USDA/APHIS Draft Environmental Assessment

In response to Pioneer Hi-Bred International Petition 06-271-01p seeking a Determination of Nonregulated Status for Herbicide Tolerant 356043 Soybean

OECD Unique Identifier DP-356Ø43-5

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services

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TABLE OF CONTENTS **Page**

I. Introduction

A. Background

Soybean *(Glycine max* L.) is a member of the Phaseoleae tribe of the Leguminosae family with its center of origin in eastern Asia. Soybean is grown as a commercial crop in over 35 countries. In the United States it is grown on greater than 70 million acres in at least 31 states with over a million acres grown in each of the following states: IA, IL, MN, IN, MO, NE, OH, SD, AR, ND, KS, MI, MS, WI, NC, KY, TN (USDA-NASS, 2006).

Soybeans do not persist as they are not frost tolerant and do not survive freezing winter conditions. Soybean plants are not weedy and are not found outside of cultivated areas, nor do they compete well with other cultivated plants. They have never been found in the wild (Hymowitz & Singh, 1987). Volunteer plants that might grow under certain environmental conditions can be easily controlled mechanically or with herbicides. Additional information on the biology of soybean can be found within an OECD (Organization for Economic Co-Operation and Development) consensus document (OECD, 2000).

Soybean is a highly self pollinated species. The soybean stigma[1] is receptive to pollen approximately 24 hours before anthesis[2] and remains receptive for approximately 48 hours. The anthers[3] mature in the flower bud and directly pollinate the stigma of the same flower, resulting in a cross pollination rate typically less than one percent between adjacent plants under normal field planting conditions (Caviness, 1966, OECD, 2000). Cross-pollination greater than 4.6 m from a pollen source has been rarely observed and it has been observed that insects can transfer the pollen (Caviness, 1966). A recent study in Arkansas has shown that different soybean cultivars vary in the amount of cross pollination that can occur under optimal growing conditions and in the presence of honeybee populations. Some cultivars averaged anywhere from 0.09-2.5% cross-pollination in rows 6 m long and 102 cm apart (Ahrent and Caviness, 1994).

In 2006, glyphosate tolerant varieties of soybean were planted on approximately 89 percent of soybean acreage in the United States. Only 11 percent of the total soybean acreage was planted with conventional soybean varieties and of that roughly 122,000 acres (0.17% of soybean acres) was devoted to organic soybean production (USDA-ERS, 2006). Ultimately, soybean growers make their choices of soybean varieties based on several factors: yield, weed and disease pressures, cost of seed, pesticides and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Gianessi, 2005).

[1] Receptive part of a flower, on which pollen is deposited, leading to fertilization and seed production.
[2] The period during which a flower is open and functional
[3] The part of the flower on which pollen is produced.

Pioneer's herbicide tolerant 356043 soybean has been genetically engineered to express modified glyphosate acetyltransferase (GAT4601[4]) and acetolactate synthase (ALS) proteins. These genes impart tolerance to both glyphosate and ALS-inhibiting herbicides (e.g., sulfonylureas and imidazolinones). The *gat4601* [5] gene is derived from *gat* genes from *Bacillus licheniformis*, a common soil bacterium. Expression of the *gat4601* gene is driven by a synthetic promoter[6] (SCP1). The gene that confers tolerance to ALS-inhibiting herbicides is *gm-hra* and is a modified soybean *als* gene. Expression of the *gm-hra* gene is controlled by a soybean promoter. A single copy of these genes and other DNA regulatory sequences were introduced into soybean somatic[7] embryos using microprojectile bombardment[8]. Genetic segregation data collected over five generations demonstrated that *gm-hra* and *als* genes were stably inherited.

Pioneer's dual herbicide tolerant soybeans have been developed to allow growers to choose herbicides with different modes of action to best address their individual weed populations. Glyphosate is a broad spectrum herbicide that is effective on many weeds when applied post-emergence. ALS-inhibiting herbicides can effectively control many weeds when applied either post-emergence or pre-emergence. Growers may choose to grow 356043 soybeans if they have identified or are concerned about development of glyphosate tolerant weed populations in their fields and can derive some benefit from using 356043. Growers may also choose to grow these soybeans if they perceive some other benefit they can derive from their use (e.g., cost savings or other economic gain).

Herbicide tolerant (HT) soybeans have been the subject of several determinations of nonregulated status by USDA APHIS since 1993. APHIS has made determinations on five separate petitions requesting nonregulated status for HT soybeans: 93-258-01p, 96-068-01p, 98-014-01p, 98-238-01p, and 06-178-01p.

In 1994, APHIS deregulated the first HT soybean; Monsanto's glyphosate tolerant soybean, 40-3-2, (OECD Unique Identifier MON-Ø4Ø32-6) (Petition 93-258-01p, 1993 and EA, 1994). This event was the result of incorporating the *cp4 epsps* gene derived from *Agrobacterium* sp. strain CP4, a common soil bacterium. Since the 1994 deregulation, glyphosate tolerant/Roundup Ready soybeans have gained in market share such that in 2005 Roundup Ready soybeans were planted on approximately 89% of the U.S. soybean acreage (USDA-NASS, 2006), and 60% of the area planted to GE crops worldwide (James, 2005). Since the adoption of Roundup Ready soybean, cost to control weeds has decreased and farmers have saved in excess of $200 million per year in weed control costs (Gianessi, 2005). In addition to significant convenience in weed control, use of glyphosate tolerant soybean has encouraged the use of conservation-tillage. Because chemical weed control is so effective, soil tillage can be avoided thereby reducing soil erosion and fuel consumption used for the tillage (Service, 2007).

[4] By convention, GAT4601 refers to the specific protein
[5] By convention, *gat4601* refers to the specific gene
[6] A promoter is a region of DNA that controls expression of a gene.
[7] Refers to a non-sex cell
[8] A method of introducing DNA into cells by physically shooting small particles of gold or tungsten to which the gene(s) of interest has been attached.

Additional herbicide tolerant lines of soybean that APHIS has deregulated are from petition submissions by AgrEvo (merged into Aventis in 2000 and Bayer CropScience in 2002) in 1996 (96-068-01p) and 1998 (98-014-01p and 98-238-01p) requesting deregulation of glufosinate tolerant soybean lines (seven in total). None of the glufosinate tolerant lines have been commercialized. Most recently, in July 2007, APHIS granted nonregulated status to glyphosate tolerant MON 89788 (petition 06-178-01p), a soybean very similar to the first deregulated soybean.

Pioneer has field tested 356043 soybean since 2003. Agronomic performance, disease, and phenotypic assessments were conducted in trials at over 35 different locations in 15 states across the United States. Pioneer assessed 356043 soybean for possible allergens and toxins and submitted this data, as well as extensive compositional analysis data, to USDA as part of the petition process. Pioneer analyzed GAT4601 and GM-HRA proteins to look for similarities to known allergens and toxins and none were identified. Pioneer noted no other biologically meaningful differences (with respect to allergens and toxins) between 356043 soybean and the comparator control soybean[9] lines (Petition, pp. 63-64).

Field tests of 356043 soybean plants in the United States have been authorized by APHIS under the permit numbers noted in Appendix 5, page 140 of the petition. Pioneer evaluated 356043 soybean plants extensively to confirm that they exhibit the desired agronomic characteristics, are tolerant to glyphosate and ALS-inhibitors, are genetically stable under field conditions, and that they do not present a plant pest risk. They assessed seed germination, seed dormancy, response to abiotic stresses, plant growth, yield, days to maturity, disease incidence, insect damage and a number of other agronomic parameters (Petition pp. 65-76). The field tests have been conducted in agricultural settings under physical and reproductive confinement conditions.

B. USDA Regulatory Authority

APHIS regulations at 7 CFR Part 340, which were promulgated pursuant to authority granted by the Plant Protection Act (7 U.S.C. 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of GE organisms and products. 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 and is also a plant pest, or if there is reason to believe that it is a plant pest. These soybean plants have been considered regulated articles because they contain non-coding DNA regulatory sequences derived from plant pathogens. An organism is no longer subject to the regulatory requirements of 7 CFR Part 340 when it is demonstrated not to be a plant pest.

Section 340.6 of the regulations, titled "Petition for Determination of Nonregulated Status," provides that a person may petition APHIS to evaluate submitted data and determine that a particular regulated article is not a plant pest, and therefore should no

[9] Non-GE soybean

longer be regulated. If APHIS determines that the regulated article is not a plant pest, then APHIS can grant the petition in whole or in part. In such a case, APHIS authorizations (i.e., permits or notifications) would no longer be required for environmental release, importation, or interstate movement of the non-regulated article or its progeny.

As a Federal agency subject to compliance with the National Environmental Policy Act (NEPA),[10] APHIS has decided to prepare an environmental assessment to consider the environmental effects of this proposed action (deregulation) and alternatives to that action consistent with NEPA regulations.[11] This EA has been prepared in order to specifically address whether the unconfined cultivation and use in agriculture of Pioneer's 356043 soybeans would significantly affect the quality of the human environment[12].

C. U.S. Environmental Protection Agency and Food and Drug Administration Regulatory Authorities

In 1986, the Federal Government's Office of Science and Technology Policy (OSTP) published a policy document known as the Coordinated Framework for the Regulation of Biotechnology. This document specifies three Federal agencies that are responsible for regulating biotechnology in the United States: the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), the Environmental Protection Agency (EPA), and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA). Products are regulated according to their intended use, and some products are regulated by more than one agency. Together, these agencies ensure that the products of modern biotechnology are safe to grow, safe to eat, and safe for the environment. USDA, EPA, and FDA apply regulations to biotechnology that are based on the specific nature of each GE organism.

Under the Coordinated Framework, the U.S. Environmental Protection Agency (EPA) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, be registered prior to distribution or sale, unless exempt by EPA regulation. In order to be registered as a pesticide under FIFRA, it must be demonstrated that when used with common practices, a pesticide will not cause unreasonable adverse effects in the environment. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), pesticides added to (or contained in) raw agricultural commodities generally are considered to be unsafe unless a tolerance or exemption from tolerance has been established. Residue tolerances for

[10] 42 United States Code (U.S.C.) 4321 *et seq.*

[11] 40 CFR parts 1500–1508, 7 CFR 1b, and 7 CFR part 372.

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

pesticides are established by EPA under the FFDCA, and the U.S. Food and Drug Administration (FDA) enforce the tolerances set by EPA. Pioneer submitted the appropriate regulatory package to EPA for registering the use of glyphosate herbicide on the HT 356043 soybean. Safe use of glyphosate and ALS inhibiting herbicides have been established by the EPA through the registration of glyphosate and ALS for use on soybeans and the setting of tolerances for both herbicides (EPA 1982, 1993).

The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992, and appears at 57 FR 22984-23005. Under this policy, FDA ensures that human food and animal feed, including those derived from bioengineered sources, are safe and wholesome. Pioneer submitted a food and feed safety and nutritional assessment summary to FDA for 356043 soybean in 2006 that is currently under agency review.

II. PURPOSE AND NEED

The United States Department of Agriculture's Animal and Plant Health Inspection Service of the (USDA APHIS) has prepared an Environmental Assessment (EA) in response to a petition (APHIS Number 06-271-01p) from Pioneer Hi-Bred International (referred to hereafter as Pioneer). Pioneer is requesting a determination of nonregulated status for genetically engineered (GE) herbicide tolerant (HT) 356043 soybean (*Glycine max*) derived from their transformation event, 356043 (referred to hereafter as 356043 soybean). Pioneer developed the GE 356043 soybean to tolerate glyphosate and acetolactate synthase (ALS) -inhibiting herbicides. 356043 soybean is currently a regulated article under USDA regulations at 7 CFR Part 340, and as such, Pioneer has conducted interstate movements, importations, and environmental release (including field testing) of 356043 soybean under notifications or permits issued by APHIS. Pioneer petitioned APHIS requesting a determination that 356043 soybean does not present a plant pest risk and therefore 356043 soybean and its progeny derived from crosses with other nonregulated soybeans should no longer be regulated articles under these APHIS regulations.

III. ALTERNATIVES

A. No Action: Continuation as a Regulated Article

Under the Federal "no action" alternative, APHIS would deny the petition. Under this alternative, 356043 soybean would continue to be a regulated article under 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of 356043 soybean. APHIS might choose this alternative if there were evidence that 356043 soybean was a plant pest or if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of glyphosate/ALS-inhibitor tolerant soybeans.

Under this alternative, parties involved in commercial scale production, handling, processing or consumption of soybean will not have access to 356043 soybean. Other genetically engineered and conventional soybeans will still be available for purchase.

B. Proposed Action: Determination that Pioneer 356043 Soybeans are No Longer Regulated Articles, in Whole (Preferred Alternative)

Under this alternative, 356043 soybeans would no longer be a regulated article under 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of 356043 soybeans. APHIS might choose this alternative if there were sufficient evidence to demonstrate that 356043 soybeans are not a plant pest or to demonstrate the lack of plant pest and environmental risks from the unconfined cultivation of glyphosate/ ALS-inhibitor tolerant soybeans derived from this event.

Under this alternative, growers and other parties who choose not to plant transgenic soybean varieties or sell transgenic soybeans, should not be significantly impacted by the expected commercial use of this product. Non-transgenic soybeans will likely still be sold and will be readily available to those who wish to plant them for the reasons explained below. If Pioneer receives regulatory approval from all appropriate agencies, it will make 356043 soybean available to growers or breeders. Introduction of 356043 soybean is not expected to significantly alter the range of soybean cultivation. 356043 soybean will likely be introduced in areas where soybeans are currently grown.

APHIS has chosen the proposed action as the preferred alternative. This is based upon the determination of the lack of plant pest characteristics of Pioneer 356043 soybeans. The assessment by APHIS indicated that none of the alternatives should significantly impact the environment as described in section V.

IV. Affected Environment

A. Soybean

As noted previously, soybean is grown as a commercial crop on over 70 million acres in at least 31 states in the U.S. (USDA-NASS 2006). Eighty-nine percent (89%) of the 2006 soybean acreage in the United States was planted with glyphosate tolerant varieties and the introduction of 356043 soybeans is not likely to alter the range where soybeans are planted. Since this soybean is a new product, there is some uncertainty as to where 356043 will be readily adopted. The highest potential for adoption may be in locations where glyphosate tolerant weed populations have been identified. As previously noted, however, soybean farmers make choices to grow soybean varieties based on several factors: yield, weed 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 (Gianessi 2005). Depending upon all these factors, growers will ultimately base their decisions regarding seed choice on their individual needs and desires.

APHIS notes that products similar to 356043 soybean have been available to growers since 2006 (http://www.deltaandpine.com/soybean_products_rrs.asp, accessed 7/9/2007).

These products are tolerant to both glyphosate and ALS-inhibiting herbicides (i.e., sulfonylurea). They contain genes from Monsanto's Roundup Ready® technology and Delta and Pine Land's (D&PL) STS® (Sulfonylurea Tolerance System) technology. These varieties were developed through traditional breeding of Roundup Ready® soybean (genetically engineered) with D&PL STS® varieties (developed through mutation breeding). D&PL notes potential uses of their RR®/STS® soybean varieties in rotation with cotton, wheat and rice on its website (http://www.deltaandpine.com/soybean_agronomy_updates.asp, accessed 7/9/2007). None of the current D&PL RR®/STS® varieties are subject to oversight by USDA/APHIS since they were developed using traditional breeding of previously deregulated Roundup Ready® soybeans with STS® varieties that are not subject to USDA/APHIS oversight under 7 CFR Part 340. It is foreseeable that 356043 soybean could compete directly with these D&PL varieties due to their trait similarities.

Finally, if 356043 soybean is deregulated, it is unlikely that the percentage of soybean acreage in the United States planted with genetically engineered soybean varieties will dramatically increase beyond current levels for the following reasons: 1) a certain small percentage (<1%) of soybean growers choose to grow organic soybeans, and genetically engineered soybean varieties cannot be grown and certified as organic, 2) some growers will choose to grow non genetically-engineered soybeans for other marketing reasons, 3) a certain percentage of soybean growers each year may choose to rotate out of single glyphosate resistant soybeans and use seed tolerant to multiple herbicides (such as D&PL RR®-STS® soybean) with alternate modes of action and/or tillage to avoid weed shifts or the selection of glyphosate tolerant weeds, and 4) they may simply choose other varieties without herbicide tolerance traits that are better suited to their specific growing conditions. Soybean acreage is not expected to increase as estimates of the 2007 soybean crop indicate that planting will be the lowest level since 1996, reflecting an 11% decrease in acreage compared to 2006 (http://www.nass.usda.gov/Newsroom/2007/03_30_2007.asp), and in the prior five years, soybean production was relatively steady varying from 72 million acres to 75.5 million acres (http://www.nass.usda.gov/QuickStats/index2.jsp).

B. Weed Competition and Control

Uncontrolled weed populations can cause yield losses of up to 50-90 percent, in soybean fields. Before the development of effective herbicides for the selective control of weeds in soybeans in the early 1960's, cultural practices including tillage, using 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 et al, 1987). By the early 1990's, over 70 individual herbicides or combination products were registered for weed control in soybeans (Gianessi et al, 2002). Along with the increased number and use of herbicides on soybeans, came plant species that developed resistance to numerous herbicide modes of action (Weed Science, 2006). With the 1996 commercial introduction of glyphosate tolerant soybeans, a major shift 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 as noted in the following table (Gianessi, et al 2002).

Percent of U.S. Soybean Acres Treated with the Following Herbicides in 1995 vs. 2001 and 2006

	1995	2001	2006		1995	2001	2006
2,4-D	10	4	3	**Glyphosate**	20	76*	96
2,4-DB	1		<1	**Imazamox**		5	<1
Acifluorfen	12	3	<1	**Imazaquin**	15	2	1
Alachlor	4	<1	<1	**Imazethapyr**	44	9	3
Bentazon	12	1	<1	**Lactofen**	5	1	<1
Chlorimuron	16	5	4	**Linuron**	2		
Clethodim	5	4	3	**Metolachlor**	7		
Clomazone	4	<1		**Metribuzin**	11	2	2
Cloransulam		5	1	**Paraquat**	2		1
Dimethenamid	1			**Pendimethalin**	26	10	3
Ethalfluralin	1			**Quizalofop**	6	<1	<1
Fenoxaprop	6	3	<1	**S-Metolachlor**		<1	1
Fluazifop	10	3	1	**Sethoxydim**	7	1	<1
Flumetsulam	2	<1	<1	**Sulfentrazone**		5	1
Flumiclorac		<1	1	**Thifensulfuron**	12	2	1
Fomesafen	4	7	2	**Trifluralin**	20	7	2

* In 2001, 68 percent of U.S. soybeans were glyphosate tolerant (Pew, 2001) (USDA NASS, 2007)

The reasons for growers rapidly switching to glyphosate tolerant varieties are numerous (Gianessi, et al 2002). These varieties allow:

- Effective post emergence treatment,
- broad spectrum control of weeds with a single herbicide,
- flexibility in time of application,
- total lower costs of the glyphosate treatment vs. alternative programs,
- reduced tillage costs and
- reduced costs of fewer herbicide applications.

As has occurred with many weeds, some weeds in soybean have developed tolerance to particular herbicide modes of action. Weeds commonly found in soybeans that have developed tolerance to glyphosate include horseweed (*Conyza canadensis)*, common waterhemp (*Amaranthus rudis*), common ragweed (*Ambrosia artemisiifolia*), giant ragweed (*Ambrosia trifida*), and Palmer amaranth (*Amaranthus palmeri)* (Weed Science, 2007). Additionally, two of these weeds, waterhemp and horseweed, have been noted to be tolerant to both ALS-inhibitors and glyphosate in localized areas (Weed Science, 2007). Weed scientists are developing management strategies to help ensure control of these weeds (Loux et al., 2004, Loux and Stachler, 2006), and companies and university scientists have developed and are developing alternative herbicide resistant crop strategies (Service, 2007). A primary use of 356043 soybean is that it can enable effective weed control using an ALS-inhibitor herbicide in areas where glyphosate tolerant weeds are present. As soybean varieties tolerant to both glyphosate and ALS-inhibitors are

currently available, 356043 is likely to compete with these dual herbicide tolerant varieties in the event 356043 is deregulated.

A study assessing the ecological impact of glyphosate on weed resistance researched the fitness costs and benefits of herbicide tolerance of glyphosate tolerant *Ipomoea purpurea* (tall morning glory) (Baucom and Mauricio, 2004). In an agricultural field in Georgia thirty-two random *I. purpurea* plants, which had been sprayed with Roundup for approximately 8 years were chosen for this evaluation. All seeds collected from each plant shared the maternal genetic contributions which were then used as the unit for the genetic analysis. Seeds from each of the 32 lines were self-pollinated for one generation; the seeds from the F2 generation were grouped according to each maternal line and planted in five spatial blocks to account for habitat heterogeneity. All plants were sprayed with enough Roundup that had previously been shown to reduce biomass production by 90%. Results demonstrated that the tolerant line produced 35% fewer seeds in the absence of Roundup than the most susceptible lines. These results suggest that in the absence of herbicide selection (e.g., spraying with Roundup), herbicide tolerance would be lost in subsequent generations due to higher metabolic costs to resistant weeds. Therefore it is possible that weeds may lose their resistance trait if herbicide use is discontinued (Baucom and Mauricio, 2004).

To minimize the development of weed resistance, the petitioner recommends grower adoption of Integrated Weed Management (IWM) programs through communication, research, education, and participation in industry coalitions such as the Herbicide Resistance Action Committee (HRAC). The HRAC is an industry based group whose mission is to "Facilitate the effective management of herbicide resistance by fostering communication and co-operation between industry, government, and farmers." Specific recommended practices include:

- Scouting fields prior to the application of any herbicide to determine the species and the need for an herbicide application.
- Using alternative weed management practices, such as mechanical cultivation, delayed planting and weed-free crop seeds.
- Rotating crops with an accompanying rotation of herbicides to avoid using herbicides with the same site of action on the same field.
- Limiting the number of applications of a single herbicide or herbicides with the same site of action in a single growing season and in successive years.
- Using mixtures or sequential treatments of the herbicides having a different site of action.
- Scouting fields after application to detect weed escapes or shifts and applying alternative control methods to avoid seed deposition in the field.
- Cleaning equipment before leaving fields suspected to have resistant weeds to minimize the spread of weed seed.

- When using herbicides, using full label application rates and compatible tank mix partners.
- Where practical, using cover crops and other methods to reduce weed seeds in the soil.

Use of 356043 soybeans is amenable to the above integrated weed management program. By having herbicide resistance to two different modes of action use of 356043 soybeans should facilitate management practices that allow the application of more than one herbicide modes of action within a season and in successive years.

V. Potential Environmental Impacts.

Potential environmental impacts addressed in this EA are those that pertain to the use of Pioneer 356043 soybeans and its progeny in the absence of confinement. APHIS considered potential impacts related to gene introgression[13] changes in soybean composition, changes in weediness, potential effects on non-target and threatened or endangered species, changes to biodiversity, changes in commercial use, changes to agricultural practices, changes to conventional or organic farmers, changes to agricultural commodities, and possible cumulative impacts. If APHIS takes no action, commercial scale production of 356043 soybean and its progeny is effectively precluded, and the presently deregulated and commercially available herbicide tolerant soybean varieties would be the only available choice of herbicide tolerant varieties. Pioneer 356043 soybeans could still be grown under APHIS permit as they have been for the past several years. However, widespread, unconfined plantings of 356043 soybean would not be allowed as long as these soybean plants are considered regulated articles. If APHIS decides to choose the "No Action" alternative there would be no notable environmental impacts associated with this action.

A. Potential Impacts from Gene Introgression from Pioneer 356043 Soybeans into its Sexually Compatible Relatives.

In assessing the risk of gene introgression from 356043 soybeans into its sexually compatible relatives, APHIS considers two primary issues: 1) the potential for gene flow and introgression; and 2) the potential impact of introgression.

The genus *Glycine* has approximately 9 species with *G. max* being placed in the subgenus *Soja* along with one other species, *G. soja* (previously *G. ussuriensis*). *G. max* is sexually compatible with only *G. soja* and no other *Glycine* species. *G. max* is the only *Glycine* species located in the United States other than a few *G. soja* plants in research plots. *G. max* has never been found in the wild (Hymowitz and Singh, 1987). Therefore, it is not likely that gene flow and introgression of 356043 soybeans into other species will occur; thus, any potential environmental impact resulting from gene flow and introgression to other species is not anticipated under either the no action or proposed action alternative.

[13] Introgression is the successful, stable incorporation of a gene (or genes) from one organism into another as a result of repeated hybridizations.

B. Potential Impacts on Soybean Composition

Data supplied in the petition and reviewed by APHIS (Chapter V, pp 24-50) support the conclusion that 356043 contains newly introduced genes *gat4601* (glyphosate acetyltransferase from *Bacillus licheniformis*, a common soil bacterium) and *gm-hra* (modified acetolactate synthase from soybean). Additionally, other DNA sequences were introduced that serve to control gene expression. Section IV (pp. 20-23) of the petition describes the genes and gene regulatory sequences introduced into 356043 soybean. Several of the additional gene sequences originate from soybean itself and others are from common plant viruses. The intended changes to 356043 result in the production of the proteins glyphosate acetyltransferase and a slightly modified acetolactate synthase that impart tolerance to glyphosate and ALS-inhibiting herbicides. Both the GAT4601 and GM-HRA (modified ALS) proteins were assessed by Pioneer for possible allergenicity and toxicity using internationally accepted guidance from the Codex Alimentarius Commission. Complete summaries of the food and feed safety assessments for the GAT4601 and GM-HRA proteins are found in sections VI-E and VI-F (pp. 63-64) of the petition. Pioneer's assessment of GM-HRA protein noted high similarity with ALS proteins found in bacteria, fungi, algae and other plants. Pioneer also analyzed protein sequence similarities with known and putative protein allergens and toxins and found no similarity that would indicate either allergenicity or toxicity of GM-HRA protein. ALS proteins have been the subject of previous FDA consultations in GE flax (http://www.cfsan.fda.gov/~lrd/biocon.html BNF 000050) and GE cotton (http://www.cfsan.fda.gov/~lrd/biocon.html BNF 000030). In both cases, FDA indicated that they had no further questions regarding safety and nutritional assessments submitted to the agency. A nearly identical ALS protein is found in a number of non-GE Clearfield® and STS™ plant varieties which are grown widely across the globe (http://www.agro.basf.com/p02/AP-Internet/en_GB/portal/show-content/content/Products, http://www.deltaandpine.com/soybean_products_sts.asp). These products were developed in the 1980s and 1990s and have a history of safe use.

Additionally, Pioneer conducted extensive analyses to assess compositional differences between 356043, the comparator non-GE 'Jack' variety, and other standard non-GE soybean varieties. Proximate analyses for protein, fat, ash, and fiber were conducted on both soybean forage and grain. Soybeans were analyzed for 24 fatty acids (10 were undetectable), 18 amino acids, 8 isoflavones, 23 free amino acids, 5 anti-nutrients, and 2 acetylated amino acids (Section VIII., pp. 77-97 of the petition). The results of these analyses are discussed below.

Pioneer assessed 356043 for levels of 8 isoflavones (e.g., genistin, glycitin, etc.) and 5 antinutrients (e.g., stachyose, phytic acid, etc.). Eleven of the thirteen analyses showed no significant differences in concentrations of these compounds between 356043 and the non-transgenic Jack variety. Pioneer noted minor differences in mean levels of one isoflavone (malonyldaidzin, Table 26, page 93 of the petition) and one antinutrient (trypsin inhibitor, (Table 27, page 95). Although statistically different from control (Jack) lines, the levels of malonyldaidzin and trypsin inhibitor noted in 356043 can be found within the range of concentrations of these same compounds noted in the control.

Because all these constituents are also found within the range of values for conventional soybeans, APHIS concludes that 356043 soybean poses no more of a plant pest risk or environmental risk from its composition than conventional soybean.

Pioneer noted increases in 2 minor fatty acids, heptadecanoic (C17:0) and heptadecenoic (C17:1) acids (Petition, pp. 81-83). These increases likely result from a change in the GM-HRA protein that shifts a metabolic pathway leading to production of the C17 fatty acids. Pioneer describes these changes in the Petition (Appendix 6, pp. 141-142). The major fatty acids in soybean consist of linoleic, linolenic, oleic, palmitic and stearic acids. In the control "Jack" variety, these major fatty acids make up over 98% of total fatty acids (Petition p. 83). Combined values of heptadecanoic and heptadecenoic fatty acids in the comparator "Jack" soybean are less than 0.25% of all the fatty acids. In 356043 soybean, the C17 fatty acids still make up less than 0.8% of the total fatty acids. Heptadecanoic and heptadecenoic acids are found in commonly consumed foods including tofu, beef, pork. lamb, bison, soy milk, salmon, frozen pizza and numerous other fast-food products (http://www.nutritiondata.com). Heptadecanoic acid is found in corn, soybean, sunflower, peanut and olive oils. Heptadecenoic acid is found in olive oil (Petition, p. 81). APHIS searched numerous scientific databases and could find no evidence that increased consumption of these fatty acids at these levels is associated with any adverse effects in humans.

Pioneer also noted increased levels of 2 acetylated amino acids from their compositional analyses. The GAT protein preferentially targets glyphosate as substrate. However this enzyme also acetylates the amino acids aspartate and glutamate. Consequently, levels of N-acetylaspartate (NAA) and N-acetylglutamate (NAG), were elevated in 356043 to levels 230 and 8 fold, respectively, above the levels found in conventional soybean (petition Table 23 p. 87). Together these acetylated amino acids represent less than 0.15% of the total amino acids in 356043 soybean. No other amino acids, free or acetylated, were found to differ significantly from levels found in conventional soybean.

N-acetylated amino acids are widely found throughout the plant and animal kingdom and so are present in many food sources (Table 1 and Table 2 p. 4 in addendum to Pioneer petition). As noted in an addendum to the petition (p. 3, Addendum 2), acetylation of proteins (which are made up of amino acids) is employed in the food industry to affect various properties of protein concentrates that may be added to food (El-Adawy, 2000, Ramos and Bora, 2004). Pioneer analyzed eggs, yeast, ground turkey, chicken and beef and found various levels of both NAA and NAG in these products (petition, p. 87 and pp. 3-4 of addendum 1). Because these amino acids are found in these common foods, it appears that they are normal components of the human diet.

NAA is an abundant amino acid in the central nervous system (CNS) (Demougeot, C., et al., 2004) but its biological function is not exactly clear (Chakraborty, G., et al., 2001). It is, however, essential for the formation and/or maintenance of myelin in the CNS (Chakraborty, G., et al., 2001). In mammals, NAG is found at high concentrations in the

liver and small intestine but it is also found in the brain (Caldovic and Tuchman, 2003). Levels of NAG in the liver increase with increased protein consumption and are also affected by growth hormone levels (Caldovic and Tuchman, 2003).

Pioneer provided potential human dietary exposure estimates of NAA and NAG that would result from an assumption that 356043 would constitute 45% of consumed soybeans (in products such as tofu, soy milk, edamame, soybean oil, etc.). On average, addition of 356043 soybean to the diet of the U.S. population was estimated to increase consumption of NAA from 2.6 µg/kg body weight/day to 6.6 µg/kg body weight/day[14] (For a 120 lb person, this translates to an increased consumption from 143 µg/day to 363 µg/day. One µg is one-millionth of a gram). NAG consumption was estimated to increase from 1.9 µg/kg/day to 3.2 µg/kg/day. APHIS searched numerous scientific databases and found no indication that exposure to either NAA or NAG from food has led to adverse effects in humans. Most species have an enzyme that readily converts N-acetylated amino acids back to the free amino acid. The small increase in exposure to N-acetylated amino acids that might result in response to 356043 constituting 45% of consumed soybeans is not considered significant as the N-acetylated amino acids are readily metabolized to the free amino acid.

A rare human condition called Canavan's disease (CD) is caused by an inherited mutation in the aspartoacylase gene (aspartoacylase converts NAA into aspartate and acetate). This condition results in the inability to transform NAA to the free amino acid, aspartic acid, and leads to an accumulation of excess NAA in the brain. The resulting deficiency in metabolism of NAA leads to inadequate myelin formation in the brain and severe developmental abnormalities (Kirmani et al., 2002; Madhavarao et al., 2005; Mehta and Namboodiri, 1995). Pioneer submitted information on the potential impact of dietary exposure of NAA on individuals with CD. Analysis of the amounts of NAA excreted by healthy individuals compared to those with CD (Petition, Addendum 2) indicates that the vast majority of NAA within the body is produced endogenously (within the body) and does not result from dietary exposure (Petition, Addendum 2). Because the levels of NAA and NAG are negligible from dietary sources compared to the amounts produced endogenously by individuals with CD, individuals with CD are not expected to have adverse effects from consuming 356043.

As soybean meal is a major constituent of animal feed, particularly for chickens, cattle, and pigs, it is expected that animal exposure to NAA and NAG would also increase should APHIS deregulate 356043 soybeans. APHIS reviewed information submitted by Pioneer relating to the safety of the acetylated amino acids NAA and NAG (Petition, Addendum 1) and noted several points in their assessment:

- Acetylated amino acids are naturally occurring compounds that are found in many plants and animals.
- Up to 80% of cellular proteins in mammalian systems are estimated to be acetylated (Brown and Roberts, 1976; Driessen et al., 1985).

- Acetylation of proteins is used in the food and feed industries (El-Adawy, 2000) (e.g., use of N-acetyl-L-methionine in place of free L-methionine for livestock).
- Metabolism studies of other acetylated amino acids on rats, pigs and humans have not raised safety issues (Magnusson et al., 1989; Arnaud et al., 2004; Boggs, 1978; Boggs et al., 1975; Neuhauser and Bassler, 1986; Stegink et al., 1980 and 1982).
- NAA and NAG are components of human and animal diets and there is no indication that they are associated with adverse effects when consumed.
- The small increase in exposure to N-acetylated amino acids predicted to occur from consuming 356043 soybeans is not expected to have any adverse effects on animals as they have the enzymes to interconvert acetylated and deacetylated amino acids.

Considering all the information noted above on compositional similarities and differences, if APHIS chooses the proposed action to deregulate soybean 356043, significant impacts are unlikely. Similarly, if APHIS chooses alternative A to continue to regulate 356043, there should also be no significant impact on the quality of the human environment.

Finally, APHIS/BRS is in contact with FDA regarding its food/feed nutritional and safety assessments for this soybean. The safety of food and feed derived from soybean 356043 falls within the regulatory purview of the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (FFDCA). Under FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from soybean 356043 must be in compliance with all applicable legal and regulatory requirements. FDA's final review for 356043 soybean is pending. Pioneer has indicated that it would not commercialize 356043 soybean without review by FDA.

C. Potential Impacts Based on the Relative Weediness of Pioneer 356043 Soybean.

APHIS assessed whether 356043 soybean is any more likely to become a weed than the non-transgenic recipient soybean line or other soybean currently cultivated. The assessment encompasses a thorough consideration of the basic biology of the conventional soybean compared to evaluation of the unique characteristics of 356043 soybean.

In the United States, soybean is not listed as a weed in the major weed references (Crockett, 1977; Holm *et al.*, 1979; Muenscher, 1980), nor is it present in the lists of noxious weed species distributed by the Federal Government (APHIS-USDA. 2006). Soybean has been grown throughout the world without any report that it is a serious weed. It is not generally persistent in undisturbed environments without human intervention. In the year following cultivation, soybean may grow as a volunteer under specific conditions and can be easily controlled by herbicides or mechanical means. It does not compete effectively with cultivated plants or primary colonizers (OECD, 2000).

G. max has never been found in the wild (Hadley and Hymowitz, 1973). For these reasons, it is unlikely to become a weed.

In 2004 and 2005, Pioneer conducted field trials to evaluate phenotypic characteristics comparing 356043 to soybean variety "Jack," the recipient conventional parental line, at over 16 field trial locations in U.S. growing regions. Trials at numerous other locations were conducted in 2006 (Appendix 5, p. 140 of the petition). Data collected on agronomic performance characteristics are described in Chapter VII of the petition (pp. 65-76). Pioneer assessed aspects of performance, such as seed germination, seedling vigor, plant height, days to maturity, seed weight, yield, disease, and insect damage. Figure 26, on page 68 of the petition, notes many of the trial data collection locations. Table 12, on page 69, describes several of the field agronomic characteristics that Pioneer measured. Tables 13 through18, on pp 70-76, document summary data collected from those trials. There were no significant differences between 356043 and Jack for any of the assessed traits. Based on analysis of data on all these parameters, soybean 356043 is unlikely to pose any more of a plant pest risk from weediness than conventional soybean. If APHIS chooses the no action alternative there should be no significant impact on the environment from increasing the weediness of soybean. Similarly, there should also be no significant increase in weediness from deregulating soybean 356043.

D. Potential Impact on Non-target and Beneficial Organisms

APHIS evaluated the potential for deleterious effects or significant impacts on non-target and beneficial organisms. First APHIS notes that neither GAT nor GM-HRA proteins are known to have toxic properties. The GAT protein sequence, which is derived from the bacterium *Bacillus licheniformis*, has been considered safe for food and feed in the U.S., Canada, and Europe (EU Commission, 2000; FDA, 2001). GM-HRA protein is a modified form of the soybean ALS protein. Similar proteins have been commercialized in Clearfield® and STS® products, which are grown on millions of acres in the U.S. every year. As such, ALS (the protein nearly identical to GM-HRA) is consumed regularly by anything that feeds on any Clearfield® or STS® products (e.g., corn, rice, sunflower, canola, wheat, and soybean).

Pioneer collected extensive data on possible effects on non-target organisms in the field. They made observations on organisms such as beetles, grasshoppers, aphids, leaf miners, stinkbugs and whiteflies (Petition, Section VII-C, page 75). Data was compiled at all locations in 2003, 2004, and 2005. They also assessed insect damage in 2005 across 6 different locations (Petition, Table 15, p. 73). No significant differences were identified between 356043 and control soybeans in any instance.

Most soybean meal produced is used in animal feed products (Petition, Section VIII-D, p. 96). In order to address the wholesomeness and nutrition of 356043 compared with control soybeans, Pioneer conducted a 42-day chicken feeding study (a recognized model for assessing the wholesomeness of feeds) where 356043 soybean was used as a large part of the chicken diet (Petition, Section VIII-D, p. 96). The study assessed mortality, weight gain, and feed efficiency parameters over a 42-day period as well as various carcass and organ data at the end of the period. Pioneer did not observe any significant

differences in the parameters analyzed (Section VIII-D, page 96) and no adverse effects on the chickens were observed.

To assess unintended effects, APHIS analyzed data submitted by the developer to determine if there were changes to phenotype, germination, vegetative growth, reproductive parameters and response to biotic stressors (insect and disease stress) associated with 356043 soybeans in comparison to the various control lines (non-transgenic). Data presented in Table 17- 18 (page 75-76 of the petition) indicates that the ecological interactions between 356043 soybeans and the control lines were similar. Considering all the data noted from field observations, the broiler chicken feeding study and known safety information on GAT and ALS proteins, as well as changes in NAA and NAG concentrations, as well as minor fatty acid changes, APHIS concludes that 356043 soybeans are unlikely to pose a safety risk to non-target and beneficial organisms.

If APHIS chooses the no action alternative, there should also be no significant impact on non-target or beneficial organisms from the commercialization of 356043 soybean.

E. Potential Impact on Threatened and Endangered Species

In addition to the analysis of potential impact to non-target organisms described above, APHIS also considered the potential impact on federally listed threatened or endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. In this analysis, APHIS considered the biology of 356043, as well as typical agricultural practices associated with cultivation of soybean. As noted previously, the 356043 soybean differs from non-transgenic soybean only in the expression of the *gat4601* and *gm-hra* genes which are responsible for herbicide tolerance to glyphosate and ALS-inhibiting herbicides, as well as an increase in the amino acids N-acetylaspartate (NAA) and N-acetylglutamate (NAG), and increases in heptadecanoic and heptadecenoic acids. As discussed in Section V. B. of this EA, the proteins produced by the inserted genes and the increased amino and fatty acids do not raise safety issues. The 356043 soybeans do not express additional proteins, natural toxicants, allelochemicals, pheromones, hormones, etc. that could directly or indirectly affect a listed TES or species proposed for listing. Data submitted on the composition of the 356043 soybeans indicate that these soybeans are not significantly different from non-transgenic soybeans and would not be expected to have any impact on TES that would be different from non-transgenic soybeans. Finally, the 356043 soybean is not sexually compatible with a federally listed TES or a species proposed for listing.

Soybeans do not grow and persist in unmanaged habitats and would not be expected to invade and/or persist in the natural environment. Cultivation of 356043 soybean is not expected to differ from typical soybean cultivation. As such, soybean fields are typically highly managed agricultural areas that would be expected to be dedicated to crop production for many years. The extent to which 356043 soybean will be grown is unknown. Presently over 90% of the United States soybean acreage is planted with varieties tolerant to glyphosate, and it is expected that varieties containing this event will be used in areas with glyphosate tolerant weeds. Although a shift to planting 356043

soybeans could result in an increase in the use of ALS-inhibiting herbicides, this increase is likely to occur anyway because of the availability of RR®/STS® varieties. Several of the ALS-inhibitor herbicides have comparable environmental impacts (as calculated by a Cornell University publication (http://nysipm.cornell.edu/publications/eiq/default.asp)) as glyphosate, which will continue to be used on vast acres across the globe. Additionally, as noted in the table on pages 9 -10 of this EA, ALS inhibitors continue to be used and have been used effectively on soybeans in the past (e.g., chlorimuron, imazaquin, thifensulfuron, and others) on a higher percentage of acres than currently used. As these herbicides have been used effectively and safely for many years on soybeans as well as other crops, there is no indication that a reversion to use on a higher percentage of acres would be associated with significant environmental impacts. It is uncertain exactly which ALS-inhibiting herbicide(s) would be recommended for use on 356043 soybean.

After reviewing possible effects of deregulating 356043 soybean, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. Consequently, an exposure analysis for individual species is not necessary. APHIS has considered the effect of 356043 soybean production on critical habitat and could identify no difference from affects that would occur from the production of other soybean varieties. Therefore, APHIS has determined that granting a petition of non-regulated status for 356043 soybean should have no effect on federally listed threatened or endangered species and species proposed for listing, or on designated critical habitat or habitat proposed for designation. Consequently, a written concurrence or formal consultation with the USFWS is not required for this action.

F. Potential Impacts on Biodiversity

Analysis of available information indicates that 356043 exhibits no traits that would cause increased weediness, that its unconfined cultivation should not lead to increased weediness of other sexually compatible relatives (of which there are none in the United States), and it is likely to have no effect on non-target organisms common to agricultural ecosystems or threatened or endangered species recognized by the U.S. Fish and Wildlife Service. Based on this analysis, there is no apparent potential for significant impact to biodiversity. If APHIS chooses the no action alternative, there would also be no impact on biodiversity.

G. Potential Impacts on Commercial Use

APHIS has evaluated field trial data reports submitted on this event and progeny and has noted no significant adverse effects on non-target organisms, no increase in fitness or weediness characteristics, and no effect on the health of other plants. APHIS expects that if these plants were grown under permit in the future, they would perform similarly. If APHIS were to grant the petition for non-regulated status in whole, 356043 soybean and its progeny would no longer be considered regulated articles. The unrestricted cultivation and distribution of 356043 soybean would be allowed and would not be subject to regulation by APHIS under 7 CFR Part 340. Pioneer informed APHIS that the company

does not intend to commercially release 356043 soybean until all key soybean import markets with functioning regulatory systems have also granted approval of 356043 soybean. Based on all these considerations, there is no apparent potential for significant impact on commercial use if APHIS chooses either the "no action" alternative or grants nonregulated status to 356043 soybean.

H. Potential Impacts on Agricultural Practices

APHIS considered potential impacts associated with the cultivation of 356043 soybeans on current agricultural practices, in particular, those associated with weed control. Potential impacts include the development of herbicide resistant weeds through continued use of glyphosate and ALS-inhibitor herbicides and the stacking of herbicide resistance traits from previously deregulated as well as other non-GE herbicide tolerant soybean lines (i.e., Roundup Ready® and STS® varieties).

STS® (not GE, tolerant to ALS-inhibitor herbicides and not tolerant to Roundup) varieties have been available for at least 10 years (http://web.aces.uiuc.edu/value/factsheets/soy/fact-sts-soy.htm) and an estimated 10 million acres of STS® varieties were grown in 2003 (http://web.aces.uiuc.edu/value/factsheets/soy/fact-sts-soy.htm). Pioneer notes STS® soybeans were grown on ~3.8 million acres in 2006 (Petition, p. 104).

As noted previously in this EA, soybeans tolerant to both glyphosate and ALS-inhibiting herbicides (e.g., sulfonylureas) have been available to growers since 2006 (Section IV.A). Those varieties (marketed as Roundup Ready/STS) were developed by hybridizing GE Roundup Ready® varieties with STS® varieties developed through mutation breeding. Five (5) RR®/STS® varieties were available for the 2007 season (http://www.deltaandpine.com/soybean_products_rrs.asp). These varieties were developed to allow growers another option for weed control, likely in areas where glyphosate tolerant weeds exist or have developed.

APHIS does note two reports of weeds that have developed tolerance to both ALS-inhibitors as well as glyphosate in Missouri and Ohio (http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12&FmHRACGroup=Go). The species listed are horseweed (*Conyza canadensis)* and waterhemp (*Amaranthus rudis)*. Growers have adapted to the development of herbicide tolerant weed populations in the past and it is reasonably foreseeable that they will continue to do so in the future. As noted, weed scientists are developing management strategies to help ensure consistent control of these weeds (Loux et al. 2004, Loux and Stachler 2006), and companies and university scientists have developed and are developing alternative herbicide resistant crop strategies (e.g. Service 2007). Pioneer has shown support for Integrated Weed Management programs in the past and it is likely that they will continue to do so in the future.

GE crop technology has improved growers' ability to control weeds, reducing the need to rely on soil cultivation and seed-bed preparation as a means to getting good weed control.

GE crop technology has also eliminated the potential damage caused by some soil-incorporated residual herbicides in crops used in rotation. Under traditional herbicide applications with conventional crops, a post-emergent herbicide application may result in 'knock-back' (crop damage from the residual herbicide application); this problem is less likely to occur in herbicide-tolerant crops. The adaptation of no-till or reduced till systems results in time savings and reduced equipment usage. While no- or reduced-till systems are not new, the resultant weed control using engineered herbicide-tolerant crops allows the farmer to continue with the no-till/reduced-till systems long after conventional crops necessitate going back to full plowing due to excessive weeds.

Along with the typical no- or reduced-till systems, there is significant fuel savings associated with making fewer spray applications (relative to conventional crops) (Brookes and Barfoot, 2006). The authors also determined that the fuel savings has also resulted in reductions in carbon dioxide emissions. In 2005 this was estimated to be about 2.1 billion fewer pounds of CO_2 emitted (arising from reduced fuel use of 94 million gallons).

No increases in glyphosate use are predicted from the decision to grant nonregulated status to 356043 because the adoption rate of glyphosate resistant soybeans is already extremely high and expansion of glyphosate resistant soybean plantings beyond the current amount are not reasonably foreseeable based on past trends and the economic benefits of planting other soybean varieties or corn. Soybeans resistant to ALS inhibitors were planted on approximately 5% of the total soybean acreage and therefore use of herbicides targeting ALS could conceivably increase especially if glyphosate resistant weeds become more widespread. However, there is some uncertainty as to the adoption rate of 356043 soybean given the fact that similar varieties with essentially identical herbicide use and weed management practices already exist in RR®/STS® varieties. Growers who choose to grow RR®/STS® varieties will be afforded another seed choice. Agricultural practices associated with either these varieties or 356043 are essentially the same. Growers who desire to use soybean varieties with tolerance to both glyphosate and ALS-inhibitors would purchase RR®/STS® varieties if 356043 varieties were not available. By this reasoning, impacts to existing agricultural practices should not be significant with either a decision to grant nonregulated status (proposed action) or the "no action" alternative. Similarly, the use of ALS inhibitors for weed control is unlikely to be impacted by the decision to grant or not to grant nonregulated status to 356043 because dual herbicide resistant varieties already have been commercialized and are widely used.

I. Potential Impacts on Conventional and Organic Farming

Organic Farming operations as described by The National Organic Program administered by USDA's Agricultural Marketing Service requires organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with prohibited substances from adjoining land that is not under organic management. Organic production operations must also 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. Excluded methods include 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. Organic certification involves oversight by an accredited certifying agent of the materials and practices used to produce or handle an organic agricultural product. This oversight includes an annual review of the certified operation's organic system plan and on-site inspections of the certified operation and its records. 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. 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. Organic certification of a production or handling operation is a process claim, not a product claim.

In 2003, of the total 73.4 million acres of soybeans in the United States (USDA-ERS 2006), 122,403 acres (0.17%) were certified organic soybeans (USDA-ERS 2005). It is not likely that farmers, including organic and conventional farmers, who choose not to plant transgenic soybean varieties or sell transgenic soybeans, will be significantly impacted by the commercial use of this product. Non-transgenic soybean will likely still be sold and will be readily available to those who wish to plant it (e.g., STS® varieties). An internet search of "soybean seed company" identifies vendors that offer all types of soybean seeds for purchase including conventional and transgenic. A few of the many searchable sites available include www.lathamseeds.com and http://www.bo-jac.com. If Pioneer receives regulatory approval from all appropriate agencies, it will make 356043 soybean available to growers and breeders. It is not likely that other farmers who choose not to plant or sell 356043 soybean or other transgenic soybeans will be significantly impacted by the expected commercial use of this product as non-transgenic soybeans: (a) will likely still be sold and will be readily available to those who wish to plant them; (b) will be able to coexist with biotech soybean producers as they do now where over 89% of soybeans are planted with transgenic varieties and no significant increase is expected for acreage planted with transgenic soybeans for the reasons given in section IV.

The industry standard for conventional farming operations for prevention of unintended contact with prohibited substances, are described by the Association of Official Seed Certifying Agencies (AOSCA). Operational procedures for soybean seed certification that ensures quality assurance of seed production includes record keeping, inspection, and testing patterned after the certification system for private label seed production. Since soybean is primarily a self-pollinating crop, a minimum of 6 feet between fields is required in order to prevent mechanical mixing and minimize cross pollination (http://www.ilcrop.com/fieldsrv/seedprog/seedprog.htm).
If APHIS chooses the no action alternative there would be no direct impact on organic or other non-transgenic soybean farmers. The current cultivation practices are unlikely to change and over 89% of the soybeans produced would likely be planted with the current herbicide tolerant biotech soybean varieties. If the 356043 line is granted nonregulated

status, there also would be no direct impact on organic or other non-transgenic soybean farmers as the market share of transgenic soybean (which may include Monsanto's new MON89788 subject of a APHIS petition 06-178-01p) is unlikely to change by the introduction of 356043.

J. Potential Impacts on Raw or Processed Agricultural Commodities

Pioneer presented extensive data in their Petition relating to plant growth parameters, disease incidence, insect susceptibility, and forage and seed composition compared to the soybean variety "Jack" as well as other soybean varieties. APHIS analysis of this data indicate no differences between 356043 soybean and the non-transgenic Jack variety that would be expected to cause either a direct or indirect plant pest effect on any raw or processed plant commodity from deregulation of 356043 soybean. Compositional analysis of 356043 soybean detected increased levels of two minor fatty acids, heptadecanoic acid and heptadecenoic acid (discussed in Section V.B.). Together, these fatty acids make up less than 0.8% of soybean total fatty acids. Similarly, elevated levels of NAA and NAG still only represent less than 0.15% of the total soybean amino acids. Neither of these noted changes would be expected to alter how 356043 soybeans are handled as commodities as these changes are extremely small in terms of the overall composition of these soybeans. Consequently, no significant effects on raw or processed commodities are expected from these small differences in composition if APHIS were to grant nonregulated status to 356043 soybean. Similarly, no significant effects would be expected if APHIS chooses the "no action" alternative.

K. Potential Cumulative Impacts

APHIS considered whether the proposed action could lead to significant cumulative impacts, when considered in light of other past, present, and reasonably foreseeable future actions, regardless of what agency or person undertakes such actions.

Past actions include previous determinations of nonregulated status for glyphosate tolerant and phosphinothricin tolerant varieties of soybean. Current glyphosate tolerant (GT) soybean acreage (~89% of all soybeans grown in the US) is almost entirely based on a USDA-APHIS determination made in 1994 and commercialized initially in 1996 (Monsanto Event 40-3-2). Along with that determination and gradual adoption of GT soybeans came increased use of glyphosate and concomitant decrease in use of other herbicides on soybean (outlined in Section IV.B table of this EA). Additionally, APHIS has recently published a determination of nonregulated status for Petition 06-178-01p, Monsanto 89788 soybean that is tolerant to glyphosate. This new line was developed to replace the original 40-3-2 event. It is expected that the new MON 89788 varieties will replace the older 40-3-2 varieties over time.

Soybean production occurs on land that is dedicated to crop production. Most soybeans are planted in fields that have been in crop production for over 10 years. As with most agricultural production, continuous production of soybean would normally include the use of tillage and herbicides to limit the growth of weeds, limit the potential impact caused by insects, animals or disease, and to maximize production. Widespread use of

356043 soybean is expected to have an insignificant impact on overall soybean production, primarily because GT soybeans are currently planted on over 89% of soybean acreage and 356043 would most likely be grown in place of a portion of those transgenic soybean acres, not as additional acreage now occupied with non-transgenic soybeans.

Although there is some uncertainty as to the adoption rate of 356043 soybean, there are a number of possible scenarios. For a grower, their decision to purchase 356043 is largely economic (i.e., all costs associated with growing and selling a crop are factored into which seed to purchase). Almost all buyers of 356043 soybeans will have previously grown GT soybean and 356043 will likely replace GT or RR®/STS® varieties. Growers will only likely buy 356043 if they can derive an economic benefit. Soybean 356043 will provide an extra weed control option since this product will allow use of ALS-inhibiting herbicides that could help a grower manage glyphosate tolerant weeds, if present. Using a variety of environmental toxicity parameters, researchers at Cornell University have developed a method to assess the environmental impacts of pesticides (http://nysipm.cornell.edu/publications/eiq/default.asp). This compilation indicates that both ALS-inhibitor and glyphosate-containing herbicides have comparable environmental impacts within agricultural production systems. Compared to the current situation (use of both glyphosate and ALS-inhibitor herbicides are used on soybean varieties), using ALS-inhibitor herbicides instead of, or in addition to, glyphosate would not be expected to result in significant environmental impacts. Since 356043 will most likely be used by growers that are presently using GT or RR®/STS® soybeans, and there are no significant differences in environmental impact between the two herbicides, cumulative impacts are likely be similarly insignificant.

Soybean acreage is not expected to increase significantly in the near future. Estimates of the 2007 soybean crop indicate that planting will be at the lowest level since 1996. This reflects an 11% decrease in acreage compared to 2006 (http://www.nass.usda.gov/Newsroom/2007/03_30_2007.asp) and in the prior five years, soybean production was relatively steady varying from 72 million acres to 75.5 million acres (http://www.nass.usda.gov/QuickStats/index2.jsp). Based on the above observations, Pioneer 356043 soybeans can be expected to replace some of the glyphosate tolerant soybeans on the market (which may include Monsanto's new MON89788, subject of APHIS petition 06-178-01p) and some of the RR®/STS® varieties available. Because the total amount of glyphosate tolerant and RR®/STS® soybean planted in the U.S. is unlikely to increase based on whether or not Pioneer 356043 is deregulated, and the development of glyphosate and ALS tolerant weeds is related to the amount of glyphosate and ALS tolerant soybean planted and glyphosate and ALS-inhibitors used, APHIS reasonably concludes that Pioneer 356043 should not have a significant cumulative impact on the development of herbicide tolerant weeds.

The release of 356043 soybean will not produce any other substance that is not normally produced by soybeans, nor is the composition of the seed produced by these soybeans significantly different from unmodified soybeans. Therefore, APHIS does not expect accumulation of a novel substance in soil, nor does APHIS expect significant impacts on

organisms living in and around these agricultural fields because of exposure to 356043 soybean compared to soybeans currently planted.
Data supplied by the applicant, including results of 3 years of field tests in various environments, indicate that 356043 soybeans have not had observable or measurable impacts on ecosystems in which they have been grown (Petition, Section VII-C., pp. 75-76). Because there is not likely to be any incremental increase in the planting of transgenic soybean, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to create cumulative impacts or reduce the long-term productivity or sustainability of any of the resources (soil, water, ecosystem quality, biodiversity, etc.) associated with the ecosystem in which 356043 soybean is planted. No resources should be significantly impacted due to cumulative impacts resulting from the proposed action. Similarly, no significant effects on resources would be expected if APHIS chooses the "no action" alternative.

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

Executive Order (EO) 12898, "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 requires federal agencies to conduct their programs in a manner that will 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 13045. None of the alternatives are expected to have a disproportionately adverse human health or environmental effect on minorities, low-income populations, or children.

EO 13112, "Invasive Species", requires 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. Both non-engineered and deregulated engineered glyphosate tolerant soybeans are widely grown in the United States. Based on historical experience with these soybeans and the data submitted by the applicant and reviewed by APHIS, these engineered 356043 plants are very similar in fitness characteristics to other soybean varieties currently grown. Due to

the fact that soybeans have never been weedy or invasive species, they are not expected to have an increased invasive potential, the majority of soybeans planted in the U.S. are genetically engineered.

EO 12114, "Environmental Effects Abroad of Major Federal Actions" requires Federal officials to take into consideration any potential significant environmental effects outside the United States, its territories, and possessions that result from actions being taken. APHIS has given this due consideration and does not expect a significant environmental impact outside the United States should nonregulated status be determined for 356043 soybean or if the other alternative is chosen. It should be noted that all the considerable, 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 APHIS determination of non-regulated status under 7 CFR Part 340. Any international traffic of Pioneer 356043 soybean subsequent to a determination of non-regulated status for 356043 soybean would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC).

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" (https://www.ippc.int/IPP/En/default.jsp). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds. The IPPC set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (157 countries as of October 2006). 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). 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. APHIS pest risk assessment procedures for bioengineered organisms are consistent with the Plant Protection Act as well as with 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 138 countries are Parties to it as of January 5, 2007 (see http://www.biodiv.org/biosafety/default.aspx). Although the United States is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, United States exporters will still need to comply with domestic regulations that importing countries that

are Parties to the Protocol have put in place 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 United States Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (http://usbiotechreg.nbii.gov). These data will be available to the Biosafety Clearinghouse. 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 United States, and within the Organization for Economic Cooperation and Development. NAPPO has completed three modules of a standard for the *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (see http://www.nappo.org/Standards/Std-e.html). 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.

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