

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

**BASF Plant Science, L.L.C.  
BPS-CV127-9 Soybean**

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

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

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS Number 09-015-01p) by BASF Plant Science, L.L.C. (hereafter referred to as BASF) for their genetically engineered (GE) BPS-CV127-9 soybean (hereafter referred to as BASF CV127 soybean) that is resistant to imidazolinone herbicides. 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 BASF CV127 soybean. The EA assesses alternatives to a determination of nonregulated status of BASF CV127 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 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 APHIS, the U.S. Food and Drug Administration (FDA), and the U.S. Environmental Protection Agency (EPA).

APHIS is responsible for regulating GE organisms and plants under the plant pest provision in the Plant Protection Act of 2000, as amended (7 USC §§ 7701 et seq.) to ensure that they do not pose a plant pest risk to the environment.

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. 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 (PIPs) 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 BASF CV127 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.

BASF has submitted a petition (APHIS Number 09-015-01p) (BASF, 2011) to APHIS seeking a determination that their genetically engineered BASF CV127 soybean is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR Part 340.

### **BASF CV127 Soybean**

BASF submitted a petition (APHIS number 09-015-01p) to APHIS in 2009 for determination of nonregulated status of BASF CV127 soybean that expresses the *csr1-2* gene from *Arabidopsis thaliana* (*A. thaliana*) (BASF, 2011). This gene encodes an acetohydroxyacid synthase large subunit (*AtAHASL*) enzyme making this soybean tolerant to certain imidazolinone herbicides. Soybeans are naturally tolerant to some imidazolinone herbicides; however, certain imidazolinone compounds, such as imazapyr and imazapic, are not readily metabolized in soybeans. As a result, conventional soybeans are very sensitive to imazapyr and imazapic. Thus, growers could apply imidazolinone herbicides (i.e., imazapyr and imazapic) at normal field application rates to BASF CV127 soybean for weed control without causing injury to the soybean plant (BASF, 2011).

The *Arabidopsis* AHASL (*AtAHAS*) is a member of the class of AHAS proteins widely found in plants. The AHASL enzyme catalyzes the first step in the biosynthesis of branched-chain amino acids, valine, leucine, and isoleucine. Typically, inhibition of the AHASL enzyme by imidazolinone herbicides leads to a deficiency in branched-chain amino acids and other compounds derived from this pathway that are needed for plant growth and survival, and results in plant death. Several AHAS genes encoding AHAS enzymes that are tolerant to imidazolinone herbicides have been discovered in plants as naturally occurring mutations and through the

process of chemically-induced mutagenesis. For example, imidazolinone-tolerant maize (*Zea mays* L.), rice (*Oryza sativa* L.), bread wheat (*Triticum aestivum* L.), and oilseed rape (*Brassica napus* and *B. juncea* L. Czern.), were developed through mutagenesis, selection, and conventional breeding technologies and have been commercialized under the Clearfield® brand name since 1992, 2003, 2002, and 1996, respectively (BASF, 2011).

BASF CV127 soybean was developed for cultivation primarily in Brazil and Argentina. Imidazolinone herbicides control a wide range of grass and broadleaf weeds. The major weeds in soybean cultivation in these countries are sensitive to the imidazolinone herbicides containing imazapyr and imazapic. The petitioner indicates that introduction of BASF CV127 soybean varieties will offer soybean growers in Brazil and Argentina an additional tool for controlling weeds, as well as an important option for weed resistance management. In addition to regulatory approvals for production in Brazil and Argentina, BASF is seeking regulatory approvals in other countries, including the U.S., for importation of grain from BASF CV127 soybean for food, feed, and processing uses (BASF, 2011).

## **Coordinated Framework Review**

### *Food and Drug Administration*

BASF initiated the consultation process with FDA for the commercial distribution of food or feed derived from BASF CV127 soybean and submitted a safety and nutritional assessment for the soybean event to the FDA on January 26, 2009 (BNF No. 000114). BASF submitted additional information on May 29, 2009 and May 10, 2011. Based on the information BASF submitted, and as of February 17, 2012, the FDA has no further questions regarding BASF CV127 soybean (US-FDA, 2012).

### *Environmental Protection Agency*

The EPA regulates PIPs under FIFRA (7 U.S.C. 136 et seq.) and certain biological control organisms under TSCA (15 U.S.C. 53 et seq.). BASF CV127 soybean does not express a pesticidal property, and, accordingly, is not regulated by the EPA.

EPA has responsibility to regulate the use of pesticides (herbicides) that may be used on food and feed crops, and must establish pesticide tolerances (maximum pesticide residue levels) for the amount of pesticide residue that can legally remain in or on the crop. BASF submitted an import tolerance petition and supporting residue data to EPA on September 29, 2010, for the use of imazapyr and imazapic on imported CV127 soybeans (Federal Register volume 76, number 24; Federal Register volume 76, number 60, respectively) (BASF, 2011).

## **Scope of the Environmental Analysis**

Although approving the petition for nonregulated status of BASF CV127 soybean would allow for new plantings of BASF CV127 soybean anywhere in the U.S., BASF CV127 soybean was developed for cultivation primarily in Brazil and Argentina. In the event that CV127 soybean were to be introduced into the U.S. environment, the data generated from field studies conducted in Brazil to support the environmental, as well as food and feed safety of BASF CV127 soybeans, are equally applicable to the environmental, food and feed safety assessments of BASF CV127 in the U.S. APHIS primarily focused the environmental analysis to those U.S.

geographic areas that currently support soybean production. Approving the petition for nonregulated status of BASF CV127 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 USDA National Agricultural Statistics Service (NASS) to determine where soybean is produced in the U.S. (USDA-NASS, 2012b).

## **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 notice<sup>1</sup> 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:

### *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 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 ecological issues because of the nature of the modification or APHIS' familiarity with the recipient organism. After developing the EA, finding of no significant impact (FONSI), and PPRA, APHIS publishes a notice in the Federal Register announcing its preliminary regulatory

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

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* notice<sup>2</sup> that was published on March 6, 2012.

APHIS has determined that this EA will follow Approach 2 following an APHIS Biotechnology Regulatory Services (BRS) decision tree 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 BASF CV127 soybean.

The public comment period for BASF CV127 soybean petition (APHIS Number 09-015-01p) closed on September 11, 2012. At its closing, 75 public submissions were made to the docket.

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

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.

Issues raised in these public comments on the petition were focused on the nature of agronomic inputs associated with this new trait, potential impacts to plants from off-target drift, management of herbicide-resistant weeds, human health considerations from exposure to herbicides, and domestic and international economic impacts associated with the development and marketing of a new herbicide-resistant product. APHIS evaluated these comments and other documents submitted and included a discussion of these and other related issues with relevant documentation and citations where appropriate in the EA.

The Draft EA and Draft PPRA were made available for public comment during a 30-day comment period that closed on December 9, 2013. Ten comments were received and were carefully analyzed to identify new issues, alternatives, or information. The public comments in response to the petition and the draft EA and PPRA, along with any attached documents, may be viewed at the federal website, [regulations.gov](http://www.regulations.gov)<sup>3</sup>.

The majority of comments were related to GE crops and herbicide use in general and expressed a general dislike of the use of GE organisms. The public comments included the following:

- There are insufficient environmental and health tests performed on GE plants.
- Crops GE to be resistant to pesticides have higher than normal amounts of pesticides applied to them, creating public health and environmental impacts.
- Studies on GE crops should not be conducted by GE seed developers but by independent and scientifically objective organizations.
- APHIS should not be looking at plant pest risk but at human health and environmental risks.
- GE crops are cross-pollinating with heirloom and native crops to the point of extinction.
- Concerns that there are economic impacts of cross pollination from GE crops to organic crops for organic growers.
- APHIS should create zones around organic farms protecting them from potential cross contamination from GE crops.
- Herbicide-resistant crops are no longer working as evidenced by increasing number of herbicide-resistant weeds. No additional herbicide-resistant crops should be developed; agroecology should be researched and promoted.
- The U.S. Midwest staple crop system, predominantly GE, is falling behind other economically and technologically equivalent regions, such as Western Europe.

Issues raised in the public comments that were related specifically to the BASF CV127 soybean petition included a comment from BASF, the petitioner, identifying some typographical errors in

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<sup>3</sup> <http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=APHIS-2012-0028> (note: this link must be copied and pasted directly in a web browser to be accessed).

the draft EA and PPRA. Another commenter expressed concern as to whether GE soybean, including BASF CV127 soybean, differs from non-GE soybean in that they cause increased estrogen.

APHIS evaluated these issues and the submitted documentation. APHIS has included a discussion of these issues in the EA or in the response to comments attached to this document. See Addendum I of this document for the APHIS responses.

### **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 BASF CV127 soybean. Issues discussed in the EA were developed by considering public concerns as well as issues raised in public comments submitted for other environmental assessments of GE 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 GE plants were addressed to analyze the potential environmental impacts of BASF CV127 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
- Soybean Seed Production
- Organic Soybean Production

#### **Socioeconomic Considerations:**

- Domestic Economic Environment
- Trade Economic Environment

#### **Human Health and Animal Feed Considerations:**

- Food and Feed
- Occupational Safety

#### **Environmental Considerations:**

- Soil Quality
- Water Resources
- Air Quality
- Climate Change

- Animal Communities
- Plant Communities
- Gene Flow and Weediness
- Microorganisms
- Biodiversity

### **Alternatives that Were Fully Analyzed**

The EA analyzes the potential environmental consequences of a determination of nonregulated status of BASF CV127 soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that BASF CV127 soybean is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS, 2014), APHIS has concluded that BASF CV127 soybean is unlikely to pose a plant pest risk. Therefore, APHIS must determine that BASF CV127 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 BASF CV127 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. BASF CV127 soybean and progeny derived from BASF CV127 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 BASF CV127 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 BASF CV127 soybean.

This alternative is not the preferred alternative because APHIS has concluded through a Plant Pest Risk Assessment that BASF CV127 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2014). 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 BASF CV127 Soybean is No Longer a Regulated Article*

Under this alternative, BASF CV127 soybean and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. BASF CV127 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2014). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of BASF CV127 soybean and progeny derived from this event. The Preferred Alternative, i.e., a determination of nonregulated status of BASF CV127 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 BASF CV127 soybean is unlikely

to pose a plant pest risk, a determination of nonregulated status of BASF CV127 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 BASF CV127 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 BASF CV127 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 BASF CV127 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 BASF CV127 soybean, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that BASF CV127 soybean is unlikely to pose a plant health risk (USDA-APHIS, 2014).

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, 2014) and the scientific data evaluated therein, APHIS concluded that BASF CV127 soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of BASF CV127 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 BASF CV127 soybean is unlikely to pose a plant pest risk (USDA-APHIS,

2014), 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 BASF CV127 Soybean and Non-GE Soybean Production and Geographical Restrictions*

APHIS has concluded that BASF CV127 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2014); therefore, 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 BASF CV127 soybean from conventional soybean production. APHIS also considered geographically restricting the production of BASF CV127 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 BASF CV127 soybean, there are no geographic differences associated with any identifiable plant pest risks for BASF CV127 soybean (USDA-APHIS, 2014). This alternative was rejected and not analyzed in detail because APHIS has concluded that BASF CV127 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 BASF CV127 soybean or to use isolation distances and other management practices to minimize gene movement between BASF CV127 soybean and non-GE soybean fields. Information to assist growers in making informed management decisions for BASF CV127 soybean is available from the Association of Official Seed Certifying Agencies (AOSCA, 2010).

### *4. Requirement of Testing for BASF CV127 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 BASF CV127 soybean does not pose a plant pest risk (USDA-APHIS, 2014), 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 BASF CV127 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
<b>Meets Purpose and Need and Objectives</b>	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied—risk assessment (USDA-APHIS, 2014)
<b>Management Practices</b>		
Acreage and Areas of Soybean Production	Current trends in cultivation and the proportion of crop acreage planted with soybean would continue. In 2012, soybean was cultivated on over 75 million acres (USDA-NASS, 2012b). Approximately 93% of U.S. soybean acreage is planted with GE soybean (USDA-ERS, 2012; USDA-NASS, 2012b). Acreage dedicated to soybean production is expected to continue within the 10-year average of 73.3 million acres.	Unchanged from No Action Alternative. The acreage and area of soybean production would remain unchanged from that of the No Action Alternative. There are no substantial agronomic or phenotypic differences between BASF CV127 soybean and its comparators.
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.	Unchanged from No Action Alternative. Practices to ensure varietal purity would remain the same as those of the No Action Alternative.
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. Organic soybean production is occurring in the presence of conventional soybean production using GE and non-GE soybean varieties, and representing 0.13 to 0.17% of total acreage. The availability of GE soybean is unrelated to proportion of organic soybean market share.	Unchanged from No Action Alternative. 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, BASF CV127 soybean does not present any new or different issues or impacts to organic soybean producers or consumers.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
<b>Socioeconomic</b>		
Domestic Economic Environment	BASF CV127 soybean would remain regulated by APHIS. In 2011, 77 million acres of soybeans were planted in the U.S., yielding 3.1 billion bushels (84.4 MMT) at a value of 35.8 billion U.S. dollars (USDA-NASS, 2012c). 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 for oil or fresh consumption.	No change from No Action Alternative. Field tests show the performance and composition of BASF CV127 soybean is not substantially different from that of other conventional soybean reference varieties. 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 U.S. will continue to be a supplier in the international market if BASF CV127 soybean remains regulated by APHIS. The U.S. is the world's largest exporter of soybeans, accounting for 41% of global soybean oilseed exports in 2011-12 (USDA-FAS, 2012c; 2012b). In 2011-12, U.S. exports of soybeans, soybean cake and meal and soybean oil totaled over \$22 billion (USDA-FAS, 2012a). China is the largest importer of U.S. soybeans and soybean products, accounting for 48% of the total value of U.S. soybean and soybean product exports, followed by Mexico (8.3% of total) and Japan (5.2%) (USDA-FAS, 2012a). The U.S. has been importing increasing quantities of soybeans over the past decade. Canada provides the majority of these soybeans to U.S. market. In 2012, approximately 6% of the total soybean imports were from South America.	No change from No Action Alternative.
<b>Human and Animal Health</b>		
Risk to Human Health	BASF CV127 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	No change from No Action Alternative. Testing shows the BASF CV127 soybean CSR1-2 protein has no amino acid sequence similar to known allergens, lacks toxic potential to mammals, and was degraded rapidly and completely in simulated gastric

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	soybean varieties have been determined to pose no risk to human health.	fluid. Laboratory and field testing also demonstrate no biologically meaningful differences for compositional and nutritional characteristics between the BASF CV127 soybean and conventional soybean varieties. Field testing shows BASF CV127 soybean is similar in growth and habit to other conventional soybean and no change to agronomic practices would be required for its cultivation. BASF has completed a food/feed safety consultation on BASF CV127 soybean with the FDA (US-FDA, 2012). No change to human health or worker safety would occur from determining BASF CV127 soybean nonregulated.
<b>Risk to Animal Feed</b>	BASF CV127 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.	Safety testing of BASF CV127 soybean CSR1-2 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. BASF has completed a food/feed safety consultation on BASF CV127 soybean with the FDA (US-FDA, 2012). Testing shows compositional and nutritional characteristics of BASF CV127 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.
<b>Environment</b>		
<b>Soil Quality</b>	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 BASF CV127 soybean is not expected to change cropping practices. Field tests show the performance and composition of BASF CV127 soybean is not substantially different from that of other conventional soybean reference varieties.
<b>Water Resources</b>	Agronomic practices that could impact water resources (e.g., irrigation, tillage practices, and the application of pesticides and fertilizers) would be expected to	The production of BASF CV127 soybean is not expected to change current agronomic practices, acreage, or range of production that may impact water resources. Field tests show the

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	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.	performance and composition of BASF CV127 soybean is not substantially different from that of other conventional soybean reference varieties.
<b>Air Quality</b>	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.	No changes to agronomic practices for the production of BASF CV127 soybean are expected that would impact air quality. Field tests show the performance and composition of BASF CV127 soybean is not substantially different from that of other conventional soybean reference varieties.
<b>Climate Change</b>	Agronomic practices having the potential to impact climate change, such as the release of CO <sub>2</sub> to the atmosphere from tillage, machinery powered by fossil fuel, and NO <sub>2</sub> emissions associated with nitrogen fertilizers would continue.	The production of BASF CV127 soybean is not expected to change current soybean cropping practices that may impact GHG emissions. Field tests show the performance and composition of BASF CV127 soybean is not substantially different from that of other conventional soybean reference varieties.
<b>Animal and Plant Communities</b>		
<b>Animal Communities</b>	Conventional and nonregulated GE soybean have been determined to have no allergenic or toxicity to animal communities. Soybean agronomic practices such as tillage, cultivation, pesticide, herbicide and fertilizer applications, and the use of agricultural equipment would continue to impact animal communities.	Testing demonstrates consumption of BASF CV127 soybean poses no allergenic or toxicity risk to animal communities. As field trials demonstrate growth and disease characteristics of BASF CV127 soybean are similar to other conventional soybean, no change to soybean agronomic practices potentially impacting animal communities would be needed to cultivate BASF CV127 soybean.
<b>Plant Communities</b>	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	No changes to agronomic practices potentially impacting plant communities would be needed to cultivate BASF CV127 soybean. Field trials and laboratory analyses show no differences between BASF CV127 soybean and other GE and non-GE soybean in growth, reproduction, or interactions with pests and diseases that may impact plant communities. Volunteers of BASF

<b>Attribute/Measure</b>	<b>Alternative A: No Action</b>	<b>Alternative B: Determination of Nonregulated Status</b>
	<p>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. Soybean volunteers would continue to be controlled with mechanical and herbicidal practices.</p>	<p>CV127 soybean would be managed similar to other nonregulated soybean varieties.</p>
<b>Gene Movement</b>	<p>BASF CV127 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 BASF CV127 soybean. Because soybean is highly self-pollinated and its pollination rate 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>Field and laboratory tests demonstrate no significant differences among the parameters that may lead to an increased potential for gene flow or weediness between BASF CV127 soybean and the conventional control. BASF CV127 soybean would not persist in unmanaged environments and does not demonstrate a competitive advantage compared to conventional soybean. Nonregulated BASF CV127 soybean would not present a plant pest risk.</p>
<b>Soil Microorganisms</b>	<p>The availability of GE, non-GE and organic soybeans would not change as a result of the continued regulation of BASF CV127 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 BASF CV127 soybean is not expected to result in changes in current soybean cropping practices that may impact microorganisms. Field and laboratory tests show no significant differences from other nonregulated soybean varieties in the parameters measured to assess the symbiotic relationship of BASF CV127 soybean and rhizobia or its responses to abiotic stressors, suggesting no different impact to the microbial community.</p>
<b>Biological Diversity</b>	<p>BASF CV127 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</p>	<p>Nonregulated status of BASF CV127 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</p>

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	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 on adjacent non-cropland (e.g., woodlots, fencerows, hedgerows, and wetlands) would continue.	with pests and diseases are similar to other nonregulated varieties. BASF CV127 soybean poses no potential for naturally occurring, pollen-mediated gene flow and transgene introgression and as such is not expected to affect genetic diversity.
<b>Other Regulatory Approvals</b>	FDA: BASF food safety consultation completed February 17, 2012 (BNF No. 000114) (US-FDA, 2012). EPA: BASF does not intend to seek a change to the pesticide label or pesticide residue tolerances. BASF has applied for an import residue tolerance.	No change from Alternative A.
<b>Compliance with Other Laws</b>		
<b>CWA, CAA, EOs</b>	Fully compliant	Fully compliant

Notes:

CAA – Clean Air Act; CWA – Clean Water Act; EOs – Executive Orders.

### 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.

From 2002-2012, the average soybean production in the U.S. has been about 74.3 million acres (USDA-NASS, 2012). In 2012 approximately 77.2 million acres of soybean were cultivated in 31 states (USDA-NASS, 2012). In 2012, GE herbicide-resistant soybean was estimated to be 93% of the U.S. soybean crop (USDA-ERS, 2012). A determination of nonregulated status of BASF CV127 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 BASF CV127 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.

*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 BASF CV127 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 BASF CV127 soybean is not expected to directly cause an increase in agricultural acreage devoted to soybean production or soybean acres devoted to GE soybean cultivation. The availability of BASF CV127 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 BASF CV127 soybean could add another GE soybean variety to the conventional soybean market, but is not expected to change the market demands for GE soybean or soybean produced using organic methods.

In 2011, there were approximately 96,000 acres of organic soybean produced across 1,203 farms in the U.S. (USDA-NASS, 2012a). This represented about 0.13 percent of total U.S. soybean production in 2011. Based on the data provided by BASF for BASF CV127 soybean (BASF, 2011), APHIS has concluded that the availability of BASF CV127 soybean would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE soybean seed production (USDA-APHIS, 2014). A determination of nonregulated status of BASF CV127 soybean will not require a change to seed production practices nor current production practices.

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

A determination of nonregulated status of BASF CV127 soybean would have no significant impacts on human or animal health. Compositional tests conducted by the petitioner indicate that BASF CV127 soybean is compositionally similar to other commercially available soybean (BASF, 2011). BASF initiated the consultation process with FDA for the commercial distribution of BASF CV127 soybean and submitted a safety and nutritional assessment of food and feed derived from BASF CV127 soybean to the FDA on January 26, 2009 (BNF No. 000114). Based on the information BASF submitted, as of February 17, 2012, the FDA has no further questions regarding BASF CV127 soybean (US-FDA, 2012).

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 BASF CV127 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). BASF has provided the FDA with information on the identity, function, and characterization of the genes for BASF CV127 soybean, including expression of the gene products. The FDA completed its Biotechnology Consultation with BASF on February 17, 2012 (US-FDA, 2012).

A determination of nonregulated status of BASF CV127 soybean would have no significant impacts on human or animal health. BASF CV127 soybean is compositionally similar to currently available soybean on the market with the exception of the CSR1-2 protein. Based on the FDA's consultation, laboratory data and scientific literature provided by BASF (BASF, 2011), APHIS has concluded that BASF CV127 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 BASF CV127 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 BASF CV127 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 BASF CV127 soybean. In the event of a determination of nonregulated status of BASF CV127 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 BASF CV127 soybean are not highly controversial. Although there is some opposition to a determination of nonregulated status of BASF CV127 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 BASF CV127 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 BASF CV127 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. A determination of nonregulated status of BASF CV127 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 BASF CV127 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 BASF CV127 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 BASF CV127 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 BASF CV127 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 BASF CV127 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), BASF CV127 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 BASF CV127 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 BASF CV127 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 BASF CV127 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 BASF CV127 soybean, APHIS would no longer have regulatory authority over this soybean. In the event of a determination of nonregulated status of BASF CV127 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 BASF CV127 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 BASF CV127 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 BASF CV127 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 BASF CV127 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 BASF CV127 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 results

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 BASF CV127 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 BASF CV127 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 BASF CV127 soybean, APHIS has determined that a determination of nonregulated status of BASF CV127 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.*

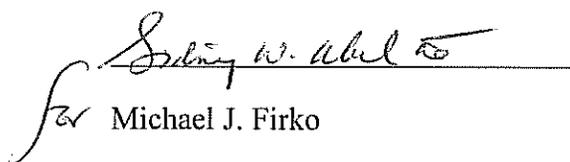
The proposed action would be in compliance with all federal, state, and local laws. Because the agency has concluded that BASF CV127 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of BASF CV127 soybean is a response that is consistent with the plant pest provisions 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 BASF CV127 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.

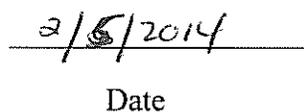
As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation 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 BASF CV127 soybean, the continued regulated status of BASF CV127 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 BASF CV127 soybean will not have any significant environmental effects.

  
Michael J. Firko

Deputy Administrator, Acting

Biotechnology Regulatory Services

  
Date

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## **Addendum 1**

### **Response to Public Comments on BASF CV127 Soybean**

On November 7, 2013, APHIS published a notice in the Federal Register (78 FR page 216, Docket No. APHIS-2012-0028) announcing the availability of the draft EA and draft PPRA regarding a request from BASF seeking a determination of nonregulated status of BASF CV127 soybean for a 30-day public review and comment period. Comments were required to be received on or before December 9, 2013. A total of 10 comments were submitted during the 30-day comment period, including nine from individuals and one from the petitioner, BASF.

All comments submitted to the docket were carefully analyzed by USDA-APHIS. The majority of these public comments did not explain or identify elements in the BASF CV127 soybean PPRA or EA that were perceived to be inadequate or provide any specific supporting evidence for their claims. A number of these comments were generically opposed to GE organisms or the use of herbicide resistant crops. Others had concerns about potential impacts associated with the herbicides used on GE crops. These issues are outside of the scope of this EA. APHIS has responded below to the issues raised during the public comment period which relate to docket APHIS-2012-0028. These comments are addressed below.

#### **Issue 1:**

APHIS should not be looking at plant pest risk but at human health and environmental risks.

#### **APHIS Response:**

As explained in Section 1.3 of the EA, since 1986, the U.S. government has regulated GE organisms under a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework 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 explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA-APHIS, the U.S. Food and Drug Administration (FDA), and the U.S. Environmental Protection Agency (EPA). As part of its NEPA analysis, APHIS considers the regulatory assessments from both FDA and EPA when assessing potential impacts that may result from a determination of nonregulated status of a GE organism.

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. USDA-APHIS has concluded that BASF CV127 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2014). Therefore, USDA-APHIS must determine that BASF CV127 soybean is no longer subject to 7 CFR Part 340 or the plant pest provisions of the PPA. As part of its EA analysis, USDA-APHIS analyzed the potential effects of BASF CV127 soybean on the environment, including any potential effects to threatened and endangered species and critical habitat. As part of this process, USDA-APHIS thoroughly reviewed BASF CV127 soybean information and data related to the plant species.

The USDA-APHIS EA adequately addresses the potential environmental impacts that may result from its regulatory decision on the petition for a determination of nonregulated status for BASF CV127 soybean.

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. 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. BASF submitted a safety and nutritional assessment and food safety consultation of BASF CV127 soybean was completed by the FDA (BNF No. 114) on February 17, 2012 (US-FDA, 2012). BASF CV127 soybean is compositionally similar to other commercially available soybeans. BASF has presented data comparing BASF CV127 soybean with other varieties on BASF CV127 soybean is compositionally similar to other commercially available soybeans (BASF, 2011). No biologically significant differences were identified between BASF CV127 soybean and other varieties. BASF has evaluated the potential toxicity of the AtAHAS protein expressed by the BASF CV127 soybean and has found no evidence of acute or chronic toxicity, allergenicity, or other health impacts (BASF, 2011; US-FDA, 2012). APHIS considers the FDA food and feed safety and nutritional assessment determination when assessing potential impacts that may result from a determination of nonregulated status of a GE organism. No change in food and feed safety is expected to occur as a result of the deregulation of BASF CV127 soybean.

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. The EPA regulates plant incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*) and certain biological control organisms under the Toxic Substances Control Act (TSCA) (15 U.S.C. 53 *et seq.*). Before planting a crop containing a PIP, a company must seek an experimental use permit from EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 registration with EPA.

Under FIFRA (7 U.S.C. 136 *et seq.*), EPA regulates the use of pesticides, and requires registration of all pesticide products for all specific uses prior to distribution for sale. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. BASF CV127 soybean does not contain a PIP and, therefore, is not regulated by EPA.

The process of registering a pesticide is a scientific, legal, and administrative procedure through which EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; and storage and disposal practices. In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with use of the product. Prior to registration for a new use for a new or previously registered pesticide, the producer of the pesticide must provide data from tests done according to EPA guidelines. EPA must determine through this submitted test data that the pesticide will not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions.

EPA uses risk assessment for registration decisions. It evaluates risk based on exposure and hazard to both humans and other organisms. EPA has developed exposure assessments for this process to characterize environmental persistence of pesticides and their byproducts from degradation following application. These assessments are based in part on scientific studies that sample and measure residue concentrations for specified time frames. The data are analyzed with statistical procedures referred to as models to extrapolate estimates for environmental fate (i.e., persistence of residues) over longer time frames than the ones sampled.

EPA uses environmental fate data to predict potential concentration of the pesticide and its degradation products in air, soil, and surface and groundwater. These data are also used to estimate residue levels in the drinking water component of human dietary risk assessments.

Results of environmental fate studies enable EPA to determine where a pesticide and its degradates (byproducts) go in the environment (i.e., air, water, and soil), how long they persist, and in what quantities. This information is used by EPA to develop estimated environmental concentrations (EECs) that can be compared to toxicity and ecotoxicology data as part of the risk assessment process. EEC values are based on the maximum allowable application rate for a pesticide although typical application rates are usually lower than the maximum allowed. This maximizes the sensitivity of comparisons made with toxicity and ecotoxicity levels that have been determined to be thresholds for safe exposure. Therefore, EPA assessments of potential impacts on human health, wildlife, and the environment are designed to be conservative and protective because safe exposure thresholds used in assessments tend to overestimate rather than underestimate risk.

According to the BASF petition, the intended use of this soybean seed is for cultivation in Argentina and Brazil. BASF does not intend to commercialize BASF CV127 soybean in the U.S. However, BASF has indicated that there may be very small plots cultivating BASF CV127 soybean in the U.S. for research or for off season seed development, generally on the order of up to five acres in a controlled environment. BASF does not intend to market this soybean in the U.S., so it is not likely to be available to growers. APHIS assumes that growers could plant BASF CV127 soybeans, if they were available, and growers could use any management practices that are suitable for the production of soy, including use of EPA registered herbicides. However, growers could not use imazapyr and imazapic because these herbicides are not labeled for use on soybeans, and there are no labels pending for this use. According to the developer, there is a very small market in the U.S. and the projected market would not support the cost associated with pursuing the change in EPA registration.

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). Before establishing a pesticide tolerance, EPA is required to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the FQPA. FDA enforces the pesticide tolerances set by EPA. To facilitate foreign production and possible importation, BASF has applied to the EPA for an import residue tolerance for the use of imazapyr and imazapic on soybean (BASF, 2011).

**References:**

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**Issue 2:**

A commenter expressed concern that there are economic impacts of cross pollination from GE crops to organic crops for organic growers. The commenter suggested that APHIS should create zones around organic farms protecting them from potential cross contamination from GE crops.

**APHIS Response:**

Discussions of crops other than soybean are outside the scope of this EA. USDA-APHIS has addressed this issue here as it relates to soybean cultivation. Cultivated soybean is highly self-pollinating (Ahrent and Caviness, 1994). When soybean plants are grown directly adjacent to other soybean plants, the amount of natural cross pollination has generally been found to be 0.5 - 1 percent (Fehr and Hadley, 1980; OECD, 2000) although higher values (up to 2.5 percent) have been noted in some varieties (Abud *et al.*, 2007). Outcrossing can be reduced to 0 – 0.01 percent with a separation distance of 10 meters (Abud *et al.*, 2007). The administrative record supports the fact that BASF CV127 soybean is not different from conventional soybean or other GE soybean in terms of pollen viability, and that it is not expected to have an increased ability to cross-pollinate with other soybean varieties when compared to other soybean varieties that are currently available for commercial planting.

Methods of spatial and temporal isolation are widely used and accepted when seed producers are seeking to minimize the influx of pollen from sources outside the seed production field. To maintain varietal purity, AOSCA (Association of Official Seed Certifying Agencies) recommends isolation distances to produce certified seed (AOSCA, 2003). Because USDA-APHIS has concluded that BASF CV127 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2014), requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

As mentioned in the EA, approximately 93% of all soybean varieties planted in the U.S. in 2012 were GE. APHIS expects BASF CV127 soybean will be used to breed soybean varieties suitable to a range of environments and replace some of the herbicide-resistant soybean varieties. The effect on agricultural practices (e.g., cultivation, spray programs, crop rotation practices, planting rates, etc.) from its introduction into the environment should not be significantly different than for the previously deregulated herbicide-resistant soybean lines already in agricultural production, and the baseline of effects would not reasonably be expected to change.

Growers have always had the choice of what crops to grow, and have had to contend with commingling, admixtures, and other unintended material in their crops (Ronald and Fouche,

2006). Studies of coexistence of major GE and non-GE crops in North America and the European Union (EU) have demonstrated that there has been no significant introgression of GE genes, and that GE and non-GE crops are coexisting with minimal economic effects (Brookes and Barfoot, 2004a), (Brookes and Barfoot, 2004b),(Gealy *et al.*, 2007).

National Organic Program (NOP) approved practices can be sufficient to maintain the integrity of a crop and the purity of seed, especially if there are economic/market motivations to implement these practices (Fernandez and Polansky, 2006; Ronald and Fouche, 2006). The essential dynamics relating to the principals of coexistence of conventional soybean and organic soybean production would not change by the deregulation of BASF CV127 soybean. Although producing a particular crop for a specific market and meeting the specifications for growing a product to be marketed might be characterized by some as a "burden", this burden is intrinsic to plant production in general and growers have, for decades, been successfully growing crops bearing different traits and often on adjoining fields despite the method by which traits were introduced (conventional breeding or recombinant DNA technology).

Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. Under the NOP, certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Organic Food Production Act. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation and the presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2007). The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps (such as isolation zones, use of buffer rows surrounding the organic crops or adjusting planting dates and appropriate cleaning of planting and harvesting equipment) to avoid contact with the products of excluded methods as detailed in their approved organic system plan.

Ultimately, organic producers are obligated to manage their operations to avoid unintentional contact with excluded methods. A number of techniques have been developed in order to maintain the concept of coexistence and to prevent cross-pollination. Isolation distances between fields help to minimize the effects of pollen flow. In addition to spatial isolation, growers can use reproductive isolation to minimize or eliminate cross-pollination (i.e., plant varieties with different maturity dates) or stagger planting dates (to obtain different flowering stages), with a minimum of three to four weeks difference between the planting of their crop and neighboring crop. Isolation distances, reproductive isolation (e.g., staggering planting dates or growing soybeans with differential maturity times), and farmer communication can be successfully used to minimize the effects of pollen-mediated gene flow.

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### **Issue 3:**

One commenter stated that both multiple rodent and human studies have proven that most GE soybean differ from non-GE soybean in that they cause increased estrogen, in turn affecting vital aspects of male and female health, and children's growth. The commenter asked if BASF CV127 soybean have the same effect.

### **APHIS Response:**

The commenter did not provide citations for the rodent and human studies referred to in their comment; therefore, USDA-APHIS cannot address the findings of those studies and any relevance to BASF CV127 soybean.

BASF presented comprehensive results of compositional analyses of multiple replicates of field trial plantings of BASF CV127 soybean, comparing them with other soybean lines. Their analysis used the Organisation for Economic Co-operation and Development (OECD) (OECD, 2000) publication on suggested parameters for chemical composition of soybean. These values include percent moisture, total fat, protein, total dietary fiber, mineral and vitamin levels, amino acid composition, fatty acid composition, anti-nutrients and allergens. The results of the compositional analyses show that the inserted *csr1-2* gene does not impact the nutritional composition of soybean produced by BASF CV127 soybeans (BASF, 2011).

BASF submitted a nutritional assessment, including the compositional analysis, for BASF CV127 soybean to FDA on January 26, 2009, and FDA completed the evaluation on February 17, 2012. Details on the compositional analysis are reported in FDA's Biotechnology Consultation Note to the File BNF No. 000114 (US-FDA, 2012b). According to FDA:

“BASF analyzed grain for 70 components (listed below) and provided data obtained for each individual test site and data aggregated from all sites. BASF conducted the statistical analysis of data obtained for CV127 soybean and the control soybean. BASF also provided compositional data for two commercial conventional varieties and, for comparison, data reported in the International Life Sciences Institute (ILSI) Crop Composition Database (version 3.0, 2008). ILSI data were not available for several components, e.g., for some vitamins and phospholipids.

BASF provided analytical data for the following grain components:

- Proximates: moisture, protein, fat, ash, and carbohydrates (calculated by difference)
- Total dietary fiber (TDF), crude fiber, NDF and ADF
- Amino acids (18)
- Fatty acids (C14-C22)
- Minerals (calcium, iron, magnesium, phosphorus, and potassium)
- Vitamins ( $\alpha$ -,  $\beta$ -,  $\gamma$ -,  $\delta$ -, and total tocopherols, vitamins E and B<sub>1</sub>, and folic acid)
- Isoflavones (daidzin, malonyl-daidzin, daidzein, glycitin, malonyl-glycitein, genistin, malonyl-genistin, and genistein)
- Phospholipids (phosphatidic acid, phosphatidyl ethanolamine, phosphatidic acid, phosphatidyl inositol, and phosphatidyl choline)
- Antinutrients (phytic acid, trypsin inhibitor, lectin, urease, raffinose, and stachyose) (US-FDA, 2012b).”

Additionally, “BASF provided composition data for processed fractions from CV127 soybean (oil, toasted meal, protein isolate, and protein concentrate), control soybean (the parental variety, Conquista), and two commercial conventional soybean varieties. Soybean grain was produced at four field trial locations during the 2006/2007 growing season and processed into fractions according to the standard soybean processing methods. Toasted meal was analyzed for proximates (moisture, ash, fat, protein, and carbohydrates (calculated by difference), fiber (ADF and NDF), antinutrients (raffinose, stachyose, trypsin inhibitor, urease, and phytic acid), and isoflavones. Protein isolate and concentrate were analyzed for proximates and refined oil was analyzed for the fatty acid composition. All data were statistically analyzed. For comparison, BASF provided data on the composition of processed fractions reported in the literature. In summary, results of these analyses demonstrate that grain from CV127 soybeans is compositionally equivalent to, and as nutritious as, grain from the isoline control well as other conventional soybean varieties”(US-FDA, 2012b).

FDA concluded that food and feed derived from BASF CV127 soybean is not materially different in composition, safety, and other relevant parameters from soybean-derived food and feed currently on the market and that the genetically engineered soybean event BASF CV127 soybean does not raise issues that would require premarket review or approval by the FDA (US-FDA, 2012a).

Beans, including soybeans, are recognized to be nutritionally beneficial, being high in protein, low in saturated fat, and high in complex carbohydrates and fiber. Beans are also a good source of several micronutrients and phytochemicals (Messina, 1999). All soybeans contain high concentrations of isoflavones. Isoflavones are sometimes called plant estrogens or phytoestrogens because they have weak estrogenic properties similar to estrogen that is produced in humans and animals and can bind to estrogen receptors (American Cancer Society, 2013). Genistein, daidzein, and glycitein are types of isoflavones found in small amounts in various foods, but are most abundant in soy (American Cancer Society, 2013).

Soy foods and isoflavones have been identified for their potential role in preventing and treating cancer and osteoporosis, as well as relieving symptoms of menopause and osteoporosis (American Cancer Society, 2013). There have been some concerns of the potential for isoflavones to increase the risk of cancer recurrence among breast cancer patients who, as a result of their treatment, have low levels of estrogen (Shu et al., 2009). However, current research, including a number of recent epidemiologic studies, concluded that soy consumption among breast cancer survivors resulted in no harmful effects (Shu *et al.*, 2009; American Institute for Cancer Research, 2012; McCullough, 2012).

The American Cancer Society provides a summary of the benefits and possible issues associated with soy consumption:

<http://www.cancer.org/treatment/treatmentsandsideeffects/complementaryandalternativemedicine/dietandnutrition/soybean>

Additionally, the American Cancer Society has addressed the reported connection between soy consumption and breast cancer:

<http://www.cancer.org/cancer/news/expertvoices/post/2012/08/02/the-bottom-line-on-soy-and-breast-cancer-risk.aspx>

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**Issue 4:**

BASF, the petitioner, submitted a comment on the Draft EA and Draft PPRA identifying typographical errors that needed correction or clarification. The specific items identified were:

- The introduction to Section 3.3, the Biological Resources (page 31, Draft Environmental Assessment) contained a typographical error in the crop.
- The source of the 2011 values for Table 2 should be clarified (page 38, Draft Environmental Assessment).
- To date, BPS-CV127-9 soybean has not been authorized for import for food and feed use by the European Union as was stated in the Draft EA (correction to pages 25 and 41, Draft Environmental Assessment).
- BASF compared BPS-CV127-9 soybean to its non-transgenic, near-isogenic control line, which was not a hybrid variety, in agronomic and phenotypic evaluations (correction to page 64, Draft Environmental Assessment).
- BPS-CV127-9 soybean contains an acetohydroxyacid synthase large subunit gene from *Arabidopsis thaliana* that encodes an imidazolinone-tolerant AHAS enzyme (AtAHAS) which is functionally identical to the native AtAHAS, except for its tolerance to imidazolinone herbicides (correction to page 4, Draft Plant Pest Risk Assessment).

**APHIS Response:**

APHIS reviewed the items BASF identified and made the suggested corrections and clarifications.