# BASF Petition (09-015-01p) for Determination of Non-regulated Status of CV127 Herbicide Tolerant Soybean

## OECD Unique Identifier:
## BPS-CV127-9

## Plant Pest Risk Assessment

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**Agency Contact**
**Cindy Eck**
**Biotechnology Regulatory Services**
**4700 River Road**
**USDA, APHIS**
**Riverdale, MD 20737**
**Fax: (301) 734-8669**

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## A. Introduction

BASF Plant Science, L.P. (BASF) has petitioned APHIS (APHIS number 09-015-01p) for a determination that genetically engineered (GE) soybean (*Glycine max*) event BPS-CV127-9 (CV127) is unlikely to pose a plant pest risk (BASF, 2011) and, therefore, should no longer be a regulated article under APHIS' 7 Code of Federal Regulations (CFR) part 340. APHIS administers 7 CFR part 340 under the authority of the plant pest provisions of the Plant Protection Act of 2000[1]. This plant pest risk assessment was conducted to determine whether CV127 soybean is unlikely to pose a plant pest risk.

Event BPS-CV127-9 was produced by transformation of embryogenic axis tissue derived from the apical meristem of soybean (*Glycine max*, cv Conquista) via biolistics transformation technology. None of the introduced genetic sequences come from plant pest organisms listed in 7 CFR 340.2. Because CV127 soybean was introduced (interstate movement and field release) under APHIS' authorization, this soybean has been considered a regulated article under APHIS regulations at 7 CFR part 340.

Potential impacts considered in this Plant Pest Risk Assessment are those that pertain to the use of CV127 soybean and its progeny in the absence of confinement. APHIS regulation 7 CFR 340.6(c) specifies the information needed for consideration in a petition for non-regulated status. APHIS will evaluate information submitted by the applicant, in addition to current literature, related to plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, any impacts on the weediness of any other plant with which it can interbreed, potential changes to agricultural or cultivation practices, potential effects on non-target organisms and transfer of genetic information to organisms with which it cannot interbreed, to determine if CV127 soybean is unlikely to pose a plant pest risk. If APHIS determines that a GE organism is not a plant pest risk, then APHIS has no regulatory authority over that organism.

## B. Development of CV127 Herbicide Tolerant[2] Soybean

For the past 50 years, the United States (U.S.) has been the world's leading producer of soybeans and in 2010 approximately 90.6 MMT were produced in the U.S., or about 35% of the world's total production (Soy Stats, 2011). The second and third largest producers of soybean are Brazil and Argentina who produced 70.0 and 49.5 MMT of soybeans, respectively, in 2010 (Soy Stats, 2011). Soybean production in Brazil has increased

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[1] Section 403 (14) of the Plant Protection Act (7USC Sec 7702(14) defines plant pest as: "Plant Pest - The term "plant pest" means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: (A) A protozoan. (B) A nonhuman animal. (C) A parasitic plant. (D) A bacterium. (E) A fungus. (F) A virus or viroid. (G) An infectious agent or other pathogen. (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs."

[2] The applicant has described CV127 soybean as "herbicide tolerant" and historically APHIS has also referred to GE plants with diminished herbicide sensitivity as "herbicide tolerant." However, the phenotype would fall under the Weed Science Society of America's (WSSA) definition of "herbicide resistance" since CV127 soybean has an inherited ability to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type variety (WSSA 1998). By the WSSA definition, "resistance [to an herbicide] may be naturally occurring or induced by such techniques as genetic engineering or selection of variants produced by tissue culture or mutagenesis." Herbicide tolerance, by the WSSA definition, only applies to plant species with an "inherent ability" to survive and reproduce after herbicide treatment.

dramatically in recent years with a 31 MMT increase in production between 2000 and 2010 (Soy Stats, 2011).

Soybean CV127 was developed for cultivation primarily in Brazil and Argentina and the introduction of CV127 soybean varieties will offer soybean growers an additional tool for controlling weeds, as well as an important option for weed resistance management. The major weeds in soybean cultivation in these countries are sensitive to the imidazolinone herbicides containing imazapyr and imazapic. 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 (BASF, 2011).

Soybeans are naturally tolerant to some imidazolinone herbicides due to an ability to metabolize specific imidazolinones (Tecle, 1993). There are certain imidazolinone compounds, for example imazapyr and imazapic, which are active ingredients in a number of imidazolinone herbicide products and are not readily metabolized in soybeans. As a result, conventional soybeans are very sensitive to imazapyr and imazapic. CV127 soybeans would be tolerant to the use of imidazolinone herbicides containing these active ingredients for effective weed control (BASF, 2011).

Imidazolinone herbicides control a wide spectrum of grass and broadleaf weeds. The growing use of glyphosate with glyphosate-tolerant soybeans in Argentina and Brazil has led to a shift in the species of prevalent weeds with those that are more tolerant to glyphosate predominating. 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*). These weeds are sensitive to imidazolinone herbicides (BASF, 2011).

There are many similarities in agronomic practices used in soybean production between the U.S. and Brazil, including weed, insect and disease control practices. The Maturity Groups of Brazilian soybean cultivars are common to those appropriate for cultivation in the southern U.S. Furthermore, environmental conditions during the growing season, including average temperatures and rainfall, are comparable between U.S. and Brazilian soybean production. Details of these similarities are presented in section IX of the petition (BASF, 2011). Therefore, in the event that CV127 soybean were to be introduced into the U.S. environment, the data generated from field studies conducted in Brazil to support the environmental as well as food and feed safety of CV127 soybeans are equally applicable to the environmental, food and feed safety assessments of CV127 in the U.S.

In the U.S., soybean was grown on approximately 75.0 million acres in 2011 (Figure 1, USDA NASS, 2011a) with a value of $29.6 billion in 2008/2009 (USDA ERS, 2011a). Growers select soybean lines adapted to the different environmental and climatic features, operator’s education, weed and disease pressures, cost of seed and other inputs, technology fees, human safety, ease and flexibility of the productions system and marketing reasons (USDA ERS, 2002; Brookes, 2011).

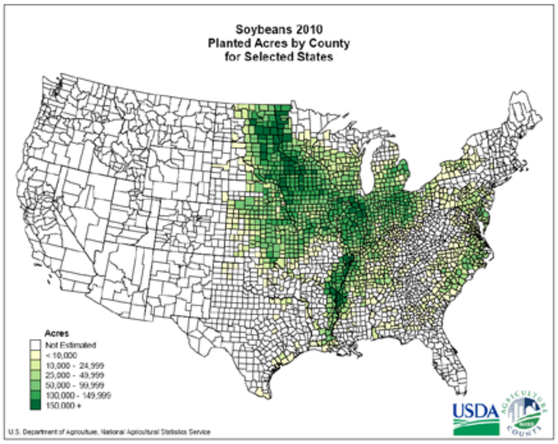

Figure 1. Soybean production areas in the U.S. (USDA NASS 2011b).

The presence of weeds in soybean fields can cause greater production losses than either insects or diseases (Gibson, 2005; Oerke, 2006). Before the development of effective herbicides for the selective control of weeds in soybeans in the early 1960's, cultural practices including tillage, use of weed free seed, row spacing and crop rotation were the only ways to control weeds (Wax, 1973). By 1987, over 30 herbicides were being used on soybeans (Jordan, 1987). With the 1996 commercial introduction and rapid adoption of glyphosate tolerant soybeans, a major change in herbicide usage occurred with an increasing use of glyphosate concurrent with the increased planting of glyphosate tolerant soybeans and a decrease in use of other soybean herbicides (Figure 2; NRC, 2010; Young, 2006). Consequently, the diversity of herbicides used for weed management has declined in soybean (Table 1; Young, 2006) resulting in weed species shifts (Johnson, 2009). CV127 soybean would provide soybean growers with additional options for the post-emergent control of both broadleaf and grass weeds. The integration of other herbicides with different modes of action with glyphosate has been encouraged to improve the duration of weed control, to enhance control of glyphosate tolerant weeds, to reduce the risk of developing glyphosate resistant weeds and to control glyphosate-resistant weeds (WSSA, 2010). This soybean product would also provide a potential remedy to the increased incidence of weed species that are more tolerant to glyphosate (BASF, 2011; NRC, 2010; WSSA, 2010).

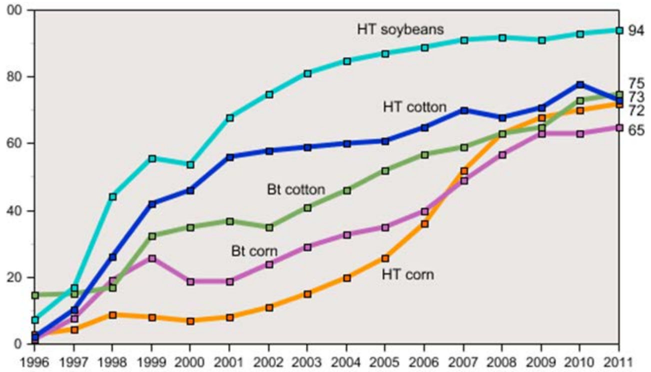

Figure 2. Percent acreage of genetically engineered crops in the U.S. (USDA ERS, 2011b).

|  | 1990 | 2000 | 2006 |  | 1990 | 2000 | 2006 |
|---|---|---|---|---|---|---|---|
| **2,4,D, Dimeth. salt** |  |  | 3 | **Imazamox** |  | 6 |  |
| **2,4,D** | 3 | 5 |  | **Imazaquin** | 16 | 4 | 1 |
| **Acetic acid (2,4-D)** | 10 | 4 | 7 | **Imazethapyr** | 11 | 12 | 3 |
| **Acifluorfen** |  | 3 |  | **Lactofen** | 1 | 2 |  |
| **Alachlor** | 13 | 1 |  | **Linuron** | 6 |  |  |
| **Bentazon** | 16 | 2 |  | **Metolachlor** | 10 | 2 |  |
| **Clethodim** |  | 4 | 3 | **Metribuzin** | 19 | 4 | 2 |
| **Clomazone** | 7 |  |  | **Paraquat** | 2 |  | 1 |
| **Ethalfluralin** | 5 |  |  | **Pendimethalin** | 14 | 11 | 3 |
| **Fenoxaprop** |  | 4 |  | **Quizalofop** | 3 |  |  |
| **Fluazifop** | 6 | 5 | 1 | **S-Metolachlor** |  |  | 1 |
| **Flumetsulam** | 2 | 2 |  | **Sethoxydim** | 4 | 2 |  |
| **Flumioxazin** |  |  | 3 | **Sulfentrazone** |  | 4 | 1 |
| **Fomesafen** | 4 | 7 | 2 | **Tribenuron, methyl** |  |  | 1 |
| **Glyphosate** | 5 | 62 | 92 | **Trifluralin** | 37 | 14 | 2 |
| **Glyphosate, diam. salt** |  |  | 4 |  |  |  |  |

Table 1. Average (across all states) percent of U.S. soybean acres treated with the following herbicides in 1990, 2000 and 2006 (USDA NASS, 2011c).

CV127 is a GE soybean line that has been developed to increase resistance to imidazolinone herbicides. The introduced genetic material results in the production of acetohydroxyacid synthase large subunit (AtAHAS) enzyme that is tolerant to imidazolinone herbicides due to a point mutation that results in a single amino acid substitution in which the serine residue at position 653 is replaced by asparagine (S653N). The introduced genetic material, the AtAHAS enzyme, is identical to the native AHAS enzyme (BASF, 2011).

## C. Expression of the Gene Product and Changes to Plant Metabolism

The CV127 soybean plants are derived from a single transformation event and were produced by introduction of the imidazolinone-tolerant acetohydroxyacid synthase large subunit (*AHAS*) gene *csr1-2* with its native promoter from *Arabidopsis thaliana* into the soybean plant genome via biolistics transformation technology. The *csr1-2* gene from *A. thaliana* encodes an acetohydroxyacid synthase large subunit (AtAHAS) enzyme that is tolerant to imidazolinone herbicides due to a point mutation that results in a single amino acid substitution in which the serine residue at position 653 is replaced by asparagine (S653N). The AtAHAS catalytic subunit encoded by the *csr1-2* gene has altered herbicide binding properties such that imidazolinone herbicides do not bind to the enzyme while retaining its normal biosynthetic function in the plant (Pang, 2002).

The *Arabidopsis* AHAS (AtAHAS) is a member of the class of AHAS proteins found ubiquitously in plants. The AHAS enzyme catalyzes the first step in the biosynthesis of the branched-chain amino acids valine, leucine, and isoleucine. Typically, inhibition of the AHAS enzyme by imidazolinone herbicides leads to a deficiency in branched-chain amino acids and other compounds derived from this pathway that are needed for plant growth and survival, and results in plant death.

Several *AHAS* genes encoding AHAS enzymes that are tolerant to imidazolinone herbicides have been discovered in plants as naturally occurring mutations and through the process of chemically-induced mutagenesis. The S653N mutation in the *csr1-2* gene is among the five most common single-point mutations in *AHAS* genes that result in resistance to imidazolinone herbicides in plants (Tan, 2005). For example, imidazolinone-tolerant maize (*Zea mays* L.), rice (*Oryza sativa* L.), bread wheat (*Triticum aestivum* L.), and oilseed rape (*Brassica napus* and *B. juncea* L. Czern.), were developed through mutagenesis, selection, and conventional breeding technologies and have been commercialized under the Clearfield® brand name since 1992, 2003, 2002, and 1996, respectively.

Molecular characterization of CV127 soybean demonstrated that the *csr1-2* gene cassette was inserted into the soybean genome as a single, intact copy (BASF, 2011; Section V). Furthermore, it was demonstrated that there are no additional fragments of DNA derived from the backbone of the plasmid used to produce the DNA transformation fragment inserted within the genome of CV127 soybeans (BASF, 2011; Section V). In the insert, there is also a 376 base pair (bp) duplication of a portion of the *csr1-2* coding sequence directly before the 3' integration point. This duplicated 376 bp segment creates a 501 bp open reading frame (ORF) that extends into the 3' flanking sequence. Reverse transcription-polymerase chain reaction (RT-PCR) results showed that this 501 bp ORF is not transcribed. In addition to the *csr1-2* native gene promoter, the region upstream of (i.e. 5' to) the *csr1-2* coding sequence contains the complete coding sequence of the *A. thaliana* SEC61 (AtSEC61) gamma (γ) subunit protein, which is a component of the DNA fragment used for transformation. This protein is part of a multi-subunit secretory complex that is ubiquitous in all eukaryotes. The At*SEC61* γ 5' UTR, as annotated by The Arabidopsis Information Resource, begins 18 nucleotides downstream from the 5' transgene integration site. As such, it is extremely unlikely that the insert contains the complete native promoter for the At*SEC61* γ gene. Protein expression studies demonstrated that no detectable *A. thaliana* SEC61 gamma protein is produced in CV127 soybean leaf tissue or grain (BASF, 2011; Section VI).

Southern blot analysis showed that the transgene insert in CV127 is stably integrated into the soybean genome across the breeding generations studied (BASF, 2011; Section V). This conclusion was confirmed in a study of the inheritance of the imidazolinone-resistance trait over multiple breeding generations of CV127 soybean (BASF, 2011; Section V). Results of this study demonstrated that the trait is stably inherited according to classical Mendelian genetics, and results were consistent with the presence of a single dominant imidazolinone-resistance gene in the soybean genome.

## D. Potential Impacts on Disease and Pest Susceptibilities

APHIS assessed whether CV127 is likely to have significantly altered disease and pest susceptibility. This assessment encompassed a consideration of the introduced trait and disease and pest susceptibility data from CV127 field trials.

Soybean is not a plant pest in the U.S. (Hymowitz and Singh, 1987). DNA sequences that were incorporated in CV127 were not derived from plant pests and do not result in the production of infectious agents or disease symptoms in plants, and so it is unlikely that CV127 could pose a plant pest risk. The description of the introduced genetic elements and expression of the gene products and their functions in CV127 has been summarized above.

CV127 was released in seven different locations in Brazil during the 2006-2007 growing season and six locations during the 2007 growing season. These were conducted in geographically distinct locations that were representative of commercial soybean production in Brazil (BASF, 2011). BASF used well-established qualitative and quantitative techniques to observe insect and disease damage (BASF, 2011). The following insect pests were evaluated in the field: Coleopterans (*Diabrotica* and *Aracanthus* spp.), Lepidopterans (*Anticarsia*, *Agrotis*, *Pseudoplusia*, and *Spodoptera* spp.), and Hemipterans (*Euschistus*, *Piezodorus*, and *Nezara* spp.). Resistance to insect damage and effects on in-field insect populations of CV127 soybean relative to the isoline control and conventional soybean varieties were assessed at different stages of plant growth and development throughout the growing season during the 2006/2007 and 2007 growing seasons (BASF, 2011; Section VIII). Based upon the results of in-field evaluations for insect populations and resistance to insect damage, CV127 soybeans were found to be no different from that of the isoline control soybean or the conventional soybean varieties.

Disease susceptibility of CV127 soybeans relative to the isoline control and conventional soybean varieties was determined at different stages of plant growth and development throughout the growing season. Diseases that were assessed included Asian soybean rust (*Phakopsora pachyrhizi*), Downy mildew (*Peronospora manshurica*), Powdery mildew (*Erysiphe diffusa*), and end-of-cycle diseases (DC) caused mainly by *Septoria glycines* (brown spot or Septoriose) and *Cercospora kikuchii* (soybean leaf spot). Assessments were made at or near vegetative stage V4 and reproductive stages R1, R5, and R7. No disease infestations were observed at the V4 stage with the exception of powdery mildew in Santo Antônio de Goiás in 2007. Where susceptibility differences were observed, they were generally between varieties with the Conquista genetic background (CV127 soybean and the isoline control) and the two conventional soybean varieties with different genetic backgrounds. Therefore, disease susceptibility of CV127 soybean was found to be no different from that of the isoline control plants. This study demonstrated that the insertion of the *csr1-2* gene into the genome of CV127 soybean did not affect the disease susceptibility of CV127 soybean. A complete description of the disease assessment methodology is included in Appendix F of the petition (BASF, 2011). No qualitative or quantitative observations indicated any biologically meaningful differences from control lines or differences outside the range of different soybean varieties.

Given the interactions between the environment, the genetic backgrounds of the cultivars used and some inherent genetic variability within soybean varieties, APHIS concludes that these results do not indicate an increased pest risk. Expression of the imidazolinone-tolerant acetohydroxyacid synthase large subunit (*AHAS*) gene *csr1-2* with its native promoter from *Arabidopsis thaliana* in CV127 soybean is not expected to cause plant disease or influence susceptibility of CV127 or its progeny to diseases or other pests.

## E. Potential Impacts on Nontarget Organisms Beneficial to Agriculture

There is no reason to believe that deleterious effects or significant impacts on non-target organisms, including beneficial organisms, would result from the cultivation of CV127 soybean. Field observations of CV127 soybean (BASF, 2011; Section IX) revealed no negative effects on non-target organisms, suggesting that the production of the AtAHAS enzyme in the plant tissues is not toxic to organisms. 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. The lack of known toxicity of AtAHAS enzyme suggests no potential for deleterious effects on beneficial organisms such as bees and earthworms. The use of imidazolinone herbicides in the cultivation of CV127 soybean or its offspring is regulated by EPA under its existing regulations for the registration of pesticide use. EPA considers the impacts on the environment, including effects on non-target organisms in establishing residue tolerances for imidazolinone tolerant lines (USEPA, 2006). APHIS has not identified any other potential mechanisms for deleterious effects on beneficial, threatened or endangered organisms.

## F. Potential for Enhanced Weediness of CV127 Soybean

APHIS assessed whether CV127 soybean is any more likely to become a weed than the non-transgenic recipient soybean line or other soybean lines currently cultivated. The assessment encompasses a consideration of the basic biology of soybean and an evaluation of unique characteristics of CV127 soybean.

Weediness for the purposes of this part of the plant pest risk assessment is an attribute, which causes a crop to act as a weed due to the addition of genes, in comparison to the non-GE comparator (isoline control). If the fitness of CV127 soybean improves in natural or agricultural ecosystems due to the inserted DNA, the potential for weediness could increase. The following analysis of the inserted DNA is intended to document that CV127 soybean has a negligible likelihood of increased weediness.

In the U.S., soybean is neither listed as a weed in the major weed references (Crockett, 1977; Holm, 1979; Muenscher, 1980) nor is it designated as noxious weed by the federal government (USDA NRCS, 2011). Soybean does not possess any of the attributes commonly associated with weeds (Baker, 1965), such as long persistence of seed in the soil, the ability to disperse, invade, and become a dominant species in new or diverse landscapes, or the ability to compete well with native vegetation. Furthermore, mature soybean seeds have no innate dormancy, are sensitive to cold, are not expected to survive in freezing winter conditions and do not reproduce vegetatively (Hermann, 1962; OECD, 2000; Padgette, 1996; Raper Jr. & Kramer, 1987).

From 2006 through 2007, BASF conducted field trials to evaluate phenotypic characteristics comparing CV127 with the non-transgenic soybean isoline control and two conventional soybean varieties (BASF, 2011). Results on growth characteristics, seed production and germination indicate that CV127 is not significantly different from its comparators (BASF, 2011). No biologically meaningful differences were observed across sites between CV127and the isoline control.

To increase weediness of the soybean plant there would have to be selection pressure on the line (Tiedge, 1989). Because imidazolinones will not affect the survival of CV127 and because soybean is not itself weedy, this type of selection pressure does not now and is unlikely to exist.

There is no indication that CV127 possesses a selective advantage that would result in increased weediness. CV127 lacks the ability to persist as a troublesome weed, and there would be no significant impact on current weed management practices for soybean cultivation.

## G. Potential Impacts on the Weediness of Any Other Plants with which It Can Interbreed

The genus *Glycine*, a member of the Fabaceae (= Leguminosae or pea family), consists of two subgenera, *soja* and *glycine* (OECD, 2000; USDA NRCS, 2012). Perennial species in the subgenus *glycine* do not occur in the U.S. (USDA NRCS, 2012), except in the U.S. territories in the South Pacific (Hymowitz and Singh, 1987). The subgenus *soja* consists of three annual species: *G. soja* Sieb. and Zucc., the wild form of soybean; *G. gracilis* Skvortz., the weedy form of soybean; and *G. max* (L.) Merr., the cultivated soybean. *G. soja* and *G. max* do not occur naturally in the U.S. (Hermann, 1962; Hymowitz, 1987; USDA NRCS, 2012). Hybrids from crosses between the subspecies have generally been sterile, and further progeny have only been obtained with extreme difficulty (OECD, 2000).

Cultivated soybean is highly self-pollinating (Ahrent, 1994). When soybean plants are grown directly adjacent to other soybean plans, the amount of natural cross pollination has generally been found to be 0.5 - 1 percent (Fehr, 1980; OECD, 2000) although higher values (up to 2.5 percent) have been noted in some varieties (Abud, 2007). Outcrossing can be reduced to 0 – 0.01 percent with a separation distance of 10 meters (Abud, 2007).

The cultivated soybean, *G. max*, lacks sexually compatible wild relatives in the U.S. and its territories. Consequently, there is no potential for gene flow from cultivated soybean plants to wild relatives in the U.S. Therefore, it is not likely that gene flow and introgression will occur between CV127 soybean and other species of soybean. APHIS has determined that any adverse consequences of gene flow from CV127 soybean to wild or weedy species in the United States are highly unlikely.

## H. Potential Changes to Agriculture or Cultivation Practices

None of the management practices currently employed for soybean production is expected to change if CV127 soybean is determined to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. BASF’s (2011) studies demonstrate that the agronomic characteristics and cultivation practices employed when growing CV127 soybean are essentially indistinguishable from practices used to grow other soybean varieties, including other herbicide-tolerant varieties (BASF, 2011; Section IX). Although CV127 soybean might be expected to replace other varieties of soybean currently cultivated, additional acreage is not expected to be developed to accommodate the cultivation of CV127 soybean (BASF, 2011). CV127 soybean is comparable to currently available soybean varieties in terms of resistance to insects and disease (BASF, 2011; Section IX). Therefore, no changes are expected for insect and disease control practices with CV127 soybean. Based on its analysis, APHIS concludes that there would be no adverse impacts on agricultural practices associated with the use of the CV127 soybean.

## I. Potential Impacts from Transfer of Genetic Information to Organism with which CV127 Soybean Cannot Interbreed

APHIS examined the potential for the new genetic material inserted into CV127 soybean to be horizontally transferred to other organisms without sexual reproduction and whether such an event could lead directly or indirectly to disease, damage, injury or harm to plants. Horizontal gene transfer and expression of DNA from a plant species to other species is highly unlikely to occur based on the following reasons.

The horizontal gene transfer (HGT) between unrelated organisms is one of the most intensively studied fields of science. Horizontal gene transfer and expression of DNA from a plant species to bacteria or animal species is unlikely to occur (Keese, 2008).

1. Many genomes (or parts thereof) from bacteria that are closely associated with plants have been sequenced, including *Agrobacterium* and *Rhizobium* (Kaneko, 2000; Kaneko, 2002; Wood, 2001). There is no evidence that these organisms contain genes derived from plants. Therefore the likelihood of any impact or new horizontal gene transfer that is not already capable of taking place in the soil is extremely unlikely.

2. No evidence has been identified for any mechanism by which soybean genes could be transferred to humans or animals, or any evidence that such gene transfer has occurred for any plant species during evolutionary history, despite animals and humans eating large quantities of plant DNA. In cases where review of sequence data implied that horizontal gene transfer occurred, these events are

inferred to occur on an evolutionary time scale on the order of millions of years (Brown, 2003; Koonin, 2001).

3. Transgene DNA promoters and coding sequences are optimized for plant expression, not prokaryotic bacterial expression. Thus even if horizontal gene transfer occurred, proteins corresponding to the transgenes are not likely to be produced.

4. FDA has evaluated horizontal gene transfer from the use of antibiotic resistance marker genes, and concluded that the likelihood of transfer of antibiotic resistance genes from plant genomes to microorganisms in the gastrointestinal tract of humans or animals, or in the environment, is extremely unlikely (FDA, 1998). Therefore APHIS concludes that horizontal gene transfer is highly unlikely to occur and thus poses no significant plant pest risk.

## J. Conclusion

APHIS has prepared this plant pest risk assessment in order to determine if event BPS-CV127-9 is likely to pose a plant pest risk. Based on the information provided by the applicant and the lack of atypical responses to disease or plant pests in the field, weedy characteristics of the CV127 soybean or other plants with which it can interbreed, changes to agricultural or cultivation practices, effects on non-targets or beneficial organisms in the agro-ecosystem, indirect effects on other agricultural products and the unlikelihood of horizontal gene transfer, APHIS has concluded that soybean event BPS-CV127-9 is highly unlikely to pose a plant pest risk.

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