact through increased yields. Monsanto plans to seek biotechnology regulatory approvals for MON 87712 soybean from all key soybean import countries that have a functioning

	share by 5% in the next 20 years.	regulatory system. Any impact to soybean market prices from the potential increase to yield from the production of MON 87712 soybean would likely be negligible because the increased yield of MON 87712 soybean is similar to other high yielding soybeans already in the market, is subject to the same variables that affect yield in other commercially available cultivars, and is unlikely to significantly increase overall U.S. soybean production.
Other Regulatory Approvals	Final FDA food safety consultation in progress. EPA tolerance exemptions and conditional pesticide registrations granted.	Final FDA food safety consultation in progress. EPA tolerance exemptions and conditional pesticide registrations granted.
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.

Approximately 75.7 million acres of soybean were harvested in the United States in 2012, up nearly 1.9 million acres or 2.5% from 2011 (USDA-NASS, 2012b). USDA projections to 2021/2022 estimate United States soybean acreage will remain relatively steady at approximately 76 million acres (USDA-OCE, 2012).

The majority of soybeans produced in the United States are grown in 31 states. The top producing states are Iowa, Illinois, Minnesota, Indiana, and Nebraska, commonly growing soybean in rotation with corn (Soyatech, 2011). United States’ soybean acreage is concentrated where soybean yields are highest, namely the Midwest (USDA-ERS, 2006b). More recently, soybean acreage has expanded to the northern and western parts of the country due to stagnant yields in wheat and improvements in better yielding short-season soybeans adapted to the climate in these areas (USDA-ERS, 2010), increasing the overall acreage devoted to soybean production in the United States.

Large scale field testing of GE crops began in the 1980s, but it was not until ten years later the first generation of GE varieties became commercially available (Fernandez-Cornejo and Caswell, 2006). Since GE soybeans' initial commercial availability in 1996 (Fernandez-Cornejo and Caswell, 2006; USDA-ERS, 2011), their use had expanded to 94% of the total U.S. soybean acreage by 2011, which was slightly reduced to 93% in 2012 (USDA-ERS, 2012). Currently, most commercially available GE soybean varieties are herbicide-resistant (USDA-ERS, 2012).

A determination of nonregulated status of MON 87712 soybean is not expected to result in changes to current soybean cropping practices as described under the No Action Alternative. As discussed in Subsection 4.2.1, Acreage and Area of Production, Monsanto's studies demonstrate MON 87712 soybean is essentially the same as other commercial soybean varieties in terms of agronomic characteristics and cultivation practices (Monsanto, 2011; USDA-APHIS, 2011). While MON 87712 soybean did have an approximately 1.6% higher earlier plant stand count, reached senescence 2 days later and physiological maturity 2.5 days later, had an approximately 3.3% higher final plant stand, and a 7.3% higher yield than variety A3525, none of these characteristics are expected to require changes to agronomic practices such as tillage, crop residue management, fertilization, crop rotation, irrigation, pest (insects and weeds) and disease management, harvest and storage practices for cultivation of MON 87712 soybean (Monsanto, 2011; USDA-APHIS, 2011). Monsanto has also indicated MON 87712 soybean will be adapted into existing maturation groups to match the area in which it would be cultivated, thus soybean planting practices would not change.

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 87712 soybean will have no significant environmental impact in relation to the availability of GE, conventional, and organic soybean varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of MON 87712 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 87712 soybean will not change the cultivation areas for soybean production in the U.S. and there are no anticipated changes in the availability of GE and non-GE soybean varieties on the market. A determination of nonregulated status of MON 87712 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.

USDA-NASS recently reported the organic crop production data collected in 2011 (USDA-NASS, 2012a). In that year, 96,080 acres of organic soybeans in 28 states were harvested, compared to approximately 73,636 million harvested acres of conventionally produced soybean (USDA-NASS, 2011). In 2011, organic soybean production consisted of about 0.09% of total U.S. soybean production and was valued at approximately \$49.4 million, capturing roughly 0.14% of the overall soybean crop value for that year (USDA-NASS, 2012c; 2012a). Organic soybean producers generally harvest lower yields than other producers (McBride and Greene, 2008; Heatherly et al., 2009). McBride and Greene (2008) also found total operating costs averaged \$30 more per acre and capital

costs averaged \$60 per acre higher for organic soybean producers than for other conventional soybean producers.

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

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 87712 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 has provided the FDA with information on the identity, function, and characterization of the genes for MON 87712 soybean, including expression of the gene products. The FDA has not yet completed its Biotechnology Consultation.

A determination of nonregulated status of MON 87712 soybean would have no significant impacts on human or animal health. MON 87712 soybean is compositionally similar to currently available soybean on the market with the exception of the BBX32 protein. Based on the FDA's in-progress consultation, laboratory data and scientific literature provided by Monsanto (Monsanto, 2011), APHIS has concluded that MON 87712-4 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 adversely impacted by a determination of nonregulated status of MON 87712 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 87712 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 87712 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 87712 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 87712 soybean are not highly controversial. Although there is some opposition to a determination of nonregulated status of MON 87712 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 EA, 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 87712 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 87712 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 87712 soybean is registered by the EPA for breeding and seed increase activities. A determination of nonregulated status of MON 87712 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 87712 soybean on wildlife or biodiversity is not different than that of other glyphosate-resistant 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 87712 soybean. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. 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 Chapter 4 of the EA, a determination of nonregulated status of MON 87712 soybean is not expected to directly cause an increase in agricultural acreage devoted to soybean production, or those acres devoted to GE soybean cultivation. A determination of nonregulated status of MON 87712 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 87712 soybean on wildlife or biodiversity is no different than that from other enhanced-trait 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 87712 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 87712 soybean. Given the extensive experience that APHIS, stakeholders, and growers have in dealing with the use of GE soybean products and enhanced-trait agricultural crops, the possible effects to the human environment from the release of 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 for MON 87712 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 87712 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 or 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 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. In the event APHIS reaches a determination of nonregulated status of MON 87712 soybean, APHIS would no longer have regulatory authority over this soybean. In the event of a determination of nonregulated status of MON 87712 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 87712 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.*

A determination of nonregulated status of MON 87712 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 87712 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 87712 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 87712 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 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 87712-4 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 EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of MON 87712 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 87712 soybean, APHIS has determined that a determination of nonregulated status of MON 87712 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.*

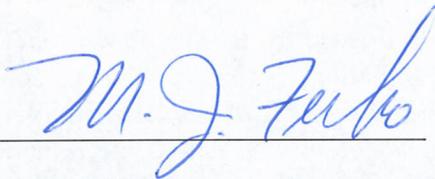
The proposed action would be in compliance with all federal, state, and local laws. Because the agency has concluded that MON 87712 soybean is unlikely to pose a plant

pest risk, a determination of nonregulated status of MON 87712 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 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 87712 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.

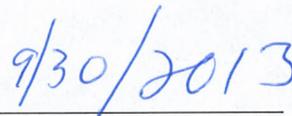
As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation 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 87712 soybean, the continued regulated status of MON 87712 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 87712 soybean will not have any significant environmental effects.



Michael J. Firko

Deputy Administrator, Acting

Biotechnology Regulatory Services



Date

Bibliography

- AOSCA (2010) "General IP Protocols Standards." The Association of Official Seed Certifying Agencies. <http://www.identitypreserved.com/handbook/aosca-general.htm> >.
- Fernandez-Cornejo, J and Caswell, M (2006) "The First Decade of Genetically Engineered Crops in the United States. Economic Information Bulletin Number 11." <http://www.ers.usda.gov/publications/eib11/>. >.
- 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> >.
- Heatherly, L; Dorrance, A; Hoeft, R; Onstad, D; Orf, J; Porter, P; Spurlock, S; and Young, B (2009) "Sustainability of U.S. soybean Production: Conventional, Transgenic, and Organic Production Systems." Council for Agricultural Science and Technology. <http://www.cast-science.org/publications/index.cfm/> >.
- Holtan, HE; Bandong, S; Marion, CM; Adam, L; Tiwari, S; Yu Shen; Maloof, JN; Maszle, DR; Ohto, M; Preuss, S; Meister, R; Petracek, M; Repetti, PP; Reuber, T; Ratcliffe, OJ; and Khanna, R (2011) "BBX32, an Arabidopsis B-Box protein, functions in light signaling by suppressing HY5-regulated gene expression and interacting with STH2/BBX21." *Plant Physiology*. 156 p 2109-23.
- McBride, WD and Greene, C (2008) "The Profitability of Organic soybean Production." *American Agricultural Economics Association Annual Meeting*. <http://ageconsearch.umn.edu/bitstream/6449/2/465035.pdf> >.
- Monsanto (2011) "Petition for the Determination of Nonregulated Status for MON 87712 soybean." Submitted by Koyejo, Taiwo O., Registration Manager. Monsanto Company. http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml >.
- Phillion, D to: Roseland, C. (2013). Personal communication from Monsanto
- Pioneer (2011) "Petition for the Determination of Nonregulated Status for Herbicide-Tolerant 73496 Canola." Pioneer, A DuPont Business.
- Soyatech (2011) "Soy Facts." Soyatech, LLC. http://72.32.142.180/soy_facts.htm >.

Specht, JE; Hume, DJ; and Kumudini, SV (1999) "soybean yield potential - A genetic and physiological perspective." *Crop Science*. 39 p 1560-70.

US-FDA (2011) "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use." Office of Food Additive Safety, Division of Biotechnology & GRAS Notice Review, Center for Food Safety and Applied Nutrition, Food and Drug Administration. Health and Human Services.
<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096156.htm> >.

USDA-APHIS (2011) "Plant Pest Risk Assessment for Monsanto MON 87701 soybeans." U.S. Department of Agriculture—Animal and Plant Health Inspection Service.
http://www.aphis.usda.gov/biotechnology/not_reg.html >.

USDA-APHIS (2012) "Plant Pest Risk Assessment for Genective Event VCO-Ø1981-5 Corn." US Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services.

USDA-ERS (2006a) "Chapter 3.1 Crop Genetic Resources." U.S. Department of Agriculture—Economic Research Service. <http://www.ers.usda.gov/publications/eib-economic-information-bulletin/eib16.aspx> >.

USDA-ERS (2006b) "soybean Backgrounder." <http://naldc.nal.usda.gov/download/41256/PDF> >.

USDA-ERS (2010) "USDA soybean Baseline, 2010-19." <http://www.ers.usda.gov/topics/crops/soybeans-oil-crops/market-outlook/usda-soybean-baseline,-2010-19.aspx> >.

USDA-ERS (2011) "Adoption of Genetically Engineered Crops in the U.S.: soybeans Varieties." U.S. Department of Agriculture—Economic Research Service.
<http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable3.htm> >.

USDA-ERS "Genetically Engineered Varieties of Corn, Upland Cotton, soybeans by State and for the United States, 2000-2012." U.S. Department of Agriculture—Economic Research Service.
<http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx>. >.

USDA-NASS (2010) "Acreage." <http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-30-2010.pdf> >.

USDA-NASS "U.S. & All States Data - Crops Planted, Harvested, Yield, Production, Price (MYA), Value of Production 1991-2011." U.S. Department of Agriculture–National Agricultural Statistics Service. <http://www.nass.usda.gov/Data and Statistics/Quick Stats 1.0/index.asp> >.

USDA-NASS (2012a) "2011 Certified Organic Production Survey." <http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1859> >.

USDA-NASS "National Statistics for soybeans." U.S. Department of Agriculture–National Agriculture Statistics Service. <http://www.nass.usda.gov/Statistics by Subject/result.php?818D7CBF-2510-3E92-B0F0-89D1ACD4737F§or=CROPS&group=FIELD%20CROPS&comm=SOYBEANS> >.

USDA-NASS "Quick Stats." U.S. Department of Agriculture–National Agriculture Statistics Service. <http://quickstats.nass.usda.gov/>. >.

USDA-NASS "Quick Stats – soybean Production (National Totals)." U.S. Department of Agriculture–National Agriculture Statistics Service. <http://www.nass.usda.gov/Statistics by Subject/index.php?sector=CROPS> >.

USDA-OCE (2012) "USDA Agricultural Projections to 2021." U.S. Department of Agriculture–Office of the Chief Economist. http://www.usda.gov/oce/commodity/archive_projections/USDAgriculturalProjections2021.pdf. >.

ⁱ Addendum I. Response to Public Review on Monsanto 87712 Soybean

APHIS received one comment that was critical of its NEPA compliance process. The comment identified two issues that are identified and addressed below.

Issue 1—Applicability and Relevancy

The commenter implies that APHIS NEPA-compliance activities are not relevant to what NEPA requires, because APHIS does not have regulatory authority over genetically engineered organisms once it has completed a plant pest risk assessment. The commenter bases this analysis on the assumption that when APHIS is deciding whether or not to approve a petition for nonregulated status under its regulations in §7 CFR 340.6, APHIS is determining whether the Agency has jurisdiction over the organism. The commenter also suggests that the "... 'Coordinated Framework' provides no authority for APHIS 'regulation' of genetically-

engineered organisms.” The commenter believes that APHIS’ NEPA analysis wastes taxpayers money and that it is used to promote private enterprise.

APHIS Response:

This comment is outside the scope of the action being taken under the regulations in 7 C.F.R. 340.6, which is to make a decision on a petition for nonregulated status for MON 87712 soybean under a process defined in the regulations. The comment is a general critique of the applicability of NEPA to the APHIS petition process. APHIS has consistently conducted NEPA analyses for actions taken under this section of the regulations since its codification in 1993. APHIS disagrees with the commenter that a scientific analysis conducted in a Plant Pest Risk Assessment (PPRA) deprives the Agency of jurisdiction over a genetically engineered (GE) plant. APHIS has a process, described in the regulations, that allows an individual to petition the Agency for nonregulated status of an organism. The scientific analysis in the PPRA is part of that process, and is the initial—not the final—step of that process. It informs by serving as a mechanism for identifying the range of alternatives to be analyzed in the EA. The PPRA is also used to identify and support the analysis of potential impacts to the human environment. The PPRA is an analysis of potential plant pest risk and is not the final determination of regulatory status. To be clear and transparent to the decisionmaker and the public, APHIS identifies in the NEPA process, how its regulatory authority would be carried out under each of the alternatives. By disclosing this information, APHIS ensures that information relevant to its decisionmaking authority is being made available before decisions are made and before actions are taken. Identifying the scope of the APHIS regulatory authority does not prejudice the Agency’s NEPA analysis. On the contrary, it provides and allows for a full and rigorous analysis of potential impacts to the human environment.

In reference to its regulatory authority, APHIS notes the following:

APHIS agrees with the interpretation that the Coordinated Framework does not establish or otherwise convey regulatory authority to any of the three federal agencies that are a party to it. APHIS emphasizes that the purpose and function of it is to delineate more precisely the regulatory roles of the three participating agencies in matters in which the enabling legislation that establishes the regulatory authority of each allows for possible overlap of responsibilities with regard to GE organisms.

APHIS disagrees with the commenter regarding its authority to regulate GE organisms that are potential plant pests, emphasizing the applicability of the following section of 7 USC § 7712.2.

“(a) In general

The Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States.”

This section coupled with the definition of “plant pest” given at 7 USC § 7702 provides the Agency with broad latitude sufficient to regulate GE organisms as plant pests:

“(14) Plant pest

“The term “plant pest” means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:

- (A) A protozoan.
- (B) A nonhuman animal.
- (C) A parasitic plant.
- (D) A bacterium.
- (E) A fungus.
- (F) A virus or viroid.
- (G) An infectious agent or other pathogen.
- (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.”

Relevant to the EA and this FONSI for MON 87712 Soybean, APHIS notes that this soybean variety incorporates a genetic trait that is derived from the herbaceous plant, *Arabidopsis thaliana*. The overarching regulatory issue is whether or not the regulated article (i.e., potential plant pest) is itself a plant pest.

The commenter also indicates that APHIS uses the NEPA process to “. . . promote private enterprise . . .” APHIS disagrees with this contention. APHIS conducts NEPA analyses to inform the decisionmaker of the impacts on the human environment that could occur when a regulatory determination is made for a petition.

The commenter also implies that APHIS documents contain “macros.” APHIS does not use any automated computer function to generate its documents. The Agency only uses a template to create a consistent format in its documents.

Issue 2—Adequacy of APHIS NEPA Documentation

The commenter challenges the adequacy of the APHIS NEPA analyses related to GE organisms. The commenter implies that APHIS documents are not written in plain language, and indicated that:

“APHIS BRS relies extensively on consideration by the United States Environmental Protection Agency (EPA) of environmental effects in the context of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) registration process, as well as FDA’s determinations under its enabling legislation.

“The regulatory and review processes of EPA and FDA cannot be relied upon to relieve APHIS from considering in the context of the National Environmental Policy Act (NEPA) process any and all effects associated with release into the environment of petitioners’ products. See *Citizens Against Toxic Sprays v. Bergland*, 428 F.Supp. 908, 927 (D. Ore. 1977).” and “APHIS BRS places a great deal of reliance on petitioners in complying with NEPA. Agencies have a responsibility under NEPA to independently investigate and assess the environmental impacts of proposals under consideration (40 C.F.R. § 1506.5(a) and (b)). See also *Illinois Commerce Comm’n v. ICC*, 848 F.2d 1246, 1258 (D.C. Cir. 1984).”

APHIS Response

APHIS disagrees with the commenters generalizations with respect to the action proposed here. APHIS is considering whether to approve the petition for nonregulated status for MON 87712 soybean. The commenter made broad statements about the inadequacy of the purpose and need, alternatives, and cumulative impacts sections of APHIS EAs. However, neither specific examples of inadequacies nor recommendations for improving this EA were provided.

APHIS also disagrees with the implication that reliance on EPA and FDA assessments is a flawed process. Under the Coordinated framework, EPA regulates pesticides, including pesticide residue on food and animal feed. FDA has primary responsibility for ensuring the safety of food and animal feed. The EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under the FIFRA. A determination of specific requirements for a pesticide is based on procedures outlined in the Label Review Manual (EPA, 2013). APHIS relies on the FDA consultations and the EPA's risk assessments and expertise because these are the best available information. APHIS uses this and other information from the scientific literature in its assessment.

APHIS also disagrees with the contention of excessive reliance by the Agency on data provided by petitioners because they provide information that can only be obtained by a developer. Much of this information is typically acquired in field studies conducted within the U.S. Such studies are approved in advance, and regulated by APHIS.