BASF Plant Science, L.P., Petition (09-015-01p) for Determination of Nonregulated Status of Herbicide-Resistant BASF BPS-CV127-9 Soybean, Event CV127

OECD Unique Identifier: BPS-CV127-9

Final Environmental Assessment

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ACRONYMS AND ABBREVIATIONS

APHIS	Animal and Plant Health Inspection Service
AIA	advanced informed agreement
AMS	Agricultural Marketing Service
AOSCA	American Organization of Seed Certifying Agencies
BRS	Biotechnology Regulatory Services (within USDA–APHIS)
CAA	Clean Air Act
CBD	Convention on Biological Diversity
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (United States)
CH_4	methane
CO	carbon monoxide
CO_2	carbon dioxide
CRP	Conservation Reserve Program
DNA	deoxyribonucleic acid
DRT	drift reduction technology
EA	environmental assessment
EO	Executive Order
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act of 1973
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FFP	food, feed, or processing
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FONSI	Finding of No Significant Impact
FQPA	Food Quality Protection Act
FR	Federal Register
GE	genetically engineered
GHG	greenhouse gas
HRAC	Herbicide Resistance Action Committee
IPCC	Intergovernmental Panel on Climate Change
ISPM	International Standard for Phytosanitary Measure
IPPC	International Plant Protection Convention
ISO	International Organization For Standardization

ACRONYMS AND ABBREVIATIONS

LMOs	Living Modified Organisms
MG	Maturity Group
MOA	mode of action
MOU	Memorandum of Understanding
NO_2	nitrogen dioxide
N_2O	nitrous oxide
NABI	North American Biotechnology Initiative
NAPPO	North American Plant Protection Organization
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NGO	Non-Governmental Organization
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NOI	notice of intent
NOP	National Organic Program
NPS	nonpoint source pollution
NRC	National Research Council
OPP	Office of Pesticide Program
PIP	plant incorporated protectant
PPRA	Plant Pest Risk Assessment
PPA	Plant Protection Act of 2000
PRA	pest risk analysis
RED	Registration Eligibility Decision
RNA	ribonucleic acid
RSPM	Regional Standards for Phytosanitary Measures
SOM	soil organic matter
SSA	sole source aquifer
TES	threatened and endangered species
TSCA	Toxic Substances Control Act
U.S.	United States
USDA	U.S. Department of Agriculture
USDA-APHIS	U.S. Department of Agriculture-Animal and Plant Health Inspection Service
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-FAS	U.S. Department of Agriculture-Foreign Agricultural Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service

ACRONYMS AND ABBREVIATIONS

USDA-NOP	U.S. Department of Agriculture-National Organic Program
USC	United States Code
WPS	Worker Protection Standard for Agricultural Pesticides

1 PURPOSE AND NEED

1.1 BACKGROUND

BASF Plant Science, L.P. (referred hereafter as BASF) submitted petition number 09-015-01p to the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), on July 13, 2009, seeking approval of the petition for nonregulated status for BASF CV127 Soybean, a genetically engineered (GE) imidazolinone herbicide-resistant[1] soybean (*Glycine max*) event BPS-CV127-9 (CV127) (referred hereafter as BASF CV127 Soybean). Field trials of BASF CV127 Soybean have been conducted in Brazil. Data resulting from these field trials are described in the BASF petition (BASF, 2011) and analyzed for plant pest risk in the USDA-APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2012).

BASF's petition states that USDA-APHIS should not regulate BASF CV127 Soybean because it does not present a plant pest risk (BASF, 2011). In the event of approval of the petition for nonregulated status, the nonregulated status would include BASF CV127 Soybean, any progeny derived from crosses between BASF CV127 Soybean and conventional soybean, and crosses of BASF CV127 Soybean with other biotechnology-derived soybean that are no longer subject to the regulatory requirements of 7 CFR (Code of Federal Regulations) Part 340 or the plant pest provisions of the Plant Protection Act of 2000 (PPA).

1.2 PURPOSE OF PRODUCT

Imidazolinone herbicides[2] control a wide spectrum of grass and broadleaf weeds (BASF, 2011; USDA-APHIS, 2012). Soybeans are naturally resistant to some of the imidazolinone herbicides due to an ability to metabolize the compound (Tan et al., 2005). However, soybeans are unable to metabolize imazapyr and imazapic, and are thus very sensitive to these imidazolinone herbicides (BASF, 2011). These two herbicides are active ingredients in a number of imidazolinone herbicide products, and imazapyr is found in Lightning® (a mixture of imazethapyr – 52.5% and imazapyr – 17.5%;) (BASF, 2008). BASF CV127 Soybean is resistant to the use of imidazolinone herbicides containing these active ingredients, which provides growers with an option for effective weed control using these two herbicides (BASF, 2011).

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[1] *Resistance* to herbicides is defined by HRAC (Herbicide Resistance Action Committee) as the inherited ability of a plant population to survive and reproduce following repeated exposure to a dose of herbicide normally lethal to the wild type HRAC, Guideline to the Management of Herbicide Resistance, 2013, Herbicide Resistance Action Committee, Available: http://www.hracglobal.com/Publications/ManagementofHerbicideResistance.aspx, January 22 2013.. Resistance may be induced by genetic engineering or selection of variants produced by tissue culture or mutagenesis HRAC, Guideline to the Management of Herbicide Resistance.. This is to be distinguished from *tolerant*, which is defined by HRAC as the inherent ability of a plant to survive and reproduce after herbicide treatment. This implies that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant HRAC, Guideline to the Management of Herbicide Resistance..

[2] Imidazolinone herbicides include imazapyr, imazapic, imazethapyr, imazamox, imazamethabenz and imazaquin Siyuan Tan, Richard R. Evans, Mark L. Dahmer, Bijay K. Singh and Dale L. Shaner, "Imidazolinone-Tolerant Crops: History, Current Status and Future," Pest Management Science 61.3 (2005)..

BASF CV127 Soybean was developed for cultivation primarily in Brazil and Argentina; 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 (BASF, 2011; USDA-APHIS, 2012). The use of glyphosate with glyphosate-resistant soybeans in Argentina and Brazil has led to a shift in prevalent weed species with those more resistant to glyphosate predominating (BASF, 2011). The major weeds in soybean cultivation in these countries are sensitive to the imidazolinone herbicides containing imazapyr and imazapic (BASF, 2011). The most common weeds in this category include Benghal dayflower (*Commelina benghalensis* L.), morning glory (*Ipomoea spp*.), Brazil pusley (*Richardia brasiliensis*), and winged false buttonweed (*Spermacoce alata*) (BASF, 2012).

BASF has stated in the petition that it does not intend to commercialize BASF CV127 Soybean in the U.S. (BASF, 2011; BASF, 2012). Regulatory approvals for CV127 are being sought in Brazil and Argentina for production as well as for food and feed uses, and in the U.S. and other countries for importation of grain from CV127 soybean for food, feed, and processing uses.

1.3 COORDINATED FRAMEWORK REVIEW AND REGULATORY REVIEW

Since 1986, the U.S. government has regulated genetically engineered (GE) organisms pursuant to Federal regulations published in the *Federal Register* (EOP-OSTP; US-FDA) entitled The Coordinated Framework for the Regulation of Biotechnology (henceforth referred to here as the Coordinated Framework). 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. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA). A summary of each agency's role follows:

1.3.1 USDA-APHIS

USDA-APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the PPA, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (i.e., 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 PPA or to the regulatory requirements of 7 CFR part 340, when USDA-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 7 CFR 340 when USDA-APHIS has reason to believe that the GE organism may be a plant pest or USDA-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 for a determination 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 PPA or the regulations at 7 CFR 340. Under § 340.6(c)(4), the petitioner must provide information related to plant pest risk that the agency can 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 PPA when USDA-APHIS determines that it is unlikely to pose a plant pest risk.

1.3.2 Environmental Protection Agency

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. 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; storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, EPA must determine through testing that the pesticide does not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions. EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide may only be legally used in accordance with directions and restrictions on its label. The overall intent of the label is to provide clear directions for effective product performance, while minimizing risks to human health and the environment. The Food Quality Protection Act (FQPA) of 1996 amended FIFRA, enabling EPA to implement periodic registration review of pesticides to ensure they are meeting current scientific and regulatory standards of safety and continue to have no unreasonable adverse effects (US-EPA, 2011b).

EPA also sets tolerances (maximum residue levels) or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA). A tolerance is the amount of pesticide residue that can remain on or in food for human consumption or animal feed. 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.

1.3.3 Food and Drug Administration

FDA regulates GE organisms under the authority of the FFDCA (21 U.S.C. 301 *et seq.*). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, on May 29, 1992 (US-FDA). Under this policy, FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of bioengineered food. This voluntary consultation process provides a way for developers to receive assistance from FDA in complying with their obligations under Federal food safety laws prior to marketing.

More recently (June 2006), FDA published recommendations in "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use" (US-FDA, 2006). This establishes voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including bioengineered plants. Early food safety evaluations help make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with FDA, but the information may be used later in the biotechnology consultation.

1.4 PURPOSE AND NEED FOR USDA-APHIS ACTION

As noted in the previous section, any party can petition USDA-APHIS to seek a determination of nonregulated status for a GE organism that is regulated under 7 CFR 340. As required by 7 CFR 340.6, USDA-APHIS must respond to petitioners that 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, USDA-APHIS must determine if the GE organism is unlikely to pose a plant pest risk. 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 PPA when APHIS determines that it is unlikely to pose a plant pest risk.

USDA-APHIS must respond to the petition from BASF requesting a determination of nonregulated status for BASF CV127 Soybean. USDA-APHIS has prepared this Environmental Assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality's (CEQ) National Environmental Policy Act of 1969 (NEPA) regulations and the USDA and USDA-APHIS NEPA implementing regulations and procedures (40 CFR Parts 1500-1508, 7 CFR Part 1b, and 7 CFR Part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from a determination of nonregulated status for BASF CV127 Soybean.

[1] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §1508.14).

1.5 PUBLIC INVOLVEMENT

USDA-APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. USDA-APHIS does this through a notice published in the *Federal Register*. On March 6, 2012, USDA-APHIS published a notice[1] 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, USDA-APHIS will publish two separate notices in the *Federal Register* for petitions for which USDA-APHIS prepares an EA. The first notice will announce the availability of the petition, and the second notice will announce the availability of USDA-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:

1.5.1 First Opportunity for Public Involvement

Once USDA-APHIS deems a petition complete, the petition will be 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. USDA-APHIS will publish a notice in the Federal Register to inform the public that USDA-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.

1.5.2 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 USDA-APHIS decides the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues:

<u>Approach 1: GE organisms that do not raise substantive new issues.</u>

This approach for public participation is used when APHIS decides, based on the review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition, that the petition involves a GE organism that *does not raise new biological, cultural, or ecological issues because of the nature of the modification or APHIS' familiarity with the recipient organism.* After developing its EA, finding of no significant impact (FONSI), and PPRA, USDA-APHIS publishes a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the EA, FONSI, and PPRA for a 30-day public review period.

If USDA-APHIS determines that no substantive information has been received that would

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

warrant USDA-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, USDA-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 USDA-APHIS.

A second approach for public participation is used when USDA-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 USDA-APHIS to have nonregulated status or when USDA-APHIS determines that gene modifications raise substantive biological, cultural, or ecological issues not previously analyzed by USDA-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.

USDA-APHIS solicits comments on its draft EA and draft PPRA for 30 days through the publication of a *Federal Register* notice. USDA-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, USDA-APHIS approves or denies the petition, announcing in the *Federal Register* the regulatory status of the GE organism and the availability of USDA-APHIS' final EA, PPRA, NEPA decision document (either a FONSI or notice of intent (NOI) to prepare an EIS), and regulatory determination.

Enhancements to public input are described in more detail in the *Federal Register* notice[1] published on March 6, 2012.

1.5.3 Public Comment Period for Petition 09-015-01p

USDA-APHIS decided this EA will follow Approach 2 because this is the first EA prepared for soybean genetically engineered for resistance to imidazolinone herbicides. The BASF petition was published for public comment on July 13, 2012, with comments accepted until September 11, 2012. A total of 75 public submissions were made to the docket. Some of the submissions to the docket contained multiple comments combined together gathered by organizations from their members. Counting these individual comments, the 75 submissions contained a total of 4,676 public comments. 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 opened on the same date that this docket was opened. The form letter submitted expressed the 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.

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

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 raised issues and the submitted documentation. APHIS has also included a discussion of these issues in this EA.

1.5.4 Public Comment Period for Draft EA for Petition 09-015-01p

The draft EA and draft PPRA were made available for public comment during a 30-day comment period closing 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 EA may be viewed at the federal website, regulations.gov[1]. APHIS evaluated the issues raised and the submitted documentation. APHIS has included a discussion of issues relative to this petition in the EA or in the response to comments attached to the National Environmental Policy Act Decision and Finding of No Significant Impact document, posted at the federal website, regulations.gov.

1.6 ISSUES CONSIDERED

The list of resource areas considered in this EA were developed by USDA-APHIS through experience in considering public concerns and issues raised in public comments submitted for this petition and 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 for this petition and in the past. The resource areas considered in this EA can be categorized as follows:

Agricultural Production Considerations

- Acreage and Areas of Soybean Production
- Soybean Seed Production
- Organic Soybean Production

Environmental Considerations

- Soil Quality
- Water Resources
- Air Quality
- Climate Change
- Animal Communities
- Plant Communities
- Soil Microorganisms
- Biological Diversity

Human Health Considerations

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

- Public Health
- Worker Safety

Livestock Health Considerations

- Animal Feed/Livestock Health

Socioeconomic Considerations

- Domestic Economics
- Trade Economics

2 ALTERNATIVES

This document analyzes the potential environmental consequences of the approval of the petition for nonregulated status of BASF CV127 Soybean. To respond favorably to a petition for nonregulated status, USDA-APHIS must determine that BASF CV127 Soybean is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2012), USDA-APHIS has concluded that BASF CV127 Soybean is unlikely to pose a plant pest risk. 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.

Two alternatives will be evaluated in this EA: 1) No Action and 2) approval of a petition for nonregulated status of BASF CV127 Soybean. USDA-APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section.

2.1 NO ACTION: CONTINUATION AS A REGULATED ARTICLE

Under the No Action Alternative, USDA-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 issued or notifications acknowledged by USDA-APHIS would still be required for introductions of BASF CV127 Soybean and measures to ensure physical and reproductive confinement would continue to be implemented. USDA-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.

However, this alternative is not the Preferred Alternative because USDA-APHIS has concluded through a PPRA that BASF CV127 Soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012). 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.

2.2 PREFERRED ALTERNATIVE: APPROVAL OF THE PETITION FOR NONREGULATED STATUS FOR BASF CV127 SOYBEAN

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. Permits issued or notifications acknowledged by USDA-APHIS would no longer be required for introductions of BASF CV127 Soybean and progeny derived from this event.

This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR Part 340 and the agency's authority under the plant pest provisions of the PPA. Because the agency has concluded that BASF CV127 Soybean is unlikely to pose a plant pest risk, approval of a petition for 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.

Under this alternative, BASF CV127 Soybean could be developed for its target markets outside of the U.S. Breeders in the U.S. would no longer require permits to be issued or notifications to be acknowledged to conduct outdoor breeding activities. BASF CV127 Soybean could be imported into the U.S. from other markets without a permit. If soybean varieties are marketed in the U.S. which contain this trait, growers could plant them without APHIS permits. Application of herbicides to this and all soybeans is regulated by EPA. Currently, imazapyr is not labeled for use on CV127 Soybean and the developer is not seeking a label for its application in the U.S. As stated in the petition, this soybean is not intended to be marketed for planting in the U.S. Growers and other parties that are involved in production, handling, processing, or consumption of soybean would continue to be able to use the current soybean products developed by conventional breeding as well as the GE soybean variety.

2.3 ALTERNATIVES CONSIDERED BUT REJECTED FROM FURTHER CONSIDERATION

USDA-APHIS assembled a comprehensive list of alternatives that might be considered for BASF CV127 Soybean. The agency evaluated these alternatives in accordance with its authority under the plant pest provisions of the PPA, and the regulations at 7 CFR Part 340. The evaluation considered environmental safety, efficacy, and practicality to identify which alternatives would be further considered for BASF CV127 Soybean. Based on this evaluation, USDA-APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

2.3.1 Prohibit Any BASF CV127 Soybean from Being Released

In response to public comments that might state a preference that no GE organisms enter the marketplace, USDA-APHIS considered prohibiting the release of BASF CV127 Soybean, including denying any permits associated with the field testing. USDA-APHIS determined that this alternative is not appropriate given that BASF CV127 Soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012).

In enacting the PPA, Congress found that—

> [D]ecisions affecting imports, exports, and interstate movement of products regulated under [the PPA] shall be based on sound science…§402(4) (codified at 7 U.S.C. §7701(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 established broad principles, consistent with Executive Order 13563, to guide agencies in the development and implementation of policies for oversight of emerging technologies such as GE that included the following guidance:

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

Consistent with this guidance and based on the findings and scientific data evaluated for the PPRA (USDA-APHIS, 2012), USDA-APHIS concluded that BASF CV127 Soybean is not likely to present a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of BASF CV127 Soybean.

2.3.2 Approve the Petition In Part

The regulations at 7 CFR 340.6(d)(3)(i) state that USDA-APHIS may "approve the petition in whole or in part." For example, approving the petition for 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. USDA-APHIS has concluded that BASF CV127 Soybean is unlikely to pose a plant pest risk, so there is no regulatory basis under the plant pest provisions of the PPA for considering approval of the petition only in part.

2.3.3 Production/Geographical Restrictions to Isolate BASF CV127 Soybean from Non-GE Soybean

In response to public concerns of gene movement between GE and non-GE plants, USDA-APHIS considered requiring an isolation distance of BASF CV127 Soybean from non-GE soybean production. However, because USDA-APHIS has concluded that BASF CV127 Soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012), an alternative based on 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.

USDA-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 in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in USDA-APHIS' PPRA for BASF CV127 Soybean, there are no geographic differences associated with any identifiable plant pest risks for BASF CV127 Soybean (USDA-APHIS, 2012). This alternative was rejected and not analyzed in detail because USDA-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 (USDA-APHIS, 2012). Therefore, such an alternative would not be consistent with USDA-APHIS' statutory authority under the plant pest provisions of the PPA and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing considerations, the imposition of isolation distances or geographic restrictions would not meet USDA-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 PPA. However, individuals might choose on their own to geographically isolate their non-GE soybean productions systems from soybean incorporating the BASF CV127 Soybean event or to use isolation distances and other management practices to minimize gene movement between soybean fields. Information to assist growers in making informed management decisions for BASF CV127 Soybean is available from Association of Official Seed Certifying Agencies (AOSCA, 2009).

2.3.4 Requirement of Testing for BASF CV127 Soybean

During the comment periods for other petitions for approving nonregulated status, some commenters requested that USDA require and provide testing for GE products in non-GE production systems. However, because BASF CV127 Soybean does not pose a plant pest risk (USDA-APHIS, 2012), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the PPA, the regulations at 7 CFR part 340, and the biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for BASF CV127 Soybean would not meet USDA-APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

2.4 COMPARISON OF ALTERNATIVES

Table 1 presents a summary of the potential impacts associated with selection of either of the alternatives evaluated in this EA. The impact assessment is presented in Section 4 of this EA.

Table 1: Summary of potential impacts and consequences of alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Nonregulation in Whole
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied by regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2012)
Management Practices		
Acreage and Areas of Soybean Production	In 2012, soybean was cultivated on over 75 million acres (USDA-NASS, 2012a). Approximately 93% of U.S. soybean acreage is planted with GE soybean (USDA-ERS, 2012a; USDA-NASS, 2012a). Acreage dedicated to soybean production is expected to continue within the 10-year average of 73.3 million acres.	No change from Alternative A
Soybean Seed Production	Soybean seed is produced throughout most of the U.S. soybean-growing regions (BASF, 2012). About 71.8 million acres were planted with certified seeds, and an estimated 1.3 to 2.7 million tons of certified soybean planting seeds were required in 2012 (USDA-ERS, 2012b).	No change from Alternative A
Organic Soybean Production	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.	No change from Alternative A
Environment		
Soil Quality	Several concerns relating to agricultural practices include increased erosion, soil compaction, degradation of soil structure, nutrient loss, increased salinity, change in pH, and reduced biological activity (USDA-NRCS, 2006c).	No change from Alternative A
Water Resources	Agricultural non-point sources from soybean production may derive from many different agronomic inputs, including fertilizer and pesticide application, and spilled oil and gasoline from farm equipment. Agricultural	No change from Alternative A

Attribute/Measure	Alternative A: No Action	Alternative B: Nonregulation in Whole
	NPS pollution is the leading source of impacts to surveyed rivers and lakes and the third largest source of impairment to estuaries, as well as a major source of impairment to groundwater and wetlands (US-EPA, 1996).	
Air Quality	Agricultural production of soybean has the potential to cause negative impacts to air quality. Agricultural emission sources include smoke from agricultural burning, tillage, heavy equipment emissions, pesticide drift from spraying, indirect emissions of carbon dioxide and nitrous oxide, the degradation of organic materials in the soil, and from the use of nitrogen fertilizer (USDA-NRCS, 2006a; Aneja et al., 2009).	No change from Alternative A
Climate Change	Agriculture is responsible for an estimated 6% of all human-induced GHG emissions in the United States, produced through the combustion of fossil fuels to run farm equipment; the use of fertilizers; from bringing new lands into production; and the decomposition of agricultural waste products including crop residues, animal wastes, and enteric emissions from livestock (US-EPA, 2012a) .	No change from Alternative A
Animal Communities	During the spring and summer months, soybean fields provide browse for rabbits, deer, rodents, other mammals; birds such as upland gamebirds, while also providing a forage base for insects (Palmer et al., No Date). During the winter months, leftover and unharvested soybeans provide a food-source for wildlife (Krapu et al., 2004). Insects and other invertebrates can be beneficial to soybean production, providing services such as nutrient cycling and preying on plant pests. Conversely, there are many insects and invertebrates that are detrimental to soybean crops (Whitworth et al., 2011; Palmer et al., No Date).	No change from Alternative A
Plant Communities	Non-crop vegetation in soybean fields is limited by the extensive weed control programs using mechanical and chemical methods. Volunteer soybean is not a widespread problem, and when they occur, it is most often in parts of the Delta and the southeastern United States. In production systems where soybean is rotated, such as	No change from Alternative A

Attribute/Measure	Alternative A: No Action	Alternative B: Nonregulation in Whole
	corn or cotton, it has shown up as a volunteer weed, yet was not generally seen as a serious problem by farmers (Owen and Zelaya, 2005). The cultivated soybean, *G. max*, lacks sexually compatible wild relatives in the United States and its territories (USDA-APHIS, 2012).	
Soil Microorganisms	An important group of soil microorganisms associated with legumes, including soybean, are the mutualists. These include mycorrhizal fungi, nitrogen-fixing bacteria, and some free-living microbes that have co-evolved with plants that supply nutrients to and obtain food from their plant hosts (USDA-NRCS, 2004). In addition to beneficial microorganisms, there are also several microbial pathogens that cause disease in soybean and vary somewhat depending on the region (Ruhl, 2007; SSDW, No Date).	No change from Alternative A
Biological Diversity	An increase in adoption of conservation tillage practices is associated with the use of GE herbicide-resistant soybeans (Givens et al., 2009). Less tillage provides more wildlife habitat by allowing other plants to establish between crop rows in either stubble or weeds. Conservation tillage also leaves a higher rate of plant residue and increases soil organic matter (Hussain et al., 1999), which benefit soil biota by providing additional food sources (energy) and increase the diversity of soil microorganisms (USDA-NRCS, 1996).	No change from Alternative A
Human Health and Animal Feed		
Human Health	The general population of the U.S. is most likely to consume soybean products or consume foods containing or prepared with soybean oil. Soybeans yield both solid (meal) and liquid (oil) products. Soybean meal is high in protein and is used for products such as tofu, soymilk, meat replacements, and protein powder; it also provides a natural source of dietary fiber (USB, 2009). Less than 2% of soybean meal produced in the United States is used to produce soy flour and proteins for food use (Soyatech, 2011). Extracted soybean liquid oils are used to produce salad and cooking oils, baking and frying fat, and margarine. Soy oil is low in saturated fats, high in poly and	No change from Alternative A

Attribute/Measure	Alternative A: No Action	Alternative B: Nonregulation in Whole
	monounsaturated fats, and contains essential omega-3 fatty acids. Soybean oil comprises nearly 70% of the oils consumed in U.S. households (ASA, 2010).	
Risk to Worker Safety	Agronomic practices used for soybean production include the application of agricultural chemicals (pesticides and fertilizers). Worker safety is taken into consideration by EPA in the pesticide registration process and reregistration process. Pesticides are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. Furthermore, the OSHA requires all employers to protect their employees from hazards associated with pesticides and herbicides. When used according to label directions, pesticides present minimal risk to human health.	No change from Alternative A
Risk to Animal Feed	Animal agriculture consumes 98% of the U.S. soybean meal produced (Soyatech, 2011) and 70% of soybeans worldwide (USB, 2011). Poultry consume more than 48% of domestic soybean meal or 11.92 million MT of the U.S. soybean crop, with soy oil increasingly replacing animal fats and oils in broiler diets (USB, 2011; ASA, 2012). Soybean can be the dominant component of livestock diets, such as in poultry, where upwards of 66% of their protein intake is derived from soy (Waldroup and Smith, No Date). Other animals fed domestic soybean by crop volumes consumed include swine (26%), beef cattle (12%), dairy cattle (9%), other (e.g., farm-raised fish 3%), and household pets (3%) (USB, 2009; ASA, 2010).	No change from Alternative A
Socioeconomics		
Domestic Economic Environment	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, 2012f). In the 20 years from 1991 to 2011, U.S. soybean acreage expanded 31% and yields increased 17.6% (USDA-NASS, 2012f) while annual value of production increased approximately 222% from approximately $11.09 billion to approximately $35.8 billion (USDA-NASS, 2012f).	No change from Alternative A

Attribute/Measure	Alternative A: No Action	Alternative B: Nonregulation in Whole
Trade Economic Environment	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; USDA-FAS, 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 Alternative A
Other Regulatory Approvals		
United States Federal Agencies	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. FDA: BASF has received a completed consultation letter from the FDA	No change from Alternative A
Other Country Approvals	BASF has submitted applications to Brazil and Argentina for approval for cultivation as well as for consumption as food or feed. Approval of the Brazil National Technical Committee for Biosafety was obtained in December 2009, and from the Secretariat of Agriculture, Livestock and Fisheries of the Argentine Republic in March 2013. Approvals for food or feed uses have also been obtained in countries that import significant numbers of soybeans including Japan, Canada, the People's Republic of China, Australia, New Zealand, the Republic of China (Taiwan), the Republic of Korea, the Philippines, Mexico, Columbia, South Africa, and the Russian Federation (McKean, 2013).	No change from Alternative A
Compliance with Other Laws		
CWA, CAA[1], EOs	Fully compliant	Fully compliant

Notes:
CAA – Clean Air Act; CWA – Clean Water Act

3 AFFECTED ENVIRONMENT

3.1 SOCIOECONOMICS

3.1.1 Areas and Acreage of Soybean Production

In the U.S. there are 310 million acres of harvested cropland (USDA-NASS, 2009). Soybean is grown as a commercial crop on over 75 million acres in the U.S. Soybean is grown on 24% of the harvested cropland. It is the second most frequently planted crop in the U.S. http://www.ers.usda.gov/topics/crops/soybeans-oil-crops/background.aspx. About 80% of the soybeans are grown in the upper Midwest. http://www.ers.usda.gov/topics/crops/soybeans-oil-crops/background.aspx

Soybean varieties differ in their response and tolerance to temperatures as well as photoperiod. Soybean is a quantitative short-day plant, flowering more quickly under short days (OECD, 2000). As a result, photoperiod and temperature responses are important in determining areas of specific cultivar adaptation. Soybean cultivars are identified based on geographic bands of adaptation that run east-west, determined by latitude and day length (Zhang et al., 2007; Pioneer, 2012). In North America, there are 13 maturity groups (MGs) described, ranging from MG 000 in the north (45 degrees [°] latitude) to MG X near the equator.

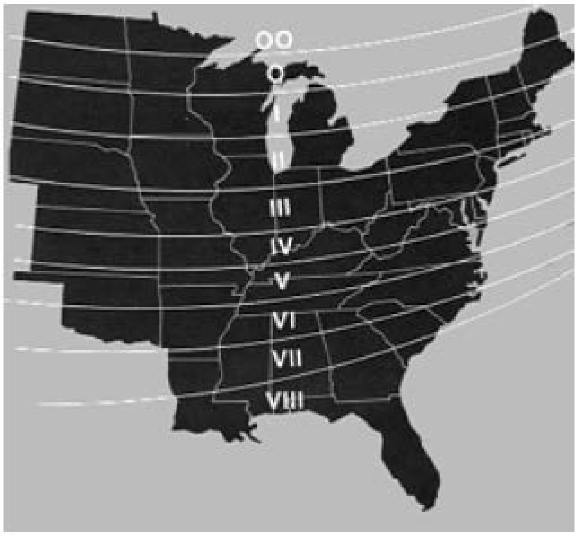

Figure 1: Soybean maturity group distributions in the U.S.

Source: (Zhang et al., 2007)[1].

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[1] Zhang et al. L. X. Zhang, S. Kyei-Boahen, J. Zhang, M.H. Zhang, T.B. Freeland, C.E. Watson Jr. and X. Liu, "Modifications of Optimum Adaptation Zones for Soybean Maturity Groups in the USA," Crop Management (2007).present proposed new soybean maturity group zones, identifying seven maturity groups in the continental United States rather than the ten more commonly considered. The proposed new maturity group designations combine several of the historically accepted maturity group zones. In the Zhang model, soybean maturity group VIII is now identified as maturity group VI, covering the same area and region. Because most of the literature continues to refer to the traditional ten maturity groups, these designations are retained in this EA.

Within each maturity group, cultivars are described as early, medium, or late maturing (OECD, 2000). Figure 1 shows the ten soybean maturity groups commonly associated with the U.S. Generally, Groups 00 through IV soybean varieties are planted in the Midwest and Eastern Coastal regions; Groups IV through VIII are planted in the southern states (Hodges and French, 1985; Helsel and Minor, 1993).

3.1.2 Soybean Seed Production

Seed quality (including genetic purity, vigor, and presence of weed seed, seed-borne diseases, and inert materials such as dirt) is a major factor in crop yields. If natural variability in seed production is not carefully controlled, the value of a new variety or cultivar may be lost (Hartman and Kester, 1975). Genetic purity in commercial seed production is generally regulated through a system of seed certification which is intended to ensure that the desired traits in the seed are maintained throughout all stages in cultivation (Hartman and Kester, 1975).

States have developed seed laws and certification agencies to ensure that purchasers who received certified seed can be assured that the seed meets established seed quality standards (Bradford, 2006). The U.S. Federal Seed Act of 1939 recognizes seed certification and official certifying agencies. Implementing regulations further recognize land history, field isolation, and varietal purity standards for Foundation, Registered, and Certified seed.

Soybean seed is produced throughout most of the U.S. soybean-growing regions by companies that produce and sell seed, and by toll seed producers, or tollers, which produce certified seed for other companies (BASF, 2012). Seed production or processing plants clean, condition, and bag the harvested soybean seed as well as monitor and inspect all the processes at the plant under standards established by the International Organization for Standardization (ISO), and includes internal and external audit (ISO, 2009). Field inspections are conducted on seed production fields throughout the soybean growing season to evaluate variety purity and ensure soybean plants are developing properly (AOSCA, 2009).

3.1.3 Organic Soybean Production

In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2012). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced.

In accordance with NOP, an accredited organic certifying agent conducts an annual review of the certified operation's organic system plan and makes on-site inspections of the certified operation and its records. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards.

The NOP regulations preclude the use of excluded methods. The NOP provides the following guidance under 7 CFR §205.105—

> …to be sold or labeled as "100 percent organic", "organic" or "made with organic (specified ingredients or group(s))," the product must be produced and handled without the use of:…
>
> (a) Synthetic substances and ingredients,…
>
> (e) Excluded methods,…

Excluded methods are then defined at 7 CFR §205.2 as—

> A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

Organic production operations must develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods. In NOP organic systems, the use of synthetic pesticides or fertilizers, and GE crops, is strictly limited. Common organic soybean production practices include crop rotation, use of cover crops, green and animal manures, application of rock minerals such as lime, other soil additives, mechanical weed control, biological control of pests, and disease control primarily through management practices (Kuepper, 2003; Heatherly et al., 2005; USB, 2011; USDA-AMS, 2012).

The NOP also requires organic farming operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management (USDA-AMS, 2012). Management practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields (NCAT, 2003).

Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2011). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of genetically engineered materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan. (Ronald and Fouche, 2006; USDA-AMS, 2011; USDA-AMS, 2012).

3.1.4 Soybean Imports and Exports

The U.S. is the world's largest producer and exporter of soybeans. Main export destinations for U.S. oilseeds, oilseed meal, and vegetable oil include China, the European Union (EU), Japan, Mexico, and Taiwan. Other important markets also import significant quantities of U.S. oilseed meals. These include: Indonesia, South Korea, Thailand, Canada, Mexico, the Philippines, and several Latin American countries. (http://www.ers.usda.gov/topics/crops/soybeans-oil-crops/trade.aspx)

The U.S. imports a limited quantity of soybeans with the majority coming from Canada (GATS database, see http://apps.fas.usda.gov/gats/ExpressQuery1.aspx). Currently less than 10% of the imported soybeans come from South America (GATS database).

3.2 HUMAN HEALTH AND ANIMAL FEED

3.2.1 Food and Feed

Humans and animals consume soybeans products made from soybeans. Soybeans yield both solid (meal) and liquid (oil) products. Soybean meal is high in protein and is used for products such as tofu, soymilk, meat replacements, and protein powder; it also provides a natural source of dietary fiber (USB, 2009). Nearly 98% of soybean meal produced in the United States is used as animal feed, while less than 2% is used to produce soy flour and proteins for food use (Soyatech, 2011). Extracted soybean liquid oils are used to produce salad and cooking oils, baking and frying fat, and margarine. Soy oil is low in saturated fats, high in poly and monounsaturated fats, and contains essential omega-3 fatty acids. Soybean oil comprises nearly 70% of the oils consumed in U.S. households (ASA, 2010).

3.2.2 Worker Safety

Agriculture is one of the most hazardous industries for U.S. workers. As a result, Congress directed the National Institute of Occupational Safety and Health to develop a program to address high-risk issues related to occupational workers. In consideration of the risk of pesticide exposure to field workers, EPA's Worker Protection Standard (WPS) (40 CFR Part170) was published in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protections to more than two and a half million agricultural workers who work with pesticides at more than 560,000 workplaces on farms, forests, nurseries, and greenhouses. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance; furthermore, the Occupational Safety and Health Administration (OSHA) require all employers to protect their employees from hazards associated with pesticides and herbicides.

Pesticides, which include herbicides, are used on most soybean acreage in the U.S., and changes in acreage, crops, or farming practices can affect the amounts and types of pesticides used and thus the potential risks to farm workers. The EPA pesticide registration process, however, involves the design of use restrictions that, if followed, have been determined to be protective of worker health. Under FIFRA, all pesticides, (which is inclusive of herbicides) sold or distributed in the U.S. must be registered by the EPA (US-EPA, 2005c). Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. All pesticides registered prior to November 1, 1984 must also be reregistered to ensure that they meet the current, more stringent standards. During the registration decision, the EPA must find that a pesticide does not cause unreasonable adverse effects to human health or the environment if used in accordance with the approved label instructions (OSTP, 2001).

3.3 PHYSICAL ENVIRONMENT

3.3.1 Soil Quality

Soil consists of solids (minerals and organic matter), liquids, and gases. This body of inorganic and organic matter is home to a wide variety of fungi, bacteria, and arthropods, as well as the growth medium for terrestrial plant life (USDA-NRCS, 2004). The soil microorganisms play a key role in soil structure (Garbeva et al., 2004); (Young and Ritz, 2000). This soil area in the root zone, the rhizosphere, is discussed in Subsection 4.5.1, Biological Resources: No Action Alternative – Soil Microorganisms and Soybeans.

Soybean fields are typically highly managed agricultural areas that are dedicated to crop production for many years. Soybeans are normally grown in managed agricultural fields for crop production and are best suited to fertile, well-drained medium-textured loam soils, yet can be produced in a wide range of soil types (Berglund and Helms, 2003; NSRL, 2012), although soybean does not do well in acid soils (OECD, 2000).

Soybeans need a variety of macronutrients, such as nitrogen, phosphorus, potassium, calcium, magnesium, and sulfur, at various levels (NSRL, 2012). They also require smaller amounts of micronutrients such as iron, zinc, copper, boron, manganese, molybdenum, cobalt, and chlorine. These micronutrients may be deficient in poor, weathered soils, sandy soils, alkaline soils, or soils excessively high in organic matter. As with proper nutrient levels, soil pH is critical for soybean development. Soybeans grow best in soil that is slightly acidic (pH 5.8 to 7.0), and soils that are high in clay and low in humus may impede plant emergence and development (NSRL, 2012).

3.3.2 Water Resources

Water resources can be partitioned into surface water, groundwater, and runoff. Surface water in rivers, streams, creeks, lakes, and reservoirs supports everyday life through the provision of water for drinking and other public uses, irrigation, and industry. Surface runoff from rain, snowmelt, or irrigation water can affect surface water quality by depositing sediment, minerals, or contaminants into surface water bodies (US-EPA, 2005b). Surface runoff is influenced by meteorological factors such as rainfall intensity and duration, and physical factors such as vegetation, soil type, and topography (US-EPA, 2003).

Groundwater is the water that flows underground and is stored in natural geologic formations called aquifers; it sustains ecosystems by releasing a constant supply of water into wetlands and contributes a sizeable amount of flow to permanent streams and rivers (US-EPA, 1990). Based on 2005 data, the largest use of groundwater in the U.S. is irrigation, representing approximately 67.2% of all the groundwater pumped [withdrawn] each day (McCray, 2012). In the U.S., approximately 47% of the population depends on groundwater for its drinking water supply. The US-EPA defines a sole source aquifer (SSA) as an aquifer that supplies at least 50% of the drinking water consumed in the area overlying the aquifer. An SSA designation is one tool to protect drinking water supplies in areas where there are few or no alternative sources to the groundwater resource. There are 77 designated SSAs in the U.S. and its territories (US-EPA, 2012b).

3.3.3 Air Quality

Dry air consists of about 78% nitrogen, 21% oxygen, 0.9% argon and 0.03% carbon dioxide. It also contains small amounts of water vapor and particulate matter. Air quality can affect the growth of plants in agricultural systems (Darley and Middleton, 1966) as well as human and animal health.

Agronomic practices used in agriculture affect air quality. Tillage exposes soil to wind erosion and utilizes motorized equipment that produces emissions. The use of herbicide-resistant crops has facilitated the adoption of conservation tillage (Towery and Werblow, 2010). Reduced tillage generates fewer particulates (dust), so potentially contributes to lower rates of wind erosion and release of soil particulates into the air, thus, benefitting air quality (Fawcett and Towery, 2002). Conservation tillage also minimizes the use of mechanized equipment that produces exhaust, so reduces emissions. Application of agricultural chemicals, such as herbicides or insecticides can also affect air quality.

3.3.4 Climate Change

Climate change represents a significant, sustained statistical change in average weather conditions over a broad region. EPA has identified CO_2, methane (CH_4), and nitrous oxide (N_2O) as the most important GHGs (greenhouse gases) contributing to climate change. While each of these occurs naturally in the atmosphere, human activity has significantly increased their concentration since the beginning of the industrial revolution. The level of human-produced gases has been accelerating since the end of World War II, when industrial and consumer consumption expanded greatly. Since the advent of the industrial age, the percent increase in the concentration of some important GHGs are as follows: CO_2, 36; $CH_{4,}$, 148 and N_2O, 18 (US-EPA, 2011a).

Agriculture, including land-use changes for farming, is estimated to be responsible for 8% of all human-induced GHG emissions in the U.S. (Massey and Ulmer, 2010). Many agricultural activities affect air quality, including smoke from agricultural burning, machinery, and N_2O emissions from the use of nitrogen fertilizer (Hoeft et al., 2000; Aneja et al., 2009; US-EPA, 2012a). Emissions released from agricultural equipment (e.g., irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (US-EPA, 2012a). Tillage contributes to GHG production because it releases CO_2 sequestered in soil and promotes oxidation of soil organic matter (Baker et al., 2005).

3.4 BIOLOGICAL RESOURCES

This section provides a summary of the biological environment and includes an overview of animals, plants, microorganisms, and biodiversity associated with soybean production. This summary provides the foundation to assess the potential impact to plant and animal communities, the potential for gene movement, and the potential for human health impacts.

3.4.1 Animals Communities

Wildlife may be found within or near soybean fields. Deer and groundhogs feed on soybean and cause soybean damage, whereas feeding damage from Eastern cottontail, raccoon, squirrels, and other rodents is of less importance (MacGowan et al., 2006). Migratory birds may feed on spilled soybean following harvest; contrasted with corn, however, soybeans are harvested close to the ground which leaves few alternative food sources or little standing crop residue for protective cover (Galle et al., 2009).

Reptiles and amphibians associated with soybean cultivation primarily inhabit the uncultivated lands adjacent to cultivated fields, particularly those lands associated with conservation reserve protection borders (See also, Stamps et al., 2008). These areas would include drainage ditches, open grassland, and flooded areas (Sharpe, 2010). Fish may inhabit wetlands, ponds, lakes, streams, and rivers proximate to soybean cultivation areas (Palmer et al., 2010; Sharpe, 2010).

Crop pest insects are considered less problematic than weeds in U.S. soybean production; nevertheless, insect injury can impact yield, plant maturity, and seed quality. A variety of insect pests may be found in U.S. soybean fields, including those that feed on reproductive tissue, foliage, and roots/nodules. Insect pests are managed during the growth and development of soybean to enhance soybean yield (Higley, 1994; Aref and Pike, 1998). Although insect injury can impact yield, plant maturity, and seed quality, insect injury in soybean seldom reaches levels to cause an economic loss, as indicated by the low percentage (16%) of the 2006 soybean acreage that receives an insecticide treatment (USDA-NASS, 2007).

There are numerous beneficial arthropods that are predators or parasites of the arthropod pests of soybean, including predatory insects and spiders and parasitoids (Stewart et al., 2007). Examples include representatives of several arthropod taxa: Hemiptera (the true bugs), such as pirate bugs (*Orius spp.*) and *Nabis spp*. (damsel bugs); Coleoptera (the beetles) such as, carabid beetles (ground beetles) and Coccinellid ladybird beetles; Neuroptera (the lacewings); Hymenoptera (parasitic wasps); Diptera (the flies), such as the syrphid or flower flies; and Arachnids (spiders) such as the Opilones (harvestmen), and Aranae (spiders) (Van Duyn, 2000; Grantham and Arnold, 2007; Stewart et al., 2007).

Honeybees are generally not considered an important part of the beneficial invertebrate community in soybeans. Honeybees are not essential to soybean pollination. Soybean is self-pollinated (OECD, 2000). Although low-levels of cross-pollination can occur, this outcrossing has been observed with surrounding plants; insect activity has been found to increase the outcrossing rate, but soybean is not a preferred plant for pollinators (Jaycox, 1970a; Jaycox; Erickson, 1975 1010; Abrams et al., 1978). Additionally, soybean does not produce a lot of pollen and so would not be a significant source of protein for honeybees, however soybean flour can be used to provide supplemental protein to bee colonies to support low levels of brood rearing during winter months in the South, Southwest, and Southeast when pollen sources are low (Standifer et al., 1977).

3.4.2 Plant Communities

The vegetative landscape surrounding a soybean field varies with region; soybean fields may be surrounded by additional soybean varieties, other crops, or woodland/pasture/grassland areas. Weeds are perceived to be the most substantial pest problem in soybean production, negatively affecting yield through competition for light, nutrients, and moisture (Aref and Pike, 1998). When weeds are left to compete with soybean for the entire growing season, yield losses can exceed 75% (Dalley et al., 2001).

Annual weeds are perceived to be the greatest pest problem in soybean production, followed by perennial weeds (Aref and Pike, 1998). In the Southeast, the most common weeds are Morningglory spp. (*Ipomoea spp.)*, crabgrass (*Digitaria spp.*), Prickly sida (*Sida spinosa*), Nutsedge (*Cyperus esculentus*), Sicklepod (*Senna obtusifoliia*), Signalgrass (*Brachiaria platyphylla*), and Palmer amaranthus and related pigweeds (*Amaranthus palmeri* and *Amaranthus spp.*) (Webster et al., 2005; Webster et al., 2009; Heap, 2013).

Soybean is not native to the U.S. and there are no feral or weedy relatives (USDA-APHIS, 2012). Consequently, soybean in the U.S. can cross only with other soybean varieties. Additionally, potential of soybean weediness is low, due to domestication syndrome traits that generally lower overall fitness outside an agricultural environment (Stewart et al., 2003). Mature soybean seeds have no innate dormancy, are sensitive to cold, and are not expected to survive in freezing winter conditions (OECD, 2000; Carpenter et al., 2002).

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% (OECD, 2000; Fehr, 2007) although higher values (up to 2.5%) have been noted in some varieties (Abud et al., 2003). Outcrossing can be reduced to 0 – 0.01% with a separation distance of 10 meters (Abud et al., 2007; USDA-APHIS, 2012).

3.4.3 Soil Microorganisms

Various bacterial and fungal species have been identified as the causal agents of various diseases afflicting soybean plants (Ruhl, 2007). Additionally, soil microorganisms may play a key role in dynamic biochemical soil processes (Garbeva et al., 2004). They may also suppress soil-borne plant diseases and promote plant growth (Doran et al., 1996). The main factors affecting microbial population size and diversity include soil type, plant type, and agricultural management practices (Garbeva et al., 2004). Microbial diversity in the rhizosphere[1] may be extensive and differ from the microbial community in the bulk soil (Garbeva et al., 2004).

3.4.4 Biological Diversity

Biological diversity, or biodiversity, refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson, 1988). Biodiversity provides valuable genetic resources for crop

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[1] The rhizosphere is defined as subsoil area in the root zone of plants in which plant roots compete with the invading root systems of neighboring plants for space, water, and mineral nutrients, and interact with soil-borne microorganisms, including bacteria, fungi, and insects feeding on the organic material in the soil T. S. Walker, H. P. Bais, E. Grotewold and J. M. Vivanco, "Root Exudation and Rhizosphere Biology," Plant Physiology 132.1 (2003)..

improvement and also provides other functions beyond food, fiber, fuel, and income (Harlan, 1975). These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 1999). The loss of biodiversity results in a need for costly management practices in order to provide these functions to the crop (Altieri, 1999).

The degree of biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem, 2) permanence of various crops within the system, 3) intensity of management, and 4) extent of isolation of the agroecosystem from natural vegetation (Altieri, 1999).

Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas; tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest limit the diversity of plants and animals (Lovett et al., 2003).

4 ENVIRONMENTAL CONSEQUENCES

4.1 SCOPE OF THE ENVIRONMENTAL ANALYSIS AND ASSUMPTIONS

BASF CV127 Soybean was developed for cultivation primarily in Brazil and Argentina. BASF does not intend to commercially cultivate BASF CV127 Soybean in the U.S. (BASF, 2011).

Soybeans are naturally tolerant of imazethapyr, which is currently labeled for use on soybeans (Senseman, 2007; BASF, 2011). Imazapyr is not currently registered for use on soybeans in the U.S., and no label for use has been submitted to EPA. According to the developer, there is a very small market in the U.S. for this soybean event; the projected market would not support the cost associated with pursuing EPA registration (BASF, 2011).

BASF presents the results of field trials comparing BASF CV127 Soybean with conventional isolines for agronomic, phenotypic and ecological interactions (See Appendix F in BASF petition) (BASF, 2011). In these field trials, BASF conducted field observations on seed germination rate, seedling vigor, days to reach select development stages, plant height and grain yield, and susceptibility to and interactions with diseases and insects (BASF, 2011). Results of these studies demonstrate that BASF CV127 Soybean is not statistically different from other conventional soybean varieties (BASF, 2011; USDA-APHIS, 2012).

Under the Preferred Alternative, USDA-APHIS assumes that U.S. growers could plant BASF CV127 soybeans, if they were available. Growers could use any management practices that are suitable for the production of soy, including EPA registered herbicides. Growers could not use imazapyr because it is not labeled for use on soybeans in the U.S.

4.2 SOCIOECONOMICS

4.2.1 No Action - Socioeconomics

4.2.1.1 No Action - Areas and Acreage of Soybean Production

Soybean acreage in the U.S. over the past five years has been relatively stable varying from 75 million to 77 million acres with a 10-year average of 73.3 million acres (USDA-NASS, 2012a). Fluctuations in soybean acreage are due to environmental, agronomic, and economic factors, as well as government programs such as the conservation reserve program (CRP) or ethanol mandates imposed by the U.S. government which drive acreage into source crops for ethanol (USDA-ERS, 2012c).

GE- and non-GE soybean varieties are continually under development. In 2012, soybean was cultivated on over 75 million acres (USDA-NASS, 2012a). Approximately 93% of U.S. soybean acreage is planted with GE soybean (USDA-ERS, 2012a; USDA-NASS, 2012a). Acreage dedicated to soybean production is expected to continue within the 10-year average of 73.3 million acres.

Government programs and incentives can influence the amount of soybean that is planted in the U.S. For example, the establishment of a bioethanol industry using corn as a feed influenced the decrease in acreage devoted to soybean, with more than 27% of the corn harvest dedicated to corn-based biofuel production (NCGA, 2012 705; USDA-ERS, 2012d). Nationwide, soybeans are most commonly grown in a crop rotation with corn (USDA-ERS, 2012f). In the Southern U.S., rotation crops include corn, soybean, sorghum, cotton, wheat, and rice, with continuous soybean the most commonly reported practice (USDA-NASS, 2012j).

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, 2012d). The majority of soybeans produced in the U.S. are used domestically for animal feed, with lesser amounts and byproducts used for oil or fresh consumption (GINA, 2013; USDA-ERS, 2013a). From 1924 when recording U.S. soybean production first began, both soybean acreage and yields have steadily increased (Egli, 2008). In comparison, total U.S. cropland has remained relatively level since 1945 (USDA-ERS, 2011). In the 20 years from 1991 to 2011, U.S. soybean acreage expanded 31% and yields increased 17.6% (USDA-NASS, 2012f; USDA-NASS, 2012g) while annual value of production increased approximately 222% from approximately $11.09 billion to approximately $35.8 billion (USDA-NASS, 2012f).

Soybean supply is a function of the amount of acreage planted and soybean yield on those acres. While domestic soybean yield has increased, current demand for soybean products has also increased, mitigating any downward pressure on farm soybean prices from potentially increased supply (NRC, 2010). The national average of U.S. soybean yield is expected to increase between 0.4 to 0.5 bushels per acre per year during the same time period, from 44.5 bushels per acre projected in 2013/2014 to 48.1 bushels per acre in 2021/2022 at a total increase of approximately 8%, without expanding acreage. While overall productivity would increase without expanding U.S. soybean acreage, the U.S. farm price per bushel of soybean is predicted to vary only from $10.30 to $11.35 from 2013/2014 to 2021/2022. Grower net returns are estimated to increase approximately 24% from $303 per acre to $375 per acre over the same period, despite an estimated approximately 3% rise in seed and residual costs, and 10.3% rise in overall per acre cost of production (USDA-OCE, 2012b).

In 2007, soybeans were grown on 279,110 farms in the US, with an average of 229 acres in soybeans. Farms with fewer than 250 acres accounted for 72% of farms growing soybeans, but produced only 26% of the total crop in 2007. Individual or family-owned farms made up 81% of all soybean-producing farms and 69% of total soybean production. Partnerships and small family-held corporations accounted for 17% of farms with other corporations and institutions owning about 1% of soybean producing farms (USDA-NASS, 2009).

USDA estimates annual production costs and returns for major field crops based on grower surveys of the actual costs incurred by producers. On average in 2011, estimates of total operating costs and allocated overhead for soybean production in the U.S. were $396.70/acre with a return over operating costs and overhead of $128.66/acre (USDA-NASS, 2013). The 2011 cost estimates are projected based on a survey of soybean producers from 2006, the last year for which survey data are available, and therefore may not reflect structural or technical change that may have taken place since 2006.

The national averages mask variation in costs and yields. In an analysis of the costs of producing U.S. soybeans in 1997, average soybean production costs ranged from $2.13 per bushel to $6.00 per bushel for the lowest and highest cost quartiles (Foreman and Livezey, 2002). A substantial yield difference of 20 bushels per acre and $77 in soybean production costs were found between high and low cost producers (Foreman and Livezey, 2002). The differences were largely due to differences in capital recovery of machinery and equipment, and other costs, with low-cost producers realizing half the machinery costs per acre of high-cost producers (Foreman and Livezey, 2002). Production practices and growing conditions varied by region, with most of the low cost producers residing in the Heartland. Off-farm income was found to be an important source of household income for many soybean producers (Foreman and Livezey, 2002).

Total U.S. soybean production was 2.9 billion bushels in 2012, down slightly from 3.1 billion bushels in 2011 (USDA-NASS, 2012c). In 2011, the price of soybeans for beans was $11.70 per bushel on average, resulting in a total value of production of nearly $36 billion (USDA-NASS, 2012d). As of November 2012, the U.S. season-average soybean price range was projected at $13.90 to $15.90 per bushel (USDA-OCE, 2012a).

4.2.1.2 No Action - Soybean Seed Production

Soybean seed is produced throughout most of the U.S. soybean-growing regions by companies that produce and sell seed, and by toll seed producers, or tollers, which produce certified seed for other companies (BASF, 2012). Seed production or processing plants clean, condition, and bag the harvested soybean seed as well as monitor and inspect all the processes at the plant under standards established by the International Organization for Standardization (ISO), and includes internal and external audit (ISO, 2009). Field inspections are conducted on seed production fields throughout the soybean growing season to evaluate variety purity and ensure soybean plants are developing properly (AOSCA, 2009).

Soybean seed production is conducted under standard procedures specified by AOSCA to prevent gene flow between varieties (AOSCA, No Date). Several best management practices to preserve varietal identity include:

- Maintaining isolation intervals to prevent pollen movement from other soybean sources;
- Planting border rows to capture any pollen present or employing natural pollen barriers; and
- Field monitoring for off types, other crops, etc.

Soybean is considered to be highly self-pollinated; therefore, cross-pollination to adjacent soybean plants occurs at a very low frequency (Caviness, 1966; OECD, 2000; Ray et al., 2003; Abud et al., 2007). Other research has also demonstrated that soybean pollen dispersal is restricted to small areas and wind mediated pollination is negligible (Yoshimura, 2011). Several factors influence optimal planting rate for soybean such as row spacing, seed germination rate, soil conditions, climate, disease and pest pressure, past tillage practices and crop rotation (Robinson and Conley, 2007). Seeding rate is also determined by the plant population desired by the grower. Growers may plant certified soybean seed, uncertified seed, and “binrun” soybean seed that is grown and stored on individual farms (Oplinger and Amberson, 1986). Approximately 93% of the soybean acres planted in the U.S. in 2012 were GE varieties (USDA-ERS, 2012a), about 71.8 million acres were planted with certified seeds, and an estimated 1.3 to 2.7 million tons of certified soybean planting seeds were required in 2012.

The production of soybean for foundation, registered, certified, or quality control seed require biological, technical, and quality control factors required to maintain varietal purity above that required for soybean production for grain. The production and certification of soybean seed is regulated by state or regional crop improvement agencies and are chartered under the laws of the state(s) they serve (e.g., see Mississippi Crop Improvement Association, 2008; Illinois Crop Improvement Association, 2013; SSCA, No Date; Virginia Crop Improvement Association, No Date).

Seed genetic purity is maintained to maximize the value of a new variety or cultivar (Sundstrom et al., 2002), of which a seed certification process ensures the desired traits remain within purity standards (Bradford, 2006) (see Subsection 3.1.2, Soybean Seed Production). Seed producers routinely submit applications to the AOSCA National Variety Review Boards for review and recommendation for inclusion into seed certification programs. For example, in September 2012, AOSCA recommended for certification the inclusion of 60 varieties of soybean expressing high yield traits by three seed producing companies (AOSCA, 2012).

Comments submitted in previous environmental assessments have expressed concern over the availability and supplies of non-GE, open-pollinated, untreated or organic seed. As soybeans are largely self-pollinating, concerns over soybean seed stock generally relate to inadvertent commingling of seed after harvest. Soybean growers have many standard management practices in place to protect and preserve product identity from seed production through harvest and market (See e.g., AOSCA, 2009; ASTA, 2011). Numerous providers of organic and non-GE seeds are listed by ATTRA and North Carolina State University (ATTRA, 2012; N.C. State University, 2012).

Under this alternative, seed production of BASF CV127 in the U.S. would require a permit from USDA-APHIS. Growers would need to apply for permits and follow permit conditions if they choose to grow this seed for breeding purposes or to export to South American markets for planting.

4.2.1.3 No Action - Organic Soybean Production

The production of organic soybeans represents between 0.13% and 0.22% of U.S. soybean production (USDA-NASS, 2012b; USDA-NASS, 2012a). In 2005, 122,217 acres of soybean in the U.S. were certified organic, and in 2008, 125,621 acres were similarly certified representing about 0.20% of total U.S. soybean production (USDA-ERS, 2013b). Certified organic soybeans were harvested from 96,080 acres in 2011, the equivalent of 0.13% of the total U.S. soybean acreage (USDA-NASS, 2012b; USDA-NASS, 2012a), and was valued at approximately $49.4 million, capturing roughly 0.17% of the overall soybean crop value for that year (reported at $35.8 billion) (USDA-NASS, 2012g; USDA-NASS, 2012h; USDA-ERS, 2013b). Iowa is the largest producer of certified organic soybean, followed by Minnesota, Michigan, New York and Illinois (USDA-NASS, 2012b). Table 2: Certified organic soybean acreage by state shows organic soybean acres planted by state in 2007, 2008, and 2011.

Table 2: Certified organic soybean acreage by state.

State	Soybean Acres 2007	Soybean Acres 2008	Soybean Acres 2011	State	Soybean Acres 2007	Soybean Acres 2008	Soybean Acres 2011
Arizona	241	241	NR[1]	**Missouri**	7,893	6,441	5,505
Arkansas	8,374	11,172	W[2]	**Nebraska**	5,672	8,825	6,211
Colorado	488	3,502	NR	**New York**	1,324	5,038	8,621
Connecticut	9	9	NR	**North Carolina**	165	94	W
Delaware	25	25	W	**North Dakota**	3,308	3,773	3,288
Idaho	1	1	W	**Ohio**	3,665	3,951	5,634
Illinois	6,277	7,225	6,633	**Oklahoma**	80	165	NR
Indiana	888	1,104	945	**Oregon**	0	141	NR
Iowa	6,989	19,913	12,659	**Pennsylvania**	,1589	1,753	1,280
Kansas	639	2,141	1311	**South Dakota**	4,531	4,786	3,962
Maine	144	194	W	**Texas**	2,093	2,141	W
Maryland	416	437	1,090	**Vermont**	0	337	527
Michigan	11,320	11,251	11,699	**Virginia**	360	363	150
Minnesota	25,518	21,229	16,150	**Wisconsin**	8,318	9,369	7,622

Source: (USDA-ERS, 2013b)

Notes:
1 NR – Not Reported
2 W – Data withheld by growers and not published by USDA-NASS.

Organic soybean producers generally harvest lower yields than other producers, and incur higher operating and capital costs when compared with conventional soybean producers (Heatherly et al., 2005; McBride and Greene, 2008; USB, 2011). These higher costs are offset by the market premium which organic soybean markets typically enjoy (McBride and Greene, 2008). Organic soybean production is occurring in the presence of conventional soybean production using GE and non-GE soybean varieties. Organic production plans prepared pursuant to the NOP include practical methods to prevent co-mingling of organic and GE soybean. The implementation of management practices to avoid pollen from a biotechnology-derived crop in organic or conventional soybean production operations is facilitated by the nature of soybean pollination, as soybean is highly self-pollinating. Organic and non-GE soybean producers can and have effectively implemented practices (e.g., isolation during the growing season, equipment cleaning during harvest, and post-harvest separation of harvested seed) that allow them to reasonably avoid biotechnology-derived soybean and maintain organic or Non-GE production status (Brookes and Barfoot, 2004).

Typically, organic growers use more than one method to prevent unwanted material from entering their fields including: isolation of the farm; physical barriers or buffer zones between organic production and non-organic production; planting border or barrier rows to intercept pollen; changing planting schedules to ensure flowering at different times; and formal communications between neighboring farms (Kuepper, 2003; Baier, 2008).

4.2.1.4 No Action - Soybean Imports and Exports

The U.S. imports oilseeds and oilseed products, although the majority of these imports are mainly rapeseed and rapeseed products (e.g. canola oil) from Canada, olive oil from Western Europe, and tropical oils from the Philippines, Indonesia and Malaysia (USDA-ERS, 2012g). In 2012, for example, the U.S. imported nearly $125 million of vegetable oil from Argentina, and $24 million of vegetable oil from Brazil, in the aggregate representing approximately 7% of the total imports of vegetable oils from Canada (USDA-FAS, 2013b).

The U.S. has been importing increasing quantities of soybeans over the past decade (Figure 2). Canada provides the majority of these soybeans to U.S. market. In 2012, approximately 6% of the total soybean imports were from South America (Figure 3).

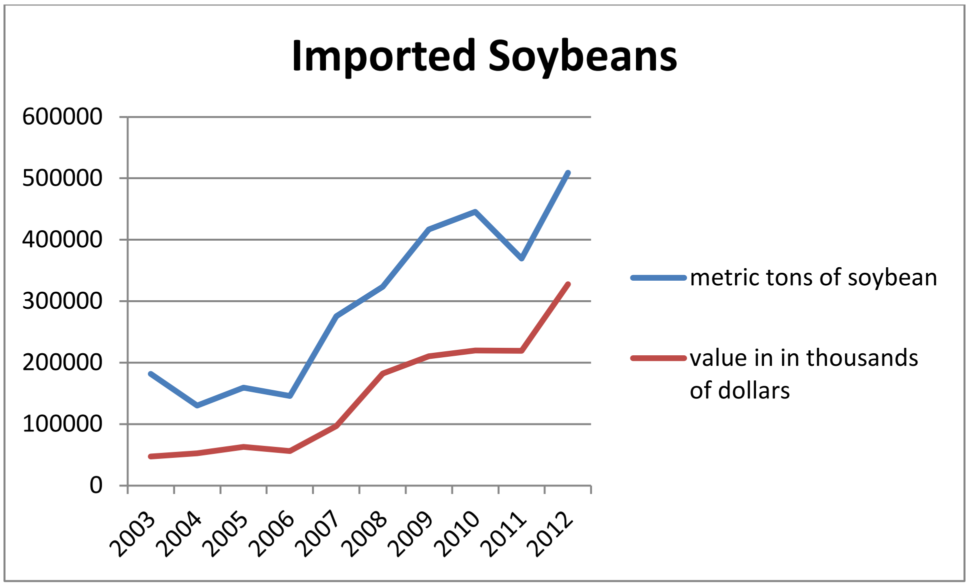

Figure 2: Soybeans imported to the U.S, 2003-12.

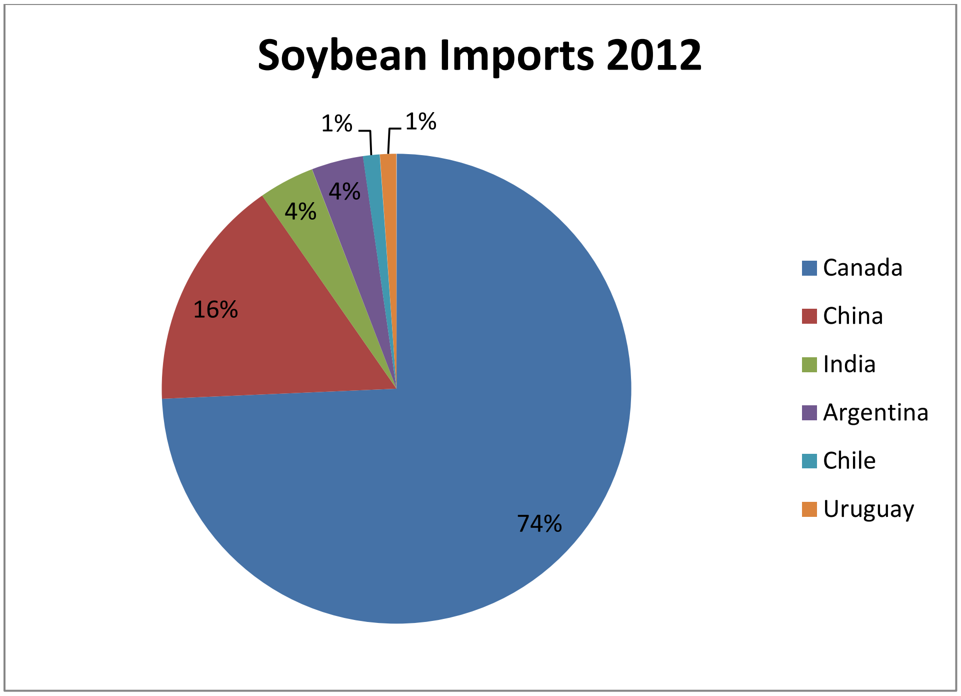

Figure 3: Countries from which the U.S. imported soybeans in 2012.

Six countries were the origin of more than 99% of the soybeans imported to the U.S. in 2012. About 6% of the soybeans were imported from South America. Under the no action alternative, importers of BASF CV127 soybeans would need to obtain a permit or acknowledged notification from USDA. These soybeans would need to be segregated in the country of origin to ensure that they were not introduced in the U.S. inadvertently in commodity shipments.

The U.S. is the world's largest producer and exporter of soybeans, accounting for 35% of total world production and 41% of global soybean oilseed exports in 2011-12 (USDA-FAS, 2012c; USDA-FAS, 2012b). Brazil and Argentina are the next largest soybean producing countries in 2011-12, accounting for 28% and 17% of total world production respectively. China is the fourth largest soybean producer, producing 6% of the world total soybean crop in 2011-12 (USDA-FAS, 2012c). The U.S. share of global exports has steadily diminished over the past 25 years, largely due to the expansion of soybean production in South America (USDA-ERS, 2012g). The USDA projects that by 2012/2013, Brazil soybean exports will surpass those of the U.S., and Argentina soybean exports will increase by 50% (USDA-FAS, 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). Because BASF CV127 would not be grown in the U.S. except under permit it would not affect the U.S. export businesses.

BASF has submitted applications to Brazil and Argentina for approval for cultivation, as well as for consumption as food or feed. Approval of the Brazil National Technical Committee for Biosafety was obtained in December 2009 and from the Secretariat of Agriculture, Livestock and Fisheries of the Argentine Republic in March 2013.

Approvals for food and feed uses have also been obtained in countries that import significant numbers of soybeans, including:

- Ministry of Health, Labor and Welfare and the Ministry of Agriculture, Forestry and Fisheries of Japan (approved for food and feed March 2013);
- Canadian Food Inspection Agency and Health Canada (approved November 2012);
- Ministry of Agriculture of the People's Republic of China (received safety certificate June 2013);
- Food Standards Australia New Zealand (approved for food July 2012) (FSANZ, 2012);
- Republic of China (Taiwan) Food and Drug Administration (approved for food April 2013);
- Rural Development Administration of the Republic of Korea and the Korean Food and Drug Administration (approved for food and feed October 2011 and April 2013, respectively);
- Bureau of Plant Industry, the Philippines (approved for food, feed and processing in October 2010);
- Government of Mexico (approved for food, feed and processing in May 2011);
- Columbian Institute of Agriculture and Livestock (approved for import and feed September 2011) and the Health and Social protection Ministry of Columbia (approved for import and food January 2012);
- Republic of South Africa Department of Agriculture, Forestry and Fisheries (approved for food and feed June 2012); and
- Russian Federation's Federal Service for veterinary and Phytosanitary Surveillance (approved for feed September 2012), and Federal Service on Consumer's Rights Protection and Well-being Surveillance (approved for food December 2012) (McKean, 2013).

These approvals will not be affected if APHIS were to choose the No Action Alternative.

4.2.2 Preferred Alternative - Socioeconomic Effects

The Preferred Alternative is not expected to change the effects on Socioeconomic or Human Health related issues when compared to the No Action Alternative except for the effects on imports of soybeans from countries producing BASF CV127 and for breeders or seed producers that might grow this seed for overseas markets. In both of these cases the Preferred Alternative has less regulatory burden than the No Action Alternative.

4.2.2.1 <u>Preferred Alternative - Areas and Acreage of Soybean Production</u>

BASF presented the results of field trials comparing BASF CV127 Soybean with conventional isolines for agronomic, phenotypic and ecological interactions (BASF, 2011, at Appendix F). In these field trials, BASF conducted field observations on seed germination rate, seedling vigor, days to reach select development stages, plant height and grain yield, and susceptibility to and interactions with diseases and insects (BASF, 2011). Results of these studies demonstrate that BASF CV127 Soybean is not statistically different from other conventional soybean varieties (BASF, 2011; USDA-APHIS, 2012). Therefore, if growers were to grow these soybeans in the U.S. the production practices would not change when compared to the no action alternative. Imazapyr is not labeled for use on soybeans in the U.S. It is not legal to apply the herbicide and so there is no change in herbicides application associated with this soybean variety if grown in the U.S.

Currently, BASF CV127 Soybean is in Maturity Group VIII. If BASF CV127 Soybeans are grown in the U.S. for research and development or off-season seed production, that cultivation would be would most likely be in areas of Louisiana, Mississippi, Alabama and Georgia, Florida and the coastal areas of South Carolina (Figure 1). Under the preferred alternative, breeders could choose to incorporate this trait into other maturity groups through breeding programs. However, because its target market is in South America and the herbicides to which this soy is resistant are not labeled for use on soybean in the U.S. this breeding is not likely. CV127 Soybean is resistant imazapyr, which is not labeled for use on soybean in the U.S. Therefore, there is no incentive to breed this trait into varieties suitable for planting in the U.S.

There are no changes in agronomic characteristics in BASF CV127 Soybean that would result in a change in the area where soybean is cultivated in the U.S. or an increase in acreage relative to the No Action Alternative (USDA-APHIS, 2012). The trend in soybean planting acreage is a function of market conditions and is not specific to a single GE soybean variety (Wallander et al., 2011) the preferred alternative will not change these influences.

4.2.2.2 Preferred Alternative - Soybean Seed Production

Approval of the petition for nonregulated status for BASF CV127 Soybean under the Preferred Alternative would not change the availability of soybean seed. Growers who produce BASF CV127 would not require a permit or acknowledged notification to plant the variety for breeding or off season seed production for South American markets. Therefore, there is a lower regulatory burden on seed growers under the Preferred Alternative.

4.2.2.3 Preferred Alternative - Organic Production

BASF CV127 is not likely to be grown in the U.S. except for breeding or seed production. BASF has presented results of agronomic trials that demonstrate that BASF CV127 Soybean is not different in plant growth, yield, and reproductive capacity from other commercial soybeans (BASF, 2011). As described in the No Action Alternative, organic producers employ cultivation methods to prevent the comingling of organic and GE soy. The practices currently employed in organic production systems would not change when compared to the No Action Alternative.

4.2.2.4 Preferred Alternative - Soybean Imports and Exports

The U.S. is the world's largest exporter of soybeans, its share of the export market has diminished over the past 25 years largely as a result of expansion of soybean production in South America (USDA-ERS, 2012g). The USDA projects that in 2013 Brazil is expected to surpass the U.S. as the largest soybean exporter (USDA-ERS, 2012g; USDA-FAS, 2012b; USDA-FAS, 2013a). The cultivation of BASF CV127 Soybean in Brazil or Argentina may contribute to the trend by providing growers in these countries with alternative weed management options. Imports of BASF CV127 soybeans from these countries would not require permits, so there would be no need to segregate these soybeans under the Preferred Alternative. This would lower the regulatory burden for imports when compared to the No Action Alternative.

4.3 HUMAN HEALTH AND ANIMAL FEED

4.3.1 No Action - Human Health and Animal Feed

4.3.1.1 No Action - Food and Feed

The general population of the U.S. is most likely to consume soybean products or consume foods containing or prepared with soybean oil. Soybeans yield both solid (meal) and liquid (oil) products. Soybean meal is high in protein and is used for products such as tofu, soymilk, meat replacements, and protein powder; it also provides a natural source of dietary fiber (USB, 2009). Nearly 98% of soybean meal produced in the U.S. is used as animal feed, while less than 2% is used to produce soy flour and proteins for food use (Soyatech, 2011). Extracted soybean liquid oils are used to produce salad and cooking oils, baking and frying fat, and margarine. Soy oil is low in saturated fats, high in poly and monounsaturated fats, and contains essential omega-3 fatty acids. Soybean oil comprises nearly 70% of the oils consumed in U.S. households (ASA, 2010).

Animal agriculture consumes 98% of the U.S. soybean meal produced (Soyatech, 2011) and 70% of soybeans worldwide (USB, 2011). Poultry consume more than 48% of domestic soybean meal or 11.92 million MT of the U.S. soybean crop, with soy oil increasingly replacing animal fats and oils in broiler diets (USB, 2011; ASA, 2012). Soybean can be the dominant component of livestock diets, such as in poultry, where upwards of 66% of their protein intake is derived from soy (Waldroup and Smith, No Date). Other animals fed domestic soybean by crop volumes consumed include swine (26%), beef cattle (12%), dairy cattle (9%), other (e.g., farm-raised fish 3%), and household pets (3%) (ASA, 2010; USB, 2011).

Although the soybean market is dominated by seed production, soybean has a long history and a standing in the U.S. as a nutritious grazing forage, hay, and silage crop for livestock (Blount et al., 2009). Soybean may be harvested for hay or grazed from the flowering stage to near maturity; the best soybean for forage is in the beginning pod stage (Johnson et al., 2007). For silage, it should be harvested at maturity before leaf loss, and mixed with a carbohydrate source, such as corn, for optimal fermentation characteristics (Blount et al., 2009). Varieties of soybean have been developed specifically for grazing and hay, but use of the standard grain varieties are recommended by some because of the whole plant feeding value (Weiderholt and Albrecht, 2003).

Growers must adhere to EPA label use restrictions for pesticides used to produce a soybean crop before using it as forage, hay, or silage. Pursuant to FFDCA, before a pesticide can be used on a food crop EPA must establish the tolerance value, which is the maximum amount of pesticide residue that can remain on the crop or in foods processed from that crop (US-EPA, 2010a). In addition, the FDA and the USDA monitor foods for pesticide residues and enforce these tolerances (USDA-AMS, 2011). If pesticide residues are found to exceed the tolerance value, the food is considered adulterated and may be seized. The USDA has implemented the Pesticide Data Program (PDP) in order to collect data on pesticides residues on food (USDA-AMS, 2012). The EPA uses PDP data to prepare pesticide dietary exposure assessments pursuant to the 1996 Food Quality Protection Act (FQPA). Tolerance levels for various pesticides have been established for a wide variety of commodities, including soybean, and are published in the *Federal Register*, CFR, and the *Indexes to Part 180 Tolerance Information for*

Pesticide Chemicals in Food and Feed Commodities (US-EPA, 2011b).

The EPA Registration Eligibility Decision (RED) for imazapyr, for example, found no human health risks from dietary uptake (US-EPA, 2006b). As the imidazolinone herbicides are currently used on many different crops, there are currently over 20 different residue tolerances for this herbicide on different crops (40 CFR §180.500). 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).

4.3.1.2 No Action - Worker Safety

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 include the application of agricultural chemicals (pesticides and fertilizers). Growers choose agronomic practices based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Heiniger, 2000; Farnham, 2001; University of Arkansas, 2006). Worker safety is taken into consideration by EPA in the pesticide registration process and reregistration process. Pesticides are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. Furthermore, the OSHA requires all employers to protect their employees from hazards associated with pesticides and herbicides. When used according to label directions, pesticides can be used with a reasonable certainty of no harm to human health and without posing unreasonable risks to the environment.

4.3.2 Preferred Alternative - Human Health and Animal Feed

4.3.2.1 Preferred Alternative - Food and Feed

Under the Preferred Alternative the effects on food and feed are no different than under the No Action Alternative. BASF CV127 is compositionally similar to other commercially available soybeans. BASF has presented data comparing BASF CV127 Soybean with other varieties (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; BASF). FDA completed its consultation on this product on February 17, 2012 (US-FDA, 2012).

4.3.2.2 Preferred Alternative - Worker Safety

A determination of nonregulated status of BASF CV127 soybean is not expected to result in changes in current soybean cropping practices. Similar to the No Action Alternative, it is expected that EPA-registered pesticides, fertilizers, and other chemicals that currently are used for soybean production would continue to be used by growers. EPA's core pesticide risk assessment and regulatory processes ensure that each registered pesticide continues to meet the highest standards of safety including all populations of non-target species and humans, and if used in accordance with the label, can be demonstrated to pose "a reasonable certainty of no harm to humans" and "no unreasonable adverse effects to the environment." Growers are required to use pesticides consistently with instructions for application provided on the EPA-approved pesticide label. These label restrictions carry the weight of law and are enforced by EPA and the states (Federal Insecticide, Fungicide, and Rodenticide Act 7 USC 136j (a)(2)(G) Unlawful Acts). Overall impacts to occupational health and safety under the Preferred Alternative are expected to be similar to the No Action Alternative.

4.4 PHYSICAL ENVIRONMENT

4.4.1 No Action Alternative – Physical Environment

4.4.1.1 No Action Alternative - Soil Quality

Cultivation and tillage practices can directly impact the attributes of soil, including its physical and biological properties. Although practices such as tillage, fertilization, the use of pesticides and other management tools can improve soil health, they can also cause substantial damage if not properly used. Several concerns relating to agricultural practices include increased erosion, soil compaction, degradation of soil structure, nutrient loss, increased salinity, change in pH, and reduced biological activity (USDA-NRCS, 2006c).

The practice of tillage for soil preparation and weed management can affect the quality of soils because of the varying impacts of erosion on soil nutrient composition. Field preparation is accomplished through a variety of tillage systems, with each system defined by the remaining plant residue on the field (US-EPA, 2012a). Conventional tillage is associated with intensive plowing and less than 15% crop residue; reduced tillage is associated with 15 to 30% crop residue; and conservation tillage, including no-till practices, is associated with at least 30% crop residue and substantially less soil erosion than other tillage practices (US-EPA, 2012a). As conservation practices are adopted, there are increases in soil organic matter that helps bind soil nutrients and corresponding significant reductions over time in the loss of cropland soil from runoff, erosion, and leaching (Leep et al., 2003; USDA-NRCS, 2006c; USDA-NRCS, 2006b). Total soil loss on highly erodible croplands and non-highly erodible croplands decreased from 462 million tons per year to 281 million tons per year or by 39.2% from 1982 to 2003 (USDA-NRCS, 2006b). This decrease in soil erosion carries a corresponding decrease in non-point source surface water pollution of fertilizer and pesticides (USDA-NRCS, 2006b). The reduction in soil erosion is also attributed to a decrease in the number of acres of highly erodible cropland being cultivated (USDA-NRCS, 2006b).

Other methods to improve soil quality include careful management of fertilizers and pesticides; use of cover crops to increase plant diversity and limit the time soil is exposed to wind and rain; and, increased landscape diversity with buffer strips, contour strips, wind breaks, crop rotations, and varying tillage practices (USDA-NRCS, 2006c). The USDA requires that growers adopt these same conservation measures to protect soil on highly erodible lands in order to qualify for crop insurance and associated Federal loans (USDA-ERS, 2012c).

There are a multitude of organisms associated with soils, ranging from microorganisms to larger organisms, such as worms and insects. One of the microorganisms associated with soybean directly affects soil conditions, and bears introduction in this subsection. A legume, the soybean plant fixes a significant portion of its own nitrogen through the symbiotic relationship with the nitrogen-fixing *Bradyrhizobia* bacteria (*B. japonicum*) that live in soybean root nodules (Hoeft et al., 2000). The soybean root nodules contain colonies of bacteria which take gaseous nitrogen from the atmosphere and fix it into a form that is more biologically available to the soybean plant. Because the nitrogen-fixing bacteria are not native to U.S. soils and would not normally be found in these soils, soybeans are frequently inoculated with these bacteria prior to planting, especially if soybean has not been grown in a field for three to five years (Pedersen, 2007). The relationship between these nodule bacteria and soybean cultivation is discussed in Subsection 4.5.1 – Biological Resources: No Action Alternative - Soil Microorganisms.

Growers applying imidazolinone herbicides for the control of weeds must be cognizant of the potential impacts of herbicide carryover (soil residuals) on rotational crops (Hahn and Stachowski, 2003; Heiser, 2007; Senseman, 2007; Hager and Refsell, 2008). Imidazolinone herbicides are already used on soybeans, and Lightning® is used on the Clearfield® varieties. In 2007, Imidazolinone herbicides were used on less than 4% of U.S. soybean acreage (USDA-NASS, 2007a).

Imidazolinone herbicides are mobile in soil, and have a variable residual half-life depending on the formulation and soil conditions (US-EPA, 1989). For example, the half-life of imazamox has been reported at 1.4 weeks, imazethapyr has been reported at 16 weeks, and for imazaquin has been reported at 191 weeks (Aichele and Penner, 2005). Imazapyr has been determined to be persistent and mobile in soil, with half-lives measured in the laboratory ranging from 1.2 years to 5.9 years. (US-EPA, 2005a). Because of the known soil residual activity associated with several of the imidazolinone herbicides (notably imazapic which may exhibit residual weed control activity for up to two years, but also imazequin, imazamethabenz, and imazethapyr), (see e.g., Heiser, 2007; Senseman, 2007; Hager and Refsell, 2008), growers must be cognizant of the sensitivity of crops in their rotation scheme to these herbicides (Heiser, 2007; Senseman, 2007; Hager and Refsell, 2008). For example, although imazaquin is already applied to soybean, several rotational crops, including barley, corn, cotton oats and sugar beets are acknowledged to be susceptible to residues in soil (Senseman, 2007). The persistence of imidazolinone herbicides in soil is a function of soil microbial populations, moisture, organic matter, soil pH, soil composition and temperature (Heiser, 2007).

4.4.1.2 No Action Alternative - Water Resources

Soil texture and structure are key components determining water availability in soils which, in turn, affects soybean root depth and density (Helsel and Helsel, 1993). Specific soil types have varying abilities to hold water; sandy soils retain the least amount of water, and silt loam and clay loam soils hold the most (Helsel and Helsel, 1993). However, although clay soils hold more water, less water is available to the plant because water adheres strongly to the clay particles (Helsel and Helsel, 1993). Soybean root depth and distribution are influenced by available water and soil physical characteristics, with deepest root systems identified in sand and clay soils, and shallowest in loam soils (Dwyer et al., 1988).

Soil erosion and runoff contribute nonpoint source pollution (NPS) to surface water. Rainfall or snowmelt runoff moving over the ground picks up and carries away soil and materials associated with the soil, such as fertilizer and pesticides, creating NPS pollution (see e.g., US-EPA, 1996; USDA-NRCS, 2006b). Agricultural non-point sources may derive from many different agronomic inputs, including fertilizer and pesticide application, spilled oil and gasoline from farm equipment, and animal manure (US-EPA, 1996). Agricultural NPS pollution is the leading source of impacts to surveyed rivers and lakes and the third largest source of impairment to estuaries, as well as a major source of impairment to groundwater and wetlands (US-EPA, 1996).

In 2009, US-EPA identified sedimentation and turbidity associated with tillage practices as two of the top 10 causes of impairment to surface water in the U.S. (US-EPA, 2009a). US-EPA has projected conservation tillage to be "the major soil protection method and candidate best management practice for improving surface water quality" (US-EPA, 2002). US-EPA identifies conservation tillage as the first of its CORE4 agricultural management practices for water quality protection (US-EPA, 2008a).

Based on the states' water quality reports, which the US-EPA makes available through its National Assessment Database, pesticides in general and herbicides in particular are a relatively minor contributor to impairment of surface water in the U.S., compared to sedimentation/siltation and turbidity (US-EPA, 2013). Pesticides accounted for less than 1% of reported causes of surface water impairment in all but four of the 17 leading U.S. soybean-producing states (US-EPA, 2013) . In those four states, pesticides accounted for 2-8% of reported causes of impairment. Of the pesticides that were reported as contributing to impairment among the 17 leading soybean-producing states, almost all are highly persistent chemicals that are no longer registered for use in the U.S. (US-EPA, 2013). Imidazolinone herbicides are not included on this list.

The soils and climate in the Eastern, Midwestern, and portions of the Great Plains region of the U.S. provide sufficient water supplies under normal climatic conditions to produce a soybean crop. The general water requirement for a high-yielding soybean crop is approximately 20 to 24 inches of water during the growing season to produce a relatively high yield of 40-50 bushels per acre (KSU, 1997; Hoeft et al., 2000). In 2006, when approximately 8% of the total soybean crop was irrigated, over 92% of the irrigation supply was from groundwater supply (USDA-ERS, 2012e). In 2006, irrigated soybean produced an average of 51 bushels per acre, where the national average for that year was 42.9 bushels per acre (USDA-NASS, 2012h).

In 2011, 65% of U.S. soybean acres reported some form of conservation tillage (USB, 2011). Intensive monitoring of surface water and groundwater proximate to agricultural fields has demonstrated that conservation tillage practices can reduce runoff from agricultural lands, decreasing NPS pollution of suspended sediment, nutrients from fertilizers, and pesticides (UT, 2011). Nutrient management reduces agricultural chemical movement into ground or surface waters (US-EPA, 2005b).

The EPA considers water resources, and potential contamination of water resources, when registering a pesticide under FIFRA. Precautions to protect water resources, including aquatic animals and plants, if required, are provided on the pesticide label. Under the No Action Alternative, current land acreage and agronomic practices, including irrigation, tillage, and nutrient management associated with U.S. soybean production, would not be expected to change. These practices and inputs would include the use of imidazolinone herbicides. No expected changes to water use beyond current trends associated with soybean production are expected for this alternative.

The EPA has considered the potential impacts to water resources from the agricultural application of imidazolinone herbicides, and has included label use restrictions and handling guidance intended to prevent impacts to water (see e.g., BASF, 2008). Label restrictions for Lightning® specific to water resources include prohibiting applications directly to water, managing proper disposal of equipment wash water, and adopting cultivation methods to limit runoff to surface water (BASF, 2008). The half-life of imazapyr in water is estimated at 3 to 5 days, and imazapyr is registered for use in aquatic areas and treated water from these sites may be diverted to irrigate food or feed crops (US-EPA, 2006a).

4.4.1.3 No Action Alternative - Air Quality

Agricultural activities have the potential to impact air quality. Agricultural air emission sources include: smoke from agricultural burning; vehicle exhaust associated with equipment used in tillage and harvest; soil particulates associated with tillage; and nitrous oxide emissions from the use of nitrogen fertilizer (Hoeft et al., 2000; USDA-NRCS, 2006a; Aneja et al., 2009; US-EPA, 2012a). Aerial application of pesticides may cause air quality impacts from drift and diffusion, and pesticides may volatilize after application to soil or plant surfaces and may also move as constituents of entrained materials in wind eroded soils (Vogel et al., 2008).

The majority of soybean grown in the U.S. is rotated with corn on a two-year rotation (OECD, 2000; USDA-ERS, 2005). Soybean fields typically are tilled and the new crop rotation planted in the following year (Hoeft et al., 2000). Reduced tillage generates fewer particulates (dust) entrained by wind erosion (Towery and Werblow, 2010). An additional benefit to air quality relates to the reduction in emission-producing equipment associated with crop tillage (USDA-NRCS, 2012).

Open combustion associated with prescribed burning as an agricultural resource management strategy produces particles of widely ranging size, depending to some extent on the rate of energy release of the fire (US-EPA, 2012a). The extent to which agricultural and other prescribed burning may occur is regulated by state air quality requirements to achieve compliance with the national ambient air quality standards (US-EPA, 2012a). Prescribed burning of fields would likely occur only as a pre-planting option for soybean production based on individual farm characteristics.

Volatilization of fertilizers, herbicides, and pesticides from soil and plant surfaces also introduces these chemicals to the air. The USDA Agricultural Research Service (ARS) has recently reported several long-term studies to identify factors that affect pesticide levels in the Chesapeake Bay region airshed (USDA-ARS, 2011). In one study, USDA-ARS has determined that pesticide volatilization is highly dependent upon exposure of disturbed unconsolidated soils and variability in measured compound levels is correlated with temperature and wind conditions. In another ARS study, moisture in dew and soils in higher temperature regimes was found to substantially increase volatilization rates (USDA-ARS, 2011).

Pesticide spraying may impact air quality from drift and diffusion. Drift is defined by EPA as "the movement of pesticide through air at the time of application or soon thereafter, to any site other than that intended for application" (US-EPA, 2000). Diffusion is gaseous transformation to the atmosphere (FOCUS, 2008). Factors affecting pesticide drift and diffusion include application equipment and method, weather conditions, topography, and the type of crop being sprayed (US-EPA, 2000). EPA's Office of Pesticide Programs (OPP) encourages pesticide applicators to use all feasible means available to them to minimize off-target drift, and most pesticides where drift is an acknowledged risk include label use restrictions intended to minimize off-target drift (see e.g.Micro Flo Company, 2012). The Agency has introduced several initiatives to help address and prevent the problems associated with drift. Currently, EPA is evaluating new regulations for pesticide drift labeling and the identification of best management practices to control such drift, as well as identifying scientific issues surrounding field volatility of conventional pesticides (US-EPA, 2009b). Additionally, EPA OPP and its Office of Research and Development are developing a new voluntary program, the Drift Reduction Technology (DRT) Program, which encourages the development, marketing and use of application technologies verified to substantially reduce spray drift (US-EPA, 2009b).

Traditional agricultural practices have the potential to cause negative impacts to air quality. Agricultural emission sources include smoke from agricultural burning, tillage, heavy equipment emissions, pesticide drift from spraying, indirect emissions of carbon dioxide and nitrous oxide, the degradation of organic materials in the soil, and from the use of nitrogen fertilizer (USDA-NRCS, 2006a; Aneja et al., 2009).

4.4.1.4 No Action Alternative - Climate Change

Soil nitrogen sequestration and emissions are affected by multiple field conditions, including soil temperature, soil moisture, fertilization, production of nitrogen fixing crops (e.g. soybeans and other legumes), retention of crop residues in the soil and decomposition of soil organic matter and plant litter (US-EPA, 2012a).

Agriculture, including land-use changes associated with farming, is responsible for an estimated 6% of all human-induced GHG emissions in the U.S. (US-EPA, 2012a). Agriculture-related GHG emissions include CO_2, N_2O, and CH_4, produced through the combustion of fossil fuels to run farm equipment; the use of fertilizers; or the decomposition of agricultural waste products, including crop residues, animal wastes, and enteric emissions from livestock. N_2O emissions from agricultural soil management (primarily nitrogen-based fertilizer use) represent 68% of all U.S. N_2O emissions (US-EPA, 2012a).

4.4.2 Preferred Alternative – Physical Environment

Because the regulatory decision on the petition for nonregulated status of BASF CV127 Soybean will not change the availability of soybean varieties or the agronomic practices associated with the available soybean varieties, there will be no change to soil quality, water quality or resources, air quality, or factors influencing climate change under the preferred alternative when compared to the no action alternative. Herbicide use in the U.S. is limited to those applications described on the label. This soybean is engineered to be resistant to an herbicide that is not labeled for use on soybeans in the U.S. and no application is pending or planned to change that situation. Therefore, if these soybeans were acquired by a U.S. grower, they would be cultivated in the same way as currently available varieties. Because the effects on these resources result from the agronomic practices and these are same the under the No Action and the Preferred Alternative, there is no change to soil quality, water resources, air quality, or factors influencing climate change associated with this decision.

4.5 BIOLOGICAL RESOURCES

4.5.1 No Action Alternative – Biological Resources

4.5.1.1 No Action Alternative - Animal Communities

Animal communities in this discussion include wildlife species and their habitats. Wildlife refers to both native and introduced species of mammals, birds, amphibians, reptiles, invertebrates, and fish/shellfish. Agriculture dominates human uses of land (Robertson and Swinton, 2005). In 2011, 917 million acres (approximately 47%) of the contiguous 48 states were devoted to farming, including: crop production, pasture, rangeland, Conservation Reserve Program, Wetlands Reserve Program, or other government program uses (Senseman, 2007; USDA-NASS, 2012e). How these lands are maintained influences the function and integrity of ecosystems and the wildlife populations that they support.

A wide array of wildlife species occur within the 31 major soybean-producing U.S. states. During the spring and summer months, soybean fields provide browse for rabbits, deer, rodents, other mammals; birds such as upland gamebirds, while also providing a forage base for insects (Palmer et al., No Date). During the winter months, leftover and unharvested soybeans provide a food-source for wildlife; however, soybeans are poorly suited for meeting nutrient needs of wildlife, such as waterfowl, that require a high-energy diet (Krapu et al., 2004).

Shifts from conventional agricultural practices to conservation tillage and no-till practices has benefitted wildlife through improved water quality, availability of waste grain, retention of cover in fields, and increased populations of invertebrates (Brady, 2007; Sharpe, 2010). Conservation tillage practices that leave greater amounts of crop residue serve to increase the diversity and density of birds and mammals (USDA-NRCS, 1999). Increased residue also provides habitat for insects and other arthropods, consequently increasing this food source for insect predators. Insects are important during the spring and summer brood rearing season for many upland game birds and other birds, as they provide a protein-rich diet to fast growing young, as well as a nutrient-rich diet for migratory birds (USDA-NRCS, 2003).

Insects and other invertebrates can be beneficial to soybean production, providing services such as nutrient cycling and preying on plant pests. Conversely, there are many insects and invertebrates that are detrimental to soybean crops, including: bean leaf beetle (*Cerotoma trifurcata*); beet armyworm (*Spodoptera exigua*); blister beetle (*Epicauta* spp.); corn earworm (*Helicoverpa zea*); grasshopper (*Acrididae* spp.); green cloverworm (*Hypena scabra*); seed corn beetle (*Stenolophus lecontei*); seedcorn maggot (*Delia platura*); soybean aphid (*Aphis glycines*); soybean looper (*Pseudoplusia includens*); soybean stem borer (*Dectes texanus*); spider mites (*Tetranychus urticae*); stink bug (green [*Acrosternum hiliare*]; brown [*Euschistus* spp.]); and velvetbean caterpillar (*Anticarsia gemmatalis*) (Whitworth et al., 2011; Palmer et al., No Date). While insects are considered less problematic than weeds in U.S. soybean production, insect injury can impact yield, plant maturity, and seed quality. Consequently, insect pests are managed during the growth and development of soybean to enhance soybean yield (Higley, 1994; Aref and Pike, 1998).

Under FIFRA, all pesticides, (which is inclusive of herbicides) sold or distributed in the U.S. must be registered by the EPA (US-EPA, 2005b). Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to the environment, including wildlife. All pesticides registered prior to November 1, 1984 must also be reregistered to ensure that they meet the current, more stringent standards. During the registration decision, the EPA must find that a pesticide does not cause unreasonable adverse effects to the environment if used in accordance with the approved label instructions (OSTP, 2001). Additionally, growers must adhere to EPA label use restrictions for herbicides and pesticides. These measures help to minimize potential impacts of their use on non-target wildlife species. EPA is currently evaluating new regulations for pesticide drift labeling and the identification of best management practices to control such drift (US-EPA, 2009b), as well as identifying scientific issues surrounding field volatility of conventional pesticides (US-EPA, 2010b).

4.5.1.2 No Action Alternative - Plant Communities

Soybeans are grown in 31 states (USDA-NASS, 2012a), encompassing a wide range of physiographic regions, ecosystems, and climatic zones. The types of vegetation, including the variety of weeds, within and adjacent to soybean fields can vary greatly, depending on the geographic area in which the field occurs. Non-crop vegetation in soybean fields is limited by the extensive cultivation and weed control programs practiced by soybean producers. Plant communities bordering soybean fields can range from forests and woodlands to grasslands, aquatic habitats, or residential areas. Adjacent crops frequently include other soybean varieties, corn, cotton, or other crops.

Weeds are classified as annuals or perennials. An annual is a plant that completes its lifecycle in one year or less and reproduces only by seed. Perennials are plants that live for more than two years. Weeds are also classified as broadleaf (dicots) or grass (monocots). Weeds can reproduce by seeds, rhizomes (underground creeping stems), or other underground parts. Annual grass and broadleaf weeds are considered the most common weed problems in soybeans (Krausz et al., 2001); however, with increased rates of conservation tillage, increases in perennial, biennial, and winter annual weed species are being observed (Durgan and Gunsolus, 2003) (Green and Martin, 1996). Some troublesome weeds of soybean include common lambsquarter (*Chenopodium album*), morning glory species (*Ipomoea* spp.), velvetleaf (*Abutilon theophrasti*), pigweed, (*Amaranthus* spp.), common cocklebur (*Xanthium strumarium*), foxtail (*Setaria* spp.), ragweed species (*Ambrosia* spp.), crabgrass (*Digitaria* spp.), barynyard grass (*Echinochloa crus-galli*), Johnsongrass (*Sorghum halepense*), and thistle (*Cirsium* spp.). Recent surveys of U.S. agronomic crop producers suggest that pigweed species, Johnsongrass, foxtail species, and velvetleaf are among the most problematic weeds (Heatherly et al., 2009).

An important concept in weed control is the seed bank, which is the reservoir of seeds that are in the soil and have the potential to germinate. Agricultural soils contain reservoirs of weed seeds ranging from 4,100 to 137,700 seeds per square meter of soil (May and Wilson, 2006). Climate, soil characteristics, cultivation, crop selection, and weed management practices affect the seed bank composition and size (May and Wilson, 2006).

Herbicide resistance is described by the Weed Science Society of America as the "inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type" (WSSA, 2011). The first reports of weed resistance to herbicides were in the 1950s (WSSA, 2011). Individual plants within a species can exhibit different responses to the same herbicide rate. Initially, herbicide rates are set to work effectively on the majority of the weed population under normal growing conditions. Genetic variability, including herbicide resistance, is exhibited naturally in normal weed populations, although at very low frequencies. When only one herbicide is used year after year as the primary means of weed control, the number of weeds resistant to that herbicide compared to those susceptible to the herbicide may change as the surviving resistant weeds reproduce. With no change in weed control strategies, in time, the weed population may be composed of more and more resistant weeds (WSSA, 2011).

The evolution of herbicide-resistant weeds has required that growers diversify weed management practices and use combinations of herbicides, tillage practices, and herbicide-resistant traits. Integrated weed management programs that use herbicides from different groups, vary cropping systems, rotate crops, and that use mechanical as well as chemical weed control methods, will delay or prevent the selection of herbicide-resistant weed populations (Gunsolus, 2002; Sellers et al., 2011).

Runoff, spray drift, and volatilization of herbicides have the potential to impact non-target plant communities growing in proximity to fields in which herbicides are used. The extent of damage to nontarget plants exposed to herbicides is determined by the overall vigor of the affected plant, the amount and type of herbicide to which the plant is exposed, and the growing conditions after contact (Ruhl et al., 2008).

The total rainfall the first few days after herbicide application can influence the amounts of leaching and runoff; however, it has been estimated that even after heavy rains, herbicide losses to runoff generally do not exceed 5- to 10% of the total applied (Tu et al., 2001; USDA-FS, 2009). Planted vegetation, such as grass buffer strips, or crop residues can effectively reduce runoff (IPPC, 2010). Volatilization typically occurs during application, but herbicides deposited on plants or soil can also volatilize. Most of the herbicides considered highly volatile are no longer used (Tu et al., 2001).

Spray drift is a concern for non-target susceptible plants growing adjacent to fields when herbicides are used in the production of soybeans. This potential impact relates to exposure of non-target susceptible plants to the off-target herbicide drift (US-EPA, 2010b). Damage from spray drift typically occurs at field edges or at shelterbelts (i.e., windbreaks), but highly volatile herbicides may drift further from a field. The risk of off-target herbicide drift is recognized by the EPA, which has incorporated both equipment and management restrictions to address drift in the EPA-approved herbicide labels. These EPA label restrictions include requirements that the grower manage droplet size, spray boom height above the crop canopy, restricted applications under certain wind speeds and environmental conditions, and using drift control agents (US-EPA, 2010b).

Volunteer soybean is not a widespread problem, and when they occur, it is most often in parts of the Delta and the southeastern U.S. In production systems where soybean is rotated, such as corn or cotton, it has shown up as a volunteer weed, yet was not generally seen as a serious problem by farmers (Owen and Zelaya, 2005). Volunteer soybean is not considered difficult to manage, as soybean seeds rarely remain viable the following season and any interference they may pose to subsequent crops are minimal; furthermore, herbicides usually used for weed control in corn are also effective at controlling volunteer soybean (Owen and Zelaya, 2005).

The potential for cross-pollination between soybean varieties is limited. Soybeans are highly self-pollinating (Ahrent and Caviness, 1994), and the frequency of natural cross pollination between varieties grown near to each other has been found to range from 0.0% to 0.5%, when row distances ranged from 1m to 10 m (OECD, 2000; Abud et al., 2003; Abud et al.).

4.5.1.3 No Action Alternative - Soil Microorganisms

Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva et al., 2004). They also suppress soil-borne plant diseases and promote plant growth (Doran et al., 1996). Estimates of the number of bacterial species that may be found in a gram of soil range from 6,000 to 50,000 (Curtis et al., 2002). In a study of soil suppressive to *Rhizoctonia solani*, a fungal pathogen in crops such as potatoes, sugar beets, and rice, (Mendes et al. (2011) found that over 33,000 prokaryotic[1] species were present in the rhizosphere. The soil microbial community include nitrogen-fixing microbes such as the soybean mutualist *B. japonicum*, mycorrhizal fungi, and free-living bacteria[2]; bacteria, actinomycetes (filamentous bacteria), and saprophytic fungi responsible for decomposition; denitrifying bacteria and fungi; phosphorus-solubilizing bacteria and fungi; as well as pathogenic and parasitic microbes (USDA-NRCS, 2004).

The main factors affecting microbial population size and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) and cropping history (Garbeva et al., 2004; Garbeva et al., 2008). Some types of soil micro-organisms share metabolic pathways with plants, and might be affected by herbicides. Tillage disrupts multicellular relationships among microorganisms, and crop rotation changes soil conditions in ways that favor different microbial communities.

Plant roots, including those of soybean, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere (root zone). Microbial diversity in the rhizosphere may be extensive and differs from the microbial community in the bulk soil (Garbeva et al., 2004). The following briefly focuses on the soybean, GE crops, and herbicide use factors with the potential to affect microbial population size and diversity.

Soybeans

An important group of soil microorganisms associated with legumes, including soybean, are the mutualists. These include mycorrhizal fungi, nitrogen-fixing bacteria, and some free-living microbes that have co-evolved with plants that supply nutrients to and obtain food from their

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[1] Prokaryotes are, for the most part, single celled organisms that lack a nucleus or other membrane-bound organelles and include bacteria and archaea.

[2] Organisms that are able to obtain food without the need for a host organism.

plant hosts (USDA-NRCS, 2004). Legumes have developed symbiotic relationships with specific nitrogen-fixing bacteria in the family *Rhizobiaceae* that induce the formation of root nodules where bacteria may carry out the reduction of atmospheric nitrogen into ammonia (NH_3) that is usable by the plant (Gage, 2004). *Bradyrhizobium japonicum* is the rhizobium bacteria specifically associated with soybeans (Franzen, 1999). Since neither soybean nor *B. japonicum* is native to North America, if a field has not been planted with soybean within three to five years, either the seed or seed zone must be inoculated with *B. japonicum* prior to soybean planting (Berglund and Helms, 2003; Pedersen, 2007).

In addition to beneficial microorganisms, there are also several microbial pathogens that cause disease in soybean and vary somewhat depending on the region. These include fungal pathogens such as Rhizoctonia Stem Rot (*Rhizoctonia solani*), Brown Stem Rot (*Phialophora gregata*), Sudden Death Syndrome (*Fusarium solani* race A), and Charcoal Root Rot (*Macrophomina phaseolina*); bacterial pathogens Bacterial Blight (*Pseudomonas syringae*) and Bacterial Pustule (*Xanthomonas campestri*); and viral pathogens Soybean Mosaic Virus and the Tobacco Ringspot Virus (Ruhl, 2007; SSDW, No Date). The Soybean Cyst Nematode (*Heterodera glycines*) is a microscopic parasite that infects the roots of soybeans. Management to control disease outbreaks varies by region, and pathogen, and parasite, but include common practices such as crop rotation, weed control, planting resistant cultivars, and proper planting and tillage practices.

Herbicides

Herbicides have a wide variety of formulations, constituents, and recommended uses and concentrations that play a role in how herbicides affect microorganism communities. Understanding and quantifying the effects of their use is further compounded by differences in environment factors, including the main factors affecting microbial population size and diversity. As mentioned previously, some types of soil microorganisms share metabolic pathways with plants, and might be negatively affected by herbicides. Alternatively, many microorganisms feed on herbicides or produce enzymes that break-down herbicides (Tu et al., 2001; Haney et al., 2002; Araujo et al., 2003; Senseman, 2007; US-EPA, 2008b). This microorganism activity is instrumental to herbicide degradation in the soil. As a result, herbicides have both positive and negative effects on microorganism groups that may increase the population of some while reducing the population of others.

4.5.1.4 No Action Alternative - Biological Diversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson, 1988). Biodiversity provides valuable genetic resources for crop improvement (Harlan, 1975) and also provides other functions beyond food, fiber, fuel, and income. These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 1999). The loss of biodiversity can result in a need for costly management practices in order to provide these functions to the crop (Altieri, 1999).

The degree of biodiversity in an agroecosystem depends on four primary characteristics: (1) diversity of vegetation within and around the agroecosystem; (2) permanence of various crops within the system; (3) intensity of management; and (4) extent of isolation of the agroecosystem from natural vegetation (Altieri, 1999). Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas. Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvesting limit the diversity of plants and animals (Lovett et al., 2003).

Biodiversity can be maintained or reintroduced into agroecosystems through the use of woodlots, fencerows, hedgerows, and wetlands. Agronomic practices that may be employed to support biodiversity include intercropping (the planting of two or more crops simultaneously to occupy the same field), agroforestry, crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically for the purpose of incorporating it into the soil in order to provide nutrients and organic matter), addition of organic matter (compost, green manure, animal manure, etc.), and hedgerows and windbreaks (Altieri, 1999). Integrated pest management strategies include several practices that increase biodiversity such as retaining small, diverse natural plant refuges and minimal management of field borders.

The potential impacts to biodiversity associated with the agricultural production of crops include a loss of diversity, which can occur at the crop, farm, and/or landscape level (Visser, 1998; Ammann, 2005; Carpenter, 2011). In this EA, crop diversity refers to the genetic uniformity within crops, farm-scale diversity refers to the level of complexity of organisms within the boundaries of a farm, and landscape level diversity refers to potential changes in land use and the impacts of area-wide weed suppression beyond the farm boundaries (Carpenter, 2011).

Crop Diversity

Genetic diversity in crops is beneficial as it may improve yields, pest and disease resistance, and quality in agricultural systems, and that greater varietal and species diversity enable growers to maintain productivity over a wide range of conditions (Krishna et al., 2009). There is concern that the adoption of GE technology potentially reduces grower-demand for crop genetic diversity because breeding programs could concentrate on a smaller number of high value cultivars, which could reduce the availability of, and demand for, non-GE varieties (Carpenter, 2011). In contrast, several studies involving GE soybeans and cotton have found this not to be the case, indicating the introduction of GE crops has not decreased crop species diversity (Ammann, 2005; Carpenter, 2011).

Concern for the loss of genetic variability has led to the establishment of a worldwide network of genebanks (van de Wouw et al., 2010). The USDA Soybean Germplasm Collection, which is part of the National Plant Germplasm System, acquires, maintains, and evaluates soybean germplasm and distributes seed samples to scientists in 35 states (University of Illinois, 2003). Nationwide, there are over 23,190 soybean varieties (USDA-ARS, 2013) that provide a vast reservoir of genetic diversity for crop development.

Farm-scale Diversity

As noted previously, agricultural practices have the potential to impact diversity at the farm level by affecting a farm’s biota, including birds, wildlife, invertebrates, soil microorganisms, and weed populations. For example, an increase in adoption of conservation tillage practices is associated with the use of GE herbicide-resistant crops (Givens et al., 2009). Less tillage provides more wildlife habitat by allowing other plants to establish between crop rows in either stubble or weeds. Conservation tillage also leaves a higher rate of plant residue and increases soil organic matter (Hussain et al., 1999), which benefit soil biota by providing additional food sources (energy) (USDA-NRCS, 1996) and increase the diversity of soil microorganisms, as discussed in Subsection 4.5.1, Biological Resources, No Action Alternative – Soil Microorganisms. In addition, invertebrates that feed on plant detritus and their predators and, in turn, birds and other wildlife that prey on them, may benefit from increased conservation tillage practices (Towery and Werblow, 2010; Carpenter, 2011). Ground-nesting and seed-eating birds, in particular, have been found to benefit from greater food and cover associated with conservation tillage (SOWAP, 2007).

Herbicide use in agricultural fields may impact biodiversity by decreasing weed quantities or causing a shift in weed species present in the field, which would affect those insects, birds, and mammals that feed on or find shelter in these weeds. The quantity and type of herbicide use associated with conventional and GE crops is dependent on many variables, including cropping systems, type and abundance of weeds, production practices, and individual grower decisions.

Landscape-scale Diversity

The greatest direct impact of agriculture on biodiversity on the landscape scale results from the loss of natural habitats caused by the conversion of natural ecosystems into agricultural land (Ammann, 2005). Increases in crop yields, such as has been observed in the last 10 years in soybean production, have the potential to reduce impacts to biodiversity by allowing less land to be converted to agriculture than would otherwise be necessary (Carpenter, 2011); however, substantial gains in yields have generally not been obtained by herbicide-resistant cultivars unless higher yielding cultivars are modified with an herbicide-resistant trait (NRC, 2010).

Similar to that discussed in farm-scale diversity, the use of herbicides at the landscape-level also has the potential to impact biodiversity. Increased conservation tillage practices associated with herbicide-resistant crops over large areas may increase certain populations of invertebrates and wildlife that benefit from conservation tillage, whereas those species dependent on the targeted weeds may be negatively impacted. Potential impacts to landscape-scale diversity can also be related to the effects of herbicides on non-target plant and animal species.

Several recent studies (Hartzler, 2010; Brower et al., 2012; Pleasants and Oberhauser, 2012) have examined the potential causes of observed decreases in overwintering monarch butterfly (*Danaus plexippus*) populations, namely the reduced infestations of common milkweed (*Asclepias syriaca*), a perennial weed, in Corn Belt agricultural fields. The loss of host milkweed plants in agricultural fields is assumed to be a result of the increased use of glyphosate associated with the high adoption rate of GE crops (Brower et al., 2012), although slight declines in milkweed abundance in non-agricultural areas not related to glyphosate use were also observed. However, it was concluded that the observed reduced monarch abundance is likely based on several contributing factors including: degradation of the forest in the overwintering areas; the loss of breeding habitat (i.e., milkweed host plants) in the U.S., resulting from the use of herbicide associated with the expansion of GE herbicide-resistant crop acreage and from continued land development; and severe weather (Hartzler, 2010; Brower et al., 2012; Pleasants and Oberhauser, 2012).

While herbicide use potentially affects biodiversity, the application of pesticides in accordance with EPA-registered label uses and careful management of chemical spray drift minimizes the potential biodiversity impacts from their use.

4.5.2 Preferred Alternative – Biological Resources

Because the regulatory decision on the petition for nonregulated status of BASF CV127 Soybean will not change the availability of soybean varieties or the agronomic practices associated with these soybean varieties, there will be no change to biological resources when compared to the No Action Alternative. Herbicide use in the U.S. is limited to those applications described on the EPA-approved labels. This soybean is engineered to be resistant to an herbicide that is not been approved by the EPA for use on soybeans and no application is pending or planned. Therefore, if these soybeans were acquired by a U.S. grower, they would be cultivated in the same way as currently available varieties. Because the effects on these resources result from the agronomic practices and these are same under the no action and the preferred alternative, there is no change to animal or plant communities, microorganisms, or biological diversity associated with this decision.

The AtAHAS protein associated with the GE modification of this variety is derived from *Arabidopsis thaliana*, and the AHAS proteins are ubiquitous in plants, thus animals are routinely exposed to this protein (BASF, 2011; BASF, 2012). The AHAS proteins are not known to be toxic or allergenic, and have a long history of safe consumption in food and feed products from many different Clearfield® crops that contain these proteins (BASF, 2011).

BASF has presented the results of analytic studies comparing the AtAHAS protein with the AHAS proteins found in the Clearfield® varieties, and has found no functional differences in structure or function (BASF, 2011). BASF has presented evidence that these proteins do not differ in their digestibility, toxicity and allergenicity (BASF, 2011; BASF, 2012). The introduced genetic material does not result in the production of novel proteins, enzymes, or metabolites in the plant that are known to have toxic properties (USDA-APHIS, 2012). Moreover, BASF has also presented the results of a feeding study in which mice were fed very high doses of AtAHAS protein, with no toxic effects (BASF, 2011; BASF). Therefore, consumption of CV127 soybeans by animals in the field will not affect animals differently than the consumption of soybeans under the No Action Alternative.

EPA has responsibility to regulate the use of pesticides (herbicides) that may be used on 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 feed crop. EPA undertakes this analysis under the authority of the FFDCA, and must conclude that such tolerances will be safe, meaning that there is a reasonable certainty that no harm to human health will result from the use of the pesticide.

5 CUMULATIVE IMPACTS

5.1 ASSUMPTIONS USED FOR CUMULATIVE IMPACTS ANALYSIS

Cumulative effects have been analyzed for each environmental issue assessed in Section 4, Environmental Consequences. The cumulative effects analysis is focused on the incremental impacts of the Preferred Alternative taken in consideration with related activities including past, present, and reasonably foreseeable future actions. In this analysis, if there are no direct or indirect impacts identified for a resource area, then APHIS assumes there can be no cumulative impacts. Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential cumulative impacts. APHIS considered the potential for BASF CV127 Soybean to extend the range of soybean production and affect the conversion of land to agricultural purposes. BASF's studies demonstrate BASF CV127 Soybean is similar in its growth habit, agronomic properties, disease susceptibility to other nonregulated varieties of soybean (BASF, 2011; USDA-APHIS, 2012). This implies that its cultural requirements would neither differ from those of other soybeans nor change the areas in which soybeans are currently cultivated. BASF does not intend to market this soybean in the U.S. so it is not likely to be available to growers. As such, land use changes associated with approving the petition for nonregulated status to BASF CV127 Soybean is not expected to influence the use of current soybean cultivars. Therefore, although the preferred alternative would allow for new plantings of BASF CV127 Soybean to occur anywhere in the U.S., actual planting would likely be limited to breeding plots or production of seed for planting in the target market. Because imazypyr and imazapic are not labeled for use on soybeans and there is no label pending, any BASF CV127 Soybeans grown in the U.S. could not be cultivated using these herbicides even though the plants are resistant to the herbicides.

5.2 PAST AND PRESENT ACTIONS

In the preceding analysis, the potential impacts from approving the petition for nonregulated status to BASF CV127 Soybean were assessed. The potential impacts under the Preferred Alternative for all the resource areas analyzed were the same as those described for the No-action Alternative.

The Preferred Alternative is not expected to directly cause a measurable change in agricultural acreage or area devoted to conventional or GE-soybean cultivation or soybean grown for seed in the U.S. The majority of soybean grown in the U.S. is GE and herbicide resistant. Because BASF CV127 Soybean will not be marketed in the U.S. it will not affect current soybean planting, management practices, or cultivation.

Based upon recent trends, adding GE varieties to the market is not related to the ability of organic production systems to maintain their market share. As described above, the majority of soybean is herbicide resistant. Since 1993, 11 GE soybean events or lines have been determined by APHIS to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA(USDA-APHIS, 2013). U.S. organic soybean production acreage is less than 100,000 acres (USDA-ERS, 2010). Approving the petition for BASF CV127 Soybean is not expected to impact the organic production of soybean. It is not likely to be grown extensively in the U.S. and the majority of the soy in the U.S. is GE.

Approving the petition for a determination of nonregulated status to BASF CV127 Soybean is not expected to result in changes to current soybean cropping practices. Studies conducted by BASF demonstrate that, in terms of agronomic characteristics and cultivation practices, BASF CV127 Soybean is similar to other soybean varieties currently grown (BASF, 2011; USDA-APHIS, 2012). Consequently, no changes to current soybean cropping practices such as tillage, crop rotation, or agricultural inputs associated with the adoption of BASF CV127 Soybean are expected if it were to be grown in the U.S.

Approving the petition for a determination of nonregulated status to BASF CV127 Soybean would have the same impacts to water, soil, air quality, and climate change as the no action alternative. Agronomic practices that have the potential to impact soil, water and air quality, and climate change such as tillage, agricultural inputs (fertilizers and pesticides), and irrigation would not change because BASF CV127 Soybean is agronomically similar to other soybeans and the herbicides (imazapyr and imazapic) to which it is resistant are not labeled for use on the plant in the U.S. (BASF, 2011; BASF, 2012).

The impacts of the Preferred Alternative to animal and plants communities, microorganisms, and biodiversity would be no different than that experienced under the No-action Alternative. BASF CV127 Soybean is both agronomically and compositionally similar to other soybean. Thus, it would not require any different agronomic practices to cultivate, and does not represent a weediness risk that is any different from other currently available soybean. Availability of BASF CV127 Soybean would not impact the development of herbicide resistant weeds or the trend to broaden weed management tactics to affect control over herbicide resistant weeds, as it was not developed to be marketed in the U.S. (BASF, 2011; BASF, 2012).

There are no differences in the potential for gene flow and weediness under the Preferred Action Alternative. Outcrossing and weediness are addressed in the PPRA (USDA-APHIS, 2012). BASF CV127 Soybean is similar to other soybean varieties. The risk of gene flow and weediness of BASF CV127 Soybean is no greater than that of other soybeans.

Food and feed derived from GE soybean must be in compliance with all applicable legal and regulatory requirements and may undergo a voluntary consultation process with the FDA prior to release onto the market to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food. BASF CV127 Soybean is expected to have no toxic effect to human health or livestock. 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. No change in food and feed safety is expected to occur under the Preferred Alternative.

BASF CV127 Soybean is not expected to affect the seed, feed, and food trade BASF CV127 soybeans. BASF CV127 Soybean does not require different agricultural management practices or agronomic inputs than from conventional soybean (BASF, 2011; BASF, 2012) . These agronomic and management similarities strongly suggest that coexistence strategies already adopted to protect and preserve soybean varietal integrity in the marketplace will not be required to change to accommodate the cultivation of BASF CV127 Soybean.

In summary, the potential cumulative effects regarding past and present actions combined with the Preferred Alternative have been analyzed, and no changes from the current baseline under the No-action Alternative would occur.

5.3 REASONABLY FORESEEABLE ACTIONS

BASF has stated in the petition that it does not intend to commercialize BASF CV127 Soybean in the U.S. (BASF, 2011; BASF, 2012). Under the preferred alternative, APHIS assumes that growers could plant BASF CV127 soybeans, if they were available. Growers could use any management practices that are suitable for the production of soy. Growers could use EPA registered herbicides on these soybeans. However, growers could not use imazapyr because it is not labeled for use on soybeans, and there is no label for use pending. According to the developer, there is a very small market in the U.S.; the projected market would not support the cost associated with pursuing the change in EPA registration (BASF, 2011).

It is likely that BASF CV127 Soybean will be adopted by growers in Brazil and Argentina. As discussed in Section 4.2.1 - Socioeconomic - No Action Alternative: Soybean Imports and Exports, BASF has submitted applications to several countries where this crop could be cultivated or consumed as food or feed. The U.S. imports about 6% of its imported soybeans from South America, mainly from Argentina, and therefore it is possible that BASF CV127 could be imported into the U.S. 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).

As described in Section 4 – Environmental Consequences, the potential for impacts of BASF CV127 Soybean would not result in any changes to the resources areas when compared to the No Action Alternative. No cumulative effects are expected from approving the petition for nonregulated status for BASF CV127 Soybean, when taken in consideration with related activities, including past, present, and reasonably foreseeable future actions.

6 THREATENED AND ENDANGERED SPECIES

6.1 USDA-APHIS' APPROACH TO EVALUATION OF POTENTIAL IMPACTS TO THREATENED AND ENDANGERED SPECIES

Congress passed the Endangered Species Act (ESA) of 1973, as amended, to prevent extinctions facing many species of fish, wildlife, and plants. The purpose of the ESA is to conserve threatened and endangered species (TES) and the ecosystems on which they depend as key components of America's heritage. To implement the ESA, the U.S. Fish and Wildlife Service (US-FWS) works in cooperation with the National Marine Fisheries Service (NMFS); other Federal, State, and local agencies; Tribes; non-governmental organizations; and private citizens. Before a plant or animal species can receive the protection provided by the ESA, it must first be added to the Federal list of threatened and endangered wildlife and plants.

A species is added to the list when it is determined by the US-FWS/NMFS to be endangered or threatened because of any of the following factors:

- The present or threatened destruction, modification, or curtailment of its habitat or range;
- Overutilization for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms; and
- The natural or manmade factors affecting its survival.

Once an animal or plant is added to the list, in accordance with the ESA, protective measures apply to the species and its habitat. These measures include protection from adverse effects of Federal activities.

Section 7 (a) (2) of the ESA requires that Federal agencies, in consultation with US-FWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the US-FWS and/or NMFS if it is determined that the action "may affect" listed species or critical habitat. To facilitate USDA-APHIS' ESA consultation process, USDA-APHIS met with the US-FWS from 1999 to 2003 to discuss factors relevant to USDA-APHIS's regulatory authority and effects analysis for petitions for nonregulated status, and developed a process for conducting an effects determination consistent with the PPA (Title IV of Public Law 106-224). USDA-APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

USDA-APHIS' regulatory authority over GE organisms under the PPA is limited to those GE organisms for which it has reason to believe might be a plant pest or those for which USDA-APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk (7 CFR §340.1). USDA-APHIS does not have authority to regulate the use of any herbicide, including imidazolinone herbicides. After completing a PPRA, if USDA-

APHIS determines that BASF CV127 Soybean does not pose a plant pest risk, then BASF CV127 Soybean would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR §340, and therefore, USDA-APHIS must reach a determination that the article is no longer regulated. As part of its EA analysis, USDA-APHIS is analyzing 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 reviews the genetically engineered product information and data related to the organism (generally a plant species, but also may be other genetically engineered organisms). As described in Appendix D, for each transgene/transgenic plant, USDA-APHIS considers the following:

- Reviews of the biology and taxonomy of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- Location(s) of the new transgene and its products (if any) produced in the plant and their quantity;
- Reviews of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Concentrations of any known plant toxicants, if applicable;
- Sexual compatibility of the transgenic plant with any threatened or endangered species (TES) of plants or a host of any TES; and
- Any other information that may inform the potential for an organism to pose a plant pest risk.

As noted in Subsection 1.2 – Purpose of Product, BASF has developed this product to provide growers in Brazil and Argentina with an alternative herbicide-resistant soybean product. As noted in Section 4 – Environmental Consequences and elsewhere in this EA, it is highly unlikely that BASF CV127 Soybean will be commercially cultivated in the U.S. Despite this expectation, USDA-APHIS presents the following analysis of the potential impacts of TES in the unlikely event that BASF CV127 Soybean is cultivated in a very limited commercial setting.

6.2 SCOPE OF APHIS' EFFECTS ANALYSIS OF THE CULTIVATION OF BASF CV127 SOYBEAN ON TES

In following its review process, USDA-APHIS, as described below, has evaluated the potential effects that approval of the petition for nonregulated status of BASF CV127 Soybean plants may have, if any, on Federally-listed TES and species proposed for listing, as well as designated critical habitat and habitat proposed for designation.

Studies performed by BASF demonstrate that agronomic characteristics and cultivation practices required for BASF CV127 Soybean are essentially indistinguishable from practices used to grow other soybean varieties, including other herbicide-resistant varieties (BASF, 2011; USDA-APHIS, 2012; BASF, 2012).

As discussed in Subsection 4.1 – Scope of the Environmental Analysis, commercial cultivation of BASF CV127 Soybean in the U.S. is expected to be very limited. If cultivated at all, BASF

CV127 Soybean will likely only be cultivated in controlled small research and development plots and small off-season seed cultivation (BASF, 2011). As discussed in Subsection 4.2.2 – Preferred Alternative - Areas and Acreage of Soybean Production, USDA-APHIS has determined BASF CV127 Soybean to be unlikely to extend the range of soybean production, and new acreage is not expected to be developed to accommodate the cultivation of BASF CV127 Soybean. In addition, BASF CV127 Soybean is not expected to replace other varieties of soybean currently cultivated (BASF, 2011; BASF, 2012).

USDA-APHIS met with US-FWS officials on June 15, 2011 to discuss whether USDA-APHIS has any obligations under the ESA regarding analyzing the impacts of herbicide use associated with all GE crops on TES. As a result of these joint discussions, US-FWS and USDA-APHIS have agreed that it is not necessary for USDA-APHIS to perform an ESA effects analysis on herbicide use associated with GE crops because US-EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under the FIFRA. USDA-APHIS has no statutory authority to authorize or regulate the use of imidazolinone herbicides, or any other herbicide, by soybean growers. Under USDA-APHIS' current CFR Part 340 regulations, USDA-APHIS only has the authority to regulate BASF CV127 Soybean or any GE organism as long as USDA-APHIS believes it may pose a plant pest risk. For GE organisms, USDA-APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of herbicides or other pesticides on those organisms. As stated in Section 5 – Cumulative Impacts - because imazypyr and imazapic are not labeled for use on soybeans, any BASF CV127 Soybeans grown in the U.S. could not be cultivated using these herbicides even though the plants are resistant to the herbicides. Moreover, BASF has no intention of seeking a label amendment to provide for the application of these herbicides to BASF CV127 Soybean (BASF, 2011). If in the future BASF or others decided to seek a label amendment, US-EPA would evaluate the request under their Endangered Species Pesticide Program (http://www.epa.gov/oppfead1/endanger/basic-info.htm). Under the program, if it is determined that the action may affect TES or critical habitat, the US-EPA would consult with US-FWS and/or the NMFS as required by Section 7 of the ESA.

USDA-APHIS obtained and reviewed the US-FWS list of TES species (listed and proposed). The source for USDA-APHIS' review was the US-FWS Environmental Conservation Online System (US-FWS, 2013).

USDA-APHIS focused its TES effects analysis on the implications of exposure to the AHAS protein and csr1-2 gene in soybean, the interaction between TES and the BASF CV127 Soybean plant including potential for sexual compatibility, and ability to serve as a host for a TES.

6.3 POTENTIAL EFFECTS OF BASF CV127 SOYBEAN ON TES

BASF CV127 Soybean is not sexually compatible with any listed TES plant species or plant proposed for listing; none of these listed plants are in the same genus nor are known to cross pollinate with species of the genus *Glycine*.

USDA-APHIS considered the possibility that BASF CV127 Soybean could serve as a host plant for a TES species. A review of the species list reveals that there are no members of the genus *Glycine* that serve as a host plant for any TES.

BASF has presented data evaluating the agronomic and morphological characteristics of BASF CV127 Soybean, as well as compositional and nutritional characteristics, and safety evaluations and toxicity tests, comparing the product to a nontransgenic isoline control (BASF, 2011; BASF, 2012). Compositional elements compared included moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and anti-nutrients (BASF, 2011; BASF, 2012). Allergenicity and toxicity studies included bioinformatics analyses, digestibility and acute protein toxicity studies (BASF, 2011; BASF). No biologically meaningful differences were observed when comparing BASF CV127 Soybean with the near isoline variety (BASF, 2011; USDA-APHIS, 2012; BASF, 2012). BASF CV127 Soybean does not appear to present any changes in agronomic inputs, morphological characteristics or composition and nutritional characteristics that would affect TES.

The AHAS protein and *csr1-2* gene in BASF CV127 Soybean are derived from *Arabidopsis thaliana* (BASF, 2011; BASF, 2012). The *Arabidopsis* AHAS (AtAHAS) is a member of the class of AHAS proteins found ubiquitously in plants (BASF, 2012).

In its petition, BASF has presented the results of laboratory assays in which non-target organisms were exposed to the AHAS proteins, as well as the results of bioinformatics studies evaluating toxicity and allergenicity of the AHAS proteins (BASF, 2011). The introduced genetic material does not result in the production of novel proteins, enzymes, or metabolites in the plant that are known to have toxic properties (BASF, 2012). The lack of known toxicity of AtAHAS enzyme suggests no potential for deleterious effects on threatened and endangered organisms (BASF, 2012). Information presented in BASF's petition support the conclusion that there are no biologically meaningful differences between BASF CV127 Soybean and commercially available soybean products.

The potential for gene movement between BASF CV127 Soybean and related soybean species is limited (BASF, 2011; USDA-APHIS, 2012; BASF, 2012). As discussed in USDA-APHIS' PPRA, 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% (OECD, 2000; Fehr, 2007) although higher values (up to 2.5%) have been noted in some varieties (Abud et al., 2003). Outcrossing can be reduced to 0 – 0.01% with a separation distance of 10 meters (Abud et al., 2007; USDA-APHIS, 2012).

The cultivated soybean, *G. max*, lacks sexually compatible wild relatives in the U.S. and its territories (USDA-APHIS, 2012). Consequently, there is no potential for gene movement from cultivated soybean plants to wild relatives in the U.S. Therefore, it is not likely that gene movement and introgression will occur between BASF CV127 Soybean and other species of soybean.

BASF CV127 Soybean does not present a potential as a weed or the potential to displace a TES. As discussed in the PPRA, soybean lacks the attributes commonly associated with weeds, such as persistence of seed in soil, the ability to disperse, invade or become a dominant species in new or diverse landscapes, or the ability to compete with native species (Baker, 1965; USDA-APHIS, 2012). The agronomic and morphologic characteristics data provided by BASF were used in the USDA-APHIS analysis of the weediness potential for BASF CV127 Soybean, and evaluated for the potential to impact TES. Agronomic studies conducted by BASF tested the hypothesis that the weediness potential of BASF CV127 Soybean is unchanged with respect to conventional soybean (BASF, 2011; USDA-APHIS, 2012; BASF, 2012). No differences were detected between BASF CV127 Soybean and nontransgenic isoline control in growth, reproduction, or interactions with pests and diseases, other than the intended effect of herbicide-resistance (USDA-APHIS, 2012). Based on the agronomic field data and literature survey on soybean weediness potential, BASF CV127 Soybean is unlikely to affect TES as a troublesome or invasive weed (BASF, 2011; USDA-APHIS, 2012; BASF, 2012).

In addition to evaluating BASF's comparisons of BASF CV127 Soybean with the non-transgenic near-isoline control also considers the US-EPA and US-FDA regulatory assessments in its environmental assessment. As discussed above in Cumulative Effects, Past and Present Actions (Subsection 5.2), BASF has completed a food and feed safety and nutritional assessments and consultation for BASF CV127 Soybean with the US-FDA. There are currently over 24 tolerances for residues of the imidazolinone herbicides; BASF has submitted an import tolerance petition and supporting residue data to the US-EPA for the use of imazapyr and imazapic on BASF CV127 Soybean (BASF, 2011).

As discussed above, cultivation of BASF CF127 Soybean in the US is unlikely, but if it were to occur, it would be limited to research and development plots and off-season seed production (BASF, 2011). BASF CV127 Soybean are not expected to replace other varieties of soybean currently cultivated in the U.S. (BASF, 2011; BASF, 2012). Moreover, as noted in Subsection 4.2.2 – Preferred Alternative - Areas and Acreage of Soybean Production, USDA-APHIS has determined that BASF CV127 Soybean is unlikely to extend the range of soybean production, and new acreage is not expected to be developed to accommodate the cultivation of BASF CV127 Soybean.

After reviewing the possible effects of the approval of the petition for nonregulated status for BASF CV127 Soybean, USDA-APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. As a result, a detailed exposure analysis for individual species is not necessary. USDA-APHIS also considered the potential effect of approval of a petition for nonregulated status of BASF CV127 Soybean on designated critical habitat or habitat proposed for designation. Soybean has been selected for domestication and cultivation under conditions not normally found in natural settings (OECD, 2000). USDA-APHIS could identify no differences from effects that would occur from the cultivation of BASF CV127 Soybean and other currently cultivated soybean varieties.

Based on these factors, USDA-APHIS has concluded that the approval of the petition for nonregulated status of BASF CV127 Soybean, and the corresponding environmental release of this soybean variety, will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, consultations under Section 7(a)(2) of the Act or the concurrences of the US-FWS and/or NMFS are not required.

7 CONSIDERATION OF EXECUTIVE ORDERS, STANDARDS, AND TREATIES RELATING TO ENVIRONMENTAL IMPACTS

7.1 EXECUTIVE ORDERS WITH DOMESTIC IMPLICATIONS

The following two executive orders require consideration of the potential impacts to minority and low income populations and children:

- **EO 12898 (US-NARA, 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,"** requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.
- **EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks,"** acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

Each Alternative was analyzed with respect to EO 12898 and EO 13045. Neither Alternative is expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

As discussed in Subsection 4.1 – Scope of the Environmental Analysis, BASF does not intend to make BASF CV127 Soybean available for cultivation in the U.S. Therefore, it is highly unlikely that minority populations, low income populations, and children will be exposed to the BASF CV127 Soybean. To the extent BASF CV127 Soybean is cultivated in the U.S., as discussed in Sections 4 and 5, U.S. cultivation would be limited to small research and development plots, a small volume of off-season seed production, and a very limited cultivation in those soybean production areas where weeds resistant to the imidazolinone herbicides are not found. These scenarios are deemed highly improbable. Moreover, BASF has indicated that such cultivation would require a change in the US-EPA's pesticide registration label, and have further asserted that BASF has no intention to seek such a label change. Based on these findings, approval of the petition for nonregulated status for BASF CV127 Soybean is not expected to have a disproportionate adverse effect on minorities, low income populations, or children.

The following EO addresses Federal responsibilities regarding the introduction and effects of invasive species:

- **EO 1311 (US-NARA, 2010), "Invasive Species,"** states that Federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause.

As discussed in Subsections 3.1.1 and 4.2.1 – Areas and Acreage of Soybean Production, non-engineered soybean and soybean engineered for herbicide-resistance are widely grown in the U.S.. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by USDA-APHIS, BASF CV127 Soybean plants are sufficiently similar in fitness characteristics to other soybean varieties currently grown and are not expected to become weedy or invasive (USDA-APHIS, 2012).

The following Treaty, Statute and EO require the protection of migratory bird populations:

- **Migratory Bird Treaty Act of 1918 (MBTA), (16 U.S.C. 703 – 712)** implements a 1916 Convention between the U.S. and Great Britain (now Canada) for the protection of migratory birds (USDA-FSA, 2012). Later amendments implemented treaties between the U.S. and Mexico, the U.S. and Japan, and the U.S. and Russia. The MBTA establishes a Federal prohibition to "pursue, hunt, take, capture, kill, attempt to take, capture or kill, possess, offer for sale, sell, offer to purchase, purchase, deliver for shipment, ship, cause to be shipped, deliver for transportation, transport, cause to be transported, carry, or cause to be carried by any means whatever, receive for shipment, transportation or carriage, or export, at any time, or in any manner, any migratory bird, included in the terms of this Convention . . . for the protection of migratory birds . . . or any part, nest, or egg of any such bird." (16 U.S.C. 703). The Secretary of the Interior has the authority to determine, consistent with the Conventions, when "hunting, taking, capture, killing, possession, sale, purchase, shipment, transportation, carriage, or export of any . . .bird, or any part, nest or egg" could be undertaken and to adopt regulations for this purpose. These determinations are to be made based on "due regard to the zones of temperature and to the distribution, abundance, economic value, breeding habits, and times of migratory flight." (16 U.S.C. 704). A list of birds protected by the U.S. Fish and Wildlife Service under the MBTA can be found at the following website: http://www.fws.gov/migratorybirds/RegulationsPolicies/mbta/mbtandx.html. Federal agency implementation of the MBTA is guided by EO 13186, described in the following bullet.
- **EO 13186 (US-NARA, 2010), "Responsibilities of Federal Agencies to Protect Migratory Birds,"** states that Federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

As discussed in Subsection 4.3, Preferred Alternative - Human Health and Animal Feed, data submitted by the applicant has shown no difference in compositional and nutritional quality of BASF CV127 Soybean compared to other GE soybean or non-GE-soybean. As noted above in the discussion regarding minorities, low income populations and children, BASF does not intend to seek commercial cultivation of BASF CV127 Soybean in the U.S. To the extent that this soybean is cultivated domestically, such cultivation would be limited to small research and development plots, off-season seed production, and limited cultivation in those soybean production areas where weeds resistant to the imidazolinone herbicides are not found. As stated above, these scenarios are deemed highly unrealistic. Moreover, BASF has indicated that such cultivation would require a change in the US-EPA's pesticide registration label, and have further asserted that BASF has no intention to seek such a label change.

Additionally, BASF has presented results of field trials conducted to evaluate field phenotypic, agronomic and environmental interactions associated with BASF CV127 Soybean. These data, presented in Section VIII of the petition (BASF, 2011) showed no differences in arthropod damage or arthropod pests and beneficial insect abundance between BASF CV127 Soybean and other varieties, supporting the conclusion that BASF CV127 Soybean is unlikely to impact food sources for migratory bird species. Additionally, as discussed in Subsection 4.5.2, Preferred Alternative – Biological Resources, BASF has presented evidence that the introduced proteins in BASF CV127 Soybean do not differ in their digestibility, toxicity and allergenicity from conventional soybeans (BASF, 2011; BASF, 2012). BASF has evaluated compositional characteristics of this soybean, including nutrients, anti-nutrients and other key compositional elements; no biologically meaningful differences were identified (BASF, 2011; BASF). Moreover, the introduced genetic material does not result in the production of novel proteins, enzymes, or metabolites in the plant that are known to have toxic properties (USDA-APHIS, 2012). BASF has also presented the results of a feeding study in which mice were fed very high doses of AtAHAS protein, with no toxic effects (BASF, 2011; BASF, 2012). It is thus unlikely that the migratory birds that may occasionally forage in soybean fields will be affected by the direct consumption of BASF CV127 Soybean.

Based on these findings, it is highly unlikely that approval of the petition for nonregulated status for BASF CV127 Soybean would impact migratory birds.

7.2 INTERNATIONAL IMPLICATIONS

EO 12114 (US-NARA, 2010), "Environmental Effects Abroad of Major Federal Actions" requires Federal officials to take into consideration any potential environmental effects outside the U.S., its territories, and possessions that result from actions being taken.

USDA-APHIS has given this EO due consideration and does not expect a significant environmental impact outside the U.S. should nonregulated status be granted to BASF CV127 Soybean. USDA-APHIS assumes that the cultivation of BASF CV127 Soybean in other soybean production regions of the world would be conducted only after appropriate local approvals are received.

It should be noted that all the existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new soybean cultivars internationally, apply equally to those covered by an USDA-APHIS approval of the petition for nonregulated status under 7 CFR Part 340.

Any international trade of BASF CV127 Soybean subsequent to approval of the petition for nonregulated status for the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the ***International Plant Protection Convention*** (IPPC, 2010). The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC, 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (177 countries as of October, 2012, see http://www.fao.org/fileadmin/user_upload/legal/docs/1_004s-e.pdf). In April 2004, a standard for pest risk analysis (PRA) of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests) (FAO, 2006). LMOs are defined by the FAO as organisms that have been modified using techniques of modern biotechnology to express one or more new or altered traits (FAO, 2006). In most cases, the LMO parent organism is not normally considered to be a plant pest but an assessment may need to be performed to determine if the genetic modification (i.e. gene, new gene sequence that regulates other genes, or gene product) results in a new trait or characteristic that may present a plant pest risk (FAO, 2006). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. USDA-APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The Cartagena Protocol on Biosafety is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which includes those modified through biotechnology. The Protocol came into force on September 11, 2003, and 193 countries are Parties to it as of October, 2012 (CBD, 2010). Although the U.S. is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with those regulations that importing countries which are Parties to the Protocol have promulgated to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol, and the required documentation.

LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (see the NBII listings posted at http://usbiotechreg.epa.gov/usbiotechreg/. These data will be available to the Biosafety Clearinghouse.

USDA-APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the Organization for Economic Cooperation and Development. NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures (RSPM No. 14), *Importation and Release into the Environment of Transgenic Plants in NAPPO Member*

Countries (NAPPO, 2003).

USDA-APHIS also participates in the ***North American Biotechnology Initiative (NABI)***, a forum for information exchange and cooperation on agricultural biotechnology issues for the U.S., Mexico, and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including: Argentina, Brazil, Japan, China, and Korea.

7.3 COMPLIANCE WITH CLEAN WATER ACT AND CLEAN AIR ACT

This Environmental Assessment evaluated the changes in soybean production due to the unrestricted use of BASF CV127 Soybean. This included an analysis of the potential impacts to water resources and air quality, presented in Subsection 4.4.2 – Physical Environment – Preferred Alternative. Potential impacts to both resource aspects involve an attendant analysis of the relationships of agronomic practices and soil resources, evaluated in Subsections 4.4.1 Physical Environment – No Action Alternative: Soil Quality.

As noted above, BASF has indicated that it does not intend to seek commercial cultivation of BASF CV127 Soybean in the U.S. Any domestic commercial cultivation will be limited to research and development, off-season seed production, and very limited cultivation in those soybean production areas where weeds resistant to the imidazolinone herbicides are not found. These scenarios are deemed highly unrealistic. Moreover, BASF has indicated that such cultivation would require a change in the US-EPA's pesticide registration label, and have further asserted that BASF has no intention to seek such a label change.

Based on these findings, it is unlikely that approval of the petition for nonregulated status for BASF CV127 Soybean will effect air or water quality. Based on this review, USDA-APHIS concludes approval of the petition for nonregulated status of BASF CV127 Soybean would inherently comply with the Clean Water Act and the Clean Air Act.

7.4 IMPACTS ON UNIQUE CHARACTERISTICS OF GEOGRAPHIC AREAS

As discussed in Subsection 4.2.2 – Preferred Alternative - Areas and Acreage of Soybean Production, cultivation of BASF CV127 Soybean will not lead to the increased production of soybean in U.S. agriculture. As noted above, BASF has indicated that it does not intend to seek commercial cultivation of BASF CV127 Soybean in the U.S. Any domestic commercial cultivation will be limited to research and development, off-season seed production, and very limited cultivation in those soybean production areas where weeds resistant to the imidazolinone herbicides are not found. These scenarios are deemed highly unrealistic. In the unlikely event that BASF CV127 Soybean is commercially cultivated, it will be cultivated on agricultural land currently suitable for production of soybean, and is not expected to increase the acreage of soybean production. BASF CV127 Soybean may displace currently cultivated varieties of soybean.

As discussed in Subsection 4.2.2 – Preferred Alternative - Areas and Acreage of Soybean Production, the common agricultural practices that would be carried out in the cultivation of BASF CV127 Soybean are not expected to deviate from current practices, with the exception of a potentially broader use of imidazolinone herbicides. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to BASF CV127 Soybean, including the use of US-EPA registered pesticides. Applicant's adherence to US-EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. As noted above, BASF has noted that a change in the US-EPA Pesticide Registration label is required in order for the imidazolinone herbicides to be used on BASF CV127 Soybean; an application for such a label change has not been submitted.

The Preferred Alternative evaluated in this EA is limited to approving the petition for nonregulated status for BASF CV127 Soybean. There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This Alternative would not convert land use to nonagricultural use and therefore would have no adverse impact on prime farm land.

Based on these findings, approving the petition for nonregulated status of BASF CV127 Soybean is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

7.5 NATIONAL HISTORIC PRESERVATION ACT (NHPA) OF 1966 AS AMENDED

The NHPA of 1966, and its implementing regulations (36 CFR Part 800), requires Federal agencies to: 1) determine whether activities they propose constitute "undertakings" that has the potential to cause effects on historic properties; and 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

As noted above, BASF has indicated that it does not intend to seek commercial cultivation of BASF CV127 Soybean in the U.S. Any domestic commercial cultivation will be limited to research and development, off-season seed production, and very limited cultivation in those soybean production areas where weeds resistant to the imidazolinone herbicides are not found. These scenarios are deemed highly unrealistic. In the unlikely event that BASF CV127 Soybean is commercially cultivated, it will be cultivated on agricultural land currently suitable for production of soybean, and is not expected to increase the acreage of soybean production.

Based on these findings, USDA-APHIS' proposed action, approving the petition for nonregulated status for 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.

USDA-APHIS' proposed action would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to approving the petition for nonregulated status for 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 US-EPA registered pesticides. Applicant's adherence to US-EPA label use restrictions for all pesticides will mitigate impacts to the human environment.

USDA-APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the soybean production regions. The cultivation of BASF CV127 Soybean does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

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