Monsanto Improved Fatty Acid Profile MON 87705 Soybean, Petition 09-201-01p

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Final Environmental Assessment

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Agency Contact
Cindy Eck
USDA, APHIS, BRS
4700 River Road, Unit 147
Riverdale, MD 20737-1237
Phone: (301) 734-0667
Fax: (301) 734-8669
Cynthia.A.Eck@aphis.usda.gov

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ACRONYMS

AIA	advanced informed agreement
AMS	Agricultural Marketing Service
AOSCA	Association of Official Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
BRS	Biotechnology Regulatory Service
CBD	Convention on Biological Diversity
CEQ	Council of Environmental Quality
CFIA	Canadian Food Inspection Agency
CFR	Code of Federal Regulations
CIBIOGEM	Intersectoral Commission for Biosafety of Genetically Modified Organisms
COGEM	Commissie Genetische Modificatie
cp4 epsps	5-enolpyruvylshikimate-3-phosphate synthase
CRP	crop reserve program
DNA	Deoxyribonucleic acid
EA	environmental assessment
ECOS	Environmental Conservation Online
EFSA	European Food Safety Agency
EFSA	European Food Safety Authority
EIS	Environmental impact statement
EO	Executive Order
EPA	Environmental Protection Agency
ESA	Endangered Species Act
EU	European Union
FAD2	soybean gene encoding delta-12 desaturase
FATB	soybean gene enconding Acyl-ACP thioesterase
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FFP	food, feed, or processing
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FR	Federal Register
GE	genetically engineered
GENOK	Norway Center for Biological Safety
GHG	greenhouse gas
GRAS	generally recognized as safe
HDL	high density lipoprotein
HT	herbicide-tolerant
IDP	identity preservation
ILDIS	International Legume Database and Information Services
IPM	Integrated Pest Management
LDL	low density lipoprotein
LMO	living modified organisms
MAFF	Ministry of Agriculture, Forestry, and Fisheries
MHLW	Ministry of Health, Labor, and Welfare

ACRONYMS, CONTINUED

MMT	million metric tons
MOU	Memorandum of Understanding
N_2O	nitrous oxide
NABI	North American Biotechnology Initiative
NEPA	National Environmental Policy Act
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NOP	National Organic Program
OECD	Organization for Economic Co-operation and Development
OSTP	Office of Science and Technology Policy
POEA	polyethoxylated alkyl amine
PPA	Plant Protection Act
PRA	pest risk analysis
RED	Reregistration Eligibility Decision
RNA	Ribonucleic acid
RSPM	Regional Standards for Phytosanitary Measures
TES	threatened or endangered species
TSCA	Toxic Substances Control Act
U.S.C.	United States Code
USDA	U.S. Department of Agriculture
USDA-GRIN	USDA Germplasm Resources Information Network
USFWS	United States Fish and Wildlife Service
WPS	Worker Protection Standard

1 PURPOSE AND NEED

1.1 REGULATORY AUTHORITY

“Protecting American agriculture” is the basic charge of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of genetically engineered (GE) varieties) can provide benefits to the environment, consumers, and farm income.

Since 1986, the United States government has regulated genetically engineered (GE) organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA’s Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

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

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act. The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. All food and feed derived from GE crops currently on the market in the United States have successfully completed this consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food.

The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act (FFDCA) and regulates certain biological control organisms under the Toxic Substances Control Act (TSCA). The EPA is responsible for regulating the sale, distribution and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology.

1.2 REGULATED ORGANISMS

The APHIS Biotechnology Regulatory Service's (BRS) mission is to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act or the regulations at 7 CFR 340. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

1.3 PETITION FOR DETERMINATION OF NONREGULATED STATUS: IMPROVED FATTY ACID PROFILE MONSANTO 87705 SOYBEAN

Monsanto Company (Monsanto) has submitted a petition to APHIS seeking a determination that Monsanto 87705 Soybean is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR Part 340.

Monsanto has developed a transgenic soybean, event MON 87705 (hereafter referred to as MON 87705 Soybean), that produces soybean seeds with lower levels of saturated (palmitic and stearic) and polyunsaturated (linoleic) fatty acids, and higher levels of monounsaturated (oleic) fatty acid than those found in non-modified soybean seeds. MON 87705 Soybean contains DNA segments designed to suppress endogenous delta-12 desaturase (*FAD2*) and Acyl-ACP thioesterase (*FATB*) genes which encode for two enzymes in the soybean fatty acid biosynthetic pathway. MON 87705 Soybean also contains the 5-enolpyruvylshikimate-3-phosphate synthase (*cp4 epsps)* gene encoding the CP4 EPSPS protein. The *cp4 epsps* gene is used as a selectable marker to identify transgenic plants during the transformation process. The CP4 EPSPS protein confers tolerance to glyphosate and has been used in many Roundup Ready® crops (e.g., canola, corn, cotton, soybean, and sugar beet).

MON 87705 Soybean is currently regulated under 7 CFR Part 340. Interstate movements, importations, and field testing of MON 87705 Soybean have been conducted under notifications acknowledged by APHIS.

MON 87705 Soybean has been field tested at 17 sites in ten states across U.S. soybean production regions as authorized by APHIS (Monsanto, 2010). Data were provided in the petition for field trials completed prior to the petition submission. Field test reports can be found in the MON 87705 Soybean petition in several appendices Monsanto has conducted multiple field trials under field release authorizations granted by USDA-APHIS in geographically diverse regions and conditions throughout the U.S., including Arkansas, Illinois, Iowa, Indiana, Kansas, Michigan, Missouri, Nebraska, Ohio, Pennsylvania, and Wisconsin (Monsanto, 2010). Field tests conducted under APHIS oversight allow for an evaluation of the crop in agricultural settings under confinement measures designed to minimize the likelihood of persistence in the environment after completion of the field trial. Under confined field trial conditions, data are gathered on multiple parameters and used by applicants to evaluate agronomic characteristics and product performance. These data are also valuable to APHIS for assessing the potential for a new variety to pose a plant pest risk. The data evaluated for MON 87705 Soybean may be found in the APHIS *Assessment of Plant Pest Risk for MON 87705 Soybean* (USDA-APHIS, 2010a).

1.4 PURPOSE OF PRODUCT

Monsanto seeks a determination of nonregulated status of MON 87705 Soybean that is genetically enhanced to suppress the endogenous *FATB* and *FAD2* ribonucleic acid (RNA) in the developing soybean seed. This enhancement improves the fatty acid profile to contain lower saturated (palmitic and stearic) fatty acids, lower polyunsaturated (linoleic) fatty acid levels, and higher levels of monounsaturated (oleic) fatty acid (Monsanto, 2010). MON 87705 Soybean also expresses CP4 EPSPS protein throughout the plant conferring tolerance to glyphosate, which is the active ingredient in the Roundup® family of agricultural herbicides.

Soybean, *Glycine max,* is grown as a commercial crop in over 35 countries (OECD, 2000). Soybean is grown for production of seed which is used for production of oils and meals. Purified Soybean oil has many applications in the food and industrial sector, including soy-based shortenings and vegetable oils, soaps and disinfectants, and biodiesel sources (OECD, 2000). Soybean meal is used as a supplement in feed rations for livestock.

Historically, the U.S. market for soybean oil was limited by the presence of undesirable off-flavors and odors (Monsanto, 2010). The double bonds in the polyunsaturated fatty acids are susceptible to oxidation resulting in the formation of "fishy" or acrid flavors and odors in soybean oil (Dutton, Lancaster, Evans, & Cowan, 1951). Chemical hydrogenation was adopted to reduce the concentrations of polyunsaturated fatty acids and prolong the shelf-life of the product (Dutton, 1963; Okkerse, De Jonge, Coenen, & Rozendaal, 1967). Hydrogenated vegetable oils, including hydrogenated soybean oil, were viewed as viable alternatives to animal fats and the high-in-saturated-fats tropical oils, such as palm oil and coconut oil (Monsanto, 2010). However, in the 1990s, nutrition research showed that the *trans* fatty acids created by the hydrogenation process had negative health consequences (Judd et al., 1994; Mensink & Katan, 1990; Zock & Katan, 1992). By 2006, the FDA had issued a regulation obligating food manufacturers to declare the *trans* fatty acid content of their product on nutrition labeling (US-FDA, 2006). Because many consumers are attempting to avoid *trans* fats, there has been a decline in soybean oil per capita consumption in the U.S. since 2006 (Soyatech, 2008).

The MON 87705 Soybean oil fatty acid profile provides new formulation options for food companies interested in the development of lower saturated fat food products to support heart health. Low saturated fats and high (>70%) oleic acid levels are also key attributes for vegetable oils targeted for biodiesel and industrial uses (Monsanto, 2010). These characteristics are vital to improved cold weather performance, improved stability, and reduced nitrous oxide emissions (Graef et al., 2009; Knothe, 2005). In addition to the altered fatty acid profile, the soybeans were engineered with glyphosate tolerance to provide growers of these soybeans with weed control options as well.

1.5 APHIS RESPONSE TO PETITION FOR NONREGULATED STATUS

Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR Part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as MON 87705 Soybean. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

APHIS has prepared this environmental assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality's (CEQ) regulations implementing NEPA (40 CFR Parts 1500-1508, 7 CFR 1b, and 7 CFR Part 372), and the USDA and APHIS NEPA implementing regulations and procedures. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from a determination of nonregulated status of MON 87705 Soybean.

[1] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §508.14).

1.6 COORDINATED FRAMEWORK REVIEW

Food and Drug Administration

MON 87705 Soybean falls within the scope of the 1992 FDA's policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (US-FDA, 1992). In compliance with this policy, Monsanto initiated a consultation with the FDA on the food and feed safety and nutritional assessment summary for MON 87705 Soybean. A copy of the completed FDA review is provided in Appendix A.

Environmental Protection Agency

EPA has authority under FIFRA to establish pesticide use restrictions; these use restrictions are presented on pesticide labels which are prepared during the pesticide registration process. The CP4 EPSPS protein expressed in MON 87705 is similar and functionally identical to endogenous plant EPSPS enzymes and is identical to the CP4 EPSPSs in other Roundup Ready® crops including Roundup Ready® soybean (40-3-2 and MON 89788). Monsanto indicates that there will be no change in the use pattern for glyphosate on this glyphosate tolerant variety and there will be no need to petition EPA for a change in the label for glyphosate (G.Rogan, personal communication, 2011). APHIS will use current glyphosate labels as the basis for its evaluation of the potential impacts associated with the use of and exposure to glyphosate.

1.7 PUBLIC INVOLVEMENT

APHIS routinely seeks public comment on draft EAs prepared in response to petitions seeking a determination of nonregulated status of GE organisms. APHIS does this through a notice published in the Federal Register. The issues discussed in this EA were developed by considering public concerns, as well as issues raised in public comments submitted for other EAs of GE organisms, concerns raised in lawsuits, as well as those issues that have been raised by various stakeholders. These issues, including those regarding the agricultural production of soybean using various production methods, and the environmental and food/feed safety of GE plants were addressed to analyze the potential environmental impacts of MON 87705 Soybean.

This EA, the petition submitted by Monsanto, and APHIS's *Assessment of Plant Pest Risk for MON 87705 Soybean* will be available for public comment for a period of 60 days (7 CFR §340.6(d)(2)). Comments received by the end of the 60-day period will be reviewed and used to inform APHIS's determination decision of the regulated status of MON 87705 Soybean and to assist APHIS in determining whether an Environmental Impact Statement is required prior to the determination decision of the regulated status of these soybean lines.

ISSUES CONSIDERED

As stated above, the issues considered in this EA were developed based on APHIS' determination that certain genetically engineered organisms are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340; and, for this particular EA, the specific petition seeking a determination of nonregulated status of MON 87705 Soybean.

Soybean Production:

- Acreage and Areas of Soybean Production
- Seed Production
- Organic Farming
- Specialty Soybean Production
- Soybean Cultivation Practices

Environmental Considerations:

- Soil and Land Use
- Water Resources
- Air Quality and Climate Change
- Gene Movement and Weediness
- Animals
- Plants
- Microorganisms
- Biodiversity

Public Health Considerations:

- Worker Safety
- Human Health

Animal Feed

Socioeconomic Issues:

- Domestic Economic Environment at Risk
- Trade Economic Environment at Risk
- Social Environment at Risk

Threatened and Endangered Species

Other Cumulative Effects

Other U.S. Regulatory Approvals and Compliance with Other Laws

2 AFFECTED ENVIRONMENT

The Affected Environment Section provides an overview of the biology, use, and composition of the soybean, followed by a discussion of the current conditions of those aspects of the human environment potentially impacted by a determination of nonregulated status of MON 87705 Soybean. For the purposes of this EA, those aspects of the human environment are: soybean production practices, the physical environment, biological resources, public health, animal feed, and socioeconomic issues.

2.1 SOYBEAN BIOLOGY, USE, AND COMPOSITION

2.1.1 Soybean Taxonomy

The taxonomy of soybean is important to the analysis of potential impacts of gene modification. The taxonomy of soybean affects the potential for gene transfer, outcrossing, and volunteer weediness.

The Organization for Economic Co-operation and Development (OECD) Consensus Document (OECD, 2000) provides detailed information about the crop biology of soybean. The genus *Glycine* consists of two subgenera, *soja* and *glycine*. 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,* the cultivated soybean. These species do not occur naturally in the U.S. (USDA-NRCS, 2008).

Glycine soja grows wild in China, Japan, Korea, the Russian Far East, and Taiwan and is commonly found in fields, hedgerows, roadsides, and riverbanks (OECD, 2000).

The taxonomic position of *G. gracilis* has been an area of debate. Neither International Legume Database and Information Service (ILDIS) nor USDA-Germplasm Resources Information Network (USDA-GRIN) recognizes *G. gracilis* as a distinct species. *G. gracilis* is known only from Northeast China, is intermediate in morphology between *G. max* and *G. soja*, and is sometimes considered a variant of the cultivated soybean, *G. max*. Cultivated soybean can only hybridize with other members of the *Glycine* subgenus *soja* (OECD, 2000). The wild and weedy relatives (*G. soja* and *G. gracilis*) of soybean do not occur in the U.S. (USDA-APHIS, 2010a).

The subgenus *glycine* consists of 22 wild perennial species which are indigenous to Australia; West, Central and South Pacific Islands; China; Russia; Japan; Indonesia; Korea; Papua New Guinea; the Philippines; and Taiwan (Hymowitz, 2004). The Monsanto Petition presents a list of the 22 wild species with their respective genomic complement in Table II-2 of the petition.

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. (USDA-APHIS, 2010b).

2.1.2 Soybean Use and Composition

The soybean is an economically important leguminous crop providing oil and protein. Soybean plants are grown for their seed, which is further processed to yield oil for a variety of uses and meal for human dietary products and livestock feed. Soybean uses in the U.S. include edible soybean oil, soy-based biodiesel, animal feed, tofu, and industrial chemicals (SoyStats, 2010d). This subsection provides an overview of the various uses and associated composition of soybean.

2.1.2.1 Soybean Use

Soybean is used in various food products, including tofu, soybean sauce, soymilk, energy bars, and meat products. A significant fraction of the soybean market is dedicated to production of purified oil for food use and industrial applications (Cahoon, 2003). Food uses include margarines, shortenings, and cooking and salad oils (OECD, 2000). Soybean oil generally has a smaller contribution to soybean’s overall value compared to soybean meal because the oil constitutes just 18 to 19% of the soybean's weight. Nonetheless, soybean oil accounted for approximately 30% of all the vegetable oils consumed globally and was the second largest source of vegetable oil worldwide, slightly behind palm oil representing approximately 32% of global consumption (Soyatech, 2010). Soybean oil also has industrial applications, including feedstock in manufacture of inks, paints, varnishes, resins, plastics, and biodiesel (Cahoon, 2003; SoyStats, 2010d).

Approximately 50% of the world soybean seed supply in 2009 was crushed to produce soybean meal and oil (Soyatech, 2008). Most of the seed was used to supply the feed industry for livestock use or the food industry for edible vegetable oil and soybean protein isolates. Another 34% of the world soybean seed supply was traded to other geographies, with China, the European Union (EU), Japan, and Mexico being the top soybean seed importers (SoyStats, 2010a). The remainder of the soybean seed produced was used as certified seed, feed, or stocks.

Soybean meal is used as a supplement in feed rations for livestock. Soybean meal is the world's most important protein feed, accounting for nearly 69% of world protein meal supplies (SoyStats, 2010e). Industrial uses of soybean range from a carbon/nitrogen source in the production of yeasts via fermentation to the manufacture of soaps, inks, paints, disinfectants, and biodiesel (see, e.g., Cahoon, 2003; SoyStats, 2010d).

In the U.S., the majority of soybean is cultivated as a commodity crop for animal feed and soybean meal (Monsanto, 2010). Recently, there has been an increase in the percentage of the crop dedicated to specialty soybean produced for a specific market or use. These specialty, value-added products may be the whole bean or a fraction, such as the oil (Lee & Herbek, 2004). The production of specialty soybean is discussed in more detail in Subsection 2.2.4.

2.1.2.2 Soybean Composition

Generally, soybean seed consists of oil (about 20%), protein (about 40%), carbohydrate (about 35%), and ash (about 5%) (USDA-APHIS, 2010b).

Soybean Oil

Soybean oil is used in a wide variety of food applications. Until 2005, soybean oil was the largest source of vegetable oil worldwide (USDA-ERS, 2010d). Since 2005, palm oil has overtaken soybean oil in volume of worldwide vegetable oil production (USDA-ERS, 2010d). Conventional soybean oil is composed of a mixture of fatty acids. Fatty acids are identified based on the number of carbons and the degree to which they are saturated. Table 2-1 presents the fatty acid composition of soybean.

Table 2-1: Fatty Acid Composition of Conventional Soybean Oil

Fatty Acid Lipid Number	Common Name	Percentage of Total Fatty Acid in Conventional Soybean Oil
C6:0*	Caproic Acid	ND
C8:0	Caprylic Acid	ND
C10:0	Capric Acid (Decanoic)	ND
C12:0	Lauric Acid	ND – 0.1
C14:0	Myristic Acid (Tetradecanoic)	ND – 0.2
C16:0	Palmitic Acid	8.0 – 13.5
C16:1	Palmitoleic Acid	ND – 0.2
C17:0	Margaric Acid (Heptadecanoic)	ND – 0.1
C17:1	Cis-10 Heptadecenoic Acid	ND – 0.1
C18:0	Stearic Acid	2.0 – 5.4
C18:1	Oleic Acid	17 - 30
C18:2	Linoleic Acid	48 – 59
C18:3	Linolenic Acid	4.5 – 11
C20:0	Arachidic Acid (Eicosanic)	0.1 – 0.6
C20:1	Eicosenoic Acid	ND – 0.5
C20:2	Eicosadienoic Acid	ND – 0.1
C22:0	Behenic Acid (Docosanoic)	ND – 0.7
C22:1	Docosenoic Acid	ND – 0.3
C22:2	Docosodienoic Acid	ND
C24:0	Lignoceric Acid (Tetracosanoic)	ND – 0.5
C24:1	Cis-tetracosenoic Acid	ND

*Fatty acids are identified based on the number of carbon atoms and the number of double bonds in that fatty acid. Hence, oleic acid is identified as C18:1, indicating that this fatty acid is comprised of 18 carbons with a single double bond.

ND – Not detectable.

Source: (CODEX, 2010)

The five major fatty acids in conventional soybean oil are linoleic acid, oleic acid, palmitic acid, linolenic acid, and stearic acid (CODEX, 2010). Linoleic and linolenic are classified as polyunsaturated fatty acids, oleic acid is a monounsaturated fatty acid, and palmitic and stearic acids are saturated fatty acids (CODEX, 2010).

The physical and chemical properties of conventional soybean oil limit its use for many food and industrial applications (Cahoon, 2003). As noted in Table 2-1, untreated soybean oil has high concentrations of the linolenic and linoleic acids, the two polyunsaturated fatty acids (US-FDA, 1996). These polyunsaturated fatty acids are subject to oxidation, which affects flavor and product stability, and thus shortens its shelf life (US-FDA, 1996). To enhance stability, selective hydrogenation has been used to decrease the percentage of polyunsaturated fatty acids in the soy oil blend (US-FDA, 1996). The selective hydrogenation dramatically improves shelf life and provides stability during deep-frying and other high temperature applications (Mozzaffarian, Katan, Ascherio, Stampfer, & Willett, 2006). Although the hydrogenation process does increase the percentage of monounsaturated oleic acids, the hydrogenation process produces substantial quantities of the *trans* isomer of oleic acid. Such *trans* fats have been identified as negatively impacting human cholesterol levels by raising the low-density lipoproteins (LDL) cholesterol and lowering the high-density lipoprotein (HDL) cholesterol. This association with *trans*-fatty acids has resulted in a decline in soybean oil consumption in the U.S. (USDA-ERS, 2006b).

Soybean Meal

Following solvent extraction of the oil, the remaining solid soybean flakes are toasted and ground to produce soybean meal (Soyatech, 2008). Soybean meal contains about 50% protein by dry weight (USDA-APHIS, 2010b).

Only a small proportion (<5%) of the soybean meal is consumed directly by humans; 95% of domestic soybean meal is used by the American livestock industry (USDA-APHIS, 2010b).

Soybean is considered to be a source of complete protein. A complete protein is one that contains significant amounts of all the essential amino acids that must be provided to the human body because of the body's inability to synthesize them. The ten essential amino acids are arginine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, and valine (Kuiken & Lyman, 1949). Soybean provides these ten essential amino acids necessary for human nutrition (Kuiken & Lyman, 1949). The essential amino acid composition of soybean and soy-based products is provided in the USDA National Nutrient Database for Standard Reference (USDA-ARS, 2008b).

Isoflavones

Soybeans contain isoflavone compounds, polyphenol compounds closely related to the antioxidant flavonoids found in other plants (USDA-APHIS, 2010b). Soybean isoflavones are described as phytoestrogens because they exhibit estrogenic activity similar to estradiol hormones (Rostagno, 2009). These isoflavones may provide both positive and negative effects, as they are variously reported to exhibit estrogenic and anti-estrogenic effects, influence cardiovascular disease, impact cancer rates, and possibly slow the rates of osteoporosis. (See Higdon and Drake, 2009 for a summary of recent research on soy isoflavones.)

Antinutrients

Antinutrients are components of a food product which may be toxic at high concentrations, bind nutrients, or otherwise prevent their digestion. Soybeans contain several key antinutrients, such as oligosaccharides, lectins, phytic acid, and protease inhibitors (OECD, 2001). Lectins are sugar-binding proteins and can be rapidly degraded upon heating. The oligosaccharides (e.g., stachyose, raffinose) can cause flatulence when consumed (USDA-APHIS, 2010b). Phytic acid binds most of the phosphorus in soybean, preventing its absorption by an animal. It is common practice to add phytic acid-degrading enzymes to the animal feed formula (Monsanto, 2010). Protease inhibitors interfere with the digestion of proteins, resulting in decreased animal growth (OECD, 2001). The antinutrients are destroyed during the heat treatment processing of the soybean products (OECD, 2001).

2.1.3 Cultivation of GE Soybeans

Adoption of genetically engineered herbicide-tolerant (HT) soybeans increased from 17% of U.S. soybean acreage in 1997 to 68% in 2001 and 93% in 2010 (USDA-ERS, 2010a, 2010b). Use of herbicide-resistant crops is a major change in agriculture. Weed control had been one of the biggest challenges for soybean growers. Infestation with weeds during an entire growing season can result in soybean yield losses ranging from 12 to 80% (Barrentine, 1989; USDA-APHIS, 2010b). By the early 1990's, there were over 70 individual herbicides or combination products registered for weed control in soybean (USDA-APHIS 2010b; see also Byrd, Blaine, & Poston, 2003). Along with the increased use of herbicides, biotypes of various plant species developed resistance to certain herbicide modes of action (Heap, 2011).

With the 1996 commercial introduction of glyphosate-tolerant soybean, a major shift occurred with an increased use of glyphosate concurrent with the increased planting of glyphosate-tolerant soybean and a decrease in use of other soybean herbicides (USDA-APHIS, 2010b; USDA-ERS, 2010a, 2010b). Other herbicide-tolerant soybeans are cultivated, including the LibertyLink® soybean varieties (a GE variety resistant to glufosinate ammonium herbicide first introduced in 1996) and STS (a conventionally bred sulfonylurea-tolerant soybean first introduced in 1993). Although these other varieties are available for selection by growers, the Roundup Ready®, glyphosate-tolerant varieties continue to dominate the market (see, e.g., Tarter, 2011).

2.2 SOYBEAN PRODUCTION

This section summarizes soybean production, seed production, organic farming, specialty soybean, general management practices (including identity preservation practices), management of weeds, insects and diseases, soybean rotational crops, and volunteer soybean management.

2.2.1 Acreage and Areas of Soybean Production

Soybean is grown as a commercial crop in over 35 countries (Monsanto, 2010). Soybean is the most extensively grown oilseed in the world, with approximately 210 million metric tons (MMT) of harvested seed produced in 2009 (Soyatech, 2010). This represents 56% of world oilseed seed production for that year (Soyatech, 2010).

In the U.S., soybeans are cultivated in 31 states, with over 77 million acres dedicated to soybean cultivation, projected to increase to nearly 80 million acres by 2020 (USDA-NASS, 2011a, 2011b; USDA-OCE, 2011). Table 2-2 presents an overview of the 2009 and 2010 acreage of soybeans planted by state.

Table 2-2: Soybean Acreage by State, 2009 and 2010

State	Acres Planted (thousands)	
	CY 2009	CY 2010
Alabama	440	350
Arkansas	3,420	3,190
Delaware	185	175
Florida	37	25
Georgia	470	270
Illinois	9,400	9,100
Indiana	5,450	5,350
Iowa	9,600	9,800
Kansas	3,700	4,300
Kentucky	1,430	1,400
Louisiana	1,020	1,030
Maryland	485	470
Michigan	2,000	2,050
Minnesota	7,200	7,400
Mississippi	2,160	2,000
Missouri	5,350	5,150
Nebraska	4,800	5,150
New Jersey	89	94
New York	255	280
North Carolina	1,800	1,580
North Dakota	3,900	4,100
Ohio	4,550	4,600
Oklahoma	405	500
Pennsylvania	450	500
South Carolina	590	465
South Dakota	4,250	4,200
Tennessee	1,570	1,450
Texas	215	205
Virginia	580	560
West Virginia	20	20
Wisconsin	1,630	1,640
Total Acreage	77,500	77,410

Note: CY = Calendar Year
Source: (USDA-NASS, 2011a, 2011b)

Soybean yield varies by growing region and by variety cultivated. Soybean yields range from 26 to 47 bushels per acre, with a trend towards higher yields in recent years (USDA-ERS, 2006b). The upward trend in yield is largely a result of new varieties that perform better under climate and pest pressures (USDA-ERS, 2006b).

2.2.2 Seed Production

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

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

Soybean seed is separated into four seed classes: 1) Breeder; 2) Foundation; 3) Registered; and 4) Certified (see, e.g., MCIA, 2009, 2010). Each class of seed is identified to designate the seed generation from the original breeder source (Hartman & Kester, 1975). The original seed Breeder seed stock is controlled by the developer of the variety (Adam, 2005; Hartman & Kester, 1975). The Breeder stock is used to produce Foundation seed stock (Adam, 2005). Foundation seed stock, in turn, is used to produce Registered seed for distribution to licensees, such as seed companies (Adam, 2005). Registered seed is used by seed companies to produce large quantities of Certified seed (Adam, 2005; Hartman & Kester, 1975). The Certified (or Select) seed is then sold to growers through commercial channels (Adam, 2005; Hartman & Kester, 1975).

Foundation seed, Registered seed, and Certified seed production is controlled by public or private seed certification programs (see, e.g., AOSCA 2010). Commercially certified soybean seed must meet state and Federal seed standards and labeling requirements. Standards for certified soybean seed are generally presented as follows (see, e.g., Certified Seed, 1988; Tennessee, 2009):

- 98% pure seed (minimum);
- 2% inert matter (maximum);
- 0.05% weed seed (maximum; not to exceed 10 per lb.);
- 0.60% total of other crop seeds (maximum);
- 0.5% other varieties (maximum; includes off-colored beans and off-type seeds);
- 0.10% other crop seeds (maximum; not to exceed three per lb.); and
- 80% germination and hard seed (minimum).

State seed certification standards vary slightly from state to state and can be more restrictive than the seed standards of the Association of Official Seed Certifying Agencies (AOSCA). All soybean seed sold may not be officially certified; however, commercial soybean seed sold and planted for normal soybean production is produced predominately to meet or exceed Certified seed standards.

Seed certification systems should be distinguished from identity preservation systems for certain agricultural commodities. Soybean Identity Preservation (IDP) refers to a system of production, handling, and marketing practices that maintains the integrity and purity of specialty crop products (Sundstrom, Williams, Van Deynze, & Bradford, 2002). Commodity grains are marketed in mass according to USDA grading standards. Specialty crops require some form of segregation or IDP to keep these grains separate from commodity grains (Elbehri, 2007). This segmentation helps preserve a specified purity of the product. With certain specialty crops (e.g., organic or designated industrial-uses), IDP is required to prevent accidental or unintended commingling.

Comments submitted in previous environmental assessments have identified issues pertaining to management practices designed to prevent accidental or unintended commingling of crops. Many of these practices are already well established in the soybean industry as part of the crop cultivation practices necessary to maintain IDP.

The need for segregation and IDP production systems has increased with the development of specialty crops or crops with special output traits, such as high oil corn, high oleic sunflower, and low-linolenic soybean (Sundstrom, et al., 2002). MON 87705 Soybean is expected to be handled and marketed within the practices of the certified seed and IDP production systems, and is expected to meet all state and Federal seed standards and labeling requirements.

2.2.3 Organic Farming

In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2010). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced (Monsanto, 2010).

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

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

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

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

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

traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

Organic farming operations, as described by the NOP, are required to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods 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. In NOP organic systems, the use of synthetic pesticides or fertilizers, and GE crops, such as MON 87705 Soybean, is strictly limited (USDA-AMS, 2010).

Common practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields (Sundstrom, Williams et al. 2002; NCAT 2003; Bradford 2006; Baier 2008). Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2010b). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of genetically engineered materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald & Fouche, 2006; USDA-AMS, 2010b).

The production of organic soybeans represents between 0.17% and 0.22% of U.S. soybean production (USDA-ERS, 2010a). In 2005, 122,217 acres of soybean in the U.S. were certified organic, and in 2008, 125,621 acres were similarly certified (USDA-ERS, 2010e).

Organic soybean markets typically enjoy a market premium offsetting the additional production and record-keeping costs associated with this production method.

2.2.4 Specialty Soybean Production

The U.S. soybean IDP production and distribution systems accommodate differences between commodity and specialty soybean. Production systems designed prior to the introduction of MON 87705 Soybean or even prior to the introduction of biotechnology-derived soybean allow for production of specialty soybean varieties to meet varied customer demands. Although soybeans are primarily a commodity crop, there is an existing specialty soybean market. Distinct identity-preserved specialty soybean with such traits as clear hilum or high protein have been grown and successfully marketed for specific food uses in domestic and export markets for many years (Cui, James, Miyazaki, Wilson, & Carter, 2004).

Specialty soybean varieties are specified by buyers and end-users of soybean for production, and premiums are paid for delivering a product that meets purity and quality standards for the soybean variety. Product differentiation and market segmentation in the specialty soybean industry includes mechanisms to keep track of the soybean (traceability), methods for IDP, such as quality assurance processes (e.g., ISO 9001-2000 certification), as well as contracts between growers and buyers that specify delivery agreements.

The distinction between the commodity soybean and the specialty soybean involves both certified seed production as well as IDP of the harvested crop. The majority of soybean in the U.S. is cultivated and marketed as a commodity for the oil and protein markets (Monsanto, 2010). The goal of the commodity supply chain is to supply a homogenous product to the end user. Although the grower producing soybean for this chain may choose from many different varieties for cultivation, the harvested soybean is viewed to be the same for all commodity soybean varieties (Monsanto, 2010). At harvest, the grower either delivers soybean to a handler or stores them on farm for later delivery. The commodity soybean is not differentiated for later use. Commodity soybean handlers typically have large volume storage capacity, and commodity soybean processors crush large volumes of soybean to produce homogeneous oil and meal products. The commodity system is designed to maximize efficiency at a low profit margin and results in comingling of different sources of soybean. The beneficial consequence of mixing soybean in the initial crush, increased homogeneity, is also one that does not affect the price received for the final product. This production system has been in place in the U.S. since the production of soybean began in earnest in the 1960s (Sonka, Bender, & Fisher, 2004).

The specialty soybean market produces soybeans that have specific physical or chemical characteristics to meet specific buyer requirements. As a result of these special needs, a separate specialty soybean channel has developed for the specialty soybean product that involves much smaller volumes than commodity soybean (Smyth & Phillips, 2002; Sonka, et al., 2004). Specialty soybean varieties are produced on approximately 12% of the U.S. soybean acreage and, according to the Midwest Shippers Association (MSA, 2009), this acreage could grow to over 25% of the crop acreage in certain states within the next decade. This supply chain typically consists of a specialty firm that contracts production of a specific variety and sets standards for quality of the harvested soybean (Lee & Herbek, 2004). In return, growers receive a premium over the price paid for commodity soybean. Growers may store harvested soybean on farm or deliver the product directly to a processor or to special containers for international shipment.

Specialty soybeans can be grouped into several broad categories (Monsanto, 2010; UK, 2010):

- non-biotechnology-derived;
- certified seed;
- organic food-grade;
- low saturated fat;
- clear hilum;
- tofu;
- natto;
- high sucrose;

- high oleic;
- low linolenic and
- high protein.

The categories refer to soybean with characteristics such as altered seed composition (e.g., low saturated fat, high sucrose, high oleic, low linolenic, and high protein), varieties of soybean with unique physical characteristics suited to their specific uses (e.g., clear hilum; i.e., small scar marking the seeds former place of attachment to the pod, for direct human consumption), or refer to a production process (e.g., organic, certified seed). The categories are not meant to be exclusive; for example, soybean used to produce natto or tofu may employ organic production processes. Moreover, soybeans of all specialty categories are often derived from varieties produced according to certified seed production practices. Tofu and soymilk produced from the tofu soybean category represent a large segment of the specialty soybean market and are produced from unique soybean varieties that have clear hilum and large seed size (Lee & Herbek, 2004). Tofu varieties also must be high in protein (40% or higher) and low in oil concentration compared with commodity soybean. Clear hilum and other characteristic are required for soybean used in the production of other soybean food products consumed directly by humans such as natto, soybean sprouts, edamame (vegetable soybean), and soy nuts (Lee & Herbek, 2004; UK, 2010).

The majority of these specialty soybean varieties are offered in Maturity Group II and early Group III varieties which are adapted to the upper Midwest/Great Plains region (Lee & Herbek, 2004).

The IDP practices used in specialty soybean production require that all equipment and storage facilities for specialty soybean must be clean of seed from other soybean varieties or plants, dirt, pathogens, and other foreign material. Some soybean contracts may require a special inspection of the handling and storage facilities. The specialty soybean for soybean foods may require special harvesting equipment because some of these soybeans are harvested before full maturity (e.g., edemame or vegetable soybean).

Weed control is extremely important for specialty soybean to maintain a high yield potential. Weeds, such as nightshade (*Solanum nigrum*), can stain harvested soybean, which is particularly undesirable in food-grade soybean (TCM, 2008).

2.2.5 Soybean Cultivation Practices

Soybean self-pollinates and is propagated by seed (OECD, 2000). Proper seedbed preparation, appropriate variety selection, appropriate planting dates and plant population, and good integrated pest management practices are important for optimizing the yield potential and economic returns of soybean (USDA-APHIS, 2010b).

Soybean varieties are developed and adapted to certain geographical zones and are separated into ten maturity groups – Group 00 to Group VIII: Group 00 through Group IV soybean varieties are planted in the Midwest and Eastern Coastal regions; Groups IV through VIII are planted in the southern states (Helsel & Minor, 1993; Hodges & French, 1985).

2.2.5.1 Pre-Season Preparation

Crop rotation, tillage system, row spacing, planting equipment, seed or variety selection(s), and soil fertility require production decisions well in advance of planting the soybean crop. Because of the many benefits associated with crop rotation, the majority of the soybean acreage is planted in a two-year corn-soybean rotation. The crop rotation sequence can be modified to take advantage of a particular economic or market opportunity.

2.2.5.2 Planting and Early Season

Adequate soil moisture and warm temperatures facilitate rapid seed germination and emergence. Planting date has the greatest impact on yield (Hoeft, Nafziger, Johnson, & Aldrich, 2000). Soybean can germinate at a soil temperature of 50ºF when planted at a depth of two inches, with the ideal soil temperature for soybean germination and emergence at 77ºF (Pedersen, 2010; Pedersen & Lauer, 2004). However, waiting for soils to reach this soil temperature will delay planting beyond the optimum planting date that will maximize yield.

Highest yields are generally obtained when planting is done in early to mid-May. Yields begin to drop off quite rapidly when planting is delayed until late May. For example, the optimum planting dates for soybean in Iowa are the last week of April in the southern two-thirds of the state and the first week of May in the northern one-third of the state (Pedersen & Lauer, 2004). In the southern U.S., yields of adapted varieties are highest when soybean is sown in May or early June. Planting before late April results in shorter plants and, in many cases, lower yields. Planting after early June generally decreases plant height and yield due to water shortages in July and August.

2.2.5.3 Mid- to Late Season

Ideal daytime temperatures for soybean growth are between 75ºF and 85ºF (Hoeft, et al., 2000). Warmer temperatures result in larger plants and earlier flowering. Sustained temperatures below 75ºF will delay the beginning of flowering significantly. Seed set also is affected by temperature. Seed set is generally ideal when pollination follows night temperatures around 70ºF. Soybean varieties differ in their response and tolerance to temperatures.

The first appearance of flowers signals the beginning of the reproductive stage (Hoeft, et al., 2000). The reproductive period consists of flowering, pod set, and seed formation. Climatic conditions such as temperature and moisture supply during the flowering period will affect the number of flowers. The soybean plant does not form a pod for each flower. It is common for a soybean plant to have 75% of its flowers fail to develop a pod (Monsanto, 2010; Scott & Aldrich, 1970).

2.2.5.4 Harvest Season

At maturity, the seed moisture content is approximately 55 to 60%. At this stage, at least one pod on the plant reaches maturity (Hoeft, et al., 2000). Under warm and dry weather conditions, seed moisture content will drop to 13 to 14% in 10 to 14 days from physiological maturity (Hoeft, et al., 2000). Soybean is harvested when the moisture content drops below 15%.

2.2.5.5 Soybean Crop Rotation and Control of Volunteers

Soybean crop rotation is an important management practice to manage weeds, to control volunteer soybeans, and to limit the potential for weeds to develop resistance to herbicides (e.g., glyphosate-resistant pigweed). According to USDA Economic Research Service, 95% of the soybean-planted acreage has been in some form of a crop rotation system since 1991 (USDA-ERS, 2010c).

The benefits of soybean rotation with, for example, corn are many and include:

- Improved yield and profitability of one or both crops;
- Decreased need for additional nitrogen on the crop following soybean;
- Increased residue cover;
- Mitigation or disruption of disease, insect, and weed cycles;
- Reduced soil erosion;
- Increased soil organic matter;
- Improved soil tilth and soil physical properties; and
- Reduced runoff of nutrients, herbicides, and insecticides (Al-Kaisi, Hanna, & Tidman, 2003).

Agronomic practices for soybean rotations vary from state to state. Continuous (i.e., non-rotation) soybean production is discouraged by most extension soybean specialists to reduce the risk of diseases and nematodes (Al-Kaisi, et al., 2003). The majority of the U.S. soybean acreage (68.6%) is rotated to corn (see Monsanto, 2010 at page 157 et seq.). Approximately 14.5% of the soybean acreage is rotated back to soybean the following year. Wheat follows soybean on approximately 11.2% of the U.S. soybean acreage, with cotton, rice, and sorghum the next largest rotational crops following soybean (4.6% of the soybean acreage). Other minor rotational crops that follow soybean production include barley, rice, oats, and dry beans.

In previous APHIS assessments, volunteer crop plants have been identified as an area of concern in the review of herbicide-tolerant plantings. Volunteer plants are considered weeds, as they compete with the subsequent crop for water, nutrients, and space. An analysis of the weediness potential of herbicide-tolerant soybean can be based upon an analysis of volunteer soybeans.

Volunteer soybean is defined as a plant that has germinated and emerged unintentionally in a subsequent crop. Soybean seeds can remain in a field after soybean harvest as a result of pods splitting before or during harvest. Soybean seeds also can remain in a field when pod placement on the plants is too close to the ground for the combine head to collect all the pods or when the combine is improperly adjusted for efficient harvesting.

Volunteer soybean, whether a GE variety specifically engineered to present herbicide tolerance or a conventional non-GE variety, are not considered a significant concern in rotational crops primarily because of climatic conditions and adequate control from mechanical and chemical methods available to manage the occasional volunteer soybean plant.

Volunteer soybean seed is typically not viable after the winter period in the North. In soybean growing areas in the southern U.S., where soybean seed may remain viable over the winter and germinate the following spring, mechanical and chemical controls are used (Carpenter et al., 2002; OECD, 2000). Pre-plant tillage is the first management tool for control of emerging volunteer soybean in the spring. If volunteer soybean plants emerge after planting, shallow cultivation will control most of the plants and effectively reduce competition with the crop.

Several post-emergence herbicides also are available to control volunteer soybean (conventional or glyphosate-tolerant soybean) in each of the major rotational crops. Control of volunteer soybean in corn can be provided by post-emergence applications of AAtrex (atrazine), Clarity (dicamba), Distinct (diflufenzopyr + dicamba), Hornet (flumetsulam + clopyralid), and Widematch (clopyralid + fluroxypyr). In wheat, Bronate Advanced (bromoxynil), Clarity, and Widematch post-emergence provide control of volunteer soybean (Zollinger, 2010).

Volunteer soybean in cotton is normally not a concern. However, extreme weather conditions, such as hurricanes, may damage a soybean crop preceding cotton production in the Mid-South states, where the unharvested soybean seed can produce volunteer plants. Pre-plant applications of paraquat or herbicide mixtures containing paraquat will effectively control volunteer glyphosate-tolerant soybean (Montgomery, Hayes, Tingle, & Kendig, 2002; Murdock, Jones, & Graham, 2002). Recent research in North Carolina indicates that Envoke (trifloxysulfuron) provides excellent post-emergence control of soybean containing traits for glyphosate and sulfonylurea herbicide tolerance in Roundup Ready® cotton (York, Beam, & Culpepper, 2005).

Volunteer soybean in rice is rarely a concern due to the combination of pre-plant tillage, flooding practices, and herbicides used in producing rice. If volunteer plants should emerge in rice, the post-emergence applications of Grasp (penoxsulam), Permit (halosulfuron), and Regiment (bispyribac), typically used for weed control in rice, effectively alleviate competition from volunteer soybean (Dillon, Scott, Pearrow, & Meins, 2006).

2.3 PHYSICAL ENVIRONMENT

The use of fertilizers, pesticides, and water may affect segments of the environment including, but not limited to: waterways by increases in nutrient pollution; biodiversity resulting from adverse effects of pesticide use; the water table resulting from excessive irrigation practices; and field productivity because irrigation may increase salinity (Hoeft, et al., 2000). Increased soil runoff and consequent siltation, elevated nutrients, pesticides, increased salinity, and pathogens are primary agricultural pollutants (USDA-ERS, 2005). This subsection provides an overview of the current physical environment in which soybean is cultivated.

2.3.1 Soil and Land Use

Soybean is grown as a commercial crop on over 75 million acres in at least 31 states in the U.S. (USDA-NASS, 2010a). Soybean acreage in the past five years has been relatively stable varying from 64.7 million to 78.9 million acres with a 10-year average of 73.3 million acres (USDA-NASS, 2010a). Fluctuations in soybean acreage are due to environmental, agronomic, and economic factors, as well as government programs such as the crop reserve program (CRP) or ethanol mandates imposed by the U.S. government which drive acreage into source crops for ethanol.

Soybean fields are typically highly managed agricultural areas that are dedicated to crop production for many years. The production of soybean is highly dependent upon soil and climatic conditions. Soybean is cultivated in a wide variety of soils, but does not do well in acid soils (OECD, 2000). In the U.S., the soil and climatic requirements for growing soybean are very similar to corn, and thus, the two crops share a similar cultivation area (Monsanto, 2010).

The practice of tillage for soil preparation and weed management can affect the quality of soils because of the varying impacts of erosion on soil nutrient composition. Field preparation is accomplished through a variety of tillage systems, with each system defined by the remaining plant residue on the field (US-EPA, 2010). Conventional tillage is associated with intensive plowing and less than 15% crop residue at the soil surface; reduced tillage is associated with 15 to 30% crop residue; and conservation tillage, including no-till practices, is associated with at least 30% crop residue and substantially less soil erosion than other tillage practices (US-EPA, 2010). As conservation practices are adopted, there are increases in soil organic matter that helps bind soil nutrients and significantly reduces the loss of cropland soil from runoff, erosion, and leaching over time (Leep, Undersander, Min, Harrigan, & Grigar, 2003; USDA-NRCS, 2006b, 2006c). Total soil loss on highly erodible croplands and non-highly erodible croplands decreased from 462 million tons per year to 281 million tons per year or by 39.2% from 1982 to 2003 (USDA-NRCS, 2006c). This decrease in soil erosion accompanies a corresponding decrease in non-point source pollution of surface water by fertilizer and pesticides (USDA-NRCS, 2006c). The reduction in soil erosion is also attributed to a decrease in the number of acres of highly erodible cropland being cultivated (USDA-NRCS, 2006c). Soil tillage can also affect water resources and air quality, which is discussed in Subsections 2.3.2 and 2.3.3, respectively.

Several authors suggest a relationship between the introduction of herbicide-tolerant soybean varieties and an increase in the practice of no-till or conservation tillage by U.S. growers. In 1995, before the introduction of glyphosate-tolerant soybeans, approximately 27% of the U.S. soybean acres used no-till production, but by 2004, no-till acres increased to 36% of the total soybean acres (Sankula, 2006). In 2008, approximately 43 million acres (62%) of soybean were planted in a no-till system (Towery & Werblow, 2010).

A few states provide statistics on the adoption of no-till acres in their state. In 2006 in Illinois, no-till farming was used on 51% of the soybean acres (Monsanto, 2010). The University of Illinois Extension Service attributed that figure to the fact that 90% of the state's acres were planted to glyphosate-tolerant varieties, along with other factors, such as high fuel prices, improved equipment, higher yields using no-till practices, and better grower awareness of the advantages to soil and water quality from no-till farming (University of Illinois, 2006).

A legume, the soybean plant fixes a significant portion of its own nitrogen through the symbiotic relationship with the nitrogen-fixing Bradyrhizobia bacteria (*Bradyrhizobium japonicum*) that live in soybean root nodules (Hoeft, et al., 2000). The soybean root nodules contain colonies of bacteria which take gaseous nitrogen from the atmosphere and fix it in forms easily used by the soybean plant. Because the nitrogen-fixing bacteria are not native to U.S. soils and would not normally be found in these soils, soybeans are frequently inoculated with these bacteria prior to planting, especially if soybean has not been grown in a field for three to five years (Pedersen, 2007).

2.3.2 Water Resources

The soils and climate in the Eastern, Midwestern, and portions of the Great Plains region of the U.S. provide sufficient water supplies under normal climatic conditions to produce a soybean crop. The general water requirement for a high-yielding soybean crop is approximately 20 inches of water during the growing season (Hoeft, et al., 2000). In 2008, over 9% of the soybean crop in the U.S. was irrigated (USDA-NASS, 2008; Table 33, USDA-NASS, 2007; USDA-NASS, 2010b). Soil texture and structure are key components determining water availability in soils which, in turn, affects soybean root depth and density. As medium-textured soils are able to hold more available water, the soybean roots in medium textured soils are more dense and extend to a typical depth of 1.2 m. By contrast, soils that are more compact (e.g., clayey soils) hold less water and, as a result, the soybean plant root mass is less dense and shallower.

With respect to the effects of nutrient runoff on water resources, conservation tillage and no-till practice has been shown to minimize surface water runoff and soil erosion. By improving soil quality, the consequent increase in soil organic matter promotes the binding of nutrients, as well as pesticides and herbicides, to soil and prevents their loss to surface waters and groundwater from runoff, erosion, and leaching (Leep, et al., 2003).

2.3.3 Air Quality and Climate Change

Agricultural air emission sources include: smoke from agricultural burning; vehicle exhaust associated with equipment used in tillage and harvest; soil particulates associated with tillage; pesticide drift from spraying; and nitrous oxide emissions from the use of nitrogen fertilizer (Aneja, Schlesinger, & Erisman, 2009; Hoeft, et al., 2000; US-EPA, 2010; USDA-NRCS, 2006a). These agricultural activities individually have the potential to cause negative impacts to air quality.

Aerial application of pesticides may cause air quality impacts from drift and diffusion. Pesticides may volatilize after application to soil or plant surfaces and may also move as constituents of entrained materials in wind eroded soils (Vogel, Majewski, & Capel, 2008).

Agriculture, including land-use changes for farming, is responsible for an estimated 6% of all human-induced greenhouse gas (GHG) emissions in the U.S. (US-EPA, 2010). It is important to note that livestock were responsible for the largest fraction of methane emissions (80% of total methane via enteric fermentation and manure management) (US-EPA, 2010). Emissions of GHG released from agricultural equipment (e.g., irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (US-EPA, 2010). Agricultural soil management practices, including nitrogen-based fertilizer application and cropping practices, are the largest source of U.S. N_2O emissions. Croplands account for 69% of the total nitrous oxide (N_2O) emissions attributable to agricultural land uses (US-EPA, 2010). Agriculture sources of methane (CH_4) emissions are primarily associated with enteric emissions of gas from cattle and manure management. Carbon dioxide (CO_2) is also a significant GHG gas associated with several agricultural practices, including classes of crops, location and soil types associated with the practices, and energy consumption (Cole et al., 1997; US-EPA, 2010).

Tillage contributes to the release of GHG because of the loss of CO_2 to the atmosphere, and the exposure and oxidation of soil organic matter (Baker, Southard, & Mitchell, 2005). Herbicide-tolerant crops may encourage dramatic increases in the adoption of conservation tillage programs whose consequences may include reductions of many of these emission concerns.

GHG may be indirectly affected by the class of crop planted and soil types; trees, grasses and field crops each play a slightly different role in the global cycle of GHG (Cole, et al., 1997; Freibauer, Rounsevell, Smith, & Verhagen, 2004; US-EPA, 2010). For example, emissions of nitrous oxide, produced naturally in soils through microbial nitrification and denitrification, can be dramatically influenced by fertilization, introduction of grazing animals, cultivation of nitrogen-fixing crops and forage, retention of crop residues (i.e., no-till conservation), irrigation, and fallowing of land (US-EPA, 2010). These same agricultural practices can influence the decomposition of carbon-containing organic matter sequestered in soil, resulting in conversion to carbon dioxide loss to the atmosphere (US-EPA, 2010). Conversion of crop land to pasture results in an increase in carbon and nitrogen sequestration in soils (US-EPA, 2010).

The EPA has also identified regional differences in GHG emissions associated with agricultural practices on different soil types, with high mineral content soils responding to GHG differently than high-organic content soils (US-EPA, 2010). Mineral soils contain from 1 to 6% organic carbon by weight; conversion of such soils from their native state to agricultural uses can cause as much as 50% of the natural organic carbon to decompose and be released to the atmosphere (US-EPA, 2010). In contrast, organic soils may contain as much as 20% carbon by weight (US-EPA, 2010). When such organic soils are prepared for agricultural use, the soils are aerated, accelerating decomposition and release of CO_2 to the atmosphere (US-EPA, 2010).

Climate change may impact agriculture. In response to climate change, the current range of weeds and pests of agriculture is expected to change. In response to these new ranges, current agricultural practices may be required to change (IPCC, 2007). Climate change may potentially provide a positive impact to agriculture. The IPCC predicts that potential climate change in North America may result in an increase in crop yield by 5-20% for this century (IPCC, 2007). However, this positive impact will not be observed across all growing regions. The IPCC report notes that certain regions of the U.S. will be negatively impacted because available water resources may be substantially reduced. Note that the extent of climate change effects on agriculture is highly speculative. Nevertheless, North American production is expected to adapt to climate change impacts with improved cultivars and responsive farm management (IPCC, 2007).

2.4 BIOLOGICAL RESOURCES

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

2.4.1 Gene Movement and Weediness

Gene flow has been defined as the "incorporation of genes into the gene pool of one population from one or more populations" (Stewart, 2008; USDA-APHIS, 2010c). Gene flow is a basic biological process in plant evolution and in plant breeding. Gene flow, itself, does not pose a plant pest risk (USDA-APHIS, 2010c); it does so when specific genes with plant pest potential are incorporated into a cultivated plant. There are two types of gene flow: horizontal and vertical. Horizontal gene flow is the movement of genes between disparate, unrelated species, such as between plants and microbes or between plants from different families (Stewart, 2008). There is no evidence that horizontal gene transfer can naturally occur between unrelated plant species (see, e.g., Stewart, 2008; Twyman, 2003).

In plant biology, when gene flow occurs between individuals from genetically distinct populations of the same species and a new plant is formed, this is called vertical gene flow and the new plant is called a hybrid (Stewart, 2008; USDA-APHIS, 2010c). Hybridization is usually thought of as the breeding of closely related species resulting in the creation of a plant that has characteristics different from either parent. When plants are moved to a new environment (with or without human intervention), they may hybridize with plants of a closely related species or subspecies in that new location. For natural hybridization to occur between two distinct but related populations, the plants from the two populations must flower at the same time, they must be close enough so that the pollen can be carried from the male parent to the female parent, fertilization must occur, and the resulting embryo must be able to develop into a viable seed that can germinate and form a new plant (Ellstrand, 2003; USDA-APHIS, 2010c).

Hybridization may occur in one generation, but in most cases, does not progress on its own through subsequent generations. If it does, and stable new populations result, the process is called introgression. For introgression to occur, hybridization of offspring with the parental types (backcrossing) must occur several times. Because hybrids of distantly related species may not produce viable seed, introgression is much less common than hybridization. For example, in studies done with canola and a weedy relative, backcrossing from the hybrids to the weeds occurred at one-hundredth to one-thousandth the rate of the original hybridization (Stewart, 2008). Nevertheless, when weed species are introduced to new areas, there is the potential that those introduced plants may hybridize with other closely related species. Novel hybrids therefore may be created. In addition, novel hybrids may be created through back-crossing (i.e., introgression) with parent species which may change the native species by incorporating non-native genetic material. Invasive weeds can result from hybridization events, which mix genetic material potentially producing a wide array of genotypes. Some of these genotypes may exhibit increased invasive properties (USDA-APHIS, 2010c; USDA-ARS, 2008a).

Characteristics that favor natural hybridization between two populations include (Mallory-Smith & Zapiola, 2008; USDA-APHIS, 2010c):

- Presence of feral populations (domestic populations gone wild) and uncontrolled volunteers;
- Presence of a high number of highly compatible relatives;
- Self-incompatibility;
- Large pollen source;

- Large amounts of pollen produced;
- Lightweight pollen;
- Strong winds (wind pollinated);
- Large insect populations (insect pollinated); and
- Long pollen viability.

There are certainly others – the creation of a hybrid depends on a series of events including:

- There must be a conduit for the parent gene of one plant species to enter the population of the species to be hybridized – requires the parent plant gene and the receptor plant to produce fertile offspring and
- The hybridization must confer a fitness advantage that allows the gene, over multiple generations, to develop into a sustainable, reproducing population.

Soybean is not native to the U.S. and there are no feral or weedy relatives. Soybean is a self-pollinated species, propagated by seed (OECD, 2000). The papilionaceous flower consists of a tubular calyx of five sepals, a corolla of five petals, one pistil, and nine fused stamens with a single separate posterior stamen. The stamens form a ring at the base of the stigma and elongate one day before pollination, at which time the elevated anthers form a ring around the stigma (OECD, 2000). The soybean flower stigma is receptive to pollen approximately 24 hours before anthesis (i.e., the period in which a flower is fully open and functional) and remains receptive for 48 hours after anthesis. The anthers mature in the bud and directly pollinate the stigma of the same flower. As a result, soybean is considered to be a highly self-pollinated species, with cross-pollination to adjacent plants of other soybean varieties occurring at very low frequency (0 to 6.3%) in adjacent plants (Caviness, 1966; Ray, Kilen, Abel, & Paris, 2003; USDA-APHIS, 2010a; Yoshimura, Matsuo, & Yasuda, 2006). Pollination typically takes place on the day the flower opens. The pollen naturally comes in contact with the stigma during the process of anthesis. Anthesis normally occurs in late morning, depending on the environmental conditions. The pollen usually remains viable for two to four hours, and no viable pollen can be detected by late afternoon. Natural or artificial cross-pollination can only take place during the short time when the pollen is viable.

Horizontal gene transfer and expression of DNA from MON 87705 Soybean to soil bacteria are unlikely to occur for several reasons (USDA-APHIS, 2010a). First, many genomes (or parts thereof) have been sequenced from bacteria that are closely associated with plants including *Agrobacterium* and *Rhizobium* (Kaneko et al., 2000; Kaneko et al., 2002; Wood et al., 2001). There is no evidence that these bacteria contain genes derived from plants. Second, in cases where review of sequence data suggest that horizontal gene transfer might have occurred, these events are expected to have occurred on an evolutionary time scale, i.e., on the order of millions of years (Brown, 2003; Koonin, Makarova, & Aravind, 2001; USDA-APHIS, 2010b). Third, transgene DNA promoters and coding sequences are optimized for plant expression, not prokaryotic bacterial expression. Thus, even if horizontal gene transfer were to occur, proteins corresponding to the transgenes are not likely to be produced. Fourth, the 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 (e.g., *E. coli*), or in the environment, is remote (US-FDA, 1998).

2.4.2 Animals

Soybean production systems in agriculture are host to many animal species. Mammals and birds may seasonally consume soybean and invertebrates can feed on the plant during the entire growing season. Animals that feed primarily on soybean are seed-feeding insects and rodents found in agricultural fields. Rodents, such as mice or squirrels, may seasonally feed exclusively on soybean seeds. Thus, these animals may have a diet containing significant amounts of soybean seeds. Deer may also browse in soybean fields on the forage and on seed left after harvest.

Insects are considered less problematic than weeds in U.S. soybean production; nevertheless, insect injury can impact yield, plant maturity, and seed quality. Consequently, insect pests are managed during the growth and development of soybean to enhance soybean yield (Aref & Pike, 1998; Higley & Boethel, 1994). Insect injury in soybean seldom reaches levels that cause significant economic loss, as indicated by the low percentage (14%) of soybean acreage that receives an insecticide treatment (USDA-NASS, 2006).

2.4.3 Plants

The development and management of herbicide tolerance or resistance in weed species has been raised as a concern. This section briefly presents a summary of the weedy non-crop plants commonly associated with soybean cultivation, the development of herbicide resistance in these weeds, and the mechanisms for control of such weeds.

Soybean production systems in agriculture (i.e., the combination of management practices) are host to many plant species. The environment surrounding a soybean field varies in plant composition depending on the region. In certain areas, soybean fields may be bordered by other soybean varieties, corn, or other crops. In addition, fields may also be surrounded by woodlands and/or pasture/grassland areas, as well as aquatic environments. Therefore, the types of vegetation, including the variety of weeds, adjacent a soybean field depend on the area where the soybean is planted.

Annual weeds are perceived to be the greatest pest problem in soybean production, followed by perennial weeds (Aref & Pike, 1998). Weed control in soybean is essential to optimizing yields. Weeds compete with soybean for light, nutrients, and soil moisture. Weeds can harbor insects and diseases, and also can interfere with harvest, causing extra wear on harvest equipment (Loux et al., 2008). The primary factors affecting soybean yield loss from weed competition are the weed species, weed density, and the duration of the competition. When weeds are left to compete with soybean for the entire growing season, yield losses can exceed 75% (Dalley, Renner, & Kells, 2001).

Generally, the effects of competition increase with increasing weed density (Monsanto, 2010). The time period that weeds compete with the soybean crop influences the level of yield loss. The later the weeds emerge, the less impact the weeds will have on yield.

Soybean plants withstand early-season weed competition longer than corn as the soybean canopy closes earlier in soybean than in corn (Mallory-Smith & Zapiola, 2008; Monsanto, 2010) . The extent of canopy closure regulates the availability of light to weeds and other plants that grow below the soybean. In addition, canopy closure occurs much sooner when soybean is drilled or planted in narrow rows.

The petitioner identifies 86 common weeds of soybean across three growing regions)Monsanto, 2010 at pages 150-151). Crop rotations and environment have a significant impact on the adaptation and occurrence of weeds in soybean. Foxtail spp., pigweed, velvetleaf (*Abutilon theophrasti)*, lambs quarters (*Chenopodium album*), and cocklebur (*Xanthium strumarium*) are common annual weeds in Midwest corn and soybean fields. However, growers consider giant ragweed (*Ambrosia artemisiifolia*), lambs quarters, Canada thistle (*Cirsium arvense*), cocklebur, and velvetleaf to be the top five most problematic weeds in corn and soybean because of the difficulty to control these weeds (Nice & Johnson, 2005). The most frequently reported common weeds in the Southeast region are morning glory (*Ipomoea spp*.), prickly sida (*Sida spinosa*), johnsongrass (*Sorghum halepense*), sicklepod (*Cassia obtusifolia*), and broadleaf signalgrass (*Brachiaria platyphylla*) (Webster, 2005).

Cultural and mechanical weed control practices are important components of an effective weed management program (Loux, et al., 2008). Crop rotation, narrow row spacing, and planting date are a few of the crop management practices that are implemented to provide the crop with a competitive edge over weeds (Monsanto, 2010). Although the primary purpose of tillage is for seedbed preparation, tillage is still used to supplement weed control with selective herbicides in soybean production.

Herbicides provide effective and economical control of weeds in soybean. Approximately 98% of the soybean acreage received an herbicide application in 2006 indicating the importance of weed control in maximizing soybean yield (USDA-ERS, 2010b). Herbicide-tolerant soybean was introduced to provide growers with additional options to improve crop safety and/or improve weed control. The Roundup Ready® soybean system, i.e., planting Roundup Ready® soybean and applying glyphosate in crop, has become the standard weed control program in U.S. soybean production and is planted on 93% of the soybean acreage (USDA-NASS, 2010a).

Herbicide resistance, and the mechanism with which such resistance emerges in weeds, has been raised previously as a concern with herbicide-tolerant crop varieties. Although some have attributed weed resistance development to gene flow from an engineered crop to an unrelated species, this situation has never been demonstrated (Stewart, 2008). The emergence of herbicide resistance in weeds is a function of natural selection. With any herbicide use, the potential exists for the selection of weeds resistant to that herbicide. Within a weed species, individuals may possess an inherent ability to resist the effects of a particular herbicide. Repeated use of that herbicide will expose the weed population to a "selection pressure," which may lead to an increase in the number of surviving resistant individuals in the population (HRAC, 2009). In other words, plants susceptible to the applied herbicide will die; whereas, those few having some type of natural resistance will survive and reproduce.

Weed resistance is generally defined by the Weed Science Society of America (website at www.wssa.net) as: (1) the ability to survive application rates of an herbicide product that once were effective in controlling it; and (2) resistance is heritable. Herbicide-resistant weeds are neither a new phenomenon nor is resistance unique to the use of glyphosate. Growers have been managing herbicide-resistant weeds for decades with the use of alternative herbicides and/or cultural methods such as tillage or crop rotation.

The occurrence of an herbicide-resistant weed biotype generally does not end the useful lifespan or preclude the effective use of the herbicide in question as part of an overall weed management system. This is particularly true for glyphosate due to the wide spectrum of weeds it effectively controls and its ability to control a weed at different growth stages, despite its lack of effectiveness on some specific resistant weed biotypes.

A list of glyphosate-resistant weeds that occur in the U.S. is provided below in Table 2-3.

Table 2-3: U.S. Glyphosate-Resistant Weeds through March 2011

Weeds identified outside of Roundup Ready® Systems	Rigid ryegrass (*Lolium rigidum*)
	Hairy fleabane (*Conyza bonariensis*)
Weeds identified in Roundup Ready® Systems	Annual bluegreass *(Poa annua)*
	Kochia (*Kochia scoparia*)
	Common ragweed (*Ambrosia artemisiifolia*)
	Giant ragweed (*Ambrosia trifida*)
	Horseweed, marestail (*Conyza canadensis*)
	Palmer amaranth (*Amaranthus palmeri*)
	Common waterhemp (*Amaranthus rudis*)
	Italian ryegrass (*Lolium multiflorum*)
	Johnson grass (*Sorghum halepense*)

Source: (Heap, 2011; Monsanto, 2010)

To date, fifteen weed species resistant to glyphosate have been identified and confirmed worldwide. Nine species resistant to glyphosate have been confirmed in the U.S., two of which were identified outside of Roundup Ready® cropping systems. The speed of the spread in geographical distribution of the resistant species has varied. The reproductive biology of the particular weed species appears to be a factor contributing to the spread of resistant biotypes. Marestail (*Conyza canadensis*), which produces a large number of wind dispersed seeds contributing to a rapid distribution, has been found in many states in the northeast, midwest and the south. Some species such as common ragweed (*Ambrosia artemisfolia*) produce seeds that do not have features that allow for such easy distribution by the wind. As a consequence, biotypes of resistant ragweed have been found in a limited number of sites across the Midwest (Lingenfelter, 2007).

One of the major factors contributing to the development of resistant weeds is poor weed control management practices. These include application of herbicides at rates below those indicated on the EPA-approved label for the weed species and sole reliance on a single herbicide for weed control without the use of other herbicides or cultural control methods (i.e., pre-plant and in-crop tillage) (Beckie, 2006; Peterson et al., 2007).

The EPA administers the Federal laws governing pesticide sale and use (FIFRA). EPA encourages pesticide manufacturers to provide growers with information regarding an herbicide's mode of action to aid growers in planning herbicide use practices and to foster the adoption of effective weed-resistance management practices as specified by EPA in PR Notice 2001-5 (US-EPA, 2001). In that document, EPA states that "*this approach to resistance management is sound and would be highly beneficial to pesticide manufacturers and pesticide users*" (US-EPA, 2001). EPA approves all pesticide label use instructions based on the Agency's evaluation of supporting data supplied by the pesticide registrant or manufacturer. After EPA approves a pesticide label, it is a violation of Federal law to use the pesticide for a use or in a manner not in accordance with the label directions.

Monsanto incorporates EPA's guidelines for pesticide resistance management labeling on its glyphosate-based agricultural herbicide labels. (An example of current Roundup WeatherMAX® product label is available at (http://www.cdms.net/ldat/ld5UJ055.pdf). EPA-approved labels for Roundup® branded herbicide weed-resistant management recommendations are designed to minimize the potential for the development of glyphosate-resistant weeds.

The risk of weeds developing resistance to herbicides and the potential impact of resistance on the usefulness of an herbicide vary greatly across different mechanisms of action and depend on a combination of factors including selection pressure, herbicide soil residual activity, herbicide chemistry, and the rate of seed production, and the level of genetic variation in plants. Weed-resistance management programs that integrate the use of herbicides with different mechanisms of action and short residual activity times in soil reduce selection pressure (Prather, Ditomaso, & Holt, 2000). In conjunction with crop rotation, which may allow the grower to manipulate planting times to avoid early-season weed germination (Jordan, Mortensen, Prenzlow, & Cox, 1995) and to use mechanical as well as chemical weed control methods, these practices impede the development of herbicide resistance in weeds.

2.4.4 Microorganisms

Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva, van Veen, & van Elsas, 2004). They also suppress soil-borne plant diseases and promote plant growth (Doran, Sarrantonio, & Liebig, 1996). The main factors affecting microbial population size and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva, et al., 2004). Plant roots, including those of soybeans, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere. Microbial diversity in the rhizosphere may be extensive and differs from the microbial community in the bulk soil (Garbeva, et al., 2004).

Members of the bacterial family *Rhizobiaceae* and *Bradyrhizobiaceae* form a highly complex and specific symbiotic relationship with leguminous plants, including soybean (Gage, 2004). The nitrogen-fixing plant-microbe symbiosis results in the formation of root nodules, providing an environment in which differentiated bacteria called bacteroids are capable of reducing or fixing atmospheric nitrogen. The product of nitrogen fixation, ammonia, then can be used by the plant. In soybean, atmospheric nitrogen is fixed into ammonia through a symbiotic association with the bacterium *Bradyrhizobium japonicum*. As a result of this relationship, nitrogen enhancement of soils may only be needed in some situations for maximal yield agricultural production of soybean thereby reducing the need to fertilize the fields.

Changes in the fatty acid composition of the soybean have the potential to impact the symbiotic relationship with *Rhizobiaceae* and *Bradyrhizobiaceae* and could correspondingly impact pest potential, the environment, or cultivation practices (i.e., need to add additional nitrogen to soybean production). Although differences in abundance of root nodules and corresponding nitrogen fixation have been identified between Roundup Ready® soybeans and other varieties, no definite conclusions regarding detrimental effects of the interactions of glyphosate with soil and plant microbial communities can be made (Kremer, 2010). Other factors which impact soil microorganisms include soil moisture and temperature, soil type, soil organic matter content, soybean variety, soil nutrient status, and crop cultivation practices, including crop rotation and tillage (Kremer, 2010). The potential impacts of the modified fatty acid on this symbiotic relationship are discussed in Subsection 4.4.4 of this report in the analysis of potential impacts to microorganisms.

Glyphosate is readily metabolized by soil bacteria, and many species of soil microorganisms can use glyphosate as the sole carbon source (USDA-FS, 2003). Microorganisms produce aromatic amino acids through the shikimate pathway, similar to plants (USDA-FS, 2003). Because glyphosate inhibits this pathway, it could be expected that glyphosate would be toxic to microorganisms. Glyphosate use has been identified as potentially causing increases in certain disease-causing microbes (Fernandez et al., 2009; Kremer, 2010). Reported increases in infections in cereal crops from pathogenic soil fungi have in some cases been determined to be more closely related to reduced tillage and continuous cropping using herbicide-tolerant crops, whereas in others, application of glyphosate correlated with increased bacterial species (Fernandez, et al., 2009). The US Forest Service, while acknowledging that in some cases, increases in soil pathogens following glyphosate treatment can be detected, concludes that “there is no indication that the transient enhancement in poplation of soil fungi or bacteria will result in any substantial or lasting damage to soil ecology” (USDA-FS, 2003).

2.4.5 Biodiversity

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

The degree of biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management; and 4) extent of isolation of the agroecosystem from natural vegetation (Altieri, 1999; Palmer, Bromley, & Anderson, 2010). The reintroduction of woodlots, fencerows, hedgerows, wetlands, etc. has been used to reintroduce biodiversity into large scale monocultures. Other enhancement strategies include intercropping (the planting of two or more crops simultaneously to occupy the same field), agroforestry, crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically for the purpose of incorporating it into the soil in order to provide nutrients and organic matter), addition of organic matter (compost, green manure, animal manure, etc.), and hedgerows and windbreaks (Altieri, 1999).

Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas. The use of broad-spectrum insecticides/herbicides is one of the most severe constraints for biological diversity in crops (USDA-APHIS, 2010c). Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest may all limit the diversity of plants and animals (Lovett, Price, & Lovett, 2003).

Herbicide use in agricultural fields is likely to indirectly impact biodiversity by decreasing weed species present in the field and those insect, bird and mammals that utilize these weeds. Ninety-eight percent of soybean acreage in the U.S. was treated with glyphosate in 2005 (USDA-NASS, 2006).

2.5 PUBLIC HEALTH

2.5.1 Worker Safety

The planting of Roundup Ready® soybean and attendant application of glyphosate on the soybean crop has become the standard weed control program in U.S. soybean production (Monsanto, 2010). In the agricultural production of soybean, growers may be exposed to glyphosate-based herbicides and other pesticides during application of these chemicals to crops.

Williams et al. (2000) have conducted a comprehensive human safety evaluation and risk assessment of glyphosate, and have concluded that glyphosate has low toxicity to mammals, is not a carcinogen, does not adversely affect reproduction and development, and does not bioaccumulate in mammals.

According to the Reregistration Eligibility Decision (RED) document for glyphosate (US-EPA, 1993a, 1993b), glyphosate is of relatively low oral and dermal acute toxicity. For this reason, glyphosate has been assigned to Toxicity Categories III and IV for these effects (i.e., Toxicity Category I indicates the highest degree of acute toxicity, and Category IV the lowest). An acute inhalation study was waived by EPA because glyphosate is a non-volatile solid (vapor pressure - 7.5x10-8 mm Hg, see Schuette, 1998) and the studies conducted on the end-use product formulation are considered sufficient (US-EPA, 1993b). Toxicological reviews from EPA (1993b) and the World Health Organization (2005) are in agreement that glyphosate does not pose any human acute exposure concerns for dietary exposures and thus negated the need to establish an acute reference dose.

With regard to subchronic and chronic toxicity, one of the more consistent effects of dietary exposure to glyphosate at high doses is reduced body weight gain compared with that in controls. Body weight loss is not seen in multiple subchronic studies, but has at times been noted in some chronic studies at excessively high doses ≥ 20,000 ppm (i.e., 2%) in diet (WHO, 2005). Other general and non-specific signs of toxicity from subchronic and chronic exposure to glyphosate include changes in liver weight, blood chemistry (may suggest mild liver toxicity), and liver pathology (USDA-FS, 2003). Glyphosate is not considered a carcinogen; it has been classified by EPA as a Group E carcinogen (evidence of non-carcinogenicity for humans) (US-EPA, 1993b).

In its human health analysis, EPA considered the potential applicator and bystander exposure resulting from increased glyphosate use. Based on the toxicity of glyphosate and its registered uses, including use on glyphosate-tolerant crops, EPA concluded that occupational exposures (short-term dermal and inhalation) to glyphosate are not of concern because acute and subchronic dermal or inhalation exposure exhibited no significant adverse effects (US-EPA 2006; 71 FR 76180).

2.5.2 Human Health

Public health concerns surrounding GE soybean primarily involve the human consumption of GE soybean products. Non-GE soybean varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for food safety prior to release in the market. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), it is the responsibility of food manufacturers to ensure that the products they market are safe and properly labeled. Food derived from GE soybean must be in compliance with all applicable legal and regulatory requirements. GE organisms for food may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. FDA evaluates the submission and responds to the developer by letter (US-FDA, 2010).

Monsanto has provided the FDA with information on the identity, function, and characterization of the genes, including expression of the gene products. The submittal to the FDA included information on the safety of the improved fatty acid profile in MON 87705 Soybean oil, including a dietary risk assessment. A copy of the completed FDA review is provided in Appendix A.

2.6 ANIMAL FEED

Animal feed concerns surrounding GE soybean primarily involve the animal consumption of GE soybean products. Non-GE soybean varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for feed safety prior to release in the market. Under the

Federal Food, Drug, and Cosmetic Act (FFDCA), it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from GE soybean must be in compliance with all applicable legal and regulatory requirements. GE organisms for feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. FDA evaluates the submission and responds to the developer by letter (US-FDA, 2010).

Soybean meal is a substantial part of animal feed. In 2009, approximately 39 million tons of soybean meal was produced, 27 million tons of which was marketed for animal feed, with the largest volumes consumed by poultry (48%), swine (26%), and beef (12%)(SoyStats, 2010g, 2010h).

Monsanto has provided the FDA with information on the identity, function, and characterization of the genes, including expression of the gene products in MON 87705 Soybean. The submittal to the FDA included information on the safety of the improved fatty acid profile in MON 87705 Soybean oil, including a dietary risk assessment. A copy of the completed FDA review is provided in Appendix A.

2.7 SOCIOECONOMIC ISSUES

Soybean first entered North America in the 18th century (Hoeft, et al., 2000). Sometime during the 1930s, soybean was processed industrially in the U.S. for edible oil and protein meal. Currently, the U.S. produces approximately 38% of the global soybean supply (SoyStats, 2010a). In 2009, the U.S. exported 1.3 billion bushels (34.9 million metric tons) of soybean, which accounted for 46% of the world's soybean exports (SoyStats, 2010b). In total, the U.S. exported $16.5 billion USD worth of soybean and soybean products globally in 2009 (SoyStats, 2010c). China is the largest export market for U.S. soybean with purchases totaling $9.2 billion. Mexico is the second largest export market with sales of $1.3 billion in the same year (SoyStats, 2010c). Other significant markets include Japan and the EU.

The major producers of soybean are the U.S., Brazil, Argentina, China, and India, which accounted for approximately 91% of the global soybean production in 2007 (Soyatech, 2010); also see Table 2-4. Soybeans produced in China and India are primarily for domestic use. A significant portion of soybean produced in the U.S., Brazil, and Argentina is traded globally in the form of soybean harvested seed, soybean meal, or soybean oil (Monsanto, 2010). Globally, the U.S. was the largest soybean seed export country; whereas Argentina led the soybean meal and soybean oil export markets in 2007 (Soyatech, 2010).

Table 2-4: World Soybean Production 2009

Country	Production (million metric tons)
U.S.	80.7
Brazil	57.0

Country	Production (million metric tons)
Argentina	32.0
China	15.5
Canada	9.3
India	9.1
Paraguay	3.9
Other	9.3
TOTAL PRODUCTION	210.9

Source: (Soyatech, 2008, 2010; SoyStats, 2010a).

Managing production costs is a major component to the economics of producing a soybean crop. Key cost decisions include the choice of which soybean varieties to plant, the amount of fertilizer to apply, and which herbicide program to use. The average operating cost for producing soybean in the U.S. in 2006 was $93.41 per acre, with the value of the production less operating cost was reported to be $161.43 per acre (USDA-ERS, 2006a).

The domestic food use of soybean oil is mainly in frying oils, salad and cooking oils, and margarines (SoyStats, 2010f). In 2009, these three categories represented approximately 85% of the soybean market in the U.S., with industrial uses consuming the remaining 15% (SoyStats, 2010f; USSEC, 2006). Soybean oil industrial uses include plastics, lubricants, coatings, printing inks and adhesives, emulsifiers, surfactants (industrial detergents and cleaners as well as solvents), resins, and biodiesel, among others (APAG, 2011; USB, 2010). Soy-based industrial oil products have many advantages in the marketplace, including being inherently biodegradable, having low ecotoxicity, and being derived from renewable resources (USSEC, 2006). The extraction of oil from soybeans also creates a highly valued solid, soybean meal, which is used for animal food in all sectors (swine, beef, poultry, dairy and fish) and human food protein (tofu, soymilk, meat substitutes, protein powder and soynuts) (Soyconnection, 2011). Changes in fatty acid profile may impact food and industrial uses of the soybean oil. Fatty acid composition of the soybean oil impacts melting point, oxidative stability, and chemical functionality, and changes in any of these can impact the market sector for the product (APAG, 2011). Table 2-5 illustrates several of the key physical properties of the fatty acid constituents of soybean oil.

Table 2-5: Properties of Select Fatty Acids

Fatty Acid	Fatty Acid Lipid Number[1]	Saturated	Unsaturated	MP (ºC)	BP (ºC)
Palmitic Acid	C16	X		62.9	167
Stearic Acid	C18	X		70	361.6
Oleic Acid	C18:1		X	14	286
Linoleic Acid	C18:2		X	-5	228
Linolenic Acid	C18-3		X	-11	230

Note:

1. As noted in Table 2-1, fatty acids are identified based on the number of carbon atoms and the number of double bonds in that fatty acid.

Source**:** (CRC, 2011)

Palmitic and stearic acids are considered saturated fatty acids, indicating that they do not have any carbon double bonds. Oleic acid is a mono-unsaturated fatty acid, containing a single double bond, and linoleic and linolenic acids are polyunsaturated fatty acids, containing 2 and 3 double bonds, respectively (APAG, 2011; SDA, 1965). Generally, the longer the carbon chain for saturated fatty acids, the higher the melting point, and the more unsaturated, the lower the melting point (APAG, 2011).

These fatty acid properties influence the market applications for the oil, and various foods and industrial products are formulated to take these properties into consideration. Many of the commercial soy oils are a carefully blended mix to take advantage of the properties of the constituent fatty acids. Commercial stearic acid, for example, commonly used as a dispersing agent, a soap and detergent constituent, and in certain rubber products, is marketed as a mixture of 45% palmitic acid, 50% stearic acid, and 5% oleic acid (APAG, 2011). A soy oil with a high content of oleic acid and low content of polyunsaturated fatty acids result in an oil with high oxidative stability, a critical property for industrial lubricants, as well as achieving the food industry goals to present a soy-based oil with lower concentrations of *trans* fatty acids (Cahoon, 2003; Soyconnection, 2011).

A key element of the acceptability of soybean oil as a feedstock is the availability of product with a consistent and specific fatty acid composition (Cahoon, 2003). The identity protection systems detailed above in Subsection 2.2.4, Specialty Soybean Production, provides controls to ensure that the product characteristics cultivated in the field are preserved through to the ultimate use. Monsanto intends to market MON 87705 Soybean as a specialty soybean in order to segregate the crop from the commodity soybean at all stages its cultivation from seed production through and including handling and processing so as to preserve the special fatty acid composition (Monsanto, 2010).

The United Soybean Board has recently assessed the potential impact of rising petrochemical prices on soy uses for industrial applications (USB, 2010). Economic conditions and performance attributes of soy products, when compared with conventional petrochemical based products, favored soy as an industrial product and feedstock (USB, 2010).

3 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of MON 87705 Soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 87705 Soybean is unlikely to pose a plant pest risk. Based on its risk assessment, *Determination of Plant Pest Risk for Monsanto Improved Fatty Acid Profile MON 87705 Soybean, Glycine max* (USDA-APHIS, 2010a) APHIS has concluded that MON 87705 Soybean is unlikely to pose a plant pest risk. Therefore APHIS must determine that MON 87705 Soybean is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

Two alternatives will be evaluated in this EA: (1) no action and (2) determination of nonregulated status of MON 87705 Soybean. APHIS has assessed the potential for environmental impacts for each alternative in the "Environmental Consequences" section

3.1 NO ACTION: CONTINUATION AS A REGULATED ARTICLE

Under the No Action Alternative, APHIS would deny the petition. MON 87705 Soybean and progeny derived from MON 87705 Soybean would continue to be regulated articles under the regulations at 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of MON 87705 Soybean and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of MON 87705 Soybean.

This alternative is not the Preferred Alternative because APHIS has concluded through a Plant Pest Risk Assessment, *Determination of Plant Pest Risk for Monsanto Improved Fatty Acid Profile MON 87705 Soybean, Glycine max* (USDA-APHIS, 2010a) that MON 87705 Soybean is unlikely to pose a plant pest risk. Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

3.2 PREFERRED ALTERNATIVE: DETERMINATION THAT MON 87705 SOYBEAN IS NO LONGER A REGULATED ARTICLE

Under this alternative, MON 87705 Soybean and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR Part 340. MON 87705 Soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2010a). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87705 Soybean and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that MON 87705 Soybean are unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87705 Soybean is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. Under this alternative, growers may have future access to MON 87705 Soybean and progeny derived from this event if the developer decides to commercialize MON 87705 Soybean.

3.3 ALTERNATIVES CONSIDERED BUT REJECTED FROM FURTHER CONSIDERATION

APHIS assembled a list of alternatives that might be considered for MON 87705 Soybean. The agency evaluated these alternatives in light of the agency's authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for MON 87705 Soybean. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

3.3.1 Prohibit Any MON 87705 Soybean from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of MON 87705 Soybean, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that MON 87705 Soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2010a).

In enacting the Plant Protection Act, Congress found that:

> [D]ecisions affecting imports, exports, and interstate movement of products regulated under (the Plant Protection Act) shall be based on sound science… §402(4) (see 7 U.S. C. §7701(4)).

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order 13563, to guide the development and implementation of policies for oversight of emerging technologies (such as genetic engineering) at the agency level. In accordance with this memorandum, agencies should adhere to Executive Order 13563 and, consistent with that Executive Order, the following principle, among others, to the extent permitted by law, when regulating emerging technologies:

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

Based on our Plant Pest Risk Assessment (USDA-APHIS, 2010a) and the scientific data evaluated therein, APHIS concluded that MON 87705 Soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87705.

3.3.2 Approve the petition in part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that MON 87705 Soybean is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3.3.3 Isolation Distance between MON 87705 Soybean and Non-GE Soybean Production and Geographic Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance of MON 87705 Soybean and non-GE soybean production. However, because APHIS has concluded that MON 87705 Soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2010a), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340. APHIS also considered geographically restricting the production of MON 87705 Soybean based on the location of production of non-GE soybean in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' plant pest risk assessment for MON 87705 Soybean, there are no geographic differences associated with any identifiable plant pest risks for MON 87705 Soybean (USDA-APHIS, 2010a). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 87705 Soybean does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Nevertheless, APHIS is not expecting significant effects. However, individuals might choose on their own to geographically isolate their non-GE soybean production systems from MON 87705 Soybean, or to use isolation distances and other management practices to minimize gene movement between soybean fields. Information to assist growers in making informed management decisions for MON 87705 Soybean is available from Association of Official Seed Certifying Agencies (AOSCA, 2010).

3.3.4 Requirement of Testing for MON 87705 Soybean

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing for GE products in non-GE production systems. APHIS notes there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because MON 87705 Soybean does not pose a plant pest risk (USDA-APHIS, 2010a), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for MON 87705 Soybean would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

COMPARISON OF ALTERNATIVES

Table 3-1 presents a summary of the potential impacts associated with selection of either of the alternatives evaluated in this EA. The impact assessment is presented in Section 4 of this EA.

Table 3-1: Summary of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	**No**	**Yes**
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2010a)
Management Practices		
Acreage and Areas of Soybean Production	Unchanged	Unchanged
Seed Production	Unchanged	Unchanged
Organic Farming	Unchanged	Unchanged
Specialty Soybean	Unchanged	Unchanged
Soybean Cultivation Practices	Unchanged	Unchanged
Physical Environment		
Water Resources	Unchanged	Unchanged
Soil and Land Use	Unchanged	Unchanged
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Biological Resources		
Gene Movement and Weediness	Unchanged	Unchanged
Animals	Unchanged	Unchanged
Plants	Unchanged	Unchanged
Microorganisms	Unchanged	Unchanged
Biodiversity	Unchanged	Unchanged
Human Health		
Worker Safety	Unchanged	Unchanged
Human Health	Unchanged	Unchanged (potential health benefits)
Animal Feed	Unchanged	Unchanged
Socioeconomic		
Domestic Economic Environment	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged
Social Environment	Unchanged	Unchanged

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Threatened and Endangered Species	Unchanged	Unchanged
Other U.S Regulatory Approvals	FDA completed consultations	FDA completed consultations
Compliance with Other Laws		
CWW, CAA, EOs	Fully compliant	Fully compliant

Notes:

1. Unchanged – the current conditions will not change as a result of the selection of this alternative.
2. Minimal – the current conditions may change slightly as a result of the selection of this alternative, but the changes, if any, are not deemed significant.

4 ENVIRONMENTAL CONSEQUENCES

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, namely taking no action and a determination by the Agency that Monsanto 87705 Soybean does not pose a plant pest risk and therefore should no longer be regulated under 7 CFR 340.

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for MON 87705 Soybean are described in detail throughout this section. A cumulative effects analysis is also included for each environmental issue. Certain aspects of this product and its cultivation would result in no differences of consequences deriving from the alternatives; those are described below.

SCOPE OF THE ENVIRONMENTAL ANALYSIS

For the discussion of environmental consequences, the following principal areas of potential environmental concern have been evaluated:

- Soybean Production (Subsection 4.2);
- Physical Environment (Subsection 4.3);
- Biological Resources (Subsection 4.4);
- Public Health (Subsection 4.5);
- Animal Feed (Subsection 4.6);
- Socioeconomics Issues (Subsection 4.7);
- Threatened and Endangered Species (Subsection 4.8);
- Other Cumulative Effects (Subsection 4.9); and
- Consideration of Executive Orders, Standards, and Treaties Relating to Environmental Impacts (Subsection 4.10).

A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. Examples include the possibility of breeding MON 87705 Soybeans with GE soybeans that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 (i.e., “stacked” traits) including herbicide tolerance or with conventional traits. If there are no direct or indirect impacts identified for a resource area, then there can be no cumulative impacts. Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential impacts. Certain aspects of this product and its cultivation may be no different between the alternatives.

Although the Preferred Alternative would allow for new plantings of MON 87705 Soybean to occur anywhere in the U.S., APHIS will limit the environmental analysis to those areas that currently support soybean production (see Table 2-2). The environmental consequences of No Action and Preferred Alternatives will be analyzed under the assumption that farmers, who produce conventional soybean, MON 87705 Soybean, or produce soybean using organic methods, are using reasonable, commonly accepted best management practices for their chosen system and varieties during agricultural soybean production. However, APHIS recognizes that not all farmers follow these best management practices for soybean. Thus, the analyses of the environmental effects will also include the assumption that some farmers do not follow these best management practices.

4.1 SOYBEAN PRODUCTION

One of APHIS's missions is to improve American agricultural productivity. Best management practices are commonly accepted, practical ways to grow soybean, regardless of whether the soybean farmer is using conventional practices with non-GE or GE varieties, or using organic practice. These management practices consider crop-specific planting dates, seeding rates, and harvest times, among others. Over the years, soybean production has resulted in well-established, widely-practiced management practices that are available through local Cooperative Extension Service offices and their respective websites. The National Information System for the Regional Integrated Pest Management Centers (IPM Centers) publishes crop profiles for major crops on a state-by-state basis. These crop profiles provide production guidance for local growers, including recommended practices for specific pest control. Crop profiles for many of the soybean production states are available at: www.ipmcenters.org/cropprofiles/index.cfm.

Monsanto's field trials have not demonstrated any agronomic or phenotypic differences between MON 87705 Soybean and control varieties of soybean(Monsanto, 2010). Based on the data provided by Monsanto for MON 87705 Soybean (Monsanto, 2010), as well as previous experience with other GE soybean varieties that have been widely adopted by growers since their introduction in 1996 (USDA-ERS, 2010a), APHIS has concluded that none of the best management practices for agricultural production of soybean are expected to change if MON 87705 Soybean is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340. Consistent with the lack of changes to agronomic properties, the potential impacts on agricultural production associated with the No Action and Preferred alternatives are the same.

4.1.1 Acreage and Areas of Soybean Production

GE and non-GE soybean varieties are continually under development. In 2009 and 2010, over 75 million acres in the U.S. were planted in soybean, with over 93% of the soybean expressing herbicide tolerance (USDA-ERS, 2010a, 2010b).

<u>No Action: Acreage and Areas of Soybean Production</u>

Based on current acreage trends, soybean production with GE varieties will likely continue to dominate. Cultivation of GE soybean increased from 17% of the U.S. soybean acreage in 1997, to over 93% in 2010. The continued cultivation of soybean and the penetration of the soybean market by GE varieties is not expected to change under the No Action Alternative. Soybeans are currently produced commercially in 31 states (USDA-NASS, 2010a) and under the No Action Alternative, this range of production is not expected to change.

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

Monsanto plans to market MON 87705 Soybean as a specialty variety to take full advantage of the modified fatty acid composition of this product (Monsanto, 2010). Monsanto's field trials have not demonstrated any agronomic or phenotypic differences between MON 87705 Soybean and control varieties of soybean (Monsanto, 2010). The changes in fatty acid composition and the tolerance to the herbicide glyphosate expressed in MON 87705 Soybean do not require changes in cultivation practices when compared with other glyphosate-tolerant soybean varieties (Monsanto, 2010). MON 87705 Soybean does not confer an increase in cold tolerance, heat resistance, or drought tolerance (these issues are discussed again below in the subsection on gene flow) and therefore MON 87705 Soybean is not anticipated to be cultivated in new regions outside of the current soybean production areas. MON 87705 Soybean is anticipated to replace plantings of both conventional and existing GE varieties where those growers seek to cultivate a specialty soybean variety to take advantage of the changed fatty acid composition of this product in conjunction with the tolerance to glyphosate (Monsanto, 2010). Under the Preferred Alternative, a determination of nonregulated status of MON 87705 Soybean is not expected to increase soybean production, or result in an increase in overall GE soybean acreage or cultivation in new regions. Impacts would be similar to the No Action Alternative.

Cumulative Effects: Acreage and Areas of Soybean Production

Cumulative effects of a determination of nonregulated status of MON 87705 Soybean are unlikely. Neither the No Action Alternative nor a determination of nonregulated status of MON 87705 Soybean is expected to directly cause an increase in agricultural acreage devoted to soybean production or those soybean acres devoted to GE soybean cultivation. The availability of MON 87705 Soybean is not expected to change cultivation areas for soybean production in the U.S., and there are no anticipated changes to the availability of GE and non-GE soybean varieties on the market under either alternative.

4.1.2 Seed Production

Soybean seed production is managed through AOSCA standard procedures to curtail gene flow between varieties (Bradford, 2006; Sundstrom, et al., 2002). Soybean is considered a self-pollinated species, exhibiting a high-percentage of self-fertilization (OECD, 2000). Common practices to preserve varietal identity include: 1) maintaining isolation distances to prevent pollen movement from other soybean sources; 2) planting border or barrier rows to intercept pollen, employing natural barriers to pollen; and 3) field monitoring for off-types, other crops, weeds, and disease.

No Action: Seed Production

Under the No Action Alternative, current soybean seed production practices are not expected to change.

Preferred Alternative: Seed Production

Monsanto's field trials have not demonstrated any agronomic or phenotypic differences between MON 87705 Soybean and control varieties of soybean (Monsanto, 2010). Based on the data provided by Monsanto for MON 87705 Soybean (Monsanto, 2010), as well as previous experience with other GE soybean varieties that have been widely adopted by growers since their introduction in 1996 (USDA-ERS, 2010a), APHIS has concluded that the availability of MON

87705 Soybean would not alter the agronomic practices, locations, and the production and quality characteristics of conventional and GE seed production (USDA-APHIS, 2010a). The overall impact of a determination of nonregulated status of MON 87705 Soybean on the availability of conventional and GE seed, and the production practices used to grow soybean seeds would be similar to the No Action Alternative. Accordingly, there are no differences between the No Action and Preferred Alternatives with regard to seed production.

Cumulative Impacts: Seed Production

Based on current acreage trends, GE soybean varieties will likely continue to dominate the market. Since 2007, the GE varieties of soybean have comprised 91 to 93% of the U.S. soybean acreage. Changes in the agronomic practices and locations for soybean seed production using MON 87705 Soybean are not expected. The availability of MON 87705 Soybean will not change cultivation areas for soybean seed production in the U.S.; no cumulative effects have been identified for this issue.

4.1.3 Organic Farming

Organic production plans prepared pursuant to the National Organic Program (NOP) include practical methods to protect organically-produced crops from accidental contamination with genetically engineered materials. Typically, organic growers use more than one method to maintain organic certification and prevent unwanted material from entering their fields including: isolation of the farm, physical barriers or buffer zones between organic production and non-organic production, as well as formal communications between neighboring farms (Baier, 2008; Kuepper, 2003; NCAT, 2003). These practices follow the same system as that utilized for the cultivation of certified seed under the AOSCA procedures.

APHIS recognizes that producers of non-GE soybean, particularly producers who sell their products to markets sensitive to GE traits (e.g., organic or some export markets), can be reasonably assumed to be using practices on their farm to protect their crop from unwanted substances and maintain their price premium. APHIS will assume that growers of organic soybean are already using, or have the ability to use, these common practices as a baseline, which APHIS uses for the analyses of the alternatives below.

Historically, organic soybean production represents a small percentage of total U.S. soybean acreage (USDA-ERS, 2010e). In 2005, 122,217 acres of soybean in U.S. were certified organic, and in 2008, 125,621 acres were similarly certified (USDA-ERS, 2010e), representing between 0.17% and 0.22%, respectively, of the soybean production in the U.S. In 2001, 68% of the soybean crop was herbicide-tolerant, and by 2010 93% of the total acreage was herbicide-tolerant (USDA-ERS, 2010a, 2010b, 2010e).

No Action: Organic Farming

Current availability of conventional (both GE and non-GE) soybean varieties, and those soybean varieties that are developed for organic production, are expected to remain the same under the No Action Alternative. Since 2001, GE varieties of soybean have dominated the market, representing 68% of the market in 2001, and 93% of the market in 2010 (USDA-ERS, 2010a).

Although organic soybeans have a place in the market, the respective share is small, and the dedicated acreage appears to be steady. Between 2005 and 2008, the total acreage devoted to soybean fluctuated between 72 million and 64 million acres, although organic soybeans ranged from 122,000 to 126,000 acres, less than 1% of the total soybean acreage (USDA-ERS, 2010e). The market share for organic soybean varieties is not expected to change under the No Action Alternative (USDA-ERS, 2010a; USDA-NASS, 2007, 2010e).

Preferred Alternative: Organic Farming

It is not likely that organic farmers, or other farmers who choose not to plant transgenic varieties or sell transgenic seed, will be substantially impacted by APHIS' a determination of nonregulated status of MON 87705 Soybean.

GE soybean varieties are currently cultivated on 93% of the U.S. soybean acreage (USDA-ERS, 2010a), and organic varieties comprise less than 1% of the total soybean acreage (USDA-ERS, 2010e). MON 87705 Soybean should not present any new or different issues and impacts for organic and other specialty soybean producers and consumers.

According to the petition, agronomic trials conducted in 2007 at 17 field locations in the U.S. demonstrated that MON 87705 Soybean is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterpart (Monsanto, 2010; USDA-APHIS, 2010a). No differences were observed in pollen diameter, weight, and viability (Monsanto, 2010; USDA-APHIS, 2010a). Consistent with the lack of difference in agronomic properties, MON 87705 Soybean is not expected to have an increased ability to cross pollinate other soybean varieties.

The practices currently employed to preserve and maintain purity of organic production systems would not be required to change to accommodate the production of MON 87705 Soybean. Commonly used production practices for soybean and the practical methods typically used by soybean farmers using organic methods to protect their crop under organic production (NCAT, 2003) provide many measures that greatly reduce the likelihood of accidental gene flow between MON 87705 Soybean and non-GE soybean fields. While organic growers, depending on the GE-sensitivities of organic buyers, may use these practices not required by growers of conventional soybean for limiting such gene flow, MON 87705 will not impose any new requirements to do so.

MON 87705 Soybean will be marketed by Monsanto as a specialty variety to take advantage of the altered fatty acid composition (Monsanto, 2010). Consistent with lack of differences in agronomic practices, and the specialty soybean market intentions, MON 87705 Soybean is not expected to displace current organic soybean production.

The acreage devoted to organic soybean is expected to remain small regardless of whether new varieties of GE or non-GE soybean varieties, including MON 87705 Soybean, become available for commercial soybean production. As noted above for the time period of 2005 to 2008, when the total U.S. acreage dedicated to soybean fluctuated between 72 million and 64 million acres, the acreage devoted to organic soybeans was relatively stable, reported between 122,000 and 126,000 acres (USDA-ERS, 2010e). Consistent with these cultivation trends, a determination of of MON 87705 Soybean is not expected to have a significant impact on organic soybean growers.

Cumulative Effects: Organic Farming

A determination of nonregulated status of MON 87705 Soybean is not expected to change the market demands for GE soybean or soybean produced using organic methods. A determination of nonregulated status of MON 87705 Soybean will add another GE soybean variety to the conventional soybean market. Based upon recent trend information, adding GE varieties to the market is not related to the ability of organic production systems to maintain their market share.

4.1.4 Specialty Soybean Production

Specific market uses for specialty soybean products generally require adherence to specialty crop practices to preserve identity from seed production through harvesting, handling, and processing. A premium is paid to growers and processors for delivering product that meets these desired purity and quality standards (Elbehri, 2007; Lee & Herbek, 2004; Muth, Mancini, & Viator, 2003; Pritchett, Fulton, Beyers, Pederson, & Lawson, 2002; Smyth & Phillips, 2002; Sundstrom, et al., 2002). Specialty soybean crop growers employ these identity protection practices and standards to not only ensure that identity is preserved, but also to ensure that their products are not pollinated by or commingled with conventional or genetically engineered crops (Bradford, 2006; Cui, et al., 2004; Massey, 2002). These identity management practices include maintaining isolation distances to prevent pollen movement from other soybean sources, planting border or barrier rows to intercept pollen, employing natural barriers to pollen, and managing planting dates and various seed handling, transportation, and ginning procedures so as to maintain separation between specialty and commodity varieties (Bradford, 2006; NCAT, 2003; Sundstrom, et al., 2002). These management practices allow the grower to meet standards for the production of specialty crop seed, maintain genetic purity, and protect the genetic diversity of soybean (Bradford, 2006).

No Action: Specialty Soybean Production

Current availability of GE, non-GE, specialty and organic soybean varieties are expected to remain the same under the No Action Alternative. Since 2001, GE varieties of soybean have dominated the market, representing 68% of the market in 2001, and 93% of the market in 2010 (USDA-ERS, 2010a). Specialty soybeans are produced on approximately 12% of the total U.S. acreage (MSA, 2009). The acreage dedicated to specialty soybeans is projected to increase to 25% of the total acreage over the next decade (MSA, 2009). The market share for specialty soybean varieties is not expected to change under the No Action Alternative (USDA-ERS, 2010a; USDA-NASS, 2007, 2010e). The cultivation of specialty soybean varieties is expected to remain the same under the No Action Alternative.

Preferred Alternative: Specialty Soybean Production

MON 87705 Soybean is expected to be cultivated as a high-value specialty soybean product, produced under identity protection system management practices so as to preserve the value of the oil (Monsanto, 2010). As a specialty soybean variety, Monsanto anticipates that MON 87705 would be cultivated following existing specialty crop practices to preserve product identity from seed production through harvesting, handling, and processing (Monsanto, 2010). A premium is paid to growers and processors for delivering product that meets these desired purity and quality standards (Elbehri, 2007; Lee & Herbek, 2004; Muth, et al., 2003; Pritchett, et al., 2002; Smyth & Phillips, 2002; Sundstrom, et al., 2002).

It is not likely that specialty system farmers, or other farmers who choose not to plant transgenic varieties or sell transgenic seed, will be substantially impacted by an APHIS determination of nonregulated status of MON 87705 Soybean. Specialty soybean varieties are already cultivated on 12% of the U.S. soybean acreage, and the industry anticipates that specialty soybean acreage could expand to over 25% of the crop in certain states within the next decade (MSA, 2009). The trend towards increasing cultivation of specialty soybeans has paralleled the adoption of GE soybeans, both commodity and specialty varieties. Cultivation of MON 87705 Soybean as a new specialty soybean variety should not present any new or different issues and impacts for specialty soybean producers and consumers. That specialty soybeans comprise 12% of the total U.S. soybean acreage, where 93% of that same acreage is cultivated with GE soybean varieties, demonstrates that existing IDP programs (e.g., the AOSCA identity protection and preservation systems) provide adequate assurance of variety and specialty characteristics.

Data presented in Monsanto's petition demonstrates that MON 87705 Soybean is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterpart (Monsanto, 2010; USDA-APHIS, 2010a). No differences were observed in pollen diameter, weight, and viability. Consistent with the lack of changes to agronomic properties, MON 87705 Soybean is not expected to have an increased ability to cross-pollinate other soybean varieties or to require different cultivation or handling techniques from currently cultivated specialty soybean varieties.

<u>Cumulative Effects: Specialty Systems</u>

A determination of nonregulated status of MON 87705 Soybean is not expected to change the market demands for GE soybean or soybean produced using specialty systems. A determination of nonregulated status of MON 87705 Soybean will add another GE variety to the existing soybean market. MON 87705 Soybean is expected to be cultivated as a specialty soybean consistent with these practices. Based on demonstrated agronomic characteristics and cultivation practices, and because the market share of specialty soybean varieties is unlikely to change by the introduction of MON 87705 Soybean, APHIS has determined that there are no past, present, or reasonably foreseeable changes that would impact specialty soybean producers and consumers.

4.1.5 Soybean Cultivation Practices

Crop rotation in soybean is conducted to manage weeds, optimize soil nutrition and fertility, reduce pathogen loads, and control certain soybean pests (Al-Kaisi, et al., 2003; University of Illinois, 2006). The adoption of herbicide tolerance complements conservation tillage practices by allowing farmers to substitute glyphosate application for some tillage operations as a weed management practice (NRC, 2010). Benbrook (2009) notes that herbicide-tolerant soybean accounts for over two-thirds of the total acreage devoted to genetically engineered crops.

Volunteer soybean is normally not a concern. Soybean is not winter hardy, and existing mechanical and chemical methods are available to manage the occasional volunteer soybean.

Benbrook has reported that the adoption of herbicide-tolerant crops has resulted in an increase in the volume of herbicides applied to crops (Benbrook, 2009). Benbrook notes that herbicide use declined between 1996 and 2001 apparently in direct response to the adoption of herbicide-tolerant crops; however, since that time, herbicide use has increased (Benbrook, 2009). Reported increases in herbicide use reflect an increase in use of conventional herbicides as well as an increase in glyphosate applications as more glyphosate-tolerant crops are planted (Benbrook, 2009). Currently, nine weeds have been identified as glyphosate-resistant, with seven of these weeds identified as difficult to control weeds in soybean: common ragweed (*Ambrosia artemisiifolia*), common waterhemp (*Amaranthus rudis*), giant ragweed (*Ambrosia trifida*), horsetail (marestail) (*Conyza canadensis*), Italian ryegrass (*Lolium multiflorum*), Johnsongrass (*Sporghum halapense*), and Palmer amaranth (*Amaranthus palmeri*) (Benbrook, 2009).

No Action: Soybean Cultivation Practices

Under the No Action Alternative, soybean crop rotation practices and herbicide pesticide use will likely remain as it is practiced today by the farming community. Growers will continue to have access to herbicide-tolerant soybean products that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 as well as conventional soybean varieties.

Preferred Alternative: Soybean Cultivation Practices

Monsanto's studies demonstrate MON 87705 Soybean is essentially indistinguishable from other soybean varieties used in terms of agronomic characteristics and cultivation practices (Monsanto, 2010; USDA-APHIS, 2010a). The mechanism for glyphosate tolerance is the same as that expressed by other varieties, so the application rates for glyphosate are not expected to change (Monsanto, 2010). Monsanto did not identify any differences between MON 87705 Soybean and conventional A3525 control soybeans in dormancy, germination potential, disease or insect response, seedling vigor, or plant maturity (Monsanto, 2010; USDA-APHIS, 2010a). The similarity in agronomic and phenotypic characteristics suggests that the changes in fatty acid profile and the incorporation of glyphosate tolerance do not impact the ability of soybean to overwinter or become a volunteer.

A determination of nonregulated status of MON 87705 Soybean is not expected to affect the use of glyphosate as a post-emergent weed herbicide. Other herbicides are available to control volunteer soybeans in corn, cotton, wheat, and rice (see Subsection 2.2.5.5, above). These herbicides are suitable for post-emergence control of volunteer soybean. The challenges which growers face in managing glyphosate-resistant weeds is also not expected to differ between MON 87705 Soybean and other glyphosate-tolerant varieties.

Consistent with the demonstrated lack of agronomic difference, soybean crop rotation and herbicide use practices are expected to be unchanged under the Preferred Alternative. Overall impacts would be similar to the No Action Alternative.

Cumulative Effects: Soybean Cultivation Practices

Soybean growers have other herbicide-tolerant variety options for soybean production in addition to those varieties expressing glyphosate tolerance; two mechanisms for this resistance are offered to growers: insensitive target enzyme and increased metabolism. LibertyLink® Soybean with glufosinate ammonium tolerance is available from numerous seed dealers (e.g., Stine Seed), as are STS soybeans, a conventionally derived resistance to ALS herbicides, which may be stacked with other resistance traits (e.g., Asgrow Seed). These options allow growers to reduce dependence on glyphosate, especially if glyphosate-resistant weeds are an important issue. Additional strategies to avoid development of glyphosate-resistant weeds can be used by growers and these include:

- Developing a diversified weed management program using herbicides with different modes of action, either concurrently or sequentially (NRC, 2010).
- Use the full recommended herbicide rate and proper application timing for the most difficult to control weeds in the field (NRC, 2010).
- Scouting the fields after herbicide application to ensure that control has been achieved and to discourage weeds from reproducing or proliferating vegetatively (NRC, 2010).
- Incorporate cultural practices such as cultivation, tillage and crop rotation, where appropriate (NRC, 2010).

A determination of nonregulated status of MON 87705 Soybean will not result in changes in the current practices of crop rotation and pesticide use. Studies demonstrate MON 87705 Soybean is essentially indistinguishable from other soybean varieties used in terms of agronomic characteristics and cultivation practices (Monsanto, 2010). It is anticipated that herbicide use will continue the trends noted by Benbrook associated with the wide adoption of glyphosate-tolerant soybean and the emergence of glyphosate-resistant weeds. APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to effect changes in crop rotation, and pesticide use.

4.2 PHYSICAL ENVIRONMENT

4.2.1 Soil and Land Use

The USDA National Resource Conservation Service has identified significant reductions in the loss of soil from croplands in the U.S., finding that total soil loss on highly erodible croplands and non-highly erodible cropland decreased by 39.2% from 1982 to 2003 (USDA-NRCS, 2006c). Herbicide-tolerant soybean has contributed to this reduction in soil loss through a shift towards conservation tillage and the use of cover crops where the cultivation of herbicide-tolerant varieties and attendant use of post-emergent herbicides replaces manual weed control techniques (University of Illinois, 2006; USDA-NRCS, 2010). Other benefits to soil of conservation tillage or no-till systems include lower dust generation, decreased fertilizer and pesticide use, reduced fuel and labor costs, and conservation of soil moisture.

No Action: Soil and Land Use

Land usage and agronomic practices associated with traditional and existing non-regulated GE soybean production would not be expected to change in response to the No Action Alternative. No changes to the impacts to the soil environment are anticipated from the current agronomic practices associated with soybean production including tillage, cultivation, fertilization, pesticide applications, fertilizer applications, and the use of agricultural equipment.

Preferred Alternative: Soil and Land Use

No changes to agronomic practices typically applied in the management of conventional soybean, including other commercially available GE soybean varieties, are required for MON 87705 Soybean.

Monsanto's field trial and laboratory analyses demonstrated that the agronomic performance of MON 87705 Soybean was functionally identical to its non-transgenic counterpart (Monsanto, 2010). No increases in fertilizers and pesticides were required, nor were any changes in cultivation, planting, harvesting, and volunteer control required (Monsanto, 2010). It is expected that similar agronomic practices that are currently used for commercially available GE soybean will also be used by growers of MON 87705 Soybean.

If MON 87705 Soybean is adopted and replaces non-GE soybean varieties (currently less than 7% of US soybean ({USDA-ERS, 2010b #437}), soils currently under non-GE soybean production may experience short-term benefits from the use of MON 87705 Soybean due to a reduction in applications of herbicides and the number of acre-treatments per year using heavy farm equipment required for herbicide applications. However, as noted by Benbrook (2009) and others, if glyphosate use is not well managed, resistant weeds may emerge, requiring use of other herbicides, as well as field tillage for their control.

Persistence of pesticides in soil is also favorably addressed by the cultivation of MON 87705 Soybean. Glyphosate would likely be the predominant post-emergent herbicide applied to MON 87705 Soybean, as it is with other glyphosate tolerant soybean. Glyphosate has been shown to rapidly dissipate from most agricultural ecosystems across a wide range of soil and climatic conditions, with a median soil half-life (the time it takes for half of the glyphosate to dissipate in the soil) of 13 days (Giesy, Dobson, & Solomon, 2000). A survey reported by Borggard and Gimseng (2008) noted soil half-lives ranging from 1.2 to 197 days, depending on a wide range of soil chemical and physical parameters.

Pesticide products approved for application to emerged weeds normally are applied with surfactants. Surfactants increase the permeability of the weed foliage to increase the foliar uptake of glyphosate and thereby improve the efficacy of the herbicide (Monsanto, 2010). Polyethoxylated alkyl amine (POEA) is the predominant surfactant used in formulated glyphosate products. Glyphosate and the POEA surfactant have similar soil dissipation rates and the same primary route of dissipation, i.e., microbial degradation (Giesy, et al., 2000). The half-life of POEA in soil is estimated to range from 7 to 14 days (Giesy, et al., 2000). On that basis, the POEA surfactant is expected to behave similarly to glyphosate in field soil, and an increase in residual soil concentrations (accumulation) of the POEA surfactant is not anticipated. Because MON 87705 Soybean does not differ in its agronomic requirements from conventional soybean or other GE varieties expressing glyphosate tolerance, agronomic practices associated with soil and land use are not expected to change with the availability of this new plant product.

Cumulative Effects: Soil and Land Use

APHIS has not identified any cumulative effects to soils. Comprehensive phenotypic, agronomic, and ecological assessments conducted by the petitioner for MON 87705 Soybean did not find significant differences between MON 87705 Soybean and control soybeans for these characteristics (Monsanto, 2010). The few differences that were identified were typically small, site specific, and unlikely to be biologically meaningful. Event MON 87705 Soybean required the same soil, fertilizer, water and pest management practices as non-GE soybean (Monsanto, 2010). Consequently, the phenotypic, agronomic, and ecological data presented by Monsanto (Monsanto, 2010) support the conclusion by APHIS that MON 87705 Soybean will not significantly modify soil characteristics associated with conventional soybean production practices.

Based on these findings, and because the amount of soybean grown in the U.S. is unlikely to change by the introduction of MON 87705 Soybean, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to impact soil.

4.2.2 Water Resources

The soils and climate in the Eastern, Midwestern and portions of the Great Plains of the U.S. provide sufficient water supplies under normal climatic conditions to produce a soybean crop. The adoption of herbicide-tolerant soybean varieties has been a factor in the adoption of conservation practices, including conservation tillage.

Water quality is also preserved in modern soybean production systems. The increase in conservation tillage practices has resulted in a reduction of runoff from agricultural lands, decreasing non-point source pollution of fertilizer and pesticides. Intensive local monitoring of surface water and sub-soils has demonstrated the benefits of no-till soybean in protecting both ground and surface water resources (University of Illinois, 2006).

Although glyphosate is very soluble in water, it is strongly adsorbed to soils; consequently, glyphosate is unlikely to leach into groundwater or surface water runoff following application (Giesy, et al., 2000; US-EPA, 1993b). Relying on toxicological data; bioaccumulation and biodegradation studies; and acute and chronic tests on fish and other aquatic organisms, EPA has determined that “the potential for environmental effects of glyphosate in surface water is minimal” (US-EPA, 1993b).

No Action: Water Resources

Under the No Action Alternative, land acreage and agronomic practices, including irrigation, associated with soybean production would not be affected. Current application rates of glyphosate for weed control are not expected to change.

Preferred Alternative: Water Resources

In 2010, herbicide-tolerant soybeans were cultivated on 93% of the soybean acreage (USDA-ERS, 2009). The introduction of herbicide-tolerant crops has resulted in the adoption of conservation practices (Monsanto, 2010; Sankula, 2006; University of Illinois, 2006). These conservation practices, including reduced tillage and precision agriculture play a significant role in water conservation and maintaining water quality by minimizing soil erosion (USDA-NRCS, 2006b).

MON 87705 Soybean does not change cultivation practices for soybean production, nor would it increase the total acres and range of U.S. soybean production areas. A determination of nonregulated status of MON 87705 Soybean will not change water use in soybean production, as the MON 87705 Soybean is expected to simply replace GE and non-GE soybean varieties already in use.

Current application rates of glyphosate for weed control are not expected to change. Based on the above information, the consequences of the Preferred Action Alternative on water use are the same as the No Action Alternative.

Cumulative Effect: Water Resources

No cumulative effects on water use have been identified associated with a determination of nonregulated status of MON 87705 Soybean. A determination of nonregulated status of MON 87705 Soybean will not change the water use and irrigation practices used in commercial soybean production.

4.2.3 Air Quality and Climate Change

Traditional agricultural practices have the potential to cause negative impacts to air quality. Agricultural emission sources include smoke from agricultural burning, tillage, traffic and harvest emissions, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizer (Aneja, et al., 2009; USDA-NRCS, 2006a). Other greenhouse gas (GHG) emission sources associated with agricultural production include equipment emissions (contributing carbon monoxide, nitrogen oxides, and reactive organic gases), particulate matter, sulfur oxides, and direct emissions of N_2O from fertilizer application (US-EPA, 2010).

The adoption of herbicide-tolerant soybean has reduced air emissions, including GHG, due to the increased adoption of conservation practices (NRC, 2010). Conservation practices, including conservation tillage associated with GE soybean production, requires fewer tractor passes across a field (Baker, et al., 2005; USDA-NRCS, 2006a). This results in a decrease in dust generation and tractor emissions (Baker, et al., 2005; USDA-NRCS, 2006a). Surface residues and untilled organic matter physically hold the soil in place thus decreasing wind erosion of soils and pesticide drift in wind-eroded soils (Baker, et al., 2005; USDA-NRCS, 2006a). Reduced tillage also increases sequestration rates of potential carbon emissions from soils (Causarano, Franzluebbers, Reeves, & Shaw, 2006).

No Action: Air Quality and Climate Change

Under the No Action Alternative, current impacts to air quality associated with land acreage and cultivation practices associated with soybean production would not be affected.

Agronomic practices associated with conventional soybean production and current GE soybean varieties and which contribute to air quality and GHG emissions, including tillage, cultivation, irrigation, pesticide application, fertilizer applications and use of agriculture equipment, would not be expected to change.

Preferred Alternative: Air Quality and Climate Change

A determination of non-regulated status of MON 87705 Soybean will not change the cultivation or agronomic practices, or agricultural land acreage associated with growing soybean, and is expected to have the same effect on air quality and climate change as the No Action Alternative.

Cumulative Effects: Air Quality and Climate Change

APHIS has not identified any cumulative effects for this issue. The use of MON 87705 Soybean in commercial soybean production is not expected to cause any cumulative effect on air quality or climate change because APHIS does not anticipate any changes in soybean production practices or an expansion of soybean acreage as a result of a determination of nonregulated status of MON 87705 Soybean. The consequences of the Preferred Action Alternative on commercial soybean production and acreage are the same as for the No Action Alternative.

4.3 BIOLOGICAL RESOURCES

4.3.1 Gene Movement and Weediness

Two forms of gene flow are evaluated: Vertical gene flow and horizontal gene flow. Vertical gene flow, or hybridization and associated introgression, is the movement of genes to sexually compatible relatives (Ellstrand, 2003; Quist, 2010). The soybean is considered self-pollinating, and has no wild relatives in the U.S. (OECD, 2000; Monsanto, 2010). Although some cross-pollination can occur, AOSCA identity protection practices have been found adequate to protect against such gene flow (OECD, 2000; Monsanto, 2010; USDA-APHIS, 2010a). The only relatives of soybean are other varieties currently cultivated. In assessing the risk of gene introgression from MON 87705 Soybean to its sexually compatible relatives, APHIS considered two primary issues: 1) the potential for gene flow and introgression to soybean relatives; and 2) the potential impact of introgression. Vertical gene flow is discussed below in the analysis of the Preferred Alternative.

Horizontal gene flow represents the stable movement of genes from one organism to another without reproduction or human intervention (Keese, 2008; Quist, 2010). There is no evidence of naturally occurring transgene movement from transgenic crops to sexually incompatible species

(Stewart, 2008). Horizontal gene transfer and consequent expression of DNA from one plant to another sexually incompatible plant or other phyla (e.g., species of bacteria) is unlikely to occur (Keese, 2008). This event would require physical relocation of the functional genetic sequences from the transgenic plant to the new location, including not only the genes which code for the production of specific proteins, but also those portions of the genome which regulate the activity of those genes (Keese, 2008; Stewart, 2008). There are no known naturally occurring vectors (such as plasmids, phages, or transposable elements) that could be responsible for inter-domain gene transfer, and there is little evidence that eukaryotic cells are naturally capable of stably incorporating genes from the environment into their genome (Brown, 2003). Although viruses do move genetic material, all viruses that infect higher plants have small RNA or DNA genomes, usually with fewer than 20 encoded proteins (Keese, 2008). These viruses are, therefore, constrained as to the type and size of novel genetic material which can be acquired by horizontal gene transfer (Stewart, 2008). The development of herbicide resistance particularly that experienced in weeds treated with glyphosate is thus not a result of gene transfer but is the result of selective pressures associated with herbicide use. This issue is discussed in the subsection on impacts to plant communities.

Two bacterial species commonly associated with plants, *Agrobacterium* and *Rhizobium*, have been evaluated to determine the probability of horizontal gene transfer between the bacterium and their host plants. *Agrobacterium* moves its genes from its bacterial plasmid to the plant causing the plant to produce the gall; *Rhizobium* aids in nitrogen fixation in legume nodules (Stewart, 2008). The genomes of both bacteria have been sequenced, and the sequenced genes evaluated in search of exogenous genes (Kaneko, et al., 2000; Kaneko, et al., 2002; Wood, et al., 2001). Despite what would appear to be millennia of symbiotic relationships between these bacteria and their host plants, there is no evidence that these organisms contain genes derived from plants (USDA-APHIS, 2010a). In cases where review of sequence data implied that horizontal gene transfer occurred, these events are inferred to occur on an evolutionary time scale of millions of years (Brown, 2003; Koonin, et al., 2001). Transgene DNA promoters and coding sequences are optimized for plant expression, not bacterial expression (USDA-APHIS, 2010d). Horizontal gene flow, resulting in the relocation of entire transgenes including the regulatory portions of the DNA (those parts of the DNA which code for the production of the specific proteins in that relocated transgene) has never been shown to occur in nature (Clarke, 2007; Stewart, 2008). Thus, even if horizontal gene transfer occurred, proteins associated with these transgenes are not likely to be produced in the new host organism (Stewart, 2008; USDA-APHIS, 2010a). Based on this information, APHIS considers the horizontal gene flow from MON 87705 Soybean or other cultivated GE soybean varieties to unrelated species to be unlikely.

No Action: Gene Movement and Weediness

Under the No Action Alternative, conventional and GE transgenic soybean production will continue to be grown commercially, while MON 87705 Soybean will remain a regulated article. Soybean cultivation practices are expected to remain the same. Gene flow from current commercially available GE cultivars to non-GE soybean cultivars is expected to remain unchanged from the current conditions.

Preferred Alternative: Gene Movement and Weediness

APHIS evaluated the potential for gene introgression to occur from MON 87705 Soybean to sexually compatible varieties and considered the possibility that such introgression would result in increased weediness. Monsanto's data found no significant difference in pollen morphology and viability from field grown MON 87705 Soybean plants and other soybean varieties. The soybean is not identified as a weed in the U.S. (USDA-APHIS, 2010a). Soybeans are not frost tolerant, do not survive freezing temperatures, and do not reproduce vegetatively (OECD, 2000; USDA-APHIS, 2010a).

Some research suggests that fatty acid composition may influence cold tolerance and survivability. Kodama (1994) and Kodama et al. (1995) have found that increases in levels of certain fatty acids, particularly hexadecatrienoic and linolenic acids, results in an increase in cold tolerance. In MON 87705 Soybean, the levels of linolenic acid are within the lower end of the commercial range of fatty acid composition when compared with other varieties (Monsanto, 2010). Changes in oleic acid or linoleic acid composition and reductions in saturated fatty acids have not been linked to increased cold tolerance. The changes in fatty acid composition MON 87705 Soybean are not expected to enhance cold tolerance (USDA-APHIS, 2010a).

In its plant pest risk assessment, APHIS assessed the weediness potential of MON 87705 Soybean based on the introduced EPSPS protein and the reductions in the *FAD2* and *FATB* genes controlling fatty acid composition (USDA-APHIS, 2010a). In each case, the changes introduced in the MON 87705 Soybean were deemed to not present a weediness risk (USDA-APHIS, 2010a).

The change in composition of fatty acid in MON 87705 Soybean is due to the silencing of the endogenous *FAD2* and *FATB* genes in the soybean. The suppression of these two genes is mediated by double-stranded RNA molecules and does not code for specific proteins. Double stranded RNAs are commonly used in plants for endogenous gene suppression and pose no novel risks from a plant pest perspective (USDA-APHIS, 2010a). The suppression of these two genes in MON 877805 is not anticipated to give rise to an enhanced weediness or gene flow.

The only introduced gene in the MON 87705 Soybean is the *cp4 epsps* gene, which confers tolerance to the herbicide glyphosate. This gene is commonly found in other Roundup Ready® crops (USDA-APHIS, 2010a). No data have been presented to suggest that the incorporation of the *cp4 epsps* gene allows soybean to survive and reproduce without human intervention (USDA-APHIS, 2010a). In its petition, Monsanto presented information on phenotypic and agronomic characteristics collected from field studies (Monsanto, 2010). These data included information on seed dormancy, germination, emergence, seedling vigor, plant height, lodging, days to maturity, shattering, seed weight, yields, disease incidence, and insect damage, among others (Monsanto, 2010).

APHIS has assessed these data to evaluate the weediness potential of MON 87705 Soybean. Monsanto observed several statistically significant differences between MON 87705 Soybean and the control in:

- early stand count;

- final stand count;
- days to 50% flowering; and
- seed weight.

MON 87705 Soybean demonstrated lower early stand and final stand counts than those for controls (Monsanto, 2010, pages 349-350, Table G-3, Appendix G). MON 87705 Soybean flowered about one day later than the control and the weight of 100 seeds was lower for MON 87705 Soybean compared with the control (15.6 g vs. 16.1 g). In addition, MON 87705 Soybean had lower percent viable hard seed (0.0 vs. 0.3%) at 20°C, lower percent germinated seed at 30°C (92.8 vs. 95.5%), higher percent dead seed at 30°C (7.3 vs. 4.5%), and higher percent dead seed at 20/30ºC (2.7 vs. 1.3%). A decrease in hard seed, a lower percent germinated seed and higher percent dead seed would not contribute to increased weediness. All values were well within the recommended standards for certified soybean seed (AOSCA, 2009).

Results from the phenotypic and agronomic assessments indicate that MON 87705 Soybean does not possess characteristics that would confer a plant pest risk compared with conventional soybean (USDA-APHIS, 2010a). These data indicate that the engineered plant is not different in any fitness characteristics from its parent that are likely to cause the MON 87705 Soybean to become weedy or invasive (USDA-APHIS, 2010a).

Based on the above information, APHIS has concluded that a determination of nonregulated status of MON 87705 Soybean will not impact other soybean varieties through gene flow or introgression, nor would it present a greater risk of weediness or invasive characteristics (USDA-APHIS, 2010a). MON 87705 Soybean is expected to have the same effect on gene movement as the No Action Alternative.

Cumulative Effect: Gene Movement and Weediness

The soybean industry has identity protection measures in place to restrict pollen movement and gene flow between soybean fields through the use of isolation distances, border and barrier rows, the staggering of planting dates and various seed handling, transportation, and cleaning procedures (Bradford, 2006; NCAT, 2003; Sundstrom, et al., 2002). As a specialty soybean variety, MON 87705 Soybean would be cultivated within these identity protection practices. In addition, there is no evidence that horizontal gene transfer and expression of DNA occurs between soybean and soil bacteria or unrelated plant species under natural field conditions, and even if this did occur, proteins corresponding to the transgenes are not likely to be produced. Gene movement between sexually compatible soybean varieties is no greater for MON 87705 Soybean than it is for other non-GE or GE cultivars. Based on the scientific evidence, APHIS has not identified any cumulative effects on gene movement that would occur from a determination of nonregulated status of MON 87705 Soybean.

4.3.2 Animals

Soybean production systems in agriculture are host to many animal species. Mammals and birds may use soybean fields and the surrounding vegetation for food and habitat throughout the year. Invertebrates can feed on soybean plants or prey upon other insects living on soybean plants as well as in the vegetation surrounding soybean fields. The cumulative effects analysis for the potential effects of the production of MON 87705 Soybean on plants and animals is found below at "Cumulative Effects: Plants, Animals, Biodiversity."

No Action: Animals

Under the No Action Alternative, conventional and GE transgenic soybean production will continue while MON 87705 Soybean remains a regulated article. Potential impacts of GE and non-GE soybean production practices on non-target animals would be unchanged.

Preferred Alternative: Animals

Monsanto data indicate that the agronomic practices used to produce MON 87705 Soybean will be the same as those used to produce other conventionally grown GE and non-GE soybean. MON 87705 Soybean production will neither change land acreage nor any cultivation practices for soybean production.

To the extent that MON 87705 Soybean displaces conventional, non-GE soybean varieties, the expression of the CP4 EPSPS protein conferring tolerance to glyphosate may have an overall positive impact on animals. As previously discussed in the analysis of water and soil, in those fields where MON 87705 Soybean is cultivated, growers would be expected to take advantage of the weed control offered by glyphosate and continue to adopt conservation practices where appropriate.

Agronomic practices used to produce MON 87705 Soybean will be the same as those used to produce other glyphosate-tolerant soybean, so any switch by growers from their current glyphosate-tolerant soybean to MON 87705 Soybean (which would also very likely express the glyphosate-tolerant trait) would not significantly change current practices or result in different or new impacts to animals associated with existing glyphosate-tolerant soybean cultivation.

Animals are known to forage on soybean foliage and seed. With the exception of the introduction of the CP4 EPSPS protein conferring resistance to glyphosate, and the modifications to two endogenous genes to change fatty acid composition, no phenotypic or morphological differences have been identified between MON 87705 Soybean and conventional soybeans.

The EPA has reviewed the safety of the CP4 EPSPS protein and has established a tolerance exemption for the protein and the genetic material necessary for its production in or on all raw agricultural commodities (US-EPA, 1996; 40 CFR §174.523). This exemption is based on a safety assessment that included rapid digestion in simulated gastric fluids, lack of homology to known toxins and allergens, and lack of toxicity in an acute oral mouse gavage study. The lack of any documented reports of adverse effects since the introduction of other Roundup Ready® crops in 1996 suggests the safety of its use. The CP4 EPSPS protein expressed in MON 87705 Soybean is the same as that previously reviewed by the EPA; accordingly, MON 87705 Soybean and the incorporated *cp4 epsps* gene is expected to be safe for animal consumption.

MON 87705 Soybean provides a modified fatty acid profile based on the suppression of two endogenous genes that are natural constituents of every soybean: *FAD2* and *FATB*. Change in fatty acid composition resulting from the suppression of the *FAD2* and *FATB* genes is not expected to cause impacts to animals consuming the soybean. MON 87705 Soybean contains only those fatty acids that are presently found in soybean oil. MON 87705 Soybean has a fatty acid profile that is comparable to commercial high oleic vegetable oils (e.g., high oleic canola, high oleic safflower, high oleic sunflower), traditional oils such as olive oil that has a long-history of consumption in the diet, and canola oil that obtained FDA GRAS (Generally Recognized as Safe) status. Table 4-1 presents a comparison of fatty acid profiles of several plant sources of vegetable oil, including conventional soybean and MON 87705 Soybean.

Table 4-1: Comparison of Fatty Acid Profiles of MON 87705 Soybean with Several Other Plant Sources

Oil	% Saturated Fat[1]	% Oleic Acid[1] (18:1)[2]	% Linoleic Acid[1] (18:2)	% Linolenic Acid[1] (18:3)	% PUFAs[1]
Canola	6	57	26	10	32
MON 87705 Soybean	6	76	10	7	17
Conventional Soybean	15	23	53	8	60
Olive	13	78	7	1	8
Palm	50	38	11	1	12
Coconut	92	6	2	0	2

Notes:

1. Percent fatty acid presented as a percent (%) of total fatty acids.
2. Ratios presented within parenthesis represent the lipid numbers for the subject fatty acid, one of the more common nomenclature systems. The first number, e.g., 18, indicates the number of carbon atoms in the fatty acid, and the second number, e.g., 1, indicates the number of double bonds in the fatty acid. A fatty acid is considered saturated when there are no double bonds in the carbon chain, hence the 18:3 linoleic acid would be considered a polyunsaturated fatty acid, presenting three double bonds across the 18 carbons.

Source: (Monsanto, 2010 pages 349-350, Table G-3, Appendix G)

The potential risks to animals from the consumption of MON 87705 Soybean with a modified fatty acid composition also have been evaluated by the FDA (2011). Soybean meal is the most common supplemental protein source in U.S. livestock and poultry rations due to its nutrient composition, availability, and price (US-FDA, 2011). Although MON 87705 Soybean is intended to be cultivated as a specialty soybean to take advantage of the changed fatty acid composition, the soybean meal remaining after the extraction of the soybean oil may become a constituent of livestock or poultry food supplements. The FDA compared the composition of MON 87705 Soybean with the conventional non-transgenic soybean variety A3525, and also evaluated the potential impacts to animal diets from the reduced intake of linoleic acid (US-FDA, 2011). Although the soybean meal derived from MON 87705 Soybean would have reduced levels of linoleic acid, the animal's requirements for linoleic acid could be met by other ingredients in animal feed (US-FDA, 2011).

Based on the above information, APHIS concludes that a determination of nonregulated status of MON 87705 Soybean is not expected to have adverse effects on non-target animals.

4.3.3 Plants

The landscape surrounding a soybean field may be bordered by other soybean (or any other crop) fields or may also be surrounded by woodland, rangelands, and/or pasture/grassland areas. These plant communities may be natural or managed plant habitats for the control of soil and wind erosion and/or serve as wildlife habitats.

Cultural and mechanical weed control programs are important aspects of soybean cultivation (Aref & Pike, 1998; Byrd, et al., 2003; Duke & Powles, 2009; Loux, et al., 2008). In this context, weeds are those plants which, when growing in the soybean field, compete with the soybean for space, water, nutrients and sunlight, and may thus include native species. The types of weeds in and around a soybean field will vary depending on the geographic region where the soybean is grown.

No Action: Plants

Plant species that typically inhabit soybean production systems will continue to be managed through the use of mechanical, cultural, and chemical control methods, including the use of glyphosate in those varieties already marketed as glyphosate-tolerant. No changes to cultivation practices are expected in the No Action Alternative.

Preferred Alternative: Plants

In the event of a determination of nonregulated status of MON 87705 Soybean, the risks to wild plants and agricultural productivity from weedy soybean populations are low; volunteer soybean populations are easily managed and there are no feral or weedy relatives.

Agronomic studies conducted by Monsanto tested the hypothesis that the weediness potential of MON 87705 Soybean is unchanged with respect to conventional soybean (Monsanto, 2010). No differences were detected between MON 87705 Soybean and nontransgenic soybean in growth, reproduction, or interactions with pests and diseases, other than the intended effect – changed fatty acid profile and glyphosate tolerance. Volunteer soybean is normally not a concern. Soybean is not winter hardy, and existing mechanical and chemical methods are available to manage the occasional volunteer soybean in cultivation areas (Carpenter, et al., 2002; OECD, 2000). Several post-emergent herbicides are also widely used to control the presence volunteer soybeans in subsequent rotational crops (Zollinger, 2010). Based on these biological limitations, as well as readily available control practices, a determination of nonregulated status of MON 87705 Soybean is not likely to result in increased weediness.

The availability of MON 87705 Soybean provides an additional glyphosate-tolerant option to soybean growers. Monsanto anticipates that MON 87705 Soybean will replace existing cultivated varieties of herbicide-tolerant soybean, and potentially other non-GE soybean varieties. The introduction and cultivation is not expected to change current herbicide use and methods for soybean production. Agricultural practices employed to manage glyphosate-resistant weeds associated with glyphosate-tolerant soybeans that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 will continue.

These strategies include:

- Developing a diversified weed management program using herbicides with different modes of action, either concurrently or sequentially (NRC, 2010).
- Use the full recommended herbicide rate and proper application timing for the most difficult to control weeds in the field (NRC, 2010).
- Scouting the fields after herbicide application to ensure that control has been achieved

and to discourage weeds from reproducing or proliferating vegetatively (NRC, 2010).
- Incorporate cultural practices such as cultivation, tillage and crop rotation, where appropriate (NRC, 2010).

To the extent that MON 87705 Soybean replaces a non-GE soybean variety, the cultivation of MON 87705 Soybean could lead to an increased use of glyphosate in those fields with the potential for development of glyphosate-resistant weeds over time. This potential impact is not limited to adoption of Mon 87705 Soybean, but would potentially arise in any field where a glyphosate-resistant crop that is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 is adopted to replace a non-GE variety. Overall impacts would be similar to the No Action Alternative.

4.3.4 Microorganisms

Microorganisms produce aromatic amino acids through the Shikimate pathway, similar to plants (USDA-FS, 2003). Because glyphosate inhibits this pathway, it could be expected that glyphosate would be toxic to microorganisms. However, field studies show that glyphosate has varying effects on soil microorganisms; in some cases, field studies have shown an increase in microbial activity due to the presence of glyphosate (USDA-FS, 2003).

Glyphosate use has been identified as potentially causing increases in certain disease-causing microbes (Fernandez, et al., 2009; Kremer, 2010). Reported increases in infections from pathogenic soil fungi may be related to reduced tillage and continuous cropping using herbicide-tolerant crops, rather than an effect of application of glyphosate in some situations, but no consistent pattern of herbicide-specific impacts on microorganisms has been demonstrated (Fernandez, et al., 2009). Herbicides in general may well may impact certain classes of bacteria; atrazine has been shown to depress bacterial nitrogen mineralization in soil, both over short and extended periods (Mahia, et al., 2011).

<u>No Action: Microorganisms</u>

There would be no changes to current cultivation practices under the No Action Alternative. Microbes in the field would continue to be exposed to glyphosate and other herbicides.

<u>Preferred Alternative: Microorganisms</u>

Monsanto conducted field trials to assess potential agronomic differences between MON 87705 Soybean and conventional soybean (variety A3525) (Monsanto, 2010). These agronomic studies included analyses of differences in disease damage and inoculation of root nodules with symbiotic bacteria (Monsanto, 2010). The disease analysis included observations of a wide range of bacterial and fungal pathogens, nematodes, and plant viruses (Monsanto, 2010). No significant differences in disease damage were noted between MON 87705 Soybean and the comparison control variety (Monsanto, 2010). The lack of difference indicates that the expression of glyphosate tolerance and modified fatty acid content by MON 87705 Soybean does not change soybean interactions with microorganisms in the field.

Monsanto also evaluated the potential impacts of these changes on the symbiotic relationship of soybean with the nitrogen-fixing root nodule bacteria *Bradyrhizobium japonicum* (Monsanto, 2010). In these studies, MON 87705 Soybean was compared with seven conventional soybean varieties (Monsanto, 2010, see appendix I). No significant differences were detected between MON 87705 Soybean and any of the comparison varieties for any of the measured parameters, including nodule number, root shoot total nitrogen (percent and mass), biomass of nodules, shoot material and root material (Monsanto, 2010). These results indicate that the expression of glyphosate tolerance and the modified fatty acid composition does not impact the inoculation of root nodules by the symbiotic bacteria.

Consistent with these test results, the impacts of a determination of nonregulated status of MON 87705 Soybean on microorganisms are the same as the No Action Alternative.

4.3.5 Biodiversity

Biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management, including selection and use of insecticides and herbicides; and 4) extent of isolation of the agroecosystem from natural vegetation (Altieri, 1999; Palmer, et al., 2010). The reintroduction of woodlots, fencerows, hedgerows, wetlands, etc., has been used to enhance biodiversity in the agroecosystem landscape. Some enhancement strategies include intercropping (the planting of two or more crops simultaneously to occupy the same field), agroforestry, crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically for the purpose of incorporating it into the soil in order to provide nutrients and organic matter), addition of organic matter (compost, green manure, animal manure, etc.), adoption of integrated pest management techniques, and the use of hedgerows and windbreaks (Altieri, 1999; Palmer, et al., 2010). The adoption of GE crops, with the concomitant reduction in insecticide use and enhanced soil conservation practices, has also contributed to the increase in biodiversity of soil microorganisms, beneficial organisms, and plants (Dively & Rose, 2003; Naranjo, 2009a; Palmer, et al., 2010; Sanvido, Stark, Romeis, & Bigler, 2006).

<u>No Action: Biological Diversity</u>

Under the No Action Alternative, MON 87705 Soybean would continue to be a regulated article. Growers and other parties who are involved in production, handling, processing, or consumption of soybean would continue to have access to GE soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, herbicide-tolerant soybean varieties, and conventional soybean varieties. The implications of agronomic practices associated with soybean production whether traditional or GE varieties with the attendant effects on biodiversity would not change.

<u>Preferred Alternative: Biological Diversity</u>

The use of genetically modified soybean such as MON 87705 Soybean affects biological diversity by providing the opportunity to use conservation practices that enhance habitat creation, which in turn, presents opportunities to positively benefit the floral and faunal communities inhabiting the fields and immediate surroundings. Incorporation of herbicide tolerance in the crop facilitates the grower adoption of no-till, crop rotation, and contour strip cropping, each of which contributes to the health of the faunal and floral communities in and around soybean fields thereby promoting biodiversity (Palmer, et al., 2010; Sharpe, 2010).

The cultivation of MON 87705 Soybean would not change the use of insecticides to manage the invertebrate pests of soybean. Practices currently employed for the management of conventional and other GE soybean would likely continue for this crop. In this regard, a determination of nonregulated status of MON 87705 Soybean would have the same impacts on biodiversity as the No Action Alternative.

Although soybean fields are cultivated as monocultures to optimize soybean yield, the landscape adjacent a soybean field may harbor a wide variety of plants. Broad spectrum herbicide application has the potential to impact off-site plant communities. MON 87705 Soybean allows growers to continue to use glyphosate for post-emergent weed control. The Roundup Ready® soybean system has become the standard weed control program in the U.S. cultivation of soybean. Approximately 92% of the U.S. soybean acreage is planted in Roundup Ready® soybean varieties. Monsanto anticipates that MON 87705 Soybean will replace glyphosate-tolerant soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340. Accordingly, the cultivation of MON 87705 Soybean is not expected to result in an increase in the application of glyphosate or changes in herbicide treatments when compared with glyphosate-tolerant soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

The emergence of glyphosate-resistant weed species has been well documented, and presents a challenge to all growers using glyphosate-tolerant crops (Benbrook, 2009). In these cases, growers must also utilize other herbicides and tillage practices for weed management. Agricultural practices employed to manage glyphosate-resistant weeds associated with glyphosate-tolerant soybeans that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 will continue. These strategies include:

- Developing a diversified weed management program using herbicides with different modes of action, either concurrently or sequentially (NRC, 2010).
- Use the full recommended herbicide rate and proper application timing for the most difficult to control weeds in the field (NRC, 2010).
- Scouting the fields after herbicide application to ensure that control has been achieved and to discourage weeds from reproducing or proliferating vegetatively (NRC, 2010).
- Incorporate cultural practices such as cultivation, tillage and crop rotation, where appropriate (NRC, 2010).

In this regard, a determination of nonregulated status of MON 87705 Soybean would present the same impact to biodiversity as other Roundup Ready® soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340. Introduction of MON 87705 Soybean is not likely to change the effects of soybean production on plant communities.

A determination of nonregulated status of MON 87705 Soybean will not change the cultivation or agronomic practices, or agricultural land acreage associated with growing soybean. MON

87705 Soybean would be an additional glyphosate-tolerant variety. The change in fatty acid composition expressed in MON 87705 Soybean is one making itsimilar to that of other current oil crops and with similar nutritional profiles.

Therefore, a determination of nonregulated status of MON 87705 Soybean is highly unlikely to have any direct toxic effects on non-target organisms and is likely to be neutral or beneficial to animal and plant biodiversity.

<u>Cumulative Effects: Animals, Plants, and Biodiversity</u>

APHIS has determined that there are no impacts from 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 associated with the ecosystem in which MON 87705 Soybean is planted.

Based on available scientific data, the changes in fatty acid composition associated with MON 87705 Soybean are not expected to directly or indirectly affect plants, animals or biodiversity. The genes responsible for the change in fatty acid composition are endogenous to the soybean and are thus already a part of the soybean cultivation environment. The EPA has reviewed the safety of the CP4 EPSPS protein and has established a tolerance exemption for the protein and the genetic material necessary for its production in or on all raw agricultural commodities (US-EPA, 1996; 40 CFR§174.523). The lack of any documented reports of adverse effects since the introduction of other Roundup Ready® crops in 1996 suggests the safety of its use. The CP4 EPSPS protein expressed in MON 87705 Soybean is the same as that previously reviewed by the EPA, accordingly, MON 87705 Soybean is anticipated to be safe for animal consumption with regard to the *cp4 epsps* gene.

Cultivation of MON 87705 Soybean is highly unlikely to have direct toxic effects on non-target organisms and is likely to be neutral to biodiversity compared with conventionally managed GE and non-GE soybean. Therefore, the likelihood of adverse cumulative effects on non-target organisms and biodiversity following the introduction of MON 87705 Soybean is minimal.

4.4 PUBLIC HEALTH

4.4.1 Worker Safety

EPA's Worker Protection Standard (WPS) (40 CFR Part 170) was published in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protections to more than two and a half million agricultural workers who work with pesticides at more than 560,000 workplaces on farms, forests, nurseries, and greenhouses. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.

<u>No Action: Worker Safety</u>

During agricultural production of soybean, agricultural workers and pesticide applicators may be exposed to a variety of EPA registered pesticides (see, e.g., http://www.cdc.gov/niosh/topics/pesticides/). Such chemicals would be expected to include those products currently used for insect pest and plant pest management in both GE and non-GE soybean cultivation. Worker safety is taken into consideration when a pesticide label is developed during the registration process. When use is consistent with the label, pesticides present minimal risk to the worker. No changes to current worker safety are anticipated under the No Action Alternative.

Preferred Alternative: Worker Safety

If MON 87705 Soybean is adopted, agricultural workers and pesticide applicators will continue to be exposed to glyphosate. As MON 87705 Soybean does not require different cultivation practices than currently available glyphosate-tolerant soybean, this level of herbicide exposure is expected to be the same as the No Action Alternative.

The introduction of novel proteins to a crop carries the risk of potential allergenicity. The only introduced protein in MON 87705 Soybean is the CP4 EPSPS protein derived from *Agrobacterium sp.* The changed fatty acid composition is a result of suppression of two endogenous soybean genes and not the introduction of new genes or proteins (Monsanto, 2010). The CP4 EPSPS protein is not known to present any allergenicity risk. FDA's consultation on MON 87705 Soybean found no evidence of potential for allergenicity of the MON 87705 Soybean (US-FDA, 2011).

The EPA has reviewed the safety of the CP4 EPSPS protein and has established a tolerance exemption for the protein and the genetic material necessary for its production in or on all raw agricultural commodities (US-EPA, 1996; 40 CFR §174.523). This exemption is based on a safety assessment that included rapid digestion in simulated gastric fluids, lack of homology to known toxins and allergens, and lack of toxicity in an acute oral mouse gavage study. The lack of any documented reports of adverse effects since the introduction of other Roundup Ready® crops in 1996 suggests the safety of its use.

The CP4 EPSPS protein expressed in MON 87705 Soybean is the same protein previously reviewed by the EPA. Accordingly, worker safety risk associated with cultivation of and exposure to MON 87705 Soybean is the same as the No Action Alternative.

Cumulative Effects: Worker Safety

MON 87705 Soybean is not expected to increase the total acreage of soybean production or the use of GE soybean. Monsanto anticipates that MON 87705 Soybean will primarily replace some of the herbicide-tolerant soybean cultivars already on the market today as its nutritional values are adopted in the market. As a result, worker safety issues related to the use of EPA registered pesticides during conventional and GM soybean production should remain the same. However, if a grower replaces a non-herbicide-tolerant soybean variety with MON 87705 Soybean it would be expected that there would be a corresponding change in the use of post-emergent herbicides. This has been the case with the adoption of other GM soybean cultivars (Benbrook, 2009). To the extent that such changes result in the replacement of more toxic herbicides with glyphosate, the change should positively benefit worker safety.

4.4.2 Human Health

Under Federal Food Drug and Cosmetic Act, 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 MON 87705 Soybean must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market.

With regard to human health effects, the FDA reviews assess the relative toxicity of the incorporated proteins on humans from the perspective of both consumption as well as exposure. Monsanto has submitted a food and feed safety and nutritional assessment to the FDA for this product. The FDA has completed their consultation on MON 87705 Soybean, a copy of which is provided in Appendix A (US-FDA, 2011).

No Action: Human Health

Under the No Action Alternative, MON 87705 Soybean would continue as a regulated article. Human exposure to existing traditional and GE soybean would not change under this alternative. Growers and consumers exposure to this product would be limited to those individuals involved in the cultivation of MON 87705 Soybean under regulated conditions.

During agricultural production of soybean, people other than agricultural workers may be exposed to a variety of EPA registered pesticides (see, e.g., http://www.cdc.gov/niosh/topics/pesticides/). Such chemicals would be expected to include those products currently used for insect pest and plant pest management in both GE and non-GE soybean cultivation. Human health and safety is taken into consideration when a pesticide label is developed during the registration process. When used consistent with the label, pesticides present minimal risk. No changes to human health are anticipated under the No Action Alternative.

Preferred Alternative: Human Health

APHIS considers the FDA regulatory assessment in making its determination of the potential impacts of a determination of nonregulated status of the new agricultural product. The FDA has completed its consultation on MON 87705 Soybean, and has concluded that the product is not materially different in any respect relevant to food safety compared to soybean varieties currently on the market (US-FDA, 2011). The FDA's conclusions are based on an evaluation of the introduced protein, CP4 EPSPS, as well as the changes in the expression of the two endogenous genes resulting in modified fatty acid content.

Similar products were no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 beginning in the mid-1990s with the introduction of Roundup Ready® products providing tolerance to glyphosate with the introduction of the *cp4 epsps* gene. In each case, FDA and EPA reviews and approvals determined that the products met the agency's review criteria for approval. The cultivation of these existing crop products would not change under either alternative. Both characteristics have been successfully cultivated in multiple crops in the ensuing years with no evidence of human health impacts.

The CP4 EPSPS protein confers tolerance to glyphosate. This protein is structurally homologous and similar functionally to endogenous plant EPSPS enzymes and is identical to the CP4 EPSPSs in other Roundup Ready® crops, including Roundup Ready® soybean (40-3-2 and MON 89788, Roundup Ready® canola, Roundup Ready® sugar beet, Roundup Ready® flax, and Roundup Ready® cotton (USDA-APHIS, 2010a). The first generation of Roundup Ready® soybean (40-3-2) was no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 in 1995 (USDA-APHIS, 2010a). The *cp4 epsps* gene has been assessed extensively in the last 15 years. The safety of CP4 EPSPS protein present in biotechnology derived crops has been evaluated as part of comprehensive reviews of the safety of glyphosate exposure and ingestion (Harrison et al., 1996; see also Hammond et al., 1996; Padgette et al., 1996). The FDA has reviewed the safety of human consumption of the CP4 EPSPS protein in MON 87705 Soybean, and concluded that this protein presents negligible risk to human health from consumption (US-FDA, 2011).

The EPA has also reviewed the safety of the CP4 EPSPS protein and has established a tolerance exemption for the protein and the genetic material necessary for its production in or on all raw agricultural commodities (US-EPA, 1996; 40 CFR §174.523). This exemption is based on a safety assessment that included rapid digestion in simulated gastric fluids, lack of homology to known toxins and allergens, and lack of toxicity in an acute oral mouse gavage study. The CP4 EPSPS protein expressed in MON 87705 Soybean is the same as that previously reviewed by the EPA. Accordingly, MON 87705 Soybean is anticipated to be safe for human and animal consumption with regard to the *cp4 epsps* gene.

APHIS has considered the human health impacts associated with the modified fatty acid profile based on the suppression of two naturally occurring, endogenous soybean genes: *FAD2* and *FATB*. Monsanto's intention in developing MON 87705 Soybean is the development of a fatty acid profile which provides nutritional benefits by presenting a healthier composition of saturated and unsaturated fats, as well as improved oil stability. Monsanto presents data comparing the fatty acid and other nutritional element concentrations with the reported ranges for conventional soybean and against commercial tolerance ranges (see e.g., Monsanto, 2010, table VII-1, page 96). In addition to evaluating the targeted fatty acid composition, Monsanto evaluated non-fatty acid nutrients, anti-nutrients, proximate and fiber levels, consistent with the compositional guidance provided by the OECD (2001). Table 4-2 presents a summary of Monsanto's reported change in fatty acid composition for MON 87705 Soybean compared with conventional soybean and commercial tolerance limits:

Table 4-2: Comparison of Targeted Fatty Acid Levels in MON 87705 Soybean with Conventional Soybean Control (A3525) and Commercial Tolerance Intervals

Fatty Acid (% Total)	MON 87705 Soybean Mean [Range]	Conventional Soybean Mean [Range]	Commercial Tolerance Interval
16:0 Palmitic	2.36 [2.25 – 2.44]	10.83 [10.51 - 11.08]	7.62 – 12.55
18:0 Stearic	3.31 [3.07 – 3.82]	4.50 [4.24 – 4.85]	2.87 – 7.15
18:1 Oleic	76.47 [73.13 – 79.17]	22.81 [21.41 – 25.08]	18.40 – 30.22
18:2 Linoleic	10.10	52.86	47.75 – 56.76

	[7.85 – 12.42]	[51.68 – 53.89]	

Source: (Monsanto, 2010, Table VII-1, page 97).

Total saturated fat (as measured by palmitic and stearic acid percentages) was decreased from 15.3% in the conventional soybean to 5.7% in MON 87705 Soybean. The mean level of oleic acid increased from 22.81% in the conventional soybean to over 76.47% in MON 87705 Soybean. There was a corresponding decrease in linoleic acid as well, with MON 87705 Soybean concentrations of 10.10% when compared to the conventional variety at 52.86%. This fatty acid profile is more heart healthy than conventional soy oil, and the changes from the conventional oil composition are within dietary guidelines for fat intake (Lichtenstein et al., 2006; Monsanto, 2010). MON 87705 Soybean contains only those fatty acids that are presently found in soybean oil. MON 87705 Soybean has a fatty acid profile that is comparable to commercial high oleic vegetable oils (e.g., high oleic canola, high oleic safflower, high oleic sunflower), to traditional oils such as olive oil that have a long-history of consumption in the diet, and to canola oil that obtained FDA GRAS status. Table 4-1 (see Subsection 4.4.2) presented a comparison of fatty acid profiles of several plant sources of vegetable oil, including conventional soybean and MON 87705 Soybean.

Monsanto also evaluated other compositional aspects of MON 87705 Soybean and compared these data with conventional soybean composition. Differences were observed in the concentrations of three other fatty acids (18:3 linolenic acid, 20:0 arachidic acid and 20:1 eicosenoic acid), total fat, and two amino acids (arginine and cysteine) (Monsanto, 2010). APHIS has evaluated the differences reported in these compositional elements, and has determined that the reported differences are within the 99% tolerance interval for soybean composition (Monsanto, 2010 Table E-13, page 303). The FDA consultation on MON 87705 Soybean evaluated this same data, and have concluded that MON 87705 Soybean is not materially different from other soybean varieties currently on the market (US-FDA, 2011).

Monsanto's petition presents a nutritional impact evaluation (Monsanto, 2010, Appendix M). In this assessment, Monsanto presents the output of a dietary replacement model, in which it is assumed that 100% of the liquid soybean oil in the marketplace is replaced with MON 87705 Soybean oil. Products assumed to be consumed included salad dressings, mayonnaise and solid spreads, home use soybean oil, and margarines (Monsanto, 2010). Fry oils were not included in Monsanto's analysis. APHIS has reviewed the outputs of the dietary model presented by Monsanto. The replacement of conventional soy oil with MON 87705 Soybean oil does not change total daily fat intake. Total oleic acid consumption increased, as would be expected by the changes in oil composition. Although the consumption of monounsaturated fatty acids are not required in the diet, they do contribute to achieving total fat intake recommendations (USHHS, 2005). Monsanto notes that substitution of oleic acid for saturated fat in the diet can reduce low density lipoprotein cholesterol (Monsanto, 2010). The dietary replacement model output, when compared with recommended dietary intake values, suggests that soybean oil based on MON 87705 Soybean is safe for human consumption at a 100% replacement. Other than corresponding differences in fatty acid composition, no differences in human health impacts are anticipated between the No Action and the Preferred Alternative.

Based on the FDA's consultation (US-FDA, 2011), our analysis of field and laboratory data and scientific literature provided by Monsanto (Monsanto, 2010), and safety data available on other

GE soybean, APHIS has concluded that under this alternative, a determination of nonregulated status of MON 87705 Soybean would have no significant impacts on human health. Overall human health impacts associated with cultivation are similar to the No Action Alternative.

The Preferred Alternative impacts to human health differ from the No Action Alternative with regard to potential human health benefits associated with consumption of the oil from this crop. The FDA analysis (US-FDA, 2011) and Monsanto's data (Monsanto, 2010) suggest that replacing food oils with the soybean oil extracted from the MON 87705 Soybean may have a positive impact on human health in those cases where the replaced oil is a polyunsaturated product. The reduction in levels of polyunsaturated fatty acids in the MON 87705 Soybean oil is considered heart healthy. The extent to which this positive benefit may be observed is contingent upon the market share of the MON 87705 Soybean and the types of food products adapting the modified oil product.

Cumulative Effects: Human Health

There are no significant impacts on human health related to the No Action Alternative or a determination of nonregulated status of MON 87705 Soybean. Moreover no cumulative effects have been identified.

4.5 ANIMAL FEED

The majority of the soybean cultivated in the U.S. is grown for animal feed, and is usually fed as soybean meal (Monsanto, 2010). Soybeans intended for animal feed are generally cultivated as commodity products, although there are some consumers demanding specific physical or chemical characteristics to meet specific feed needs (Monsanto, 2010). In these cases, the soybean meeting those specialized needs are cultivated as a specialty soybean crop. The cultivation practices necessary to maintain identity protection have been previously discussed in Subsection 2.2.4 above.

Under FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from MON 87705 Soybean must be in compliance with all applicable legal and regulatory requirements. GE organisms for feed may undergo a voluntary consultation process with the FDA prior to release onto the market. The FDA has completed a consultation on the MON 87705 Soybean, a copy of which is presented in Appendix A (US-FDA, 2011).

No Action: Animal Feed

Under the No Action Alternative, soybean-based animal feed will still be available from currently cultivated soybean varieties, both conventional varieties as well as GE soybean that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 expressing herbicide tolerance. No change in the availability of these crops as animal feed is expected under the No Action Alternative.

Under the No-Action Alternative, MON 87705 Soybean will remain a regulated product. There have been instances where growers involved in field trials of regulated products have been authorized to introduce the regulated product into animal feed for local consumption. As discussed in more detail below, the FDA has reviewed the characteristics and composition of MON 87705 Soybean and has not identified any differences between it and other soybean varieties. Consistent with these findings, if MON 87705 Soybean is introduced into animal feed while still a regulated article, no impacts to animal health are expected.

Preferred Alternative: Animal Feed

The FDA has completed its consultation on the MON 87705 Soybean (US-FDA, 2011). Based on a review of composition and nutritional characteristics of MON 87705 Soybean, the FDA has concluded that MON 87705 Soybean is not materially different in any respect relevant to feed safety compared to soybean varieties already on the market (US-FDA, 2011).

Monsanto has submitted compositional and nutritional characteristics of MON 87705 Soybean to APHIS (Monsanto, 2010). As part of field trials, samples of MON 87705 Soybean and conventional variety A3525 were collected from five different field trial locations during the 2007-2008 growing season (Monsanto, 2010). These samples were analyzed for comparable nutritional components, including proximate (protein, fat, carbohydrates, fiber, ash, moisture), vitamins, amino acids, fatty acids, and the antinutrient factors of soybean (which included lectin, trypsin inhibitors, isoflavones, and phytic acid) APHIS has reviewed Monsanto's results and has concluded that with the exception of the changes in fatty acid composition, the levels of nutrients, anti-nutrients, and secondary metabolites in MON 87705 Soybean are not statistically different from those found in the conventional variety.

The change in fatty acid composition is not expected to impact the value of MON 87705 Soybean as an animal feed. The total fat content of the oil is unchanged. To the extent that consumers desire an animal feed providing elevated concentrations of oleic acid, with corresponding decreased concentrations of palmitic and linoleic acids, MON 87705 Soybean contains only those fatty acids that are presently found in soybean oil. MON 87705 Soybean has a fatty acid profile that is comparable to commercially available high oleic vegetable oils (e.g., high oleic canola, high oleic safflower, high oleic sunflower), traditional oils such as olive oil that has a long-history of consumption in the diet, and canola oil that obtained FDA GRAS status. As MON 87705 Soybean is intended to be cultivated as a specialty soybean, APHIS anticipates that consumers would not purchase this crop without understanding and desiring the changed fatty acid profile. To the extent that soybean meal derived from MON 87705 Soybean is used as animal feed, and the user requires a higher concentration of linoleic acid, other sources of linoleic acid could be readily provided (e.g., corn) (US-FDA, 2011).

MON 87705 Soybean expresses the CP4 EPSPS protein, derived from *Agrobacterium sp.*, to achieve glyphosate herbicide tolerance. The EPA has reviewed the safety of the CP4 EPSPS protein and has established a tolerance exemption for the protein and the genetic material necessary for its production in or on all raw agricultural commodities (US-EPA, 1996; 40 CFR §174.523). This exemption is based on a safety assessment that included rapid digestion in simulated gastric fluids, lack of homology to known toxins and allergens, and lack of toxicity in an acute oral mouse gavage study. The lack of any documented reports of adverse effects since the introduction of other Roundup Ready® crops in 1996 suggests the safety of its use.

Based on this information APHIS has concluded that a determination of nonregulated status of MON 87705 Soybean would have no significant impacts on animal feed or animal health. Overall impacts are similar to the No Action Alternative.

Cumulative Effects: Animal Feed

There are no significant impacts on animal health related to the No Action Alternative or a determination of nonregulated status of MON 87705 Soybean; and no cumulative effects have been identified.

4.6 SOCIOECONOMIC ISSUES

4.6.1 Domestic Economic Environment at Risk

Herbicide tolerant soybean is cultivated on 93% of the U.S. soybean acreage (USDA-ERS, 2010a, 2010b). The U.S. acreage of soybeans planted has varied over time, but the USDA has noted that the acreage dedicated to soybean has declined in recent years as returns on investment favored corn production (USDA-ERS, 2008). Although acreage has declined, the yield per acre has continued to increase (USDA-ERS, 2008). Short-season varieties have provided northern growers with the option to replace wheat crops with soybeans (USDA-ERS, 2008).

Soybean oil lost market share in the food industry early in the decade as consumers sought vegetable oils that were lower in *trans*-fatty acids; this trend has slowed with the availability of low-linolenic and high-oleic varieties of soybean (USDA-ERS, 2008). The decline in food uses was replaced by an increase in demand for commodity-grade soy oil for biodiesel production (USDA-ERS, 2008).

No Action: Domestic Economic Environment

Under the No Action Alternative, MON 87705 Soybean and its progeny would continue to be regulated under 7 CFR Part 340. Growers and other parties who are involved in production, handling, processing, or consumption of soybean would not have access to MON 87705 Soybean and its progeny, but would continue to have access to GE herbicide tolerant soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 as well as conventional varieties. Domestic growers will continue to utilize currently available traditional and GE soybean varieties based upon availability and market demand.

Preferred Alternative: Domestic Economic Environment

Monsanto anticipates that MON 87705 Soybean and its progeny would replace currently available herbicide-tolerant soybean varieties and would be cultivated as a specialty crop to preserve the desired characteristics continuing on to the ultimate consumer (Monsanto, 2010). Monsanto does not anticipate that MON 87705 Soybean would change soybean production practices or increase soybean acreage (Monsanto, 2010). APHIS concurs that properties of MON 87705 are not different enough from commodity oil to require additional acreage for new soybean varieties or to initiate substantially new uses. Existing soybean users will either change their expectations for soy oils to those expressed by this variety, or remain users of commodity soy oil.

Stewardship of MON 87705 Soybean. Soybean oil users who may have concerns about undesirable changes in standard properties of this modified oil have been identified by Monsanto, and dialogues have begun to solicit both specific issues of importance and to provide these stakeholders with relevant information (Monsanto, 2010, Addendum 1). As noted in Addendum 1 to the MON 87705 petition, these groups include trade organizations representing oil processors, elevators, grain and oilseed processors, agricultural businesses and exporters, bakers, and grocery producers. Issues of commingling have been addressed in Addendum 1 (see for example, impacts on international specifications for commodity soybean oil, and allowable changes in nutrition facts labeling). Increasing quantities of commingled MON 87705 with commodity oil has been shown to increase the oil stability index, which would benefit those oil applications involving severe heat processing. Commingling of MON 87705 up to 15% content in the commodity oil had no impact on flavor of French fries (Figure 6, Appendix 3).

Management plans for MON 87705 Soybean have been designed for production integrity at all steps of seed production, including field production by the grower and on-farm storage, grain elevators, oil and meal processors, and food companies as well as product identity and assessment (Appendix D; Addendum 1, (Monsanto, 2010)). Contract buyers of MON 87705 will have Near Infrared Transmittance equipment provided them, for identifying MON 87705 Soybean at grain elevators, and by contract, sampling for MON 87705 grain will be required for each arriving truckload. Processors will use gas chromatography to provide oil constituent analysis. In addition to contracts and agreements with Monsanto, product identity at all steps will be maintained by dedication of soybean sellers and oil processors to capture premium prices. With this as a goal, the soybean industry will observe best management practices, use appropriate identification procedures and proprietary inventory systems and ensure traceability requirements. Through these proposed measures, which would be established by contractual agreements with growers, elevators and processors, Monsanto aims to provide stewardship during all phases of production for stakeholders invested in uses of soybean oil.

Monsanto characterizes the vegetable oil industry as highly adept at handling multiple crop species and the oils extracted from them (Appendix D: Addendum 1). Oil processors and users are able to appropriately characterize, segregate and blend for special functions the identity preserved oils available to them for attaining the final quality needed in specialty products. The Monsanto Vistive low-linolenic variety has been available to oil users for six years, and is grown on over 3 million acres since 2005 (Appendix D: Addendum1). The identity preserved production plan for current Vistive low linolenic oil is similar to the plan described here for MON 87705 Soybean oil and thus provides Monsanto with relevant experience in establishing and maintaining IDP soybean processes.

Market Share/Uses of MON 87705 Soybean. The majority of soybean cultivated in the U.S. is grown as a commodity product intended for animal feed. MON 87705 Soybean is considered a specialty soybean product and will be marketed in accordance with other high-value specialty crop products (Monsanto, 2010). Specific market uses for specialty soybean products generally require adherence to specialty crop practices to preserve identity, from seed production through harvesting, handling, and processing. To maintain the IDP for the product, growers cultivating MON 87705 Soybean may potentially incur increased costs for production and distribution throughout the supply chain (mostly IDP costs). A premium is paid to growers and processors for delivering product that meets these desired purity and quality standards (Elbehri, 2007; Lee

& Herbek, 2004; Muth, et al., 2003; Pritchett, et al., 2002; Smyth & Phillips, 2002; Sundstrom, et al., 2002). The extent to which MON 87705 Soybean displaces other cultivated varieties cannot be predicted, as market segment is contingent on variety acceptance by both growers and consumers.

Monsanto has developed MON 87705 Soybean to improve soybean oil's oxidative stability profile without the need for hydrogenation, and to lower the saturated fat content of the oil (Monsanto, 2010). Both characteristics are perceived as providing added value to the variety. The changes in fatty acid composition are perceived to potentially expand the food market applications of soy oil with a heart healthy product. The modified oil is also a candidate source for industrial and biofuel products.

An analysis of introduction of a high oleic soybean variety by economists demonstrates the potential for increasing the market share of the high oleic variety relative to that of commodity soybean oil (Giannakas and Yiannaka, 2010). The main variables that determine outcomes will be consumer acceptance (including that of food and industrial producers) and price of the commodity (Giannakas and Yiannaka, 2010). The greatest impacts will occur if the price of the novel soybean oil is relatively low, and consumer evaluation is highly favorable, which could result in the modified fatty acid product driving conventional soybean from the market. In this event, increased economic benefit would ensue to producers of the novel oil. Because these variables associated with MON 87705 Soybean cannot be determined at present, no definitive conclusions can be made about market share impacts on soybean oil producers.

Potential Market Response to MON 87705 Soybean. Changes in total acreage of specific crop varieties in response to market demand can be readily observed. In 1995, the National Sunflower Association began developing sunflower varieties to take advantage of pending label requirements for *trans* fatty acids (NSA, 2006). By 2005, it was estimated that 80% of the U.S. sunflower acreage was planted in NuSun™, a conventionally produced high-oleic variety (NSA, 2006). This transition occurred after the food industry conducted extensive studies of food chemistry, supported by human health assessments (NSA, 2006).

An increase in the percentage of acreage dedicated to MON 87705 Soybean is contingent on satisfying specific industry standards as well as its ability to compete with other modified fatty acid soybean products. After the 2006 FDA *trans* fat labeling requirement, soybean lost market share to palm and certain canola oils (Waltz, 2010). MON 87705 Soybean is one of several soybean varieties developed in the attempt to recapture soybean's market share for food oil (Waltz, 2010). MON 87705 Soybean will compete in the market with other modified fatty acid soybeans, conventional and GE, including Pioneer's "Plenish high-oleic soybean" (Waltz, 2010). The industry acceptance and ultimate success of each variety is contingent on MON 87705 Soybean satisfying consumer taste tests, frying tests, and shelf-life tests similar to those demonstrated by high-oleic sunflower oil (NSA, 2006; Waltz, 2010). As noted above, the market share for MON 87705 Soybean could be quite variable. However, Monsanto has estimated that the acreage potential in the U.S. for its Vistive III soybean variety, a high oleic and low linolenic product, at 10 to 20 million acres, or potentially up to 25% of the U.S. market (see Petition Addendum 1and (AGRA, 2009)).

The value to the consumer from the changes presented in MON 87705 Soybean is a direct function of the physical and chemical changes associated with the changed concentrations of the fatty acids. MON 87705 Soybean was developed as a response to challenges associated with the composition of conventional soybean oil (Monsanto, 2010). The double bonds in the polyunsaturated fatty acids, particularly linolenic acid, are susceptible to oxidation resulting in the formation of “fishy” or acrid flavors and odors, reducing shelf-life and product stability (Dutton, et al., 1951; Monsanto, 2010). Chemical hydrogenation had been adopted to reduce the content of polyunsaturated fatty acids (linoleic and linolenic acids); however, in the 1990s, nutrition research showed that the *trans* fatty acids created by the hydrogenation process had negative health consequences (Judd, et al., 1994; Mensink & Katan, 1990; Zock & Katan, 1992). In addition, the saturated fatty acids, particularly palmitic acid, were also identified as contributing to cardiovascular disease (Monsanto, 2010).

MON 87705 Soybean provides substantially reduced levels of polyunsaturated fatty acids. Linoleic acid is produced at concentrations of approximately 10% of total fatty acid content, as compared with approximately 53% in convention soybean (Monsanto, 2010). Comparable reductions in palmitic acid are also shown, with approximately 2% of total fatty acid as compared with nearly 11% in conventional soybean oil (Monsanto, 2010, see Table VII-1, page 97). While the polyunsaturated and saturated fatty acid concentrations are reduced, the concentrations of oleic acid, a mono-unsaturated fatty acid, are increased, to over 76% of the volume when compared with approximately 23% in conventional soybean oil. The concentration of linolenic acid in the MON 87705 Soybean oil is functionally the same as that in commodity soybean oil, approximately 7% of the total. High oleic acid content in the soybean oil provides oxidative stability, which in turn preserves shelf stability and reduces the need for hydrogenation (Monsanto, 2010).

These characteristics are perceived to be of value in the human food applications, as well as certain industrial applications. The food value is based on the reduction in the level of polyunsaturated fatty acids, the higher oxidative stability without the need for hydrogenation, a reduced concentration of *trans* fatty acids associated with the decrease in hydrogenation, and lower levels of saturated fats compared to commodity soybean (AGRA, 2009; Monsanto, 2010).

Increased oxidative stability is also a valuable aspect useful for certain industrial lubricant applications (Monsanto, 2010; USB, 2010). Low saturated fats and high (>70%) oleic acid levels are key attributes for vegetable oils targeted for biodiesel and industrial uses because these characteristics are vital to improved cold weather performance, improved stability, and reduced nitrous oxide emissions (AGRA, 2009; Graef, et al., 2009; Knothe, 2005; Monsanto, 2010). High concentrations of oleic acid in the soybean oil provide thermal oxidative and hydrolytic stability (AGRA, 2009). At current pricing, high oleic soybean oil has the potential to be a cost-effective replacement for a portion of Group II+ and/or Group III[2] oil, even with a premium for identity preservation (USB, 2010).

[2] There are four different types of base stock used in the motor oil market today.
Group I - Conventional - Mineral oil derived from crude oil

The costs of developing and managing IDP specialty soybean crops have been identified as a barrier to the market, so price premiums such as noted above are essential for these specialty soybeans to be adopted (Pritchett, et al., 2002). The cost for entry into the IDP system has been estimated as high as 25% above the cost of conventional crop production (Smyth & Phillips, 2002). Consumers of specialty crops also have cost burdens associated with these crops. In addition to the costs incurred for specialty crop production, specialty crop consumers accrue added IDP costs from five general activities: certifying and obtaining ingredients; testing ingredients or final products; separating equipment and facilities; scheduling production and conducting changeover procedures; and conducting recordkeeping (Muth, et al., 2003).

These IDP management costs may be offset by premium value received for the crop and the product, as well as increased yields for certain IDP varieties. Pritchett reports that specialty soybean yields are generally higher than those reported for commodity soybeans, which he attributes to either the managerial talent of the specialty grower or higher land quality which is recognized and optimized by the grower (Pritchett, et al., 2002). There is no information whether these market entry costs for cultivation and use of specialty soybean would be offset by increased yields and premium prices for the products of MON 87705 Soybean. Irrespective of the value added application of oils derived from MON 87705 Soybean, adherence to soybean IDP practices will be essential to ensure that the crop value is preserved.

In the alternative, inadvertent consumption of MON 87705 Soybean by a user desiring an alternative fatty acid composition may give rise to negative impacts to those consumers. For example, the taste commonly associated with fried food is due to the presence of linoleic acid (AGRA, 2009). High-oleic acid soy oils are not considered ideal for fried food applications (AGRA, 2009). While MON 87705 is not likely to be produced without conventional breeding to a low linolenic line (Appendix D; Addendum 1, Monsanto, 2010), it would not have ideal properties for deep frying (see Table 4-3 in Cumulative Impacts). Thus, if a shipment of MON 87705 Soybean were inadvertently processed for fried food applications, the resulting food products would likely be unacceptable if the derived oil were in high concentration (which, as demonstrated in Addendum 1 (Appendix D), would be a highly unlikely event because the level of misdirection would need to be implausibly high).

The need to maintain identity and control product characteristics are similar concerns for industrial applications. For example, high oleic acid soy oil has value in oleo-chemical applications, including lubricants, coatings and paints and foam products, as well as a feedstock for biodiesel applications (AGRA, 2009; Graef, et al., 2009; Knothe, 2005). In contrast, oils

Group II - Hydroprocessed - Highly refined mineral oil
Group III – Severe hydroprocessed - Ultra refined mineral oil
Group IV – Full synthetics (chemically derived) - Chemically built Polyalphaolefins (PAO).
Groups I – III basestocks are derived from crude oil pumped from the ground ; Group 4 basestocks are chemically derived, most often from ethylene gas, and contain none of the contaminants present in mineral oils (see http://www.mobil.com/australia-english/lcw/audiences/synthetic_v_mineral.asp)

[3] APHIS will provide FWS a draft EA that will address the impacts, if any, of gene movement to the TES plant

with high concentrations of linolenic acid are comparable to linseed oil and are very desirable in the coatings industry where they are used to enhance drying of paints, inks, and varnishes (Cahoon, 2003). While the inadvertent substitution of one specialty oil for specialty oil is highly unlikely, the results of such an accidental substitution in the industrial sector are nonetheless substantial. If the IDP practices preserving the distinction between MON 87705 Soybean and either conventional soy oil or other specialty oils are not maintained, desired oil composition would be compromised and the product would not meet its specifications.

It is conceivable that MON 87705 Soybean might only be cultivated as a specialty crop because of the specialized IDP practices required to preserve product integrity. Market share predictions for MON 87705 Soybean are subject to much uncertainty. However, Monsanto has estimated that the acreage potential in the United States for its “Vistive III soybean” variety (MON 87705 conventionally bred with low linolenic varieties, and thus, a high oleic and low linolenic product) at 10 to 20 million acres, or potentially up to 25% of the U.S. market (AGRA, 2009).

As with the MON 87705 Soybean derived product, these low-lin varieties have lower saturated fat content than that of partially hydrogenated commodity soybean oil. Cultivated as specialty crops, these varieties provide the grower with a premium price as high as $1.25 per bushel (Conley & Gaska, 2008). In 2005, when Monsanto introduced the low-linolenic soybean “Vistive” variety, food producers such as Kellogg noted that there was a high demand and significant shortage for soy oils with these traits (Woznicki, 2005). MON 87705 Soybean market share will be contingent on a demonstrated price and high yield potential as well as consumer and producer preference to other modified fatty acid soybean varieties.

Net income differentials cannot be projected. The net income of soybean producers growing only herbicide-tolerant soybean is not available (USDA-ERS, 2010d). However, as Monsanto anticipates that MON 87705 Soybean would be cultivated as a specialty crop, resulting domestic socioeconomic impacts are expected to be similar to the no action alternative and are contingent on adherence to IDP practices at all stages of MON 87705 Soybean cultivation and production.

Cumulative Effects: Domestic Economic Environment

MON 87705 Soybean is intended to be cultivated as a specialty soybean product and its oil fraction will be produced and utilized within an IDP system (Monsanto, 2010). Consistent with the agronomic analyses conducted by Monsanto, a determination of nonregulated status of MON 87705 Soybean is not expected to result in an increase in acreage devoted to cultivation of soybean, but could potentially replace existing specialty soybean varieties for those growers seeking a new specialty oil product which also presents herbicide tolerance.

Monsanto anticipates that MON 87705 Soybean will be cultivated as a specialty soybean (Monsanto, 2010). Agronomic and phenotypic analyses conducted by Monsanto did not demonstrate any substantial differences between MON 87705 Soybean and conventional varieties, and none of the modifications expressed by MON 87705 Soybean are considered likely to result in new acreage devoted to soybean cultivation outside of those regions where soybean is currently cultivated (Monsanto, 2010). Consistent with this expectation that MON 87705 Soybean will be a specialty product, with no new agronomic characteristics providing benefits for cultivation beyond traditional soybean cultivation regions, a determination of nonregulated status of MON 87705 Soybean is not expected to lead to an expansion of U.S. soybean acreage.

The percentage of the U.S. soybean acreage dedicated to specialty oil soybeans does have the potential to change, contingent upon market acceptance and consumer demand, and specific applications of the specialty products.

To further enhance the oxidative stability of soybean oil (Monsanto, 2010), Monsanto has conventionally bred the Vistive low-linolenic variety with MON 87705 Soybean, and this has produced a variety that is substantially reduced in linolenic acid and increased in linoleic (Table 2, Addendum 1, Monsanto (2010); See also Table Y below). Other conventional low-linolenic varieties include, for example, four ultra-low linolenic acid varieties introduced by the Iowa State University Research Foundation (Iowa State University, 2008). The four varieties introduced by Iowa State include three non-GE varieties: IA2096, IA2097, and IA3042; and IA2098RR, a GE variety which also expresses glyphosate resistance (Iowa State University, 2008). Additional Pioneer low linolenic varieties are available through Bunge and elevators to purchase these varieties are found in a six state region ({Pioneer, 2011 #623}). Low linolenic varieties may be used for blending with other oils, such as those high in oleic acid (Cargill, 2011), since low linolenic oils are not adequate for heavy frying operations (Agra, 2009). The producers of these existing low linolenic acid soybean varieties could experience a decrease in demand because the need for blending would decline, and because MON 87705 oils could be used as a replacement. Introduction of MON 87705 may result in a conversion of commodity soybean acreage to this or other specialty soybean varieties.

Table 4-3: Characteristic Fatty Acid Profiles for Desirable Properties of Frying Oils: MON 87705 and MON 87705 Crossed with Vistive Low Linolenic Varieties

Fatty Acid	Full Deep Fried Flavor[1]	Stability[1]	MON 87705[2]	MON 87705 X Vistive Low Linolenic[3]
Oleic		50-65%	76%	72%
Linoleic	20-30%	20-30%	10%	17%
Linolenic		<3%	7%	2.9%

1. {Eckel, 2007 #626}
2. Monsanto, 2010
3. Addendum 1, Monsanto, 2010

MON 87705 Soybean has the potential to displace other non-soy oil crops. Competitors in the food market include corn oil, canola oil, cottonseed oil, peanut oil, olive oil, palm oil and sunflower oil. While soybean oil lost market share to other food oils after the 2006 FDA *trans* fat labeling requirements, it is nonetheless the least expensive domestic vegetable oil (USDA-ERS, 2011). Table 4-3 provides a summary of the comparative prices for these commodity oils over the past decade. For the past decade, soybean oil has consistently been the least expensive domestic vegetable oil (USDA-ERS, 2011). If MON 87705 Soybean oil achieves market acceptance, the product has the potential to displace other vegetable food oils, including canola and sunflower oils presenting similar high-oleic oil characteristics.

Table 4-4: U.S. Vegetable Oil Prices (dollars/gallon)

Marketing Year	Soybean Oil	Cottonseed Oil	Sunflower oil	Canola Oil	Peanut Oil	Corn Oil
2000/01	1.09	1.23	1.22	1.35	2.69	1.044
2001/02	1.27	1.38	1.79	1.81	2.48	1.47
2002/03	1.70	2.91	2.55	2.29	3.60	2.17
2003/04	2.31	2.40	2.57	2.60	4.68	2.19
2004/05	1.77	2.16	3.37	2.37	4.13	2.15
2005/06	1.80	2.27	3.13	2.39	3.42	1.94
2006/07	2.39	1.98	4.47	3.12	4.08	2.45
2007/08	4.01	5.66	7.02	5.05	7.28	5.34
2008/09	2.48	2.09	3.87	3.04	6.04	2.52
2009/10	2.77	3.01	4.07	3.30	4.59	3.03
2010/11	4.27	4.46	5.92	4.77	6.31	4.65

Source: (USDA-ERS 2011, Table 9, converted to dollars per gallon based on a vegetable oil conversion factor of 7.7 pounds per gallon).

4.6.2 Trade Economic Environment at Risk

Although soybean oil constitutes only a small percent of soybean weight (approximately 19%), soybean oil accounts for up to 65% of all vegetable oil and fat consumed in the U.S. (USDA-ERS, 2010d). The worldwide market share is not as high. Until 2005, soybean oil was the largest source of vegetable oil worldwide (USDA-ERS, 2010d). In 2005, however, palm oil overtook soybean oil in volume of production; palm oil and rapeseed oil (canola) production are expected to continue to grow over the next few years (USDA-ERS, 2010d). In 2009, the U.S. exported 1.3 billion bushels (34.9 million metric tons) of soybean, which accounted for 46% of the world's soybean exports (SoyStats, 2010b). In total, the U.S. exported $16.5 billion USD worth of soybean and soybean products in 2009 (SoyStats, 2010c). China is the largest export market for U.S. soybean with purchases totaling $9.2 billion. Mexico is the second largest export market with sales of $1.3 billion in the same year (SoyStats, 2010c). Other significant markets include Japan and the EU.

The global demand for soybeans is expected to increase by a full third over 2010 consumption in the next ten years, with China accounting for 80% of the expected increase in total demand (FAPRI, 2009; Hartnell, 2010). China and India are predicted to import 46% of the total soybean market by 2018/2019 (FAPRI, 2009). The USDA has predicted that U.S. exports will remain flat during much of this period, as a result of increase in domestic consumption and competition from South America (FAPRI, 2009; USDA-ERS, 2009). To a certain extent, competition with South American producers will be offset by increased demand from China (FAPRI, 2009). The USDA predicts that the U.S. share of this export market could potentially decline from the current 46% to 30% at the end of the decade (FAPRI, 2009; USDA-ERS, 2009). It is also noted that as a result of higher prices for vegetable oils as a result of increased demand for food use as well as for biodiesel and other industrial uses, previously uncropped land in Brazil, Indonesia, and Malaysia are being brought into production for soybean and palm oil (USDA-ERS, 2009). This will increase global competition for export market share.

Income benefits from cultivation of herbicide tolerant soybeans have been substantial. Global farm income has been estimated to have increased over 6% in 2007 as a consequence of adopting these varieties (Brookes & Barfoot, 2010; Hartnell, 2010). Global gains from adoption of herbicide-tolerant soybeans have been estimated as high as $7 billion per year (Hartnell, 2010). Continued expansion of these crops internationally will be an extension of consumer demand as well as government regulation of GE commodities.

Costs of production also play a role in U.S. soybean export competitiveness. In Argentina, for example, the cost of herbicide-tolerant soybean production is substantially lower than U.S. costs because Monsanto was unable to patent the technology in Argentina (Brookes & Barfoot, 2010). As a consequence, Argentinian growers are able to save seed and not pay technology fees or royalty fees on farm-saved seed (Brookes & Barfoot, 2010).

No Action: Trade Economic Environment

Approximately 93% of the soybean varieties currently cultivated in the U.S. are GE varieties (USDA-ERS, 2010a, 2010b). Specialty soybeans comprise approximately 12% of the soybean acreage (MSA, 2009). U.S. soybeans will continue to play a role in global soybean production, and will continue to be a supplier in the international market.

Under the No Action alternative, there would be no changes to the existing soybean market.

Preferred Alternative: Trade Economic Environment

To support commercial introduction of MON 87705 Soybean in the U.S., regulatory submissions will be made by the petitioner to countries that import significant quantities of soybean or its processed fractions from the U.S. and have established regulatory approval processes in place (Monsanto, 2010). These will include submissions to a number of foreign government regulatory authorities, including: Ministry of Agriculture, People's Republic of China; Japan's Ministry of Agriculture, Forestry, and Fisheries (MAFF) and the Ministry of Health, Labor, and Welfare (MHLW); the Canadian Food Inspection Agency (CFIA) and Health Canada; the Intersectoral Commission for Biosafety of Genetically Modified Organisms (CIBIOGEM), Mexico; the European Food Safety Authority (EFSA); and the regulatory authorities in other soybean importing countries with functioning regulatory systems. As appropriate, notifications of importation will be made by the petitioner to importing countries that do not have a formal approval process.

MON 87705 Soybean is intended to be cultivated as a specialty GE soybean variety and the low saturated fat, high-oleic acid soybean oil will be produced and processed utilizing an identity preservation system to capture the food quality value of the oil (Monsanto, 2010). The cultivation of MON 87705 Soybean is not expected to result in an increase in the total acreage devoted to soybean cultivation, although the allocation of acreage to specialty soybean cultivation could increase contingent upon market demand. As with the No Action Alternative, U.S. soybeans will continue to play a role in the global soybean market.

To the extent that the modified fatty acid soybean oil derived from MON 87705 Soybean achieves market acceptance, it is conceivable that this soybean-based oil could displace other high-oleic vegetable oils in the international market. Products potentially displaced by MON 87705 Soybean oil include high-oleic canola and sunflower oils, both of which have been marketed as high-stability, high-oleic products (see, e.g., Canola Council 2011a; 2011b; NSA, 2006).

Consistent with the potential increase in international demand for this specialty oil product, as well as price competitiveness illustrated above in Table 4-3, a determination of nonregulated status of MON 87705 Soybean may have a positive benefit on U.S. exports as soy oil based on this product displaces other high-oleic food oils. The international market share of MON 87705 Soybean as a high-oleic variety is contingent on global vegetable oil market requirements, food processor acceptance, consumer preference, demonstrated availability of the product, and price competitiveness (Monsanto, 2010). One economic analysis of a similar high oleic soybean predicts that in the environment of high acceptance by consumers, along with high consumption, coupled with low price of the oil, the US may obtain a higher share of the world oil market for soybeans Giannakas and Yiannaka, 2010). However, with an inability to predict the size of these variable inputs, APHIS cannot reliably foresee the outcome for an increase in world market share of soybean resulting from planting of this variety.

Global sensitivities to GE products, including international restrictions on import of GE products and inability of the petitioner to gain local approval for cultivation or importation, will continue to impede trade with those countries. These challenges to international trade in GE products are already in place. Restrictions on international trade in GE products, including MON 87705 Soybean, are unlikely to change with a determination of nonregulated status of MON 87705 Soybean.

Trade in MON 87705 Soybean or its products requires approvals in those countries with an established regulatory approval process actualized by law. Approvals will be sought by Monsanto from countries that import significant quantities of soybean. Monsanto intends to complete an application process for People's Republic of China (Ministry of Agriculture), Japan (Ministry of Agriculture, Forestry and Fisheries), Canada (Canadian Food Inspection Service and Health Canada), Mexico (Commission for Biosafety of Genetically Modified Organisms) and the EU (European Food Safety Authority). Monsanto supports the program established by the Biotechnology Industry Organization, Product Launch Stewardship Policy, and has considered Annex 2, "Special Use traits in Commodity Crops," which specifies that "prior to full commercial launch", the product developer should" secur[e] regulatory approvals in key export countries".

A determination of nonregulated status of MON 87705 Soybean will not adversely impact the trade economic environment and could potentially enhance it through the subsequent development and global adoption of the MON 87705 Soybean line and its products. The MON 87705 Soybean follows trends in the development of specialty soybeans with modified fatty acid profiles. The trade economic impacts associated with a determination of nonregulated status of MON 87705 Soybean are anticipated to be very similar to the No Action Alternative.

Cumulative Effects: Trade Economic Environment

Consistent with the analysis of international markets for GE soybean, low saturated fat and high-oleic vegetable oils, and GE crops generally, APHIS has determined that there are no past, present, or reasonable foreseeable effects of the proposed action which would present a negative cumulative impact on the trade economic environment. Since 2006, as a result of the FDA *trans* fat labeling requirement, the U.S. soybean growers have lost market share to other vegetable oils with presenting lower saturated and *trans* fats, as well as higher oxidative stability, including high-oleic canola and sunflower oils (Waltz, 2010). MON 87705 Soybean is one of several soybean varieties developed in the attempt to recapture soybean's market share for food oil (Waltz, 2010). Contingent upon producer and consumer acceptance, availability, and price, MON 87705 Soybean has the potential to displace some of these comparable, non-soybean vegetable oils on the international market.

4.6.3 Social Environment at Risk

The social environment evaluated in this subsection relates to the general soybean farm, as well as the individuals or workers employed by the businesses potentially impacted by this product, including food processers and industrial users.

Data from the 2007 Census of Agriculture indicated that 279,110 U.S. farms raised soybeans in 2007, down from 511,000 in 1982 (USDA-ERS, 2010d; USDA-NASS, 2007). Although acreage planted to soybeans was also lower in 2007 than in 2002 as growers shifted to corn production, harvested soybean acreage per farm increased from 114 acres in 1978 to 229 acres in 2007 (USDA-ERS, 2010d). Although small farms with less than 250 acres accounted for 72% of the farms growing soybeans, these farms produced only 26% of the 2007 crop (USDA-ERS, 2010d). Irrigation was used on 5.2 million acres of soybean, or 8% of U.S. soybean acreage in 2007 (USDA-ERS, 2010d). Individual or family farms accounted for 81% of all soybean farms in 2007 and 69% of soybean production, with the balance identified largely as partnerships and small family-held corporations; corporations accounted for less than 1% of soybean farms and soybean production (USDA-ERS, 2010d).

Farms which specialized in soybean production have been reported as generally smaller in terms of farm size and sales than farms which do not specialize in soybean cultivation (USDA-ERS, 2006b). Many of the farms which specialize in soybean cultivation have reported non-farm incomes. Fewer than half of the growers specializing in soybean cultivation listed farming as their primary occupation (36%); whereas, 65% of growers who cultivated a wide variety of crops on less specialized soybean farms reported farming as the primary occupation (USDA-ERS, 2006b).

Average acreage of all operated soybean farms is reported as approximately 623 acres; whereas, the average acreage of a more specialized soybean farm operator is reported at 390 acres

(USDA-ERS, 2006b). Nearly 60% of these specialty soybean farmers reported annual income less than $40,000; whereas, 76% of commodity soybean farmers reported incomes exceeding $40,000 per year (USDA-ERS, 2006b).

No Action: Social Environment

Under the No Action Alternative, there would be no changes from the status quo impacts on the social environment surrounding soybean farming, food processing, or industrial uses. The cropping and marketing decisions currently made by soybean growers are unlikely to change with the selection of this alternative.

Preferred Alternative: Social Environment

MON 87705 Soybean is not intended to confer any competitive advantage in terms of weediness or to extend the range of cultivation outside of existing cultivation areas. Monsanto expects that MON 87705 Soybean will be cultivated as a specialty crop, with the low saturated fat, high oleic acid soybean oil produced and processed under existing identity protection systems to capture the food quality value of the oil (Monsanto, 2010). The variety will be bred with conventionally obtained low linolenic acid soybeans, and so will also express this trait (Monsanto, 2010 Addendum I). Consistent with the expectations that this variety is to be cultivated as a specialty crop, a determination of nonregulated status of MON 87705 Soybean is not expected to result in an expansion of the number of soybean acres. Soybean acreage is expected to remain stable, and overall impacts relative to the total soybean market system are similar to the No Action Alternative.

To the extent that MON 87705 Soybean is accepted by producers and consumers, MON 87705 Soybean has the potential to displace other specialty soybean varieties. Those growers currently cultivating specialty soybean varieties have already invested in equipment and practices to maintain the identity of the product from seed through harvest and processing and would not be impacted by this change. To the extent that a grower currently cultivating commodity soybean elects to cultivate MON 87705 Soybean, that grower will need to invest in handling equipment and management practices to capture and preserve the food quality value of the oil. Growers adopting specialty varieties already make such investment decisions based upon perceived value and return on investment (Iowa State University, 2008).

The soybean market also includes seed production, equipment manufacturers, handlers, and producers. Monsanto's analysis of agronomic characteristics did not identify any differences between MON 87705 Soybean and conventional varieties (Monsanto, 2010). Monsanto expects that MON 87705 Soybean would be cultivated, handled, and processed consistent with existing identity protection practices and systems (Monsanto, 2010). Other than equipment required to maintain identity protection, no specialized equipment is required to cultivate, handle, or process MON 87705 Soybean. Although there is some expectation that specialty soybean production will gradually increase to meet the demands now met by hydrogenated soybean oils and other vegetable oils which have the high oleic, low linolenic traits (Monsanto, 2010), these increases would most likely be accompanied by decreases in production of conventional commodity soybean. Thus, there may be movement of some growers into increased specialty soybean production and required investment into mechanisms needed to adequately segregate the adopted variety of soybean (because it would be an identity preserved product). However, any choices made by growers will be voluntary ones, based upon consideration of the costs of conversion, prices of the identity preserved soybean, and necessary commitments to changes required by any such conversion. In the event that all these considerations were favorable ones for the growers, some economists propose that there is potential for economic gains beyond those accruing from production of conventional commodity soybean (Giannakas and Yiannaka, 2010).

Food processors potentially impacted by MON 87705 Soybean include those parts of the industry using soybean oil for frying, and cooking oil, and shortening products where shelf life and oxidative stability are important features. Monsanto intends to market the low saturated fat, high-oleic fatty acid content of MON 87705 Soybean oil as a replacement product for comparable existing oils, including canola and sunflower oils (Canola Council, 2011a; NSA, 2006; Monsanto, 2010) and other uses where hydrogenated soybean oils are currently employed (Addendum 1,Monsanto, 2010) . Because these other modified oil products are already present in the commodity oil market and routinely handled by processors using standard industry processing methods and equipment, no new processes or equipment are required to introduce MON 87705 Soybean. Thus, workers in these areas are not likely to be impacted by any major alterations of soybeans or of qualities of soybeans processed.

Monsanto has evaluated the market and trade applications of MON 87705 Soybean, and has determined that this product is appropriate for all the same uses as hydrogenated soybean (Monsanto, 2010). In the event that MON 87705 Soybean is introduced into commodity oil, the result would be a reduction in saturated and polyunsaturated fats, which would improve the functionality of the oil and improve the nutritional profile (Monsanto, 2010). Other consequences for applications using soybean oils have been examined by Monsanto, and are noted in the EA section, 4.6.1, Domestic Economic Environment.

Potential impacts to industrial users of soybean products are similar. Existing identity protection measures are already in place to allow industrial users to manage feedstocks and products for specific applications and needs (Smyth & Phillips, 2002; Sonka, et al., 2004). No new equipment or practices are required to incorporate MON 87705 Soybean into this industrial market. However, for industrial users that require close tolerances in the ratios of fatty acid to ensure product quality, continuous monitoring of properties of input oils may be necessary. This scrutiny may already have been enhanced, given that the industry has increasingly begun to encounter and already needs to manage an increasing range of different soy-based feedstocks, ranging from ultra-low linolenic acid varieties, through and including feedstock oils for blending from other crops, such as high-oleic and high linolenic varieties that have various uses (APAG, 2011; USB, 2010). Thus, APHIS does not expect that changes to the social environment including workforce will be altered by entry of this variety into the soybean market.

Consistent with the above assessment of potential impacts to the growers, and workforce in the food processing and industrial use categories, the impacts of a determination of nonregulated status of MON 87705 Soybean are expected to be the same as the No Action Alternative.

Cumulative Effects: Social Environment

Based on the information described above, APHIS has determined that there are no past, present, or reasonably foreseeable actions that in aggregate with effects of the proposed action would impact the social environment surrounding soybean farming.

4.7 THREATENED AND ENDANGERED SPECIES

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

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

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

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

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or critical habitat. To facilitate APHIS' ESA consultation process, APHIS met with the USFWS to discuss factors relevant to their effects analysis for petitions for nonregulated status and developed a process for conducting an effects determination (Appendix B). This process is used by APHIS to assist the program in fulfilling their obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

As part the environmental review process, APHIS thoroughly reviews GE product information and data to inform the ESA effects analysis and, if necessary, the biological assessment. For each transgene(s)/transgenic plant the following information, data, and questions are considered by APHIS:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant); and
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES.

In following this process, APHIS evaluated the potential effects that a determination of nonregulated status to MON 87705 Soybean would have on Federally listed threatened and endangered species and species proposed for listing, as well as designated critical habitat and habitat proposed for designation. Based upon the scope of the EA and production areas identified in the Affected Environment section of the EA, APHIS obtained a list of TES species (listed and proposed) for each state where soybean is commercially produced from the USFWS Environmental Conservation Online System (ECOS), see Appendix C.

As discussed above in the analysis of Gene Movement and Weediness and Plants, APHIS has determined that there is no risk to unrelated plant species from the cultivation of MON 87705 Soybean. Monsanto submitted results of a comparison of agronomic and phenotypic differences between MON 87705 Soybean and conventional soybean; no differences were identified (Monsanto, 2010; USDA-APHIS, 2010a). Consistent with these studies, APHIS has concluded the determination of nonregulated status of MON 87705 Soybean does not present a plant pest risk, does not present a risk of weediness, and does not present an increased risk of gene flow when compared to other currently cultivated varieties.

Accordingly, APHIS focuses our assessment of potential impacts on TES animal species, particularly those potentially at risk from the consumption of MON 87705 Soybean. Few TES animal species are likely to frequent soybean fields because the habitat would not be suitable. Some animal species, particularly migratory birds, may visit soybean fields, but their presence would be fleeting as the habitat is either not suitable or does not contain constituent elements required by the species. An exception may be the Delmarva fox squirrel (*Sciurus niger cinereus*). Once found throughout the Delmarva Peninsula, remnant populations of the Delmarva fox squirrel now persist naturally only in portions of Queen Anne's, Talbot, and Dorchester Counties in Maryland. Translocated populations now exist in other areas of Maryland, Virginia, Delaware and a small area in Chester County, Pennsylvania. The fox squirrel is found mostly in mixed stands of mature (acornproducing) hardwoods and mature loblolly pines. Other areas include groves of trees along streams and bays, small woodlots in agricultural fields and forest near salt marshes. (see http://ecos.fws.gov/speciesProfile/profile/speciesProfile.action?spcode=A00B). Diet includes acorns, nuts/seeds of hickory, beech, walnut, and loblolly pine; buds and flowers of trees, fungi, insects, fruit, and an occasional bird egg. They will feed largely on green pine cones when these are available, and often forages on the ground (NatureServe, 2010). It is not certain that squirrels actually feed on soybean, although other wildlife certainly do {Havera, 1980 #622}. Some reports indicate that soybean is consumed by tree squirrels {Craven, 1995 #623})

It is reasonable to assume that populations of the species adjacent to soybean production fields could be impacted by aspects of cultivation of MON 87705 Soybean or could feed on MON 87705 Soybean. The EPA and the FDA have conducted independent evaluations of these potential risks directly relevant to APHIS' analysis.

Monsanto evaluated compositional aspects of MON 87705 Soybean and compared these data with conventional soybean composition. Differences were observed in the concentrations of three other fatty acids (18:3 linolenic acid, 20:0 arachidic acid and 20:1 eicosenoic acid), total fat, and two amino acids (arginine and cysteine) (US-EPA, 1993b). APHIS evaluated the differences reported in these compositional elements, and has determined that the reported differences are within the 99% tolerance interval for soybean composition (see Monsanto, 2010 Table E-13, page 303) . Accordingly, although statistically significant differences in concentrations in these constituents were identified between MON 87705 Soybean and conventional soybean, the reported values for MON 87705 Soybean are within the acceptable tolerance ranges. As discussed above in Subsection 4.4.2, the analysis of potential impacts to animals consuming MON 87705 Soybean, the FDA has completed its consultation on this product and concluded that the consumption of MON 87705 Soybean presents minimal risk to animals consuming this crop (US-FDA, 2011). Because the composition of MON 87705 Soybean is similar to other commercial soybean plants with the exception of having tolerance to glyphosate and enhanced levels of the certain fatty acids with no expected hazards associated with consumption, it is unlikely that MON 87705 Soybean poses a hazard to TES animal species. Because no hazards are identified, the risk of MON 87705 Soybean affecting TES animal species is also unlikely, regardless of exposure.

Additionally, the EPA has published an exemption from tolerance for the *cp4 epsps* gene and the material necessary for its production in all plants (US-EPA, 1996). Roundup Ready® crops incorporating the *cp4 epsps* gene have been marketed since the mid-1990s with no reports of any non-target impacts associated with exposure to or consumption of the modified crop. Accordingly, no impacts to TES are anticipated as a result of exposure to the *cp4 epsps* gene in MON 87705 Soybean.

With regard to the utilization of glyphosate as the herbicide of choice for MON 87705 Soybean, the EPA has conducted a review of the potential impacts to non-target species, and has determined that when used in accordance with the FIFRA label, the potential impacts to non-target species is not significant (US-EPA, 1993a, 1993b). As the action agency for pesticide registrations, EPA has the responsibility to conduct an assessment of effects of a registration action on TES. The EPA Endangered Species Protection Program web site, http://www.epa.gov/espp/, describes the EPA assessment process for endangered species. Some of the elements of that process, generally taken from the web site, are summarized below.

When registering a pesticide or reassessing the potential ecological risks from use of a currently registered pesticide, EPA evaluates extensive exposure and ecological effects data to determine how a pesticide will move through and break down in the environment. Risks to birds, fish, invertebrates, mammals and plants are routinely assessed and used in EPA's determinations of whether a pesticide may be licensed for use in the U.S.

EPA's core pesticide risk assessment and regulatory processes ensure that protections are in place for all populations of nontarget species, including TES. These assessments provide EPA with information needed to develop label use restrictions for the pesticide. These label restrictions carry the weight of law and are enforced by EPA and the states (Federal Insecticide, Fungicide, and Rodenticide Act 7 USC §136j (a)(2)(G) Unlawful acts). Because TES may need specific protection, EPA has developed risk assessment procedures, described in the Overview of the Ecological Risk Assessment Process (US-EPA, 2004), to determine whether individuals of a listed species have the potential to be harmed by a pesticide; and if so, what specific protections may be appropriate. EPA's conclusion regarding the potential risks a pesticide may pose to a listed species and any designated critical habitat for the species, after conducting a thorough ecological risk assessment, results in an "effects determination" in accordance with Section 7 (a)(2) of the ESA.

As a part of EPA's TES effects assessment for the California red-legged frog (US-EPA, 2008), EPA evaluated the effect of glyphosate use at rates up to 7.95 lb a.i./A on fish, amphibians, aquatic invertebrates, aquatic plants, birds, mammals, and terrestrial invertebrates. The EPA assessment was uncertain of the effects on terrestrial invertebrates, citing the potential to affect small insects at all application rates and large insects at the higher application rates.

EPA considered these potential effects as part of their review process and label use restrictions for glyphosate tolerant crops imposed under authority of FIFRA. To mitigate potential adverse effects to TES, EPA has imposed specific label use restrictions for glyphosate use when applied with aerial equipment including "The product should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g., when wind is blowing away from the sensitive areas)."

To facilitate pesticide applicators adherence to EPA label use restrictions for glyphosate, Monsanto has designed a web-based program (www.Pre-Serve.org), designed to ensure no effect of glyphosate applications on threatened and endangered plant species. Pre-Serve instructs growers to observe specific precautions including buffer zones when spraying glyphosate herbicides on glyphosate-tolerant crops near threatened and endangered plant species that may be at risk. In addition, label requirements for Monsanto's Roundup® formulations and glyphosate formulations marketed by other manufacturers prohibit application in conditions or locations where adverse impact on federally designated endangered/threatened plants or aquatic species is likely.

In conclusion, there are legal precautions in place (EPA label use restrictions) and "best practice" guidance to reduce the possibility of exposure and adverse impacts to TES from glyphosate application to MON 87705 Soybean. EPA has considered potential impacts to TES as part of their registration and labeling process for glyphosate; and adherence to EPA label use restrictions by the pesticide applicator will ensure that the use of glyphosate will not adversely affect TES or critical habitat. Based on these factors and the legal requirements for pesticide applicators to follow EPA label use restrictions, APHIS has determined that the use of EPA registered glyphosate for MON 87705 Soybean production will not adversely impact listed species or species proposed for listing and would not adversely impact designated critical habitat or habitat proposed for designation.

Based on the above information, APHIS has determined that the Preferred Alternative, a determination of nonregulated status of MON 87705 Soybean, would 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.

4.8 OTHER CUMULATIVE EFFECTS

Potential cumulative effects regarding specific issues have been analyzed and addressed above. No further potential cumulative effects have been identified. To date, none of the GE soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 and used for commercial soybean production or soybean breeding programs have been subsequently found to pose a plant pest risk.

Specialty soybeans are cultivated to meet specific consumer needs. MON 87705 Soybean is anticipated to be cultivated as another specialty soybean, offering growers and consumers an option for a high oleic variety also providing herbicide tolerance. Herbicide tolerant soybean is already extensively deployed in the seed market, and high oleic traits in other vegetable oil sources are also available. No additional potential cumulative impacts to the commodity soybean market or the specialty soybean market can be reliably anticipated as a result of a determination of nonregulated status and cultivation of MON 87705 Soybean.

MON 87705 Soybean will compete in the market with other high-oleic, low saturated fat vegetable oils, including high oleic canola and sunflower oils (Canola Council, 2011a; NSA, 2006). MON 87705 Soybean success in replacing these other high-oleic vegetable oils will be contingent upon producer and customer acceptance, availability of the product, and price. As illustrated in Table 4-3, soybean has been generally less expensive to produce than either of these oils. Such a change in market is not unusual, and in this case not dissimilar to the loss in market share which soybean has itself experienced following the FDA's 2006 requirement that foods be labeled as to their *trans* fat content. Since 2006, soybean lost market share to palm and certain canola oils (Waltz, 2010). MON 87705 Soybean is one of several soybean varieties developed in the attempt to recapture soybean's market share for food oil (Waltz, 2010).

Cultivation of stacked varieties, those crop varieties that may contain more than one trait, are currently found in the marketplace and in agricultural production. In the event APHIS reaches a determination of nonregulated status, MON 87705 Soybean may be combined with non-GE and GE soybean varieties by traditional breeding techniques. APHIS' regulations at 7 CFR Part 340 do not provide for Agency oversight of GE soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, nor over stacked varieties combining GE varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 unless it can be positively shown that such stacked varieties were to pose a likely plant pest risk.

There is no guarantee that MON 87705 Soybean will be stacked with any particular non-GE or GE soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, as company plans and market demands play a significant role in those business decisions. Predicting all potential combinations of stacked varieties that could be created using both non-GE and GE soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 is hypothetical and purely speculative. No further analysis is required.

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

4.9.1 Executive Orders with Domestic Implications

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

- ***Executive Order (EO) 12898 (US-NARA, 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,"*** requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.

- ***EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks,"*** acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

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

Available mammalian toxicity, along with the history of safe use of CP4 ESPS protein conferring tolerance to glyphosate other soybean varieties expressing CP4 ESPS proteins, establishes the safety of MON 87705 Soybean and its products to humans, including minorities, low income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken.

None of the impacts on agricultural practices expected to be associated with a determination of nonregulated status of MON 87705 Soybean are expected to have a disproportionate adverse effect on minorities, low income populations, or children. As noted above, the cultivation of soybean varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 with similar herbicide tolerance traits has been associated with a decrease and or shift in pesticide applications for those who adopt these varieties that is either favorable or neutral with respect to environmental and human toxicity. If pesticide applications are reduced, there may be a beneficial effect on children and low income populations that might be exposed to the chemicals. These populations might include migrant farm workers and their families, and other rural dwelling individuals who are exposed to pesticides through groundwater contamination or other means of exposure. It is expected that EPA and USDA Economic Research Service would monitor the use of this product to determine impacts on agricultural practices such as chemical use as they have done previously for herbicide-tolerant products.

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

Non-engineered soybean as well as other herbicide-tolerant and modified fatty acid soybean varieties are widely grown in the U.S. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by APHIS, MON 87705 Soybean plants are sufficiently similar in fitness characteristics to other soybean varieties currently grown and are not expected to become weedy or invasive (USDA-APHIS, 2010a).

> ***EO 13186 (US-NARA, 2010), "Responsibilities of Federal Agencies to Protect Migratory Birds,"*** states that Federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

Data submitted by the applicant has shown no difference in compositional and nutritional quality of MON 87705 Soybean compared to other GE soybean or non-GE-soybean, apart from the modification of the fatty acid composition.

EPA has established an exemption from the requirement of a tolerance for residues of CP4 EPSPS protein and the genetic material necessary for its production in all plants (US-EPA, 1996). This exemption was based on a safety assessment that included rapid digestion in simulated mammalian gastrointestinal fluids, lack of homology to toxins and allergens, and lack of toxicity in an acute oral mouse gavage study. Because the MON 87705 Soybean-produced CP4 EPSPS protein is equivalent to the exempted CP4 EPSPS protein, a similar conclusion can be reached that the MON 87705 Soybean-produced CP4 EPSPS is safe for human and animal consumption.

Monsanto has presented results of field trials conducted to evaluate field phenotypic, agronomic and environmental interactions. These data, presented in Appendix G of the petition (Monsanto, 2010) showed no differences in arthropod damage or arthropod pest and beneficial insect abundance between MON 87705 Soybean and other varieties, supporting the conclusion that the modified oil trait is unlikely to impact food sources for migratory bird species. Migratory bird use of soybean in harvested fields is reduced in terms of species numbers as well as population densities compared to their use of corn and sunflower fields {Galle, 2009 #625}, so usefulness of soybean for these birds may be for only a secondary source of grain.

The migratory birds that occasionally forage in soybean fields are unlikely to ingest high amounts of MON 87705 Soybean seed as soybean seed is limited by seed germination and harvest. Exposure to the herbicide glyphosate itself poses minimal risk to birds, fish, and invertebrates (US-EPA, 1993a, 1993b). The incorporation of herbicide tolerance in soybean products such as MON 87705 Soybean has resulted in the reduction in use of more toxic herbicides (USDA-APHIS, 2010c).

Based on APHIS' assessment of MON 87705 Soybean, it is unlikely that a determination of nonregulated status of MON 87705 Soybean will have a negative effect on migratory bird populations.

4.9.2 International Implications

EO 12114 (US-NARA, 2010), "Environmental Effects Abroad of Major Federal Actions" requires Federal officials to take into consideration any potential environmental effects outside the U.S., its territories, and possessions that result from actions being taken. APHIS has given this careful consideration and does not expect a significant environmental impact outside the U.S. in the event of a determination of nonregulated status of MON 87705 Soybean. It should be noted that all the existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new soybean cultivars internationally, apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR Part 340.

Any international trade of MON 87705 Soybean subsequent to a determination of nonregulated status for the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the ***International Plant Protection Convention*** (IPPC, 2010). The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC, 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (172 countries as of March 2010). 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 genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The Cartagena Protocol on Biosafety is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which includes those modified through biotechnology. The Protocol came into force on September 11, 2003, and 160 countries are Parties to it as of December, 2010 (CBD, 2010). Although the U.S. is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with those regulations that importing countries which are Parties to the Protocol have promulgated to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol, and the required documentation.

LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (see the NBII listings posted at http://usbiotechreg.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 U.S., and within the Organization for Economic Cooperation and Development. NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures (RSPM) No. 14, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO, 2003).

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.

4.9.3 Compliance with Clean Water Act and Clean Air Act

This Environmental Assessment evaluated the changes in soybean production due to a determination of nonregulated status of MON 87705 Soybean. Cultivation of MON 87705 Soybean will not lead to the increased production of soybean in U.S. agriculture.

There is no expected change in water use due to the cultivation of MON 87705 Soybean compared to current soybean seed and production regimes. There is no expected change in air quality associated with agronomic practices associated with the cultivation of MON 87705 Soybean.

Based on this review, APHIS concludes that the cultivation of MON 87705 Soybean would inherently comply with the Clean Water Act and the Clean Air Act.

4.9.4 Impacts on Unique Characteristics of Geographic Areas

A determination of non-regulated status of MON 87705 Soybean is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

The common agricultural practices that would be carried out in the cultivation of MON 87705 Soybean are not expected to deviate from current practices. The product will be deployed on agricultural land currently suitable for production of soybean, will replace existing varieties, and is not expected to increase the acreage of soybean production.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to a determination of non-regulated status of MON 87705 Soybean. This action would not convert land use to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 87705 Soybean including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment.

4.9.5 National Historic Preservation Act (NHPA) of 1966 as Amended

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

APHIS' proposed action, a determination of nonregulated status of MON 87705 Soybean will not adversely impact cultural resources on tribal properties. Any farming activities that may be taken by farmers on tribal lands are only conducted at the tribe’s request; thus, the tribes have control over any potential conflict with cultural resources on tribal properties.

APHIS’ proposed action would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of non-regulated status of MON 87705 Soybean. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of EPA registered pesticides. Applicant’s adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment.

APHIS’ proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the soybean production regions. The cultivation of MON 87705 Soybean does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

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APPENDIX A

FDA CONSULTATION ON BIOENGINEERED FOODS

MON 87705 SOYBEAN

US Food and Drug Administration

Biotechnology Consultation Note to the File BNF No. 000121

DATE: January 14, 2011

Subject: High Oleic Soybean MON 87705

Keywords: Soybean, *Glycine max*, glyphosate, *cp4 epsps*, fatty acid, palmitic acid, oleic acid, linoleic acid, *FAD2*, *FATB*, RNA interference, MON 87705, Monsanto, herbicide resistant, modified oil, high oleic, OECD Unique Identifier MON-877Ø5-6

Purpose

This document summarizes FDA's evaluation of biotechnology notification file (BNF) No. 000121. In a submission dated October 29, 2009, Monsanto Company (Monsanto) submitted to the Food and Drug Administration (FDA) a safety and nutritional assessment of the bioengineered soybean MON 87705, which has a fatty acid profile that has been altered from that of conventional soybean varieties. Monsanto provided additional information on December 16, 2009, January 21, 2010, February 15, 2010, March 26, 2010, and June 14, 2010. FDA evaluated the information in Monsanto's submissions to ensure that regulatory and safety issues regarding human food and animal feed derived from the new plant variety have been resolved.

FDA considered all information provided by Monsanto as well as other information available to the agency. This document is not intended to restate the information provided in the final consultation in its entirety.

Intended Effect

The intended effect of the modification in soybean MON 87705 is to produce soybean seeds with decreased levels of palmitic and stearic acids and increased levels of oleic acid, with an associated decrease in linoleic acid. To accomplish this objective, Monsanto used RNA-based suppression of two key endogenous soybean genes [fatty acid acyl carrier protein thioesterase (*FATB1-A*) and fatty acid desaturase (*FAD2-1A*)], the gene products of which are involved in the soybean fatty acid biosynthetic pathway. Monsanto states that *FATB1-A* and *FAD2-1A* gene segments were assembled in a single suppression cassette under the control of a seed promoter. Monsanto states that transcription of the introduced *FATB1-A* and *FAD2-1A* gene segments produces ribonucleic acids (RNAs) with inverted repeats that form double stranded RNA (dsRNA). The dsRNA thus formed suppresses the production of endogenous soybean FATB and FAD2 transcripts via RNA interference. The notifier states that this suppression results in the altered fatty acid profile in soybean MON 87705.

Regulatory Considerations

The purpose of this evaluation is to assess whether the developer has introduced a substance requiring premarket approval as a food additive or has unintentionally adulterated the food with respect to the Federal Food, Drug, and Cosmetic Act (FFDCA).

Genetic Modification and Characterization

Parental Variety

The non-transgenic conventional soybean variety A3525 was used as the recipient in the transformation to create soybean MON 87705.

Transformation Vector and Method

Monsanto used *Agrobacterium*-mediated transformation of soybean meristem tissue to introduce DNA into soybean A3525. The genetic elements introduced into soybean A3525 from transformation vector PV-GMPQ/HT4404 include a single copy of T-DNA I cassette and a single copy of T-DNA II cassette each flanked by insertion border region sequences. T-DNA I contains a partial-suppression cassette, under the control of the *7Sα´* seed promoter, that contains the sense segments of the *FAD2-1A* intron and the *FATB1-A* 5´ untranslated region (UTR) and plastid targeting sequence, and a *cp4 epsps* expression cassette, under the control of the *FMV/Tsf1* promoter sequence, that contains the *cp4 epsps* gene and the CTP2 targeting sequence. T-DNA II contains the 3´ UTR sequence of the *H6* gene and a partial-suppression cassette comprised of antisense segments of the *FAD2-1A* intron and the *FATB1-A* 5´ UTR and plastid targeting sequence.

Characterization, Inheritance, and Stability of the Introduced DNA

In order to characterize the introduced DNA, Monsanto conducted Southern hybridization analyses, DNA sequencing, genomic comparisons, and bioinformatic analyses. Monsanto states that the results of the Southern hybridization analyses show that soybean MON 87705 contains a single copy of T-DNA I and a single copy of T-DNA II inserted at a single locus in the genome. Monsanto notes that further analysis of soybean MON 87705 for plasmid backbone sequence using Southern hybridization showed that soybean MON 87705 does not contain any detectable backbone sequence from the transformation vector PV-GMPQ/HT4404.

Monsanto states that the results of DNA sequencing analyses complement the Southern hybridization analyses and show that the cassettes within T-DNA I, as well as the cassettes within T-DNA II, are intact.

Monsanto performed open reading frame (ORF) bioinformatic analyses of the junction site between the soybean genomic DNA and the inserted DNA to determine whether insertion of the introduced DNA might have created any ORF that might encode a toxin or allergen. From the bioinformatic analyses, Monsanto concludes that, even in the highly unlikely occurrence of translation of any of these ORFs, the polypeptide products are unlikely to exhibit allergenic, toxic, or otherwise biologically adverse properties.

Monsanto reports that the same hybridization pattern was observed using Southern hybridization analyses of genomic DNA isolated from plants from three successive generations. Thus, Monsanto concludes that the inserted DNA in soybean MON 87705 is stably integrated into the genome.

During the development of soybean MON 87705, Monsanto recorded segregation data to assess the heritability and stability of the inserted coding sequences present in the genome. Based on the chi square analysis of the segregation data from three generations, Monsanto concludes that the inserted coding sequences of soybean MON 87705 show a Mendelian inheritance pattern as a single locus. Monsanto also concludes that the data on trait inheritance, as revealed by chi-square analysis, are consistent with the molecular characterization data on the stability of the insert across generations.

Protein Characterization - CP4 EPSPSIdentity, Function, and Characterization

Monsanto states that the *cp4 epsps* gene was used as a selectable marker during the transformation of the parental soybean variety. Monsanto also states that the CP4 EPSPS protein expressed in soybean MON 87705 is identical to the CP4 EPSPS protein in other Roundup Ready™ crops and it confers tolerance to glyphosate. The CP4 EPSPS protein expressed in soybean MON 87705 is derived from *Agrobacterium* sp. strain CP4 and is similar and functionally identical to endogenous plant EPSPS enzymes, but has a much lower affinity for glyphosate. Monsanto characterized soybean MON 87705-produced CP4 EPSPS protein using various analytical techniques[1] and demonstrated the protein's equivalence with *Escherichia coli*-produced CP4 EPSPS protein. Due to the low levels of CP4 EPSPS protein produced in soybean MON 87705, the *E. coli*-derived CP4 EPSPS protein was used for safety assessment studies.

The CP4 EPSPS protein levels in soybean MON 87705 were measured in replicated samples of leaf, root, forage, and mature seeds from five field sites using a validated enzyme-linked immunosorbent assay (ELISA). Monsanto reports that the range of CP4 EPSPS protein in soybean MON 87705 leaf, root, forage, and mature seeds was 40 to 1000 micrograms per gram dry weight (μg/g DW). The mean CP4 EPSPS protein concentrations (μg/g DW) in soybean MON 87705 were 200 to 530 for leaf at four vegetative stages, 120 for root, 110 for forage, and 77 for mature seeds.

Assessment of Potential for Allergenicity and Toxicity

Monsanto performed studies to assess the potential for allergenicity and toxicity of the CP4 EPSPS protein.

Monsanto performed a sequence similarity search of the CP4 EPSPS amino acid sequence against the TOX_2009 database (which contains sequences of proteins that may be harmful to human and animal health) using the FASTA algorithm. Monsanto states that the results of the sequence comparisons show that no relevant alignments (alignments that display an E-score of less than 1×10^{-5}) were observed between the CP4 EPSPS sequence and sequences in the TOX_2009 database.[2] Monsanto thus reports that no structurally relevant similarity exists between the CP4 EPSPS protein and any known toxins or other biologically active proteins that would be harmful to human or animal health.

Monsanto conducted an acute oral toxicity study in mice. A single dose of up to 572 milligrams CP4 EPSPS protein per kilogram body weight (mg/kg) was administered by gavage to ten male and ten female mice. No treatment-related effects on survival, clinical observations, body weight gain, food consumption, or gross pathology were observed. Monsanto thus concludes that the No Observable Adverse Effect Level (NOAEL) for CP4 EPSPS is 572 mg/kg.

Monsanto evaluated the likelihood that health risks would arise from the acute dietary intake of CP4 EPSPS protein from consumption of food derived from soybean MON 87705. Monsanto calculated the margins of exposure (MOEs) for the general population and for non-nursing infants to be 43,600 and 1,100, respectively. Monsanto concludes that these large MOEs indicate that there are no meaningful risks to human health from dietary exposure to the CP4 EPSPS protein derived from soybean MON 87705.

Monsanto notes that soybean is one of the eight major food allergens. Monsanto compared the amino acid sequence of the CP4 EPSPS protein to the amino acid sequences of known allergens in the Food Allergy Research and Resource Program Database (FARRP_2009) using the FASTA sequence alignment program. None of the identified alignments meet the threshold of greater than or equal to 35% identity over 80 amino acids, and no contiguous stretches of 8 or greater amino acids are shared between the CP4 EPSPS protein and the proteins in the allergen database.[3]

Monsanto also reports that the CP4 EPSPS protein is rapidly (< 15 seconds) degraded in simulated gastric fluid *in vitro*.

Based on the results of the allergenicity and toxicity studies, Monsanto concludes that the CP4 EPSPS protein poses a negligible risk to human and animal health upon consumption.

Evidence for Suppression of *FATB1-A* and *FAD2-1A* Genes

Monsanto examined the expression of RNA from the endogenous *FAD2-1A* and *FATB1-A* genes by Northern hybridization analyses. The results of these analyses show that levels of transcripts of *FATB1-A* and *FAD2-1A* in immature seeds of soybean MON 87705 are significantly diminished in comparison with those from the control soybean (A3525). This decreased level of transcription confirms that the endogenous *FATB1-A* and *FAD2-1A* genes are functionally suppressed in soybean MON 87705.

Food & Feed Uses of Soybean

Soybean

Monsanto describes historical and current uses of soybean in food and animal feed, and states that it intends to market soybean MON 87705 for these same purposes. Soybean seeds are processed primarily into oil and meal. Commodity soybean oil is rich in polyunsaturated fatty acids and is commonly used as a salad and cooking oil and in the production of margarine and other food ingredients. Monsanto states that soybean MON 87705 was developed to produce an oil with an unsaturated fatty acid profile more like olive oil or canola oil, while having lower levels of saturated fatty acids like commodity soybean oil. A small fraction of soybean meal is further processed into soy flours and soy proteins for a variety of food uses. Traditional foods prepared from soybeans include tofu, miso, soymilk, tempeh, and soy sauce.

Soybean meal is the most common supplemental protein source in U.S. livestock and poultry rations due to its nutrient composition, availability, and price. Soybean meal is processed in moist heat to inactivate trypsin inhibitors and lectins, which are antinutrients occurring in raw soybeans. Although soybean and soybean-derived products have some use (~5%) in the manufacture of industrial products including soaps, inks, paints, disinfectants, and biodiesel, the food and feed uses of soybean and its processed products remain the predominant use of soybeans produced in the U.S. and globally.

Composition

Scope of Analysis

Monsanto analyzed the composition of forage and seed from soybean MON 87705 and the control soybean A3525 to assess whether the transgenic soybean is similar to non-transgenic soybeans except for the intended change in fatty acid composition. Monsanto also assessed the composition of forage and seed from a total of twenty conventional reference soybean varieties ("reference varieties") grown under the same field conditions as soybeans MON 87705 and A3525. Monsanto used data derived from those 20 reference varieties to generate a 99% tolerance interval for each component.[4] Monsanto states that the data illustrate the natural variability in commercially grown soybean varieties. The compositional analysis included key nutrients and antinutrients.

Study Design

Monsanto states that soybean MON 87705, soybean A3525, and 20 conventional soybean varieties (four different conventional soybean varieties per site) were included in this study. However, one reference variety, damaged by an early frost, was excluded from the study. Seed and forage were obtained from soybeans grown in three replicated plots, planted in a randomized complete block design, at each of five field sites across Chile during the 2007/2008 growing season. Monsanto measured and evaluated 60 components in seed and seven in forage. Monsanto analyzed forage for crude protein, crude fat, moisture, ash, carbohydrates by calculation, acid detergent fiber (ADF), and neutral detergent fiber (NDF). Compositional analysis of seed included crude protein, crude fat, moisture, ash, carbohydrates by calculation, ADF, NDF, fatty acids (26: C8-C24), 18 amino acids, Vitamin E, isoflavones (daidzein, genistein, and glycitein), and antinutrients (phytic acid, trypsin inhibitor, lectin, raffinose, and stachyose). Of the measured components, 17 fatty acids in seed had more than 50% of the observations below the assay limit of quantitation and these components were not statistically analyzed. Thus, statistical analyses were conducted for 50 components (43 in seed and seven in forage).

The data sets were assessed using a mixed model of variance. Six sets of statistical analyses were conducted, five based on the data from each of the replicated field sites (individual-site) and the sixth based on data from a combination of all five field sites (combined-site). Each individual component for soybean MON 87705 was compared with that of soybean A3525. Statistical significance was declared at 5% level ($P \leq 0.05$). When a statistically significant difference in a component was detected between soybeans MON 87705 and A3525 in the combined-site comparison, an analysis was conducted to assess whether the difference was biologically meaningful from a food and feed safety or nutritional perspective. This analysis included reproducibility across individual sites, magnitude of differences, and comparisons of soybean MON 87705 mean component values to the 99% tolerance interval for the population of reference varieties (grown concurrently) and values in published literature and the International Life Sciences Institute Crop Composition Database (ILSI-CCD).[5]

Results of analyses:

Compositional analysis of soybean forage

A significant difference between soybeans MON 87705 and A3525 was detected ($P < 0.02$) for ash. Monsanto reports that the mean ash level measured for both soybeans MON 87705 and A3525 falls within the 99% tolerance interval calculated by Monsanto for the reference varieties, and within the range of literature values for this component. Thus, Monsanto concludes that the difference in ash content is not biologically significant.

Compositional analysis of soybean seed

For the combined-site analyses, a statistically significant difference between soybeans MON 87705 and A3525 was detected ($P < 0.048$ and $P < 0.043$) for arginine and cystine (as % of dry weight (DW)). Monsanto reports that the mean arginine and cystine levels measured for both soybeans MON 87705 and A3525 fall within the 99% tolerance intervals calculated by Monsanto for the reference varieties and within the range of literature values. A significant difference between soybeans MON 87705 and A3525 was also detected ($P < 0.001$) for crude fat (% DW). Monsanto reports that the mean crude fat levels measured for both soybeans MON 87705 and A3525 fall within the 99% tolerance interval calculated by Monsanto for the reference varieties and within the range of literature values. Monsanto concludes that the small differences in arginine, cystine, and total fat are not considered biologically meaningful for food and feed safety or nutrition.

Intended Compositional Change - Fatty Acids

Monsanto states that soybean MON 87705 was developed to produce soybean oil with higher levels of 18:1 oleic acid, an associated decrease in 18:2 linoleic acid and lower levels of 16:0 palmitic and 18:0 stearic acids through suppression of FAD2 and FATB RNAs. Thus, Monsanto reports that there are statistically significant decreases in palmitic acid ($P < 0.001$) and linoleic acid ($P < 0.001$) and an increase in oleic acid ($P < 0.001$), which are associated with the intended effects of the change in this variety (Table 1). Monsanto states that although stearic acid levels are statistically lower in soybean MON 87705 when compared with soybean A3525, all values for soybeans MON 87705 and A3525 fall within the 99% tolerance interval calculated by Monsanto for the reference varieties and within the range of values in the ILSI database. The three remaining statistically significant differences in the combined-site analysis are 18:3 linolenic, 20:0 arachidic, and 20:1 eicosenoic acids. The decrease in linolenic acid is expected, given that this fatty acid is produced from linoleic acid which is reduced by the suppression of the *FAD2* gene. Although arachidic acid levels are statistically lower in soybean MON 87705 when compared with soybean A3525, all values for soybeans MON 87705 and A3525 fall within the 99% tolerance interval calculated by Monsanto for the reference varieties. The mean level of eicosenoic acid in soybean MON 87705 is significantly higher than in soybean A3525 in the combined-site and all five individual-site analyses. However, the absolute magnitude of these differences is small (< 0.18% of total fatty acids). The combined-site mean for eicosenoic acid (0.34% of total fatty acids) is slightly (0.09% of total fatty acids) outside the upper end (0.25% of total FA) of the 99% tolerance interval, but within the values reported in the ILSI-CCD. Monsanto concludes that the small differences in linolenic, arachidic, and eicosenoic acids are not considered biologically meaningful for food and feed safety or nutrition.

Table 1. Summary of Key Fatty Acid Levels in Soybean MON 87705 vs. its Isogenic Control (Soybean A3525) and Conventional Varieties

Fatty Acid	Soybean MON 87705[Range]	Control(Soybean A3525)[Range]	Conventional Tolerance Interval[a]
16:0 Palmitic	2.25-2.44	10.51-11.08	7.62, 12.55
18:0 Stearic	3.07-3.82	4.24-4.85	2.87, 7.15
18:1 Oleic	73.13-79.17	21.41-25.08	18.40, 30.22
18:2 Linoleic	7.85-12.42	51.68-53.89	47.75, 56.46

[a]A 99% tolerance interval represents, with 95% confidence, 99% of the values contained in a population of conventional soybean varieties grown at the same location as the test varieties.

Compositional analysis of processed fractions (meal, oil, protein isolates, and lecithin)

Seed from soybeans MON 87705 and A3525 were collected from two plots at each of two sites across the U.S. during the 2007 growing season. In addition, 12 conventional soybean varieties produced at three locations in separate U.S. field trials in 2007 were included for the generation of a 99% tolerance interval. A subsample of each soybean MON 87705, control soybean (A3525), and reference soybean seed was processed into toasted and defatted (TD) soybean meal, refined bleached and deodorized (RBD) oil, protein isolate, and crude lecithin. Seed and a subsample of the processed products from MON 87705, A3525, and the 12 conventional soybean varieties were analyzed for composition. In all, 27 components were analyzed in meal, 39 in oil, 19 in protein isolates, and 4 in lecithin. The components in soybean meal included moisture, crude protein, crude fat, ash, carbohydrates by calculation, ADF, NDF, amino acids (18), phytic acid, and trypsin inhibitor.

Oil samples were analyzed for fatty acids (38; C8-C24) and vitamin E. Of the measured components, 21 fatty acids in oil had more than 50% of the observations below the assay limit of quantitation and these components were not statistically analyzed. The components in protein isolates included amino acids (18) and moisture. The components in lecithin were L-α-phosphatidic acid, L-α-phosphatidylcholine, L-α-phosphatidylethanolamine, and L-α-phosphatidylinositol.

Analyses of components in the processed product samples (meal, oil, protein isolates, and lecithin) show no statistically significant differences between soybeans MON 87705 and A3525 for 49 of 68 comparisons. In soybean meal, significant differences were observed for alanine ($P < 0.019$), glycine ($P < 0.023$), isoleucine ($P < 0.006$), lysine ($P < 0.030$), valine ($P < 0.003$), and NDF ($P < 0.016$). For these five amino acids, the absolute magnitude of the mean differences from soybean A3525 were small (< 0.1% DW) and the mean values for soybeans MON 87705 and A3525 fall within the 99% tolerance interval for the reference varieties and also within the range of published values for conventional soybean varieties. Monsanto reports that the mean NDF values measured for soybeans MON 87705 and A3525 fall within the 99% tolerance intervals for reference varieties and also within the range of published values for conventional soybean varieties. Of the 17 fatty acids that could be statistically analyzed, significant differences between soybeans MON 87705 and A3525 in RBD oil were observed for 13 fatty acids. Four of the 13 differences were expected as they were due to the intended changes in fatty acid levels as described above. For six of the remaining nine fatty acids (myristic, palmitoleic, margaric, arachidic, eicosenoic, and behenic acids), the absolute magnitude of the differences between the mean values for soybeans MON 87705 and A3525 is less than 0.15% of total fatty acids and the soybean MON 87705 mean values fall within the 99% tolerance intervals for the reference varieties. The three remaining fatty acids [17:1 9cis heptadecenoic acid, 18:2 other trans isomer fatty acids (excluding 9trans,12trans linoleic), and 18:2 6cis,9cis octadecadienoic acid] are minor components in RBD oil (< 0.2% of total fatty acids) and were found in the processed oil and not in the seed prior to being processed. There are no statistically significant differences ($P < 0.05$) between soybeans MON 87705 and A3525 for the components measured in the protein isolate and crude lecithin fractions.

Monsanto states that the compositional and nutritional assessment supports the conclusion that, except for the intended changes in the levels of specific fatty acids, soybean MON 87705 is compositionally equivalent to conventional soybean varieties. Monsanto concludes that the small, but statistically significant, differences in the components mentioned above are not considered biologically meaningful for food and feed safety or nutrition.

Endogenous Allergens

Monsanto conducted a study to determine whether the transformation process may have increased the overall allergenicity of soybean MON 87705 compared to the conventional soybean variety. Using sera from clinically documented, soybean-allergic patients, Monsanto conducted immunoglobulin E (IgE) ELISA studies using protein extracts from soybeans MON 87705 and A3525. Monsanto reports that soybean-specific IgE binding to endogenous allergens in soybeans MON 87705 and A3525 is comparable with the IgE binding to conventional soybeans currently on the market. Therefore, Monsanto concludes that soybean MON 87705 does not pose an increased endogenous soybean allergen risk compared to conventional soybean varieties.

Fatty Acid Intake

Human Diet

Monsanto generated estimates of dietary exposure to various fatty acids from the consumption of oil from soybean MON 87705. Monsanto concludes that based on conservative intake estimates calculated on the assumption that oil from soybean MON 87705 would replace soybean oil currently used in a subset of targeted foods, the intake of oleic acid would increase, while the intakes of palmitic and linoleic acids would decrease and the total fat intake would not be affected. Since humans consume oils from a variety of sources, Monsanto concludes that consumption of oil from soybean MON 87705 will not affect the human diet.

Animal Diets

When oil is removed from the soybean, a defatted meal is generated that is used as a protein supplement for animal feed. In an amendment dated January 21, 2010, Monsanto provided examples of poultry and swine diets to demonstrate that the reduced intake of linoleic acid would not lead to a nutritional deficiency for animals consuming feeds containing meal derived from soybean MON 87705. Even though meal derived from soybean MON 87705 would have reduced amounts of linoleic acid, Monsanto states that the animals' linoleic acid requirements would be easily met by other ingredients that would be included in the diet, such as corn.

Common or Usual Name of the Oil Product

Based on the intended change in fatty acid composition, it is our understanding that Monsanto has concluded that the common or usual name "high oleic soybean oil" is appropriate to distinguish oil from soybean MON 87705 from that of conventional soybean varieties.

Conclusion

Monsanto has concluded that, with the exception of the intended change in fatty acid composition, soybean MON 87705 and the foods and feeds derived from it are not materially different in composition, safety, or any other relevant parameter from other soybean varieties now grown, marketed, and consumed in the U.S. At this time, based on Monsanto's data and information, the agency considers Monsanto's consultation on soybean MON 87705 to be complete.

Shayla West-Barnette, Ph.D.

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[1]The analytical techniques discussed in the submission include N-terminal sequence analysis, mass determination of the tryptic peptides by matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS), sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE), Western hybridization analysis, CP4 EPSPS enzymatic activity analysis, and glycosylation analysis.

[2]The E-score was set at $< 1 \times 10^{-5}$ to ensure that sequences have sufficient sequence similarity to infer homology.

[3]These criteria can be found in the guidelines for the evaluation of the potential allergenicity of introduced proteins, published in 2003 by the Codex Alimentarius Commission.

[4]A 99% tolerance interval represents, with 95% confidence, 99% of the values contained in the population of conventional soybean varieties.

[5]Monsanto used version 3.0 (accessed on 8-27-06) of the ILSI-CCD in its analysis. The database is maintained by ILSI and can be accessed at http://www.cropcomposition.org/.

APPENDIX B

APHIS THREATENED AND ENDANGERED SPECIES DECISION TREE FOR FWS CONSULTATIONS

DECISION TREE ON WHETHER SECTION 7 CONSULTATION WITH FWS IS TRIGGERED FOR PETITIONS OF TRANSGENIC PLANTS

This decision tree document is based on the phenotypes (traits) that have been permitted for environmental releases under APHIS oversight (for a list of approved notifications and environmental releases, visit Information Systems for Biotechnology, at http://isb.vt.edu.) APHIS will re-evaluate and update this decision document as it receives new applications for environmental releases of new traits that are genetically engineered into plants.

BACKGROUND

For each transgene(s)/transgenic plant the following information, data, and questions will be addressed by APHIS, and the EAs on each petition will be publicly available. APHIS review will encompass:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant),
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES.

FDA published a policy in 1992 on foods derived from new plant varieties, including those derived from transgenic plants (http://vm.cfsan.fda.gov/~lrd/fr92529b.html and http://vm.cfsan.fda.gov/~lrd/consulpr.html). The FDA's policy requires that genetically engineered foods meet the same rigorous safety standards as is required of all other foods. Many of the food crops currently being developed using biotechnology do not contain substances that are significantly different from those already consumed by human and thus do not require pre-market approval. Consistent with its 1992 policy, FDA expects developers to consult with the agency on safety and regulatory questions. A list of consultations is available at http://vm.cfsan.fda.gov/~lrd/biocon.html . APHIS considers the status and conclusion of the FDA consultations in its EAs.

Below is a description of our review process to whether a consultation with U.S. Fish and Wildlife Service is necessary.

If the answer to any of the questions 1-4 below is yes, APHIS will contact FWS to determine if a consultation is required:

Is the transgenic plant sexually compatible with a TE plant[3] without human intervention?

1. Are naturally occurring plant toxins (toxicants) or allelochemicals increased over the normal concentration range in parental plant species?
2. Does the transgene product or its metabolites have any significant similarities to known toxins[4]?
3. Will the new phenotype(s) imparted to the transgenic plant allow the plant to be grown or employed in new habitats (e.g., outside agro-ecosystem)[5].
4. Does the pest resistance[6] gene act by one of the mechanisms listed below? If the answer is YES then a consultation with U.S. Fish and Wildlife Service is NOT necessary.

A. The transgene acts only in one or more of the following ways:

i. As a structural barrier to either the attachment of the pest to the host, to penetration of the host by the pest, to the spread of the pest in the host plant (e.g., the production of lignin, callose, thickened cuticles);
ii. In the plant by inactivating or resisting toxins or other disease causing substances produced by the pest;
iii. By creating a deficiency in the host of a component required for growth of the pest (such as with fungi and bacteria);
iv. By initiating, enhancing, or potentiating the endogenous host hypersensitive disease resistance response found in the plant;
v. In an indirect manner that does not result in killing or interfering with normal growth, development, or behavior of the pest;

B. A pest derived transgene is expressed in the plant to confer resistance to that pest (such as with coat protein, replicase, and pathogen virulence genes).

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[3] APHIS will provide FWS a draft EA that will address the impacts, if any, of gene movement to the TES plant

[4] Via a comparison of the amino acid sequence of the transgene's protein with those found in the protein databases like PIR, Swiss-Prot and HIV amino acid data bases.

[5] Such phenotypes might include tolerance to environmental stresses such as drought, salt, frost, aluminum or heavy metals.

[6] Pest resistance would include any toxin or allelochemical that prevents, destroys, repels or mitigates a pest or effects any vertebrate or invertebrate animal, plant, or microorganism.

For the biotechnologist:

Depending on the outcome of the decision tree, initial the appropriate decision below and incorporate its language into the EA. Retain a hard copy of this decision document in the petition's file.

________ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS has reached a determination that the release following a determination of non-regulated status would have no effects on listed threatened or endangered species and consequently, a written concurrence or formal consultation with the Fish and Wildlife Service is not required for this EA.

________ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of non-regulated status is not likely to adversely affect any listed threatened or endangered species and consequently obtained written concurrence from the Fish and Wildlife Service.

________ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of non-regulated status is likely to affect adversely one or more listed threatened or endangered species and has initiated a formal consultation with the Fish and Wildlife Service.

APPENDIX C

THREATENED AND ENDANGERED SPECIES STATE LISTS

Alabama (US-FWS, 2011a)

Animals – 103 Listings

Status	Species
E	Acornshell, southern (*Epioblasma othcaloogensis*)
T	Bankclimber, purple (mussel) (*Elliptoideus sloatianus*)
E	Bat, gray (*Myotis grisescens*)
E	Bat, Indiana (*Myotis sodalis*)
E	Bean, Cumberland (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Villosa trabalis*)
E	Beetle, American burying (Nicrophorus americanus)
E	Blossom, tubercled (pearlymussel) Entire Range; Except where listed as Experimental Populations (Epioblasma torulosa torulosa)
E	Blossom, turgid (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma turgidula*)
E	Blossom, yellow (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma florentina florentina*)
E	Butterfly, Mitchell's satyr (Neonympha mitchellii mitchellii)
E	Campeloma, slender (*Campeloma decampi*)
E	Cavefish, Alabama (*Speoplatyrhinus poulsoni*)
T	Chub, spotfin Entire (*Erimonax monachus*)
E	Clubshell Entire Range; Except where listed as Experimental Populations (Pleurobema clava)
E	Clubshell, black (Pleurobema curtum)
E	Clubshell, ovate (*Pleurobema perovatum*)
E	Clubshell, southern (*Pleurobema decisum*)
E	Combshell, Cumberlandian Entire Range; Except where listed as Experimental Populations (*Epioblasma brevidens*)
E	Combshell, southern (*Epioblasma penita*)
E	Combshell, upland (*Epioblasma metastriata*)
E	Darter, amber (Percina antesella)
E	Darter, boulder (*Etheostoma wapiti*)
T	Darter, goldline (*Percina aurolineata*)
T	Darter, slackwater (*Etheostoma boschungi*)
T	Darter, snail (*Percina tanasi*)
E	Darter, vermilion (*Etheostoma chermocki*)
E	Darter, watercress (*Etheostoma nuchale*)
T	Elimia, lacy (snail) (*Elimia crenatella*)
E	Fanshell (*Cyprogenia stegaria*)
E	Frog, Mississippi gopher Wherever found west of Mobile and Tombigbee Rivers in AL, MS, and LA (Rana capito sevosa)
T	Heelsplitter, Alabama (=inflated) (*Potamilus inflatus*)
E	Hornsnail, rough (*Pleurocera foremani*)
E	Kidneyshell, triangular (*Ptychobranchus greenii*)

Status	**Species**
E	Lampmussel, Alabama Entire Range; Except where listed as Experimental Populations (*Lampsilis virescens*)
E	Lilliput, pale (pearlymussel) (*Toxolasma cylindrellus*)
E	Lioplax, cylindrical (snail) (*Lioplax cyclostomaformis*)
E	Manatee, West Indian (*Trichechus manatus*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (Quadrula fragosa)
T	Moccasinshell, Alabama (*Medionidus acutissimus*)
E	Moccasinshell, Coosa (*Medionidus parvulus*)
E	Moccasinshell, Gulf (*Medionidus penicillatus*)
E	Monkeyface, Cumberland (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Quadrula intermedia*)
E	Mouse, Alabama beach (*Peromyscus polionotus ammobates*)
E	Mouse, Perdido Key beach (*Peromyscus polionotus trissyllepsis*)
T	Mucket, orangenacre (*Lampsilis perovalis*)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)
E	Mussel, oyster Entire Range; Except where listed as Experimental Populations (*Epioblasma capsaeformis*)
E	Mussel, scaleshell (Leptodea leptodon)
E	Panther, Florida (Puma (=Felis) concolor coryi)
E	Pearlymussel, cracking Entire Range; Except where listed as Experimental Populations (*Hemistena lata*)
E	Pearlymussel, dromedary Entire Range; Except where listed as Experimental Populations (*Dromus dromas*)
E	Pearlymussel, littlewing (*Pegias fabula*)
E	Pebblesnail, flat (*Lepyrium showalteri*)
E	Pigtoe, dark (*Pleurobema furvum*)
E	Pigtoe, finerayed Entire Range; Except where listed as Experimental Populations (*Fusconaia cuneolus*)
E	Pigtoe, flat (*Pleurobema marshalli*)
E	Pigtoe, Georgia (*Pleurobema hanleyianum*)
E	Pigtoe, heavy (*Pleurobema taitianum*)
E	Pigtoe, oval (*Pleurobema pyriforme*)
E	Pigtoe, rough (*Pleurobema plenum*)
E	Pigtoe, shiny Entire Range; Except where listed as Experimental Populations (*Fusconaia cor*)
E	Pigtoe, southern (*Pleurobema georgianum*)
E	Pimpleback, orangefoot (pearlymussel) (*Plethobasus cooperianus*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
T	Pocketbook, finelined (*Lampsilis altilis*)
E	Pocketbook, shinyrayed (*Lampsilis subangulata*)
E	purple cat's paw (=purple cat's paw pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma obliquata obliquata*)
E	Riffleshell, tan (Epioblasma florentina walkeri (=E. walkeri))
E	Ring pink (mussel) (*Obovaria retusa*)
E	Riversnail, Anthony's Entire Range; Except where listed as Experimental Populations (*Athearnia anthonyi*)
E	Rocksnail, interrupted (=Georgia) (*Leptoxis foremani*)
T	Rocksnail, painted (*Leptoxis taeniata*)
E	Rocksnail, plicate (*Leptoxis plicata*)
T	Rocksnail, round (*Leptoxis ampla*)
T	Salamander, frosted flatwoods (Ambystoma cingulatum)
T	Salamander, Red Hills (*Phaeognathus hubrichti*)
E	Sawfish, smalltooth (Pristis pectinata)

Status	**Species**
T	Sculpin, pygmy (*Cottus paulus (=pygmaeus)*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, hawksbill (*Eretmochelys imbricata*)
E	Sea turtle, Kemp's ridley (*Lepidochelys kempii*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
T	Shiner, blue (*Cyprinella caerulea*)
E	Shiner, Cahaba (*Notropis cahabae*)
E	Shiner, palezone (*Notropis albizonatus*)
E	Shrimp, Alabama cave (*Palaemonias alabamae*)
T	Slabshell, Chipola (*Elliptio chipolaensis*)
E	Snail, armored (*Pyrgulopsis (=Marstonia) pachyta*)
E	Snail, tulotoma (*Tulotoma magnifica*)
T	Snake, eastern indigo (*Drymarchon corais couperi*)
E	Stirrupshell (*Quadrula stapes*)
E	Stork, wood AL, FL, GA, SC (*Mycteria americana*)
E	Sturgeon, Alabama (*Scaphirhynchus suttkusi*)
T	Sturgeon, gulf (*Acipenser oxyrinchus desotoi*)
T	Tortoise, gopher W of of Mobile/Tombigbee Rs. (*Gopherus polyphemus*)
E	Turtle, Alabama red-belly (*Pseudemys alabamensis*)
T	Turtle, flattened musk species range clarified (*Sternotherus depressus*)
E	Wartyback, white (pearlymussel) (*Plethobasus cicatricosus*)
E	Whale, finback (*Balaenoptera physalus*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 19 listings

Status	**Species**
T	Amphianthus, little (*Amphianthus pusillus*)
T	Bladderpod, lyrate (*Lesquerella lyrata*)
T	Button, Mohr's Barbara (*Marshallia mohrii*)
E	Chaffseed, American (*Schwalbea americana*)
T	Fern, Alabama streak-sorus (*Thelypteris pilosa var. alabamensis*)
T	Fern, American hart's-tongue (*Asplenium scolopendrium var. americanum*)
E	Grass, Tennessee yellow-eyed (*Xyris tennesseensis*)
E	Harperella (*Ptilimnium nodosum*)
E	Leather flower, Alabama (*Clematis socialis*)
E	Leather flower, Morefield's (*Clematis morefieldii*)
E	Pinkroot, gentian (*Spigelia gentianoides*)
E	Pitcher-plant, Alabama canebrake (*Sarracenia rubra alabamensis*)
E	Pitcher-plant, green (*Sarracenia oreophila*)
E	Pondberry (*Lindera melissifolia*)
T	Potato-bean, Price's (*Apios priceana*)
E	Prairie-clover, leafy (*Dalea foliosa*)

Status	Species
E	Quillwort, Louisiana (Isoetes louisianensis)
E	Trillium, relict (*Trillium reliquum*)
T	Water-plantain, Kral's (*Sagittaria secundifolia*)

Arkansas (US-FWS, 2011b)

Animals – 25 listings

Status	Species
E	Bat, gray (*Myotis grisescens*)
E	Bat, Indiana (*Myotis sodalis*)
E	Bat, Ozark big-eared (*Corynorhinus (=Plecotus) townsendii ingens*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Blossom, turgid (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma turgidula*)
T	Cavefish, Ozark (*Amblyopsis rosae*)
E	Crayfish, cave (*Cambarus aculabrum*)
E	Crayfish, cave (*Cambarus zophonastes*)
T	Darter, leopard (*Percina pantherina*)
T	fatmucket, Arkansas (*Lampsilis powellii*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (*Quadrula fragosa*)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)
E	Mussel, scaleshell (*Leptodea leptodon*)
E	Panther, Florida (*Puma (=Felis) concolor coryi*)
E	Pearlymussel, Curtis (*Epioblasma florentina curtisii*)
E	Pocketbook, fat (*Potamilus capax*)
E	Pocketbook, Ouachita rock (*Arkansia wheeleri*)
E	Pocketbook, speckled (*Lampsilis streckeri*)
T	Shagreen, Magazine Mountain (*Mesodon magazinensis*)
T	Shiner, Arkansas River Arkansas R. Basin (*Notropis girardi*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Woodpecker, ivory-billed entire (*Campephilus principalis*)
E	Woodpecker, red-cockaded (*Picoides borealis*)

Plants – 6 listings

Status	Species
T	bladderpod, Missouri (*Physaria filiformis*)
E	Clover, running buffalo (*Trifolium stoloniferum*)
E	Harperella (*Ptilimnium nodosum*)
T	*Geocarpon minimum* (No common name)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)

Status	Species
E	Pondberry (*Lindera melissifolia*)

Delaware (US-FWS, 2011c)

Animals – 16 listings

Status	Species
E	Beetle, American burying (Nicrophorus americanus)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Puma (=cougar), eastern (Puma (=Felis) concolor couguar)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, hawksbill (*Eretmochelys imbricata*)
E	Sea turtle, Kemp's ridley (*Lepidochelys kempii*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
E	Squirrel, Delmarva Peninsula fox Entire, except Sussex Co., DE (*Sciurus niger cinereus*)
E	Sturgeon, shortnose (*Acipenser brevirostrum*)
T	Turtle, bog (=Muhlenberg) northern (*Clemmys muhlenbergii*)
E	Wedgemussel, dwarf (Alasmidonta heterodon)
E	Whale, finback (*Balaenoptera physalus*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Whale, right (*Balaena glacialis (incl. australis)*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (Canis lupus)

Plants – 7 listings

Status	Species
T	Amaranth, seabeach (*Amaranthus pumilus*)
T	Beaked-rush, Knieskern's (Rhynchospora knieskernii)
E	Chaffseed, American (Schwalbea americana)
E	Dropwort, Canby's (*Oxypolis canbyi*)
T	Joint-vetch, sensitive (Aeschynomene virginica)
T	Pink, swamp (*Helonias bullata*)
T	Pogonia, small whorled (*Isotria medeoloides*)

Florida (US-FWS, 2011d)

Animals – 61 listings

Status	Species
T	Bankclimber, purple (mussel) (*Elliptoideus sloatianus*)
E	Bat, gray (*Myotis grisescens*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Butterfly, Schaus swallowtail (*Heraclides aristodemus ponceanus*)
T	Caracara, Audubon's crested FL pop. (*Polyborus plancus audubonii*)
T	Coral, elkhorn (*Acropora palmata*)

Status	Species
T	Coral, staghorn (*Acropora cervicornis*)
T	Crocodile, American FL pop. (*Crocodylus acutus*)
E	Darter, Okaloosa (*Etheostoma okaloosae*)
E	Deer, key (*Odocoileus virginianus clavium*)
E	Kite, Everglade snail FL pop. (*Rostrhamus sociabilis plumbeus*)
E	Manatee, West Indian (*Trichechus manatus*)
E	Moccasinshell, Gulf (*Medionidus penicillatus*)
E	Moccasinshell, Ochlockonee (*Medionidus simpsonianus*)
E	Mouse, Anastasia Island beach (*Peromyscus polionotus phasma*)
E	Mouse, Choctawhatchee beach (*Peromyscus polionotus allophrys*)
E	Mouse, Key Largo cotton (*Peromyscus gossypinus allapaticola*)
E	Mouse, Perdido Key beach (*Peromyscus polionotus trissyllepsis*)
T	Mouse, southeastern beach (*Peromyscus polionotus niveiventris*)
E	Mouse, St. Andrew beach (*Peromyscus polionotus peninsularis*)
E	Panther, Florida (*Puma (=Felis) concolor coryi*)
E	Pigtoe, oval (*Pleurobema pyriforme*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Pocketbook, shinyrayed (*Lampsilis subangulata*)
E	Rabbit, Lower Keys marsh (*Sylvilagus palustris hefneri*)
E	Rice rat lower FL Keys (*Oryzomys palustris natator*)
T	Salamander, frosted flatwoods (*Ambystoma cingulatum*)
E	salamander, Reticulated flatwoods (*Ambystoma bishopi*)
E	Sawfish, smalltooth (*Pristis pectinata*)
T	scrub-jay, Florida (*Aphelocoma coerulescens*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, green FL, Mexico nesting pops. (*Chelonia mydas*)
E	Sea turtle, hawksbill (*Eretmochelys imbricata*)
E	Sea turtle, Kemp's ridley (*Lepidochelys kempii*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
E	Seal, Caribbean monk (*Monachus tropicalis*)
T	Shrimp, Squirrel Chimney Cave (*Palaemonetes cummingi*)
T	Skink, bluetail mole (*Eumeces egregius lividus*)
T	Skink, sand (*Neoseps reynoldsi*)
T	Slabshell, Chipola (*Elliptio chipolaensis*)
T	Snail, Stock Island tree (*Orthalicus reses (not incl. nesodryas)*)
T	Snake, Atlantic salt marsh (*Nerodia clarkii taeniata*)
T	Snake, eastern indigo (*Drymarchon corais couperi*)
E	Sparrow, Cape Sable seaside (*Ammodramus maritimus mirabilis*)
E	Sparrow, Florida grasshopper (*Ammodramus savannarum floridanus*)
E	Stork, wood AL, FL, GA, SC (*Mycteria americana*)
T	Sturgeon, gulf (*Acipenser oxyrinchus desotoi*)
E	Sturgeon, shortnose (*Acipenser brevirostrum*)
T	Tern, roseate Western Hemisphere except NE U.S. (*Sterna dougallii dougallii*)
E	Three-ridge, fat (mussel) (*Amblema neislerii*)
E	Vole, Florida salt marsh (*Microtus pennsylvanicus dukecampbelli*)

[Status]()	Species
E	Warbler (=wood), Bachman's (*Vermivora bachmanii*)
E	Warbler, Kirtland's (*Dendroica kirtlandii*)
E	Whale, finback (*Balaenoptera physalus*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Whale, right (*Balaena glacialis (incl. australis)*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Wolf, red except where EXPN (*Canis rufus*)
E	Woodpecker, red-cockaded (*Picoides borealis*)
E	Woodrat, Key Largo (*Neotoma floridana smalli*)

Plants – 55 listings

Status	Species
E	Aster, Florida golden (*Chrysopsis floridana*)
E	Beargrass, Britton's (*Nolina brittoniana*)
E	Beauty, Harper's (*Harperocallis flava*)
E	Bellflower, Brooksville (*Campanula robinsiae*)
T	Birds-in-a-nest, white (*Macbridea alba*)
E	Blazingstar, scrub (*Liatris ohlingerae*)
T	Bonamia, Florida (*Bonamia grandiflora*)
T	Buckwheat, scrub (*Eriogonum longifolium var. gnaphalifolium*)
T	Butterwort, Godfrey's (*Pinguicula ionantha*)
E	Cactus, Key tree (*Pilosocereus robinii*)
E	Campion, fringed (*Silene polypetala*)
E	Chaffseed, American (*Schwalbea americana*)
E	Cladonia, Florida perforate (*Cladonia perforata*)
E	Fringe-tree, pygmy (*Chionanthus pygmaeus*)
T	Gooseberry, Miccosukee (*Ribes echinellum*)
E	Gourd, Okeechobee (*Cucurbita okeechobeensis ssp. okeechobeensis*)
E	Harebells, Avon Park (*Crotalaria avonensis*)
E	Hypericum, highlands scrub (*Hypericum cumulicola*)
E	Jacquemontia, beach (*Jacquemontia reclinata*)
E	Lead-plant, Crenulate (*Amorpha crenulata*)
E	Lupine, scrub (*Lupinus aridorum*)
E	Meadowrue, Cooley's (*Thalictrum cooleyi*)
E	Milkpea, Small's (*Galactia smallii*)
E	Mint, Garrett's (*Dicerandra christmanii*)
E	Mint, Lakela's (*Dicerandra immaculata*)
E	Mint, longspurred (*Dicerandra cornutissima*)
E	Mint, scrub (*Dicerandra frutescens*)
E	Mustard, Carter's (*Warea carteri*)
E	Pawpaw, beautiful (*Deeringothamnus pulchellus*)
E	Pawpaw, four-petal (*Asimina tetramera*)
E	Pawpaw, Rugel's (*Deeringothamnus rugelii*)
T	Pigeon wings (*Clitoria fragrans*)

Status	Species
E	Pinkroot, gentian (*Spigelia gentianoides*)
E	Plum, scrub (*Prunus geniculata*)
E	Polygala, Lewton's (*Polygala lewtonii*)
E	Polygala, tiny (*Polygala smallii*)
E	Pondberry (Lindera melissifolia)
E	Prickly-apple, fragrant (*Cereus eriophorus var. fragrans*)
E	Rhododendron, Chapman (*Rhododendron chapmanii*)
E	Rosemary, Apalachicola (*Conradina glabra*)
E	Rosemary, Etonia (*Conradina etonia*)
E	Rosemary, short-leaved (*Conradina brevifolia*)
E	Sandlace (*Polygonella myriophylla*)
T	Seagrass, Johnson's (*Halophila johnsonii*)
T	Skullcap, Florida (*Scutellaria floridana*)
E	Snakeroot (*Eryngium cuneifolium*)
E	Spurge, deltoid (*Chamaesyce deltoidea ssp. deltoidea*)
T	Spurge, Garber's (*Chamaesyce garberi*)
T	Spurge, telephus (*Euphorbia telephioides*)
E	Torreya, Florida (*Torreya taxifolia*)
E	Warea, wide-leaf (*Warea amplexifolia*)
E	Water-willow, Cooley's (*Justicia cooleyi*)
T	Whitlow-wort, papery (*Paronychia chartacea*)
E	Wireweed (*Polygonella basiramia*)
E	Ziziphus, Florida (*Ziziphus celata*)

Georgia (US-FWS, 2011e)

Animals – 53 listings

Status	Species
E	Acornshell, southern (*Epioblasma othcaloogensis*)
T	Bankclimber, purple (mussel) (*Elliptoideus sloatianus*)
E	Bat, gray (*Myotis grisescens*)
E	Bat, Indiana (*Myotis sodalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
T	Chub, spotfin Entire (*Erimonax monachus*)
E	Clubshell, ovate (*Pleurobema perovatum*)
E	Clubshell, southern (*Pleurobema decisum*)
E	Combshell, upland (*Epioblasma metastriata*)
E	Darter, amber (*Percina antesella*)
T	Darter, Cherokee (*Etheostoma scotti*)
E	Darter, Etowah (*Etheostoma etowahae*)
T	Darter, goldline (*Percina aurolineata*)
T	Darter, snail (*Percina tanasi*)
E	Hornsnail, rough (*Pleurocera foremani*)
E	Kidneyshell, triangular (*Ptychobranchus greenii*)
E	Lioplax, cylindrical (snail) (*Lioplax cyclostomaformis*)

Status	Species
E	Logperch, Conasauga (*Percina jenkinsi*)
E	Manatee, West Indian (*Trichechus manatus*)
T	Moccasinshell, Alabama (*Medionidus acutissimus*)
E	Moccasinshell, Coosa (*Medionidus parvulus*)
E	Moccasinshell, Gulf (*Medionidus penicillatus*)
E	Moccasinshell, Ochlockonee (*Medionidus simpsonianus*)
E	Mussel, oyster Entire Range; Except where listed as Experimental Populations (*Epioblasma capsaeformis*)
E	Panther, Florida (*Puma (=Felis) concolor coryi*)
E	Pigtoe, Georgia (*Pleurobema hanleyianum*)
E	Pigtoe, oval (*Pleurobema pyriforme*)
E	Pigtoe, southern (*Pleurobema georgianum*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
T	Pocketbook, finelined (*Lampsilis altilis*)
E	Pocketbook, shinyrayed (*Lampsilis subangulata*)
E	Riversnail, Anthony's Entire Range; Except where listed as Experimental Populations (*Athearnia anthonyi*)
E	Rocksnail, interrupted (=Georgia) (*Leptoxis foremani*)
T	Salamander, frosted flatwoods (*Ambystoma cingulatum*)
E	salamander, Reticulated flatwoods (*Ambystoma bishopi*)
E	Sawfish, smalltooth (*Pristis pectinata*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, hawksbill (*Eretmochelys imbricata*)
E	Sea turtle, Kemp's ridley (*Lepidochelys kempii*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
T	Shiner, blue (*Cyprinella caerulea*)
T	Snake, eastern indigo (*Drymarchon corais couperi*)
E	Stork, wood AL, FL, GA, SC (*Mycteria americana*)
T	Sturgeon, gulf (*Acipenser oxyrinchus desotoi*)
E	Sturgeon, shortnose (*Acipenser brevirostrum*)
T	Tern, roseate Western Hemisphere except NE U.S. (*Sterna dougallii dougallii*)
E	Three-ridge, fat (mussel) (*Amblema neislerii*)
E	Whale, finback (*Balaenoptera physalus*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Whale, right (*Balaena glacialis (incl. australis)*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Woodpecker, red-cockaded (*Picoides borealis*)

Plants – 24 listings

Status	Species
T	Amphianthus, little (*Amphianthus pusillus*)
T	Button, Mohr's Barbara (*Marshallia mohrii*)
E	Campion, fringed (*Silene polypetala*)
E	Chaffseed, American (*Schwalbea americana*)
E	Coneflower, smooth (*Echinacea laevigata*)

Status	Species
E	Dropwort, Canby's (*Oxypolis canbyi*)
E	Grass, Tennessee yellow-eyed (*Xyris tennesseensis*)
E	Harperella (*Ptilimnium nodosum*)
E	Leather flower, Alabama (Clematis socialis)
E	Meadowrue, Cooley's (Thalictrum cooleyi)
T	Pink, swamp (*Helonias bullata*)
E	Pitcher-plant, green (*Sarracenia oreophila*)
T	Pogonia, small whorled (*Isotria medeoloides*)
E	Pondberry (*Lindera melissifolia*)
E	Quillwort, black spored (*Isoetes melanospora*)
E	Quillwort, mat-forming (*Isoetes tegetiformans*)
E	Rattleweed, hairy (*Baptisia arachnifera*)
T	Skullcap, large-flowered (*Scutellaria montana*)
T	Spiraea, Virginia (*Spiraea virginiana*)
E	Sumac, Michaux's (*Rhus michauxii*)
E	Torreya, Florida (*Torreya taxifolia*)
E	Trillium, persistent (*Trillium persistens*)
E	Trillium, relict (*Trillium reliquum*)
T	Water-plantain, Kral's (*Sagittaria secundifolia*)

Illinois (US-FWS, 2011f)

Animals – 26 listings

Status	Species
E	Amphipod, Illinois cave (*Gammarus acherondytes*)
E	Bat, gray (*Myotis grisescens*)
E	Bat, Indiana (*Myotis sodalis*)
E	Beetle, American burying (Nicrophorus americanus)
E	Blossom, tubercled (pearlymussel) Entire Range; Except where listed as Experimental Populations (Epioblasma torulosa torulosa)
E	Butterfly, Karner blue (*Lycaeides melissa samuelis*)
E	Clubshell Entire Range; Except where listed as Experimental Populations (*Pleurobema clava*)
E	Dragonfly, Hine's emerald (*Somatochlora hineana*)
E	Fanshell (*Cyprogenia stegaria*)
E	Higgins eye (pearlymussel) (*Lampsilis higginsii*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (Quadrula fragosa)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)
E	Mussel, scaleshell (Leptodea leptodon)
E	Pearlymussel, cracking Entire Range; Except where listed as Experimental Populations (Hemistena lata)
E	Pimpleback, orangefoot (pearlymussel) (*Plethobasus cooperianus*)
E	Plover, piping Great Lakes watershed (*Charadrius melodus*)
E	Pocketbook, fat (*Potamilus capax*)
E	Puma (=cougar), eastern (Puma (=Felis) concolor couguar)
E	purple cat's paw (=purple cat's paw pearlymussel) Entire Range; Except where listed as Experimental Populations (Epioblasma obliquata obliquata)

Status	Species
E	Riffleshell, northern (Epioblasma torulosa rangiana)
E	Ring pink (mussel) (Obovaria retusa)
E	Snail, Iowa Pleistocene (*Discus macclintocki*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Wartyback, white (pearlymussel) (Plethobasus cicatricosus)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (Canis lupus)

Plants – 10 listings

Status	Species
T	Aster, decurrent false (*Boltonia decurrens*)
T	Bush-clover, prairie (*Lespedeza leptostachya*)
E	Clover, running buffalo (Trifolium stoloniferum)
T	Daisy, lakeside (*Hymenoxys herbacea*)
T	Milkweed, Mead's (*Asclepias meadii*)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)
T	Pogonia, small whorled (*Isotria medeoloides*)
T	Potato-bean, Price's (*Apios priceana*)
E	Prairie-clover, leafy (*Dalea foliosa*)
T	Thistle, Pitcher's (*Cirsium pitcheri*)

Indiana (US-FWS, 2011g)

Animals – 26 listings

Status	Species
E	Bat, gray (*Myotis grisescens*)
E	Bat, Indiana (*Myotis sodalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Butterfly, Karner blue (*Lycaeides melissa samuelis*)
E	Butterfly, Mitchell's satyr (*Neonympha mitchellii mitchellii*)
E	Catspaw, white (pearlymussel) (*Epioblasma obliquata perobliqua*)
E	Clubshell Entire Range; Except where listed as Experimental Populations (*Pleurobema clava*)
E	Dragonfly, Hine's emerald (*Somatochlora hineana*)
E	Fanshell (*Cyprogenia stegaria*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (*Quadrula fragosa*)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)
E	Mussel, scaleshell (*Leptodea leptodon*)
E	Pearlymussel, cracking Entire Range; Except where listed as Experimental Populations (*Hemistena lata*)
E	Pigtoe, rough (*Pleurobema plenum*)
E	Pimpleback, orangefoot (pearlymussel) (*Plethobasus cooperianus*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Plover, piping Great Lakes watershed (*Charadrius melodus*)
E	Pocketbook, fat (*Potamilus capax*)

Status	Species
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)
E	purple cat's paw (=purple cat's paw pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma obliquata obliquata*)
E	Riffleshell, northern (*Epioblasma torulosa rangiana*)
E	Ring pink (mussel) (*Obovaria retusa*)
T	Snake, copperbelly water Indiana north of 40 degrees north latitude, Michigan, Ohio (*Nerodia erythrogaster neglecta*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Wartyback, white (pearlymussel) (*Plethobasus cicatricosus*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 5 listings

Status	Species
E	Clover, running buffalo (*Trifolium stoloniferum*)
T	Milkweed, Mead's (*Asclepias meadii*)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)
T	Thistle, Pitcher's (*Cirsium pitcheri*)
E	Goldenrod, Short's (*Solidago shortii*)

Iowa (US-FWS, 2011h)

Animals – 13 listings

Status	Species
E	Bat, Indiana (*Myotis sodalis*)
E	Higgins eye (pearlymussel) (*Lampsilis higginsii*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Shiner, Topeka (*Notropis topeka (=tristis)*)
E	Snail, Iowa Pleistocene (*Discus macclintocki*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (*Quadrula fragosa*)
E	Mussel, scaleshell (*Leptodea leptodon*)
E	Pimpleback, orangefoot (pearlymussel) (*Plethobasus cooperianus*)
E	Pocketbook, fat (*Potamilus capax*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 5 listings

Status	Species
T	Bush-clover, prairie (*Lespedeza leptostachya*)
T	Milkweed, Mead's (*Asclepias meadii*)

Status	Species
T	Monkshood, northern wild (*Aconitum noveboracense*)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)
T	Orchid, western prairie fringed (*Platanthera praeclara*)

Kansas (US-FWS, 2011i)

Animals – 13 listings

Status	Species
E	Bat, gray (*Myotis grisescens*)
E	Bat, Indiana (*Myotis sodalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Crane, whooping except where EXPN (*Grus americana*)
E	Curlew, Eskimo (*Numenius borealis*)
E	Ferret, black-footed entire population, except where EXPN (*Mustela nigripes*)
T	Madtom, Neosho (*Noturus placidus*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
T	Shiner, Arkansas River Arkansas R. Basin (*Notropis girardi*)
E	Shiner, Topeka (*Notropis topeka (=tristis)*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 3 listings

Status	Species
T	Milkweed, Mead's (*Asclepias meadii*)
T	Orchid, western prairie fringed (*Platanthera praeclara*)
E	Clover, running buffalo (*Trifolium stoloniferum*)

Kentucky (US-FWS, 2011j)

Animals – 35 listings

Status	Species
E	Bat, gray (*Myotis grisescens*)
E	Bat, Indiana (*Myotis sodalis*)
E	Bat, Virginia big-eared (*Corynorhinus (=Plecotus) townsendii virginianus*)
E	Bean, Cumberland (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Villosa trabalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Blossom, tubercled (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma torulosa torulosa*)
E	Clubshell Entire Range; Except where listed as Experimental Populations (*Pleurobema clava*)
E	Combshell, Cumberlandian Entire Range; Except where listed as Experimental Populations (*Epioblasma*

Status	Species
	brevidens)
T	Dace, blackside (*Phoxinus cumberlandensis*)
E	Darter, duskytail Entire (*Etheostoma percnurum*)
E	Darter, relict (*Etheostoma chienense*)
E	Elktoe, Cumberland (*Alasmidonta atropurpurea*)
E	Fanshell (*Cyprogenia stegaria*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (*Quadrula fragosa*)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)
E	Mussel, oyster Entire Range; Except where listed as Experimental Populations (*Epioblasma capsaeformis*)
E	Mussel, scaleshell (*Leptodea leptodon*)
E	Pearlymussel, cracking Entire Range; Except where listed as Experimental Populations (*Hemistena lata*)
E	Pearlymussel, dromedary Entire Range; Except where listed as Experimental Populations (*Dromus dromas*)
E	Pearlymussel, littlewing (*Pegias fabula*)
E	Pigtoe, rough (*Pleurobema plenum*)
E	Pimpleback, orangefoot (pearlymussel) (*Plethobasus cooperianus*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Pocketbook, fat (*Potamilus capax*)
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)
E	purple cat's paw (=purple cat's paw pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma obliquata obliquata*)
E	Riffleshell, northern (*Epioblasma torulosa rangiana*)
E	Riffleshell, tan (*Epioblasma florentina walkeri (=E. walkeri)*)
E	Ring pink (mussel) (*Obovaria retusa*)
E	Shiner, palezone (*Notropis albizonatus*)
E	Shrimp, Kentucky cave (*Palaemonias ganteri*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Wartyback, white (pearlymussel) (*Plethobasus cicatricosus*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 8 listings

Status	Species
E	Clover, running buffalo (*Trifolium stoloniferum*)
E	Goldenrod, Short's (*Solidago shortii*)
T	Goldenrod, white-haired (*Solidago albopilosa*)
T	Potato-bean, Price's (*Apios priceana*)
E	Rock-cress, Braun's (*Arabis perstellata*)
T	Rosemary, Cumberland (*Conradina verticillata*)
E	Sandwort, Cumberland (*Arenaria cumberlandensis*)
T	Spiraea, Virginia (*Spiraea virginiana*)

Louisiana (US-FWS, 2011k)

Animals – 26 listings

Status	Species
T	Bear, Louisiana black (*Ursus americanus luteolus*)
T	Heelsplitter, Alabama (=inflated) (*Potamilus inflatus*)
E	Manatee, West Indian (*Trichechus manatus*)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)
T	Pearlshell, Louisiana (*Margaritifera hembeli*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, hawksbill (*Eretmochelys imbricata*)
E	Sea turtle, Kemp's ridley (*Lepidochelys kempii*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
T	Sturgeon, gulf (*Acipenser oxyrinchus desotoi*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
T	Tortoise, gopher W of of Mobile/Tombigbee Rs. (*Gopherus polyphemus*)
T	Turtle, ringed map (*Graptemys oculifera*)
E	Whale, finback (*Balaenoptera physalus*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Woodpecker, red-cockaded (*Picoides borealis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Frog, Mississippi gopher Wherever found west of Mobile and Tombigbee Rivers in AL, MS, and LA (*Rana capito sevosa*)
E	Jaguar (*Panthera onca*)
E	Panther, Florida (*Puma (=Felis) concolor coryi*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Pocketbook, fat (*Potamilus capax*)
E	Sawfish, smalltooth (*Pristis pectinata*)

Plants – 4 listings

Status	Species
E	Chaffseed, American (*Schwalbea americana*)
T	*Geocarpon minimum* (No common name)
E	Quillwort, Louisiana (*Isoetes louisianensis*)
E	Pondberry (*Lindera melissifolia*)

Maryland (US-FWS, 2011l)

Animals – 20 listings

Status	Species
E	Bat, Indiana (*Myotis sodalis*)
E	Darter, Maryland (*Etheostoma sellare*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, hawksbill (*Eretmochelys imbricata*)
E	Sea turtle, Kemp's ridley (*Lepidochelys kempii*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
E	Squirrel, Delmarva Peninsula fox Entire, except Sussex Co., DE (*Sciurus niger cinereus*)
E	Sturgeon, shortnose (*Acipenser brevirostrum*)
T	Tiger beetle, northeastern beach (*Cicindela dorsalis dorsalis*)
T	Tiger beetle, Puritan (*Cicindela puritana*)
T	Turtle, bog (=Muhlenberg) northern (*Clemmys muhlenbergii*)
E	Wedgemussel, dwarf (*Alasmidonta heterodon*)
E	Whale, finback (*Balaenoptera physalus*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Whale, right (*Balaena glacialis (incl. australis)*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 10 listings

Status	Species
T	Amaranth, seabeach (*Amaranthus pumilus*)
E	Bulrush, Northeastern (*Scirpus ancistrochaetus*)
E	Dropwort, Canby's (*Oxypolis canbyi*)
E	Gerardia, sandplain (*Agalinis acuta*)
E	Harperella (*Ptilimnium nodosum*)
T	Joint-vetch, sensitive (*Aeschynomene virginica*)
T	Pink, swamp (*Helonias bullata*)
E	Chaffseed, American (*Schwalbea americana*)
E	Coneflower, smooth (*Echinacea laevigata*)
T	Pogonia, small whorled (*Isotria medeoloides*)

Michigan (US-FWS, 2011m)

Animals – 15 listings

Status	Species
E	Bat, Indiana (*Myotis sodalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Beetle, Hungerford's crawling water (*Brychius hungerfordi*)
E	Butterfly, Karner blue (*Lycaeides melissa samuelis*)
E	Butterfly, Mitchell's satyr (*Neonympha mitchellii mitchellii*)
E	Catspaw, white (pearlymussel) (*Epioblasma obliquata perobliqua*)
E	Clubshell Entire Range; Except where listed as Experimental Populations (*Pleurobema clava*)
E	Dragonfly, Hine's emerald (*Somatochlora hineana*)
T	Lynx, Canada (Contiguous U.S. DPS) (*Lynx canadensis*)
E	Plover, piping Great Lakes watershed (*Charadrius melodus*)
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)
E	Riffleshell, northern (*Epioblasma torulosa rangiana*)
T	Snake, copperbelly water Indiana north of 40 degrees north latitude, Michigan, Ohio (*Nerodia erythrogaster neglecta*)
E	Warbler, Kirtland's (*Dendroica kirtlandii*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 9 listings

Status	Species
E	Chaffseed, American (*Schwalbea americana*)
T	Daisy, lakeside (*Hymenoxys herbacea*)
T	Fern, American hart's-tongue (*Asplenium scolopendrium var. americanum*)
T	Goldenrod, Houghton's (*Solidago houghtonii*)
T	Iris, dwarf lake (*Iris lacustris*)
E	monkey-flower, Michigan (*Mimulus michiganensis*)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)
T	Pogonia, small whorled (*Isotria medeoloides*)
T	Thistle, Pitcher's (*Cirsium pitcheri*)

Minnesota (US-FWS, 2011n)

Animals – 11 listings

Status	Species
E	Butterfly, Karner blue (*Lycaeides melissa samuelis*)
E	Higgins eye (pearlymussel) (*Lampsilis higginsii*)
T	Lynx, Canada (Contiguous U.S. DPS) (*Lynx canadensis*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (*Quadrula fragosa*)
E	Plover, piping Great Lakes watershed (*Charadrius melodus*)
E	Shiner, Topeka (*Notropis topeka (=tristis)*)

Status	Species
T	Wolf, gray MN (*Canis lupus*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Mussel, scaleshell (*Leptodea leptodon*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 4 listings

Status	Species
T	Bush-clover, prairie (*Lespedeza leptostachya*)
E	Lily, Minnesota dwarf trout (*Erythronium propullans*)
T	Orchid, western prairie fringed (*Platanthera praeclara*)
T	roseroot, Leedy's (*Rhodiola integrifolium ssp. leedyi*)

Mississippi (US-FWS, 2011o)

Animals – 41 listings

Status	Species
E	Bat, Indiana (*Myotis sodalis*)
T	Bear, Louisiana black (*Ursus americanus luteolus*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Clubshell, black (*Pleurobema curtum*)
E	Clubshell, ovate (*Pleurobema perovatum*)
E	Clubshell, southern (*Pleurobema decisum*)
E	Combshell, Cumberlandian Entire Range; Except where listed as Experimental Populations (*Epioblasma brevidens*)
E	Combshell, southern (*Epioblasma penita*)
E	Crane, Mississippi sandhill (*Grus canadensis pulla*)
T	Darter, bayou (*Etheostoma rubrum*)
E	Frog, Mississippi gopher Wherever found west of Mobile and Tombigbee Rivers in AL, MS, and LA (*Rana capito sevosa*)
T	Heelsplitter, Alabama (=inflated) (*Potamilus inflatus*)
E	Manatee, West Indian (*Trichechus manatus*)
T	Moccasinshell, Alabama (*Medionidus acutissimus*)
T	Mucket, orangenacre (*Lampsilis perovalis*)
E	Panther, Florida (*Puma (=Felis) concolor coryi*)
E	Pigtoe, flat (*Pleurobema marshalli*)
E	Pigtoe, heavy (*Pleurobema taitianum*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Pocketbook, fat (*Potamilus capax*)
E	Sawfish, smalltooth (*Pristis pectinata*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, hawksbill (*Eretmochelys imbricata*)
E	Sea turtle, Kemp's ridley (*Lepidochelys kempii*)

Status	Species
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
T	Snake, eastern indigo (*Drymarchon corais couperi*)
E	Stirrupshell (*Quadrula stapes*)
E	Stork, wood AL, FL, GA, SC (*Mycteria americana*)
E	Sturgeon, Alabama (*Scaphirhynchus suttkusi*)
T	Sturgeon, gulf (*Acipenser oxyrinchus desotoi*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
T	Tortoise, gopher W of of Mobile/Tombigbee Rs. (*Gopherus polyphemus*)
E	Turtle, Alabama red-belly (*Pseudemys alabamensis*)
T	Turtle, ringed map (*Graptemys oculifera*)
T	Turtle, yellow-blotched map (*Graptemys flavimaculata*)
E	Whale, finback (*Balaenoptera physalus*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Woodpecker, red-cockaded (*Picoides borealis*)

Plants – 4 listings

Status	Species
E	Chaffseed, American (*Schwalbea americana*)
E	Pondberry (*Lindera melissifolia*)
T	Potato-bean, Price's (*Apios priceana*)
E	Quillwort, Louisiana (*Isoetes louisianensis*)

Missouri (US-FWS, 2011p)

Animals – 21 listings

Status	Species
E	Bat, gray (*Myotis grisescens*)
E	Bat, Indiana (*Myotis sodalis*)
E	Bat, Ozark big-eared (*Corynorhinus (=Plecotus) townsendii ingens*)
E	Beetle, American burying (*Nicrophorus americanus*)
T	Cavefish, Ozark (*Amblyopsis rosae*)
E	Cavesnail, Tumbling Creek (*Antrobia culveri*)
T	Darter, Niangua (*Etheostoma nianguae*)
E	Dragonfly, Hine's emerald (*Somatochlora hineana*)
E	Higgins eye (pearlymussel) (*Lampsilis higginsii*)
T	Madtom, Neosho (*Noturus placidus*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (*Quadrula fragosa*)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)
E	Mussel, scaleshell (*Leptodea leptodon*)
E	Pearlymussel, Curtis (*Epioblasma florentina curtisii*)

Status	Species
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Pocketbook, fat (*Potamilus capax*)
E	Shiner, Topeka (*Notropis topeka (=tristis)*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Woodpecker, red-cockaded (*Picoides borealis*)

Plants – 10 listings

Status	Species
T	Aster, decurrent false (*Boltonia decurrens*)
T	bladderpod, Missouri (*Physaria filiformis*)
E	Clover, running buffalo (*Trifolium stoloniferum*)
T	Milkweed, Mead's (*Asclepias meadii*)
T	*Geocarpon minimum* (No common name)
T	Orchid, western prairie fringed (*Platanthera praeclara*)
T	Pogonia, small whorled (*Isotria medeoloides*)
E	Pondberry (*Lindera melissifolia*)
T	Sneezeweed, Virginia (*Helenium virginicum*)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)

Nebraska (US-FWS, 2011q)

Animals – 12 listings

Status	Species
E	Beetle, American burying (*Nicrophorus americanus*)
E	Crane, whooping except where EXPN (*Grus americana*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Shiner, Topeka (*Notropis topeka (=tristis)*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Tiger beetle, Salt Creek (*Cicindela nevadica lincolniana*)
E	Higgins eye (pearlymussel) (*Lampsilis higginsii*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (*Quadrula fragosa*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Curlew, Eskimo (*Numenius borealis*)
E	Ferret, black-footed entire population, except where EXPN (*Mustela nigripes*)

Plants – 5 listings

Status	Species
T	Butterfly plant, Colorado (*Gaura neomexicana var. coloradensis*)

Status	Species
T	Orchid, western prairie fringed (*Platanthera praeclara*)
E	Penstemon, blowout (*Penstemon haydenii*)
T	Ladies'-tresses, Ute (*Spiranthes diluvialis*)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)

New Jersey (US-FWS, 2011r)

Animals – 19 listings

Status	Species
E	Bat, Indiana (*Myotis sodalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Butterfly, Mitchell's satyr (*Neonympha mitchellii mitchellii*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, hawksbill (*Eretmochelys imbricata*)
E	Sea turtle, Kemp's ridley (*Lepidochelys kempii*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
E	Sturgeon, shortnose (*Acipenser brevirostrum*)
E	Tern, roseate northeast U.S. nesting pop. (*Sterna dougallii dougallii*)
T	Tiger beetle, northeastern beach (*Cicindela dorsalis dorsalis*)
T	Turtle, bog (=Muhlenberg) northern (*Clemmys muhlenbergii*)
E	Wedgemussel, dwarf (*Alasmidonta heterodon*)
E	Whale, finback (*Balaenoptera physalus*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Whale, right (*Balaena glacialis (incl. australis)*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 7 Listings

Status	Species
T	Amaranth, seabeach (*Amaranthus pumilus*)
T	Beaked-rush, Knieskern's (*Rhynchospora knieskernii*)
E	Chaffseed, American (*Schwalbea americana*)
T	Joint-vetch, sensitive (*Aeschynomene virginica*)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)
T	Pink, swamp (*Helonias bullata*)
T	Pogonia, small whorled (*Isotria medeoloides*)

New York (US-FWS, 2011s)

Animals – 23 listings

Status	Species
E	Bat, Indiana (*Myotis sodalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Butterfly, Karner blue (*Lycaeides melissa samuelis*)
E	Clubshell Entire Range; Except where listed as Experimental Populations (*Pleurobema clava*)
T	Lynx, Canada (Contiguous U.S. DPS) (*Lynx canadensis*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Plover, piping Great Lakes watershed (*Charadrius melodus*)
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, hawksbill (*Eretmochelys imbricata*)
E	Sea turtle, Kemp's ridley (*Lepidochelys kempii*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
T	Snail, Chittenango ovate amber (*Succinea chittenangoensis*)
E	Sturgeon, shortnose (*Acipenser brevirostrum*)
E	Tern, roseate northeast U.S. nesting pop. (*Sterna dougallii dougallii*)
T	Tiger beetle, northeastern beach (*Cicindela dorsalis dorsalis*)
T	Turtle, bog (=Muhlenberg) northern (*Clemmys muhlenbergii*)
E	Wedgemussel, dwarf (*Alasmidonta heterodon*)
E	Whale, finback (*Balaenoptera physalus*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Whale, right (*Balaena glacialis (incl. australis)*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 11 listings

Status	Species
T	Amaranth, seabeach (*Amaranthus pumilus*)
E	Bulrush, Northeastern (*Scirpus ancistrochaetus*)
E	Chaffseed, American (*Schwalbea americana*)
T	Fern, American hart's-tongue (*Asplenium scolopendrium var. americanum*)
E	Gerardia, sandplain (*Agalinis acuta*)
T	Goldenrod, Houghton's (*Solidago houghtonii*)
T	Monkshood, northern wild (*Aconitum noveboracense*)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)
T	Pink, swamp (*Helonias bullata*)
T	Pogonia, small whorled (*Isotria medeoloides*)
T	roseroot, Leedy's (*Rhodiola integrifolium ssp. leedyi*)

North Carolina (US-FWS, 2011t)

Animals – 40 listings

Status	Species
E	Bat, gray (*Myotis grisescens*)
E	Bat, Indiana (*Myotis sodalis*)
E	Bat, Virginia big-eared (*Corynorhinus (=Plecotus) townsendii virginianus*)
E	Bean, Cumberland (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Villosa trabalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Butterfly, Saint Francis' satyr (*Neonympha mitchellii francisci*)
T	Chub, spotfin Entire (*Erimonax monachus*)
E	Elktoe, Appalachian (*Alasmidonta raveneliana*)
E	Heelsplitter, Carolina (*Lasmigona decorata*)
E	Manatee, West Indian (*Trichechus manatus*)
E	Mussel, oyster Entire Range; Except where listed as Experimental Populations (*Epioblasma capsaeformis*)
E	Pearlymussel, littlewing (*Pegias fabula*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)
E	Riffleshell, tan (*Epioblasma florentina walkeri (=E. walkeri)*)
E	Sawfish, smalltooth (*Pristis pectinata*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, hawksbill (*Eretmochelys imbricata*)
E	Sea turtle, Kemp's ridley (*Lepidochelys kempii*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
E	Shiner, Cape Fear (*Notropis mekistocholas*)
T	Silverside, Waccamaw (*Menidia extensa*)
T	Snail, noonday (*Mesodon clarki nantahala*)
E	Spider, spruce-fir moss (*Microhexura montivaga*)
E	Spinymussel, James (*Pleurobema collina*)
E	Spinymussel, Tar River (*Elliptio steinstansana*)
E	Squirrel, Carolina northern flying (*Glaucomys sabrinus coloratus*)
E	Stork, wood AL, FL, GA, SC (*Mycteria americana*)
E	Sturgeon, shortnose (*Acipenser brevirostrum*)
E	Tern, roseate northeast U.S. nesting pop. (*Sterna dougallii dougallii*)
T	Tern, roseate Western Hemisphere except NE U.S. (*Sterna dougallii dougallii*)
E	Wedgemussel, dwarf (*Alasmidonta heterodon*)
E	Whale, finback (*Balaenoptera physalus*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Whale, right (*Balaena glacialis (incl. australis)*)
E	Whale, sperm (*Physeter catodon (=macrocephalus)*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Wolf, red except where EXPN (*Canis rufus*)
E	Woodpecker, red-cockaded (*Picoides borealis*)

Plants – 27 Listings

Status	Species
T	Amaranth, seabeach (*Amaranthus pumilus*)
E	Arrowhead, bunched (*Sagittaria fasciculata*)
E	Avens, spreading (*Geum radiatum*)
E	Bittercress, small-anthered (*Cardamine micranthera*)
T	Blazingstar, Heller's (*Liatris helleri*)
E	Bluet, Roan Mountain (*Hedyotis purpurea var. montana*)
E	Chaffseed, American (*Schwalbea americana*)
E	Coneflower, smooth (*Echinacea laevigata*)
E	Dropwort, Canby's (*Oxypolis canbyi*)
T	Goldenrod, Blue Ridge (*Solidago spithamaea*)
E	Harperella (*Ptilimnium nodosum*)
T	Heartleaf, dwarf-flowered (*Hexastylis naniflora*)
T	Heather, mountain golden (*Hudsonia montana*)
E	Irisette, white (*Sisyrinchium dichotomum*)
T	Joint-vetch, sensitive (*Aeschynomene virginica*)
E	Lichen, rock gnome (*Gymnoderma lineare*)
E	Loosestrife, rough-leaved (*Lysimachia asperulaefolia*)
E	Meadowrue, Cooley's (*Thalictrum cooleyi*)
T	Pink, swamp (*Helonias bullata*)
E	Pitcher-plant, green (*Sarracenia oreophila*)
E	Pitcher-plant, mountain sweet (*Sarracenia rubra ssp. jonesii*)
T	Pogonia, small whorled (*Isotria medeoloides*)
E	Pondberry (*Lindera melissifolia*)
E	Sedge, golden (*Carex lutea*)
T	Spiraea, Virginia (*Spiraea virginiana*)
E	Sumac, Michaux's (*Rhus michauxii*)
E	Sunflower, Schweinitz's (*Helianthus schweinitzii*)

North Dakota (US-FWS, 2011u)

Animals – 7 listings

Status	Species
E	Crane, whooping except where EXPN (*Grus americana*)
E	Ferret, black-footed entire population, except where EXPN (*Mustela nigripes*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Beetle, American burying (*Nicrophorus americanus*)

Plants – 1 listing

Status	Species
T	Orchid, western prairie fringed (*Platanthera praeclara*)

Ohio (US-FWS, 2011v)

Animals – 24 listings

Status	Species
E	Bat, Indiana (*Myotis sodalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Butterfly, Karner blue (*Lycaeides melissa samuelis*)
E	Catspaw, white (pearlymussel) (*Epioblasma obliquata perobliqua*)
E	Clubshell Entire Range; Except where listed as Experimental Populations (*Pleurobema clava*)
E	Fanshell (*Cyprogenia stegaria*)
E	Madtom, Scioto (*Noturus trautmani*)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)
E	Plover, piping Great Lakes watershed (*Charadrius melodus*)
E	purple cat's paw (=purple cat's paw pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma obliquata obliquata*)
E	Riffleshell, northern (*Epioblasma torulosa rangiana*)
T	Snake, copperbelly water Indiana north of 40 degrees north latitude, Michigan, Ohio (*Nerodia erythrogaster neglecta*)
T	Snake, Lake Erie water subspecies range clarified (*Nerodia sipedon insularum*)
E	Dragonfly, Hine's emerald (*Somatochlora hineana*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (*Quadrula fragosa*)
E	Mussel, scaleshell (*Leptodea leptodon*)
E	Pearlymussel, cracking Entire Range; Except where listed as Experimental Populations (*Hemistena lata*)
E	Pimpleback, orangefoot (pearlymussel) (*Plethobasus cooperianus*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Pocketbook, fat (*Potamilus capax*)
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)
E	Ring pink (mussel) (*Obovaria retusa*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Butterfly, Mitchell's satyr (*Neonympha mitchellii mitchellii*)

Plants – 6 listings

Status	Species
E	Clover, running buffalo (*Trifolium stoloniferum*)
T	Daisy, lakeside (*Hymenoxys herbacea*)
T	Monkshood, northern wild (*Aconitum noveboracense*)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)
T	Spiraea, Virginia (*Spiraea virginiana*)
T	Pogonia, small whorled (*Isotria medeoloides*)

Oklahoma (US-FWS, 2011w)

Animals – 18 listings

Status	Species
E	Bat, gray (*Myotis grisescens*)
E	Bat, Indiana (*Myotis sodalis*)
E	Bat, Ozark big-eared (*Corynorhinus (=Plecotus) townsendii ingens*)
E	Beetle, American burying (*Nicrophorus americanus*)
T	Cavefish, Ozark (*Amblyopsis rosae*)
E	Crane, whooping except where EXPN (*Grus americana*)
E	Curlew, Eskimo (*Numenius borealis*)
T	Darter, leopard (*Percina pantherina*)
T	Madtom, Neosho (*Noturus placidus*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (*Quadrula fragosa*)
E	Mussel, scaleshell (*Leptodea leptodon*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Pocketbook, Ouachita rock (*Arkansia wheeleri*)
T	Shiner, Arkansas River Arkansas R. Basin (*Notropis girardi*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Vireo, black-capped (*Vireo atricapilla*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Woodpecker, red-cockaded (*Picoides borealis*)

Plants – 2 listings

Status	Species
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)
T	Orchid, western prairie fringed (*Platanthera praeclara*)

Pennsylvania (US-FWS, 2011x)

Animals – 19 listings

Status	Species
E	Bat, Indiana (*Myotis sodalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Butterfly, Karner blue (*Lycaeides melissa samuelis*)
E	Clubshell Entire Range; Except where listed as Experimental Populations (*Pleurobema clava*)
E	Fanshell (*Cyprogenia stegaria*)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)
E	Pearlymussel, cracking Entire Range; Except where listed as Experimental Populations (*Hemistena lata*)
E	Pigtoe, rough (*Pleurobema plenum*)
E	Pimpleback, orangefoot (pearlymussel) (*Plethobasus cooperianus*)
E	Plover, piping Great Lakes watershed (*Charadrius melodus*)
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)

Status	Species
E	Riffleshell, northern (*Epioblasma torulosa rangiana*)
E	Ring pink (mussel) (*Obovaria retusa*)
E	Squirrel, Delmarva Peninsula fox Entire, except Sussex Co., DE (*Sciurus niger cinereus*)
E	Sturgeon, shortnose (*Acipenser brevirostrum*)
T	Tiger beetle, northeastern beach (*Cicindela dorsalis dorsalis*)
T	Turtle, bog (=Muhlenberg) northern (*Clemmys muhlenbergii*)
E	Wedgemussel, dwarf (*Alasmidonta heterodon*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 6 listings

Status	Species
E	Bulrush, Northeastern (*Scirpus ancistrochaetus*)
T	Pogonia, small whorled (*Isotria medeoloides*)
T	Spiraea, Virginia (*Spiraea virginiana*)
E	Coneflower, smooth (*Echinacea laevigata*)
T	Joint-vetch, sensitive (*Aeschynomene virginica*)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)

South Carolina (US-FWS, 2011y)

Animals – 26 listings

Status	Species
E	Heelsplitter, Carolina (*Lasmigona decorata*)
E	Manatee, West Indian (*Trichechus manatus*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
T	Salamander, frosted flatwoods (*Ambystoma cingulatum*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, hawksbill (*Eretmochelys imbricata*)
E	Sea turtle, Kemp's ridley (*Lepidochelys kempii*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
E	Stork, wood AL, FL, GA, SC (*Mycteria americana*)
E	Sturgeon, shortnose (*Acipenser brevirostrum*)
E	Warbler (=wood), Bachman's (*Vermivora bachmanii*)
E	Whale, finback (*Balaenoptera physalus*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Whale, right (*Balaena glacialis (incl. australis)*)
E	Woodpecker, red-cockaded (*Picoides borealis*)
E	Bat, Indiana (*Myotis sodalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Panther, Florida (*Puma (=Felis) concolor coryi*)
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)
T	Snake, eastern indigo (*Drymarchon corais couperi*)

Status	Species
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Sawfish, smalltooth (*Pristis pectinata*)
T	Tern, roseate Western Hemisphere except NE U.S. (*Sterna dougallii dougallii*)
E	Warbler, Kirtland's (*Dendroica kirtlandii*)
E	Wolf, red except where EXPN (*Canis rufus*)

Plants – 21 listings

Status	Species
T	Amaranth, seabeach (*Amaranthus pumilus*)
T	Amphianthus, little (*Amphianthus pusillus*)
E	Arrowhead, bunched (*Sagittaria fasciculata*)
E	Chaffseed, American (*Schwalbea americana*)
E	Coneflower, smooth (*Echinacea laevigata*)
E	Dropwort, Canby's (*Oxypolis canbyi*)
T	Gooseberry, Miccosukee (*Ribes echinellum*)
E	Harperella (*Ptilimnium nodosum*)
T	Heartleaf, dwarf-flowered (*Hexastylis naniflora*)
E	Irisette, white (*Sisyrinchium dichotomum*)
E	Lichen, rock gnome (*Gymnoderma lineare*)
E	Loosestrife, rough-leaved (*Lysimachia asperulaefolia*)
T	Pink, swamp (*Helonias bullata*)
E	Pitcher-plant, mountain sweet (*Sarracenia rubra ssp. jonesii*)
T	Pogonia, small whorled (*Isotria medeoloides*)
E	Pondberry (*Lindera melissifolia*)
E	Quillwort, black spored (*Isoetes melanospora*)
E	Sumac, Michaux's (*Rhus michauxii*)
E	Sunflower, Schweinitz's (*Helianthus schweinitzii*)
E	Trillium, persistent (*Trillium persistens*)
E	Trillium, relict (*Trillium reliquum*)

South Dakota (US-FWS, 2011z)

Animals – 11 listings

Status	Species
E	Beetle, American burying (*Nicrophorus americanus*)
E	Crane, whooping except where EXPN (*Grus americana*)
E	Ferret, black-footed entire population, except where EXPN (*Mustela nigripes*)
E	Mussel, scaleshell (*Leptodea leptodon*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Shiner, Topeka (*Notropis topeka (=tristis)*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Status	Species
E	Curlew, Eskimo (*Numenius borealis*)
E	Higgins eye (pearlymussel) (*Lampsilis higginsii*)

Plants – 1 listing

Status	Species
T	Orchid, western prairie fringed (*Platanthera praeclara*)

Tennessee (US-FWS, 2011aa)

Animals – 72 listings

Status	Species
E	Acornshell, southern (*Epioblasma othcaloogensis*)
E	Bat, gray (*Myotis grisescens*)
E	Bat, Indiana (*Myotis sodalis*)
E	Bean, Cumberland (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Villosa trabalis*)
E	Bean, purple (*Villosa perpurpurea*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Blossom, green (pearlymussel) (*Epioblasma torulosa gubernaculum*)
E	Blossom, tubercled (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma torulosa torulosa*)
E	Blossom, turgid (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma turgidula*)
E	Blossom, yellow (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma florentina florentina*)
T	Chub, slender (*Erimystax cahni*)
T	Chub, spotfin Entire (*Erimonax monachus*)
E	Clubshell Entire Range; Except where listed as Experimental Populations (*Pleurobema clava*)
E	Clubshell, ovate (*Pleurobema perovatum*)
E	Clubshell, southern (*Pleurobema decisum*)
E	Combshell, Cumberlandian Entire Range; Except where listed as Experimental Populations (*Epioblasma brevidens*)
E	Combshell, upland (*Epioblasma metastriata*)
E	Crayfish, Nashville (*Orconectes shoupi*)
T	Dace, blackside (*Phoxinus cumberlandensis*)
E	Darter, amber (*Percina antesella*)
E	Darter, bluemask (=jewel) (*Etheostoma sp.*)
E	Darter, boulder (*Etheostoma wapiti*)
E	Darter, duskytail Entire (*Etheostoma percnurum*)
T	Darter, goldline (*Percina aurolineata*)
T	Darter, slackwater (*Etheostoma boschungi*)
T	Darter, snail (*Percina tanasi*)
E	Elktoe, Appalachian (*Alasmidonta raveneliana*)
E	Elktoe, Cumberland (*Alasmidonta atropurpurea*)

Status	Species
E	Fanshell (*Cyprogenia stegaria*)
E	Kidneyshell, triangular (*Ptychobranchus greenii*)
E	Lampmussel, Alabama Entire Range; Except where listed as Experimental Populations (*Lampsilis virescens*)
E	Lilliput, pale (pearlymussel) (*Toxolasma cylindrellus*)
E	Logperch, Conasauga (*Percina jenkinsi*)
E	Madtom, pygmy Entire (*Noturus stanauli*)
E	Madtom, smoky Entire (*Noturus baileyi*)
T	Madtom, yellowfin except where EXPN (*Noturus flavipinnis*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (*Quadrula fragosa*)
E	Marstonia, royal (snail) (*Pyrgulopsis ogmorhaphe*)
E	Moccasinshell, Coosa (*Medionidus parvulus*)
E	Monkeyface, Appalachian (pearlymussel) (*Quadrula sparsa*)
E	Monkeyface, Cumberland (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Quadrula intermedia*)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)
E	Mussel, oyster Entire Range; Except where listed as Experimental Populations (*Epioblasma capsaeformis*)
E	Mussel, scaleshell (*Leptodea leptodon*)
E	Panther, Florida (*Puma (=Felis) concolor coryi*)
E	Pearlymussel, birdwing Entire Range; Except where listed as Experimental Populations (*Conradilla caelata*)
E	Pearlymussel, cracking Entire Range; Except where listed as Experimental Populations (*Hemistena lata*)
E	Pearlymussel, dromedary Entire Range; Except where listed as Experimental Populations (*Dromus dromas*)
E	Pearlymussel, littlewing (*Pegias fabula*)
E	Pigtoe, Cumberland (*Pleurobema gibberum*)
E	Pigtoe, finerayed Entire Range; Except where listed as Experimental Populations (*Fusconaia cuneolus*)
E	Pigtoe, Georgia (*Pleurobema hanleyianum*)
E	Pigtoe, rough (*Pleurobema plenum*)
E	Pigtoe, shiny Entire Range; Except where listed as Experimental Populations (*Fusconaia cor*)
E	Pigtoe, southern (*Pleurobema georgianum*)
E	Pimpleback, orangefoot (pearlymussel) (*Plethobasus cooperianus*)
T	Pocketbook, finelined (*Lampsilis altilis*)
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)
E	purple cat's paw (=purple cat's paw pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma obliquata obliquata*)
E	Rabbitsfoot, rough (*Quadrula cylindrica strigillata*)
E	Riffleshell, tan (*Epioblasma florentina walkeri (=E. walkeri)*)
E	Ring pink (mussel) (*Obovaria retusa*)
E	Riversnail, Anthony's Entire Range; Except where listed as Experimental Populations (*Athearnia anthonyi*)
T	Shiner, blue (*Cyprinella caerulea*)
E	Shiner, palezone (*Notropis albizonatus*)
T	Snail, painted snake coiled forest (*Anguispira picta*)
E	Spider, spruce-fir moss (*Microhexura montivaga*)
E	Squirrel, Carolina northern flying (*Glaucomys sabrinus coloratus*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Wartyback, white (pearlymussel) (*Plethobasus cicatricosus*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 21 listings

Status	Species
E	Aster, Ruth's golden (*Pityopsis ruthii*)
E	Avens, spreading (*Geum radiatum*)
E	Bladderpod, Spring Creek (*Lesquerella perforata*)
E	Bluet, Roan Mountain (*Hedyotis purpurea var. montana*)
E	Chaffseed, American (*Schwalbea americana*)
E	Coneflower, Tennessee purple (*Echinacea tennesseensis*)
T	Fern, American hart's-tongue (*Asplenium scolopendrium var. americanum*)
T	Goldenrod, Blue Ridge (*Solidago spithamaea*)
E	Grass, Tennessee yellow-eyed (*Xyris tennesseensis*)
E	Ground-plum, Guthrie's (=Pyne's) (*Astragalus bibullatus*)
E	Leather flower, Morefield's (*Clematis morefieldii*)
E	Lichen, rock gnome (*Gymnoderma lineare*)
E	Pitcher-plant, green (*Sarracenia oreophila*)
T	Pogonia, small whorled (*Isotria medeoloides*)
T	Potato-bean, Price's (*Apios priceana*)
E	Prairie-clover, leafy (*Dalea foliosa*)
E	Rock-cress, Braun's (*Arabis perstellata*)
T	Rosemary, Cumberland (*Conradina verticillata*)
E	Sandwort, Cumberland (*Arenaria cumberlandensis*)
T	Skullcap, large-flowered (*Scutellaria montana*)
T	Spiraea, Virginia (*Spiraea virginiana*)

Texas (US-FWS, 2011ab)

Animals – 64 listings

Status	Species
E	Amphipod, Peck's cave (*Stygobromus (=Stygonectes) pecki*)
E	Bat, Mexican long-nosed (*Leptonycteris nivalis*)
T	Bear, Louisiana black (*Ursus americanus luteolus*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Beetle, Coffin Cave mold (*Batrisodes texanus*)
E	Beetle, Comal Springs dryopid (*Stygoparnus comalensis*)
E	Beetle, Comal Springs riffle (*Heterelmis comalensis*)
E	Beetle, Helotes mold (*Batrisodes venyivi*)
E	Beetle, Kretschmarr Cave mold (*Texamaurops reddelli*)
E	Beetle, Tooth Cave ground (*Rhadine persephone*)
E	Crane, whooping except where EXPN (*Grus americana*)
E	Curlew, Eskimo (*Numenius borealis*)
E	Darter, fountain (*Etheostoma fonticola*)
E	Falcon, northern aplomado (*Falco femoralis septentrionalis*)
E	Flycatcher, southwestern willow (*Empidonax traillii extimus*)

Status	Species
E	Gambusia, Big Bend (*Gambusia gaigei*)
E	Gambusia, Clear Creek (*Gambusia heterochir*)
E	Gambusia, Pecos (*Gambusia nobilis*)
E	Gambusia, San Marcos (*Gambusia georgei*)
E	Ground beetle, [unnamed] (*Rhadine exilis*)
E	Ground beetle, [unnamed] (*Rhadine infernalis*)
E	Harvestman, Bee Creek Cave (*Texella reddelli*)
E	Harvestman, Bone Cave (*Texella reyesi*)
E	Harvestman, Cokendolpher Cave (*Texella cokendolpheri*)
E	Jaguar (*Panthera onca*)
E	Jaguarundi, Gulf Coast (*Herpailurus (=Felis) yagouaroundi cacomitli*)
E	Manatee, West Indian (*Trichechus manatus*)
E	Margay Mexico southward (*Leopardus (=Felis) wiedii*)
E	Meshweaver, Braken Bat Cave (*Cicurina venii*)
E	Meshweaver, Government Canyon Bat Cave (*Cicurina vespera*)
E	Meshweaver, Madla's Cave (*Cicurina madla*)
E	Meshweaver, Robber Baron Cave (*Cicurina baronia*)
T	Minnow, Devils River (*Dionda diaboli*)
E	Minnow, Rio Grande silvery Entire, except where listed as an experimental population (*Hybognathus amarus*)
E	Ocelot (*Leopardus (=Felis) pardalis*)
T	Owl, Mexican spotted (*Strix occidentalis lucida*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Prairie-chicken, Attwater's greater (*Tympanuchus cupido attwateri*)
E	Pseudoscorpion, Tooth Cave (*Tartarocreagris texana*)
E	Pupfish, Comanche Springs (*Cyprinodon elegans*)
E	Pupfish, Leon Springs (*Cyprinodon bovinus*)
E	Salamander, Barton Springs (*Eurycea sosorum*)
T	Salamander, San Marcos (*Eurycea nana*)
E	Salamander, Texas blind (*Typhlomolge rathbuni*)
E	Sawfish, smalltooth (*Pristis pectinata*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, hawksbill (*Eretmochelys imbricata*)
E	Sea turtle, Kemp's ridley (*Lepidochelys kempii*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
T	Shiner, Arkansas River Arkansas R. Basin (*Notropis girardi*)
E	Snail, Pecos assiminea (*Assiminea pecos*)
T	Snake, Concho water (*Nerodia paucimaculata*)
E	Spider, Government Canyon Bat Cave (*Neoleptoneta microps*)
E	Spider, Tooth Cave (*Leptoneta myopica*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Toad, Houston (*Bufo houstonensis*)
E	Vireo, black-capped (*Vireo atricapilla*)
E	Warbler (=wood), golden-cheeked (*Dendroica chrysoparia*)
E	Whale, finback (*Balaenoptera physalus*)

Status	Species
E	Whale, humpback (*Megaptera novaeangliae*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Wolf, red except where EXPN (*Canis rufus*)
E	Woodpecker, red-cockaded (*Picoides borealis*)

Plants – 29 listings

Status	Species
E	Ambrosia, south Texas (*Ambrosia cheiranthifolia*)
E	Ayenia, Texas (*Ayenia limitaris*)
E	Bladderpod, white (*Lesquerella pallida*)
E	Bladderpod, Zapata (*Lesquerella thamnophila*)
E	Cactus, black lace (*Echinocereus reichenbachii var. albertii*)
T	Cactus, Chisos Mountain hedgehog (*Echinocereus chisoensis var. chisoensis*)
T	Cactus, Lloyd's Mariposa (*Echinomastus mariposensis*)
E	Cactus, Nellie cory (*Coryphantha minima*)
E	Cactus, Sneed pincushion (*Coryphantha sneedii var. sneedii*)
E	Cactus, star (*Astrophytum asterias*)
E	Cactus, Tobusch fishhook (*Ancistrocactus tobuschii*)
E	Cat's-eye, Terlingua Creek (*Cryptantha crassipes*)
T	Cory cactus, bunched (*Coryphantha ramillosa*)
E	Dawn-flower, Texas prairie (*Hymenoxys texana*)
E	Dogweed, ashy (*Thymophylla tephroleuca*)
E	Frankenia, Johnston's (*Frankenia johnstonii*)
E	Ladies'-tresses, Navasota (*Spiranthes parksii*)
E	Manioc, Walker's (*Manihot walkerae*)
T	Oak, Hinckley (*Quercus hinckleyi*)
E	Phlox, Texas trailing (*Phlox nivalis ssp. texensis*)
E	Pitaya, Davis' green (*Echinocereus viridiflorus var. davisii*)
E	Pondweed, Little Aguja (=Creek) (*Potamogeton clystocarpus*)
E	Poppy-mallow, Texas (*Callirhoe scabriuscula*)
E	Rush-pea, slender (*Hoffmannseggia tenella*)
E	Sand-verbena, large-fruited (*Abronia macrocarpa*)
E	Snowbells, Texas (*Styrax texanus*)
T	Sunflower, Pecos (=puzzle, =paradox) (*Helianthus paradoxus*)
E	Wild-rice, Texas (*Zizania texana*)
T	*Geocarpon minimum* (No common name)

Virginia (US-FWS, 2011ac)

Animals – 53 listings

Status	Species
E	Bat, gray (*Myotis grisescens*)
E	Bat, Indiana (*Myotis sodalis*)

Status	Species
E	Bat, Virginia big-eared (*Corynorhinus (=Plecotus) townsendii virginianus*)
E	Bean, Cumberland (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Villosa trabalis*)
E	Bean, purple (*Villosa perpurpurea*)
E	Blossom, green (pearlymussel) (*Epioblasma torulosa gubernaculum*)
T	Chub, slender (*Erimystax cahni*)
T	Chub, spotfin Entire (*Erimonax monachus*)
E	Combshell, Cumberlandian Entire Range; Except where listed as Experimental Populations (*Epioblasma brevidens*)
E	Darter, duskytail Entire (*Etheostoma percnurum*)
E	Fanshell (*Cyprogenia stegaria*)
E	Isopod, Lee County cave (*Lirceus usdagalun*)
T	Isopod, Madison Cave (*Antrolana lira*)
E	Logperch, Roanoke (*Percina rex*)
T	Madtom, yellowfin except where EXPN (*Noturus flavipinnis*)
E	Monkeyface, Appalachian (pearlymussel) (*Quadrula sparsa*)
E	Monkeyface, Cumberland (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Quadrula intermedia*)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)
E	Mussel, oyster Entire Range; Except where listed as Experimental Populations (*Epioblasma capsaeformis*)
E	Pearlymussel, birdwing Entire Range; Except where listed as Experimental Populations (*Conradilla caelata*)
E	Pearlymussel, cracking Entire Range; Except where listed as Experimental Populations (*Hemistena lata*)
E	Pearlymussel, dromedary Entire Range; Except where listed as Experimental Populations (*Dromus dromas*)
E	Pearlymussel, littlewing (*Pegias fabula*)
E	Pigtoe, finerayed Entire Range; Except where listed as Experimental Populations (*Fusconaia cuneolus*)
E	Pigtoe, rough (*Pleurobema plenum*)
E	Pigtoe, shiny Entire Range; Except where listed as Experimental Populations (*Fusconaia cor*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Rabbitsfoot, rough (*Quadrula cylindrica strigillata*)
E	Riffleshell, tan (*Epioblasma florentina walkeri (=E. walkeri)*)
E	Salamander, Shenandoah (*Plethodon shenandoah*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, hawksbill (*Eretmochelys imbricata*)
E	Sea turtle, Kemp's ridley (*Lepidochelys kempii*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
E	Snail, Virginia fringed mountain (*Polygyriscus virginianus*)
E	Spinymussel, James (*Pleurobema collina*)
E	Squirrel, Delmarva Peninsula fox Entire, except Sussex Co., DE (*Sciurus niger cinereus*)
E	Sturgeon, shortnose (*Acipenser brevirostrum*)
E	Tern, roseate northeast U.S. nesting pop. (*Sterna dougallii dougallii*)
T	Tiger beetle, northeastern beach (*Cicindela dorsalis dorsalis*)
E	Wedgemussel, dwarf (*Alasmidonta heterodon*)
E	Whale, finback (*Balaenoptera physalus*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Whale, right (*Balaena glacialis (incl. australis)*)

Status	Species
E	Woodpecker, red-cockaded (*Picoides borealis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Butterfly, Mitchell's satyr (*Neonympha mitchellii mitchellii*)
T	Dace, blackside (*Phoxinus cumberlandensis*)
E	Spider, spruce-fir moss (*Microhexura montivaga*)
E	Squirrel, Carolina northern flying (*Glaucomys sabrinus coloratus*)

Plants – 17 listings

Status	Species
T	Amaranth, seabeach (*Amaranthus pumilus*)
T	Birch, Virginia round-leaf (*Betula uber*)
E	Bittercress, small-anthered (*Cardamine micranthera*)
E	Bulrush, Northeastern (*Scirpus ancistrochaetus*)
E	Chaffseed, American (*Schwalbea americana*)
E	Coneflower, smooth (*Echinacea laevigata*)
T	Joint-vetch, sensitive (*Aeschynomene virginica*)
E	Mallow, Peter's Mountain (*Iliamna corei*)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)
T	Pink, swamp (*Helonias bullata*)
T	Pogonia, small whorled (*Isotria medeoloides*)
E	Rock-cress, shale barren (*Arabis serotina*)
T	Sneezeweed, Virginia (*Helenium virginicum*)
T	Spiraea, Virginia (*Spiraea virginiana*)
E	Sumac, Michaux's (*Rhus michauxii*)
E	Harperella (*Ptilimnium nodosum*)
E	Lichen, rock gnome (*Gymnoderma lineare*)

West Virginia (US-FWS, 2011ad)

Animals – 16 listings

Status	Species
E	Bat, gray (*Myotis grisescens*)
E	Bat, Indiana (*Myotis sodalis*)
E	Bat, Virginia big-eared (*Corynorhinus (=Plecotus) townsendii virginianus*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Blossom, tubercled (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma torulosa torulosa*)
E	Clubshell Entire Range; Except where listed as Experimental Populations (*Pleurobema clava*)
E	Fanshell (*Cyprogenia stegaria*)
T	Isopod, Madison Cave (*Antrolana lira*)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)

Status	Species
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)
E	Riffleshell, northern (*Epioblasma torulosa rangiana*)
E	Ring pink (mussel) (*Obovaria retusa*)
T	Salamander, Cheat Mountain (*Plethodon nettingi*)
T	Snail, flat-spired three-toothed (*Triodopsis platysayoides*)
E	Spinymussel, James (*Pleurobema collina*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 6 listings

Status	Species
E	Bulrush, Northeastern (*Scirpus ancistrochaetus*)
E	Clover, running buffalo (*Trifolium stoloniferum*)
E	Harperella (*Ptilimnium nodosum*)
T	Pogonia, small whorled (*Isotria medeoloides*)
E	Rock-cress, shale barren (*Arabis serotina*)
T	Spiraea, Virginia (*Spiraea virginiana*)

Wisconsin (US-FWS, 2011ae)

Animals – 11 listings

Status	Species
E	Beetle, American burying (*Nicrophorus americanus*)
E	Butterfly, Karner blue (*Lycaeides melissa samuelis*)
E	Dragonfly, Hine's emerald (*Somatochlora hineana*)
E	Higgins eye (pearlymussel) (*Lampsilis higginsii*)
T	Lynx, Canada (Contiguous U.S. DPS) (*Lynx canadensis*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (*Quadrula fragosa*)
E	Mussel, scaleshell (*Leptodea leptodon*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Plover, piping Great Lakes watershed (*Charadrius melodus*)
E	Warbler, Kirtland's (*Dendroica kirtlandii*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 7 listings

Status	Species
T	Bush-clover, prairie (*Lespedeza leptostachya*)
T	Iris, dwarf lake (*Iris lacustris*)
T	Locoweed, Fassett's (*Oxytropis campestris var. chartacea*)
T	Milkweed, Mead's (*Asclepias meadii*)
T	Monkshood, northern wild (*Aconitum noveboracense*)

Status	Species
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)
T	Thistle, Pitcher's (*Cirsium pitcheri*)

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APPENDIX D

ADDENDUM 1 of PETITION FOR NONREGULATED STATUS, MARKET IMPACT OF MON 87705 HIGH OLEIC SOYBEAN OIL MONSANTO PETITION NUMBER : 09-SY-201U

Petition for the Determination of Nonregulated Status for Improved Fatty Acid Profile MON 87705 Soybean

ADDENDENDUM I

Market Impact of MON 87705

High Oleic Soybean Oil

Submitted April 7, 2011

OECD Unique Identifier: MON-87705-6
Monsanto Petition Number: 09-SY-201U

1. Introduction

Overall total use of oils derived from plant sources (vegetable oil) for food and industrial applications exceeded 14 million tons in North America in 2009. Due to its abundance, reliable supply and price, soybean oil is one of the most highly used of the vegetable oils (Attachment I, Table 3.1, pg 62). In 2009, soybean oil accounted for approximately 8.2 million tons of food and 1.2 million ton of industrial vegetable oil uses (See Attachment I, Part 1b, pg 17-18). Soybean oil use in foods peaked at roughly 9.3 million tons in the 2006/2007 timeframe just before the U.S. Food and Drug Administration required food labels to report *trans-fat* content in 2006. (http://www.fda.gov/Food/LabelingNutrition/ConsumerInformation). The demand for soybean oil for frying and baking applications has declined in recent years due to the desire to lower unhealthy *trans-fat* in the diet and changes in food labeling policy.

High oleic soybean oil produced using MON 87705 has a fatty acid profile that has reduced saturated fats, and higher monounsaturated fat. These properties, particularly the reduction in polyunsaturated fats (18:2), result in increased oil oxidative stability greatly improving oil performance in frying and baking applications. The decrease in saturated fat (16:0, 18:0) further improves the nutritional profile of the oil for use in food preparation. MON 87705 will be bred into Vistive® low-linolenic soybean further improving the oil profile by lowering the level of linolenic acid and eliminating the need to hydrogenate the oil.

Monsanto has conducted a market and trade assessment to evaluate the potential impacts on commodity soybean oil and other vegetable oils due to the introduction of high oleic soybean oil. The assessment considered that other vegetable oils including high oleic vegetable oils are currently on the market and are routinely handled by oil processors and food formulators. The system responsible for production, harvest, processing and handling of soybean and other vegetable oils includes critical control points as well as economic incentives for identity preserved soybean oils and other vegetable oils. Typically, the processor will assess the fatty acid profile of the oil sold to a food manufacturer prior to sale. If the fatty acid profile were different from commodity soybean oil, the oil could be blended (a common industry practice) to reach the appropriate fatty acid content based on specific food applications. On the basis of this assessment it is concluded that the introduction of high oleic soybean oil will have little if any potential for negative market impacts. In the event that comingling did occur, the economic impact of comingling to a food manufacturer would be minimal and remedied through blending.

A summary of the intended uses for high oleic soybean oil, current processes for handling vegetable oils and potential impacts to commodity soybean oil as well as other vegetable oils is provided in this document.

2. Intended Uses of High Oleic Soybean Oil

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Commodity soybean oil does not have the optimum fatty acid profile to satisfy many of the needs of the food industry[7]. The fatty acid profile for soybean oil does not provide optimal oxidative stability compared to other vegetable oils unless modified via hydrogenation or through blending with other vegetable oils. Hydrogenation creates unhealthy *trans-fat* making soybean oil less desirable for use in some applications. In addition, due to low oxidative stability, commodity soybean oil is not highly stable for cooking and frying when used in these applications, causing several operational challenges such as more frequent exchange of vegetable oil stocks and/or replacement of oil and polymerization, leading to frequent costly equipment cleaning. For these reasons, in recent years, soybean oil has lost share to other vegetable oils in food applications (Wilson, 2004; Attachment I, Part 2, pg 38).

Given recent food labeling policy changes and modifications to dietary guidelines, the food industry is seeking vegetable oils that not only have enhanced functionality but minimize levels of trans- and saturated fat; the balance of fatty acids (high oleic, low saturated fat, low linolenic) is often difficult to achieve with current vegetable oil options. Soybean oil competes with other oils such as palm, canola, sunflower, peanut and corn. These oils are generally blended to satisfy food companies seeking to address functional or nutrition related needs. High oleic soybean oil can provide a complementary option either as a straight replacement of blended oils or as a blending alternative to end users. While blending achieves the food company's objective, it is costly due to increased handling, average oil price and required technical support (Attachment I, Part 4, pg 75).

Through conventional plant breeding, MON 87705 will be bred with Vistive low-linolenic soybean. Vistive low-linolenic soybean was developed through conventional plant breeding to produce lower levels of linolenic acid allowing food companies to avoid hydrogenation of soybean oil helping to eliminate unhealthy *trans* fatty acids from the diet. The low linolenic soybean has a mutation in the *Fad3-1c* and *Fad3-1b* genes that result in reduced levels of linolenic acid. The Vistive low-linolenic soybean oil is currently commercially sold in the United States. The soybean oil from MON 87705 in the Vistive low-linolenic soybean background has the following specification: palmitic acid (< 4.0%); stearic acid (< 4.0%); oleic acid (55 - 85%); linoleic acid (8 – 30%); and linolenic acid (< 4.0%). The modification of the fatty acid profile provides an equal or better alternative to vegetable oil options available today and offers the opportunity to reduce the practice of blending which has become the solution for fry applications to avoid *trans-fats*. The observed fatty acid profile of MON 87705 Soybean and MON 87705 in a Vistive low-linolenic soybean genetic background are presented in Table 1.

[7]http://qualisoy.com

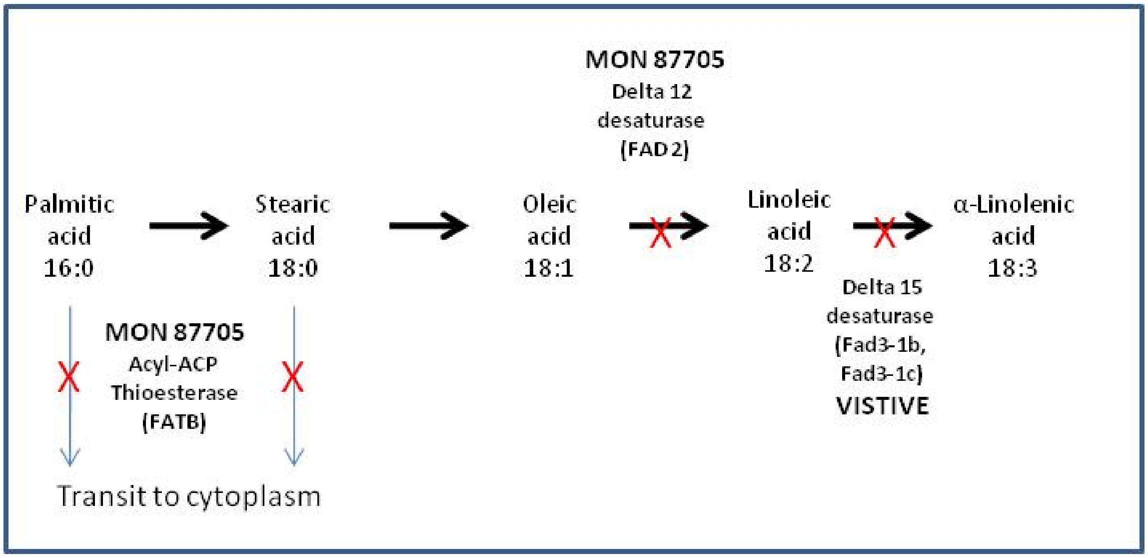

Figure 1. Fatty acid synthesis in MON 87705 in a Vistive low-linolenic genetic background

Table 1. Fatty acid composition (% weight of soybeans) of MON 87705 Soybeans and MON 87705 in a Vistive low-linolenic soybean background

Year	C16:0	C18:0	C18:1	C18:2	C18:3
MON 87705					
2007[1]	2.36	3.31	76.47	10.10	6.69
MON 87705 in a Vistive low-linolenic soybean background					
2007[2]	2.60	3.05	77.27	13.77	2.63
2008[2]	2.47	2.97	75.30	15.60	2.96
2009[3]	2.31	3.29	71.21	19.03	3.20
2010[4]	2.20	3.43	76.83	13.73	2.47

[1]Samples were obtained from field trials conducted in Chile in the 2007/2008 growing season. See USDA Petition Number 09-201-01p.
[2]Grown in Jerseyville, IL.
[3]Samples were obtained from 8 U.S. locations (2 sites each in the states of IA, IL, IN, and OH). Value is mean of the 8 individual site values.
[4]Samples were obtained from 3 U.S. locations (2 sites in IL and one site in OH). Value is mean of the 3 individual site values.

The safety of MON 87705 Soybeans in a Vistive low-linolenic soybean genetic background is based on the long-standing history of safe consumption of the levels and types of fatty acids contained in commercial vegetable oils with a fatty acid profile similar to MON 87705 Soybeans in Vistive low-linolenic background. Monsanto has completed a safety assessment[8] of high oleic soybean oil and high oleic soybean oil is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use. MON 87705 Soybean in a Vistive low-linolenic soybean genetic background does not contain any new fatty acids that are not presently found in conventional food oils and the fatty acid profile of this oil is similar to many other commercial oils currently available including canola, olive oil, high oleic safflower oil, and high oleic sunflower oil (See Table 2). The oil from MON 87705 Soybeans in a Vistive low linolenic soybean genetic background provides options for food formulation that is virtually *trans* fat-free, and, unlike palm oil, is low in saturated fat.

Table 2. Fatty acid composition (% weight) of MON 87705 in Vistive background in comparison to soybean oil and other high oleic vegetable oils [1]

Oil	Saturated fats	*trans* fats	Oleic acid	Linoleic acid	Linolenic acid	Other fatty acids
Soybean oil, all purpose	15.2	0.7	22.6	50.1	6.5	4.9
PH Soybean [2]	24.7	34.1	31.4	4.5	0.2	5.1
MON 87705 in Vistive background [3]	6.8	0.22	71.7	16.9	2.9	1.5
HOSO (305423) [4]	14.27	0	70.6	5.5	7.2	3.4
Olive oil	13.8	0	71.3	9.8	0.8	4.3
HOLLCO [5]	3	0	84	7	2	4
High oleic canola	6.5	0.8	70	14.3	2.6	5.8
Canola	7.6	1.6	60.6	17.7	6.4	6.1
High oleic Sunflower	9.7	0	82.6	3.6	0.2	3.9

[1] The fatty acid profiles of PH soybean oil (partially hydrogenated soybean oil), olive oil, canola oil, high oleic canola oil, and high oleic sunflower oil were obtained from the USDA nutrient database (USDA 2008, National Nutrient Database for Standard Reference. U.S. Department of Agriculture (USDA), Agricultural Research Service (ARS), Nutrient Data Laboratory; Beltsville, Maryland. Available from: http://www.nal.usda.gov/fnic/foodcomp/search/).
[2] PH Soybean: partially hydrogenated soybean oil.
[3] MON 87705 in Vistive background fatty acid composition is based on the pooled analysis of 8 oil lots.
[4] HOSO (305423): high oleic soybean oil from Pioneer/DuPont, defined in Delaney (2008).
[5] HOLLCO: High oleic low linolenic canola oil, values from Möllers (2004).

[8] See FDA GRAS assessment at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm061846.htm#Q1

Vegetable oils are used in twelve broadly grouped end use sectors: snacks, salad oils (use in mayonnaise, salad dressings and other food products), margarine, bottled oils (home use), par fry, ingredient, confectionary, baked goods, industrial fry, restaurant, institutional, and food service (Attachment I, Part 2, pg 37). High oleic soybean oil is targeted for ten of the twelve end use sectors with bottled and salad oils not considered a commercial target for high oleic soybean oil because commodity soybean oil currently serving these sectors does not require hydrogenation and products currently have acceptable shelf lives.

Industrial uses such as bio lubricants and biodiesel are also possible end uses of high oleic soybean oil. High oleic soybean oil is a renewable resource and is an attractive option as the price of crude petroleum continues to increase. The increased levels of oleic acid in high oleic soybean oil enhance the stability and lubricity of the oil making it a superior bio lubricant compared to petroleum based oils and a good feedstock for biodiesel (Graef et. al, 2009).

Food and industrial end use sectors are currently supplied by commodity soybean oil as well as domestic and imported blends of other vegetable oils (e.g. palm oil). Thus, high oleic soybean oil would potentially replace commodity soybean oil and oil blends currently used for these applications.

3. Market Potential of High Oleic Soybean Oil

In order to assess the market potential for high oleic soybean oil, Monsanto commissioned a study that included an in-depth analysis of the vegetable oil market in North America that was performed by LMC International (Attachment I). The study was conducted to assess the potential demand for vegetable oil with the fatty acid properties of high oleic soybean oil. Factors considered included current uses of vegetable oils and their physical properties, health attributes of the oil, availability and price. The market potential estimate assumed that high oleic soybean oil was used in the target food sectors described above as a direct replacement for hydrogenated soybean oil and other vegetable oils (such as canola, corn, palm and sunflower) used in food applications (Attachment I, part 5; pg 88). The demand for high oleic soybean oil is price sensitive relative to other vegetable oils. To estimate of the maximum high oleic soybean the lowest price premium ($50/metric ton) was used. At the lowest price premium, high oleic soybean would achieve a demand for the oil estimated at 3.5 million metric tons. On the basis of this analysis, approximately 16 million acres of high oleic soybean would satisfy the demand if high oleic soybean oil were to replace current uses of hydrogenated soybean and other high oleic vegetable oils in food and industrial applications (Attachment I, Part 5, pg 90)[9]. Additional acres would likely be planted to supply high oleic soybean oil for industrial uses. Based on assumptions regarding product adoption and acceptance by the industry, Monsanto estimates it would take at least a decade for high oleic soybeans to achieve this acreage and at peak penetration, this level would represent approximately 23% of total planted soybean acres[10].

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[9] One bushel of soybean = 60 lbs and contains 10.7 lb oil (Wilson, 2004); average yield of soybean = 43.7 bushels per acre in 2010 (USDA NASS: http://www.nass.usda.gov)

[10] Assumes 70 million acres of soybean are planted.

Subsequently, there would continue to be adequate supply of both commodity and high oleic soybeans to serve the vegetable oil market needs.

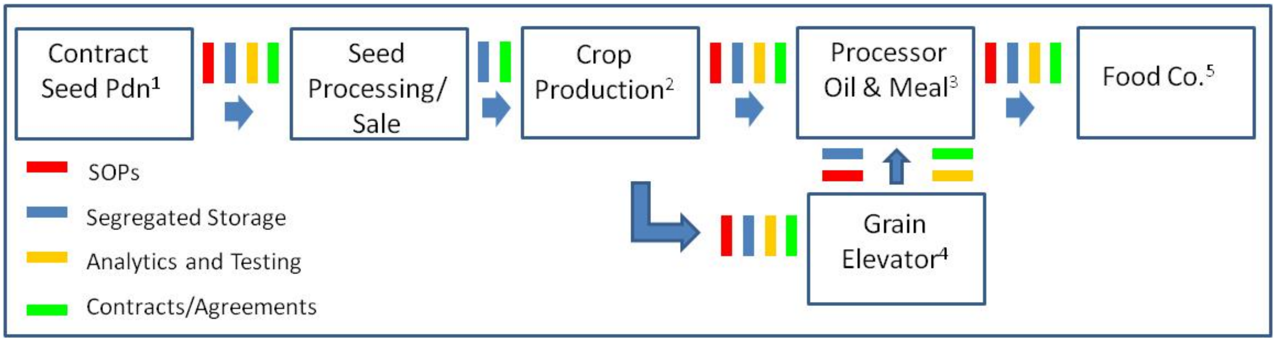
4. Production and Handling of Vegetable Oils

Crop production and distribution systems as well as oil processors and food manufactures have demonstrated the ability to handle multiple vegetable oils derived from numerous crop species. A summary of the current practices including critical control points for production of soybean oil and specialty soybean oil (e.g. Vistive low linolenic) is provided below. There are numerous vegetable oils on the market today including: palm, coconut, palm kernel, cottonseed, soybean, groundnut, rapeseed and sunflower (Attachment I, Part 2, pg 38). Other minor use oils include olive, corn, high oleic canola, high oleic sunflower oil and low linoleic soybean oil (Vistive). The processing industry (e.g. Cargill, Bunge, ADM, etc.) and end users of such oils are highly adept at handling these vegetable oils in their normal course of business. As a result, processors have developed methods to segregate multiple vegetable oil feedstocks as they are financially motivated to prevent mishaps with their customers. High oleic soybean, for planting and subsequent processing, would be introduced to the market place as an option for processors to supply food companies and those who seek a U.S. based vegetable oil option.

Once key global market approvals are obtained, oil from MON 87705 will be available as an option for use by food processors and will be produced in an identity preserved (IDP) fashion similar to the system that has been successfully implemented for production of Vistive low linolenic soybean and other specialty vegetable oils. IDP practices are implementd for value added specialty soybean to capture the enhanced value of the product and ensure that the end-user or processor receives the soybean with the desired identity, fatty acid profile and quality. Vistive low-linolenic soybean was made available to growers in 2005 and has been grown on over 3.0 million acres since its initial launch.

A summary of the quality control systems associated with seed production, crop production, processing and end uses of high oleic soybean oil is presented in Figure 2.

Figure 2. Production and use checkpoints for high oleic soybean



[1]Monsanto contracts soybean seed production with growers under ISO standards.
[2]Growers produce crop under a contract – typically growers have segregated on farm storage of harvested grain. Grower may deliver soybean directly to a processor or to a grain elevator.
[3]Processor has on-site segregated storage, performs testing of soybean with on-site NIR method. The fatty acid profile of the ingredient is analyzed prior to acceptance of soybean and on processed oil. Test results are provided to the Food Co. by the processor.
[4]Grower delivers to elevator, analytical testing of soybean using on-site NIR method, elevator holds soybeans until called by processor. Delivery of grain to processor triggers same process as delivery from grower.
[5]Food Co. handles multiple vegetable oil ingredients. Food company follows existing ingredient and batch identification procedures, and product tracking throughout the production and distribution system including retailer shipments.

Seed Production and Processing. Monsanto is a leader in crop biotechnology having successfully introduced numerous biotech crops to the marketplace. Monsanto has developed and implemented seed quality practices to assure that soybean seed meets the standards established for purity of a trait. These standards apply to all soybean seed sold by Monsanto and are based upon measures that seed producers put in place to assure the genetic purity of improved planting seed. This system is used to assure that farmers receive seed of known quality with a minimum level of off types.

The first step in the process for production of high oleic soybean is the production, processing and delivery of high quality seed to the grower. The entire seed production process at the majority of the seed companies and tollers operate using International Organization for Standardization (ISO) certification or standards and; therefore, include internal and external audits (ISO, 2009). ISO standards ensure desirable characteristics of seeds and services, such as quality, safety, reliability, and efficiency. The ISO standards represent an international consensus on good management practices with the aim of ensuring that the organization can consistently deliver excellent product or services. The standards not only must meet the customer's requirements and applicable seed regulatory requirements, but must aim to enhance customer satisfaction and achieve continual improvement of its performance in pursuit of these objectives (ISO, 2009).

Commercially certified soybean seed must meet state and federal seed standards and labeling requirements. The Association of Official Seed Certifying Agencies (AOSCA) standards for certified soybean seed are as follows: 98% pure seed (minimum), 2% inert matter (maximum), 0.05% weed seed (maximum, not to exceed 10 per lb.), 0.60% total of other crop seeds (maximum), 0.5% other varieties (maximum, includes off-colored beans and off-type seeds), 0.10% other crop seeds (maximum, not to exceed three per lb.), and 80% germination and hard seed (minimum) (AOSCA, 2009). Seed that meets or exceeds these standards are provided in appropriately labeled seed bags to growers

Production of Soybean Grain Containing High Oleic Soybean Oil. Specialty soybean (e.g. Vistive low linolenic) is currently produced under contracts issued by processors or elevators. It is expected that high oleic soybean will be produced using this system as well.

There are three major factors needing to be satisfied before a farmer will produce a specialty soybean containing a modified soybean oil, like high oleic. These factors have become evident in Monsanto's experience in the crop production of Vistive low linolenic soybeans.

1. Yield of the soybean must be comparable to commodity soybeans routinely planted
2. The option to market, price & deliver the grain must be comparable to commodity grain
3. The premium paid to the farmer to offset the cost to identity preserve the high oleic containing grain must provide incremental income opportunity above the production of commodity grain. The income opportunity cannot be realized by the farmer unless the grain is delivered to the processor within specifications or in its identity preserved state. Therefore, the motivation is a financial incentive for the farmer to avoid comingling with commodity grain, keeping all the grain identity preserved within this closed loop system of seed – farmer - processor. Many farmers willingly choose to plant all their acreage to this specialty soybean because it eliminates any risk of contamination from inadvertent errors that may occur during the harvest. If a farmer chooses to produce the specialty grain for the processor, the farmer will arrange to store the grain on farm or at their local elevator, if the elevator is participating in the specialty program with the processor.

The steps involved in securing grain production are:

1. Monsanto will sell and distribute high oleic soybean seed to the farmer after the farmer has signed and agreed to the conditions of Monsanto's Technology and Stewardship Agreement. The agreement will mandate that the farmer sell any soybean produced into an identity preservation channel (See Figure 2).
2. Processors will be responsible to contract with elevators and growers the acreage needed to fulfill the expected demand for high oleic soybean.
3. After harvest, the farmer will deliver the grain produced to the location specified in his contract, either a participating elevator or processor. If to the elevator, the elevator will keep the grain segregated from commodity grain and pay the farmer his premium, provided it passes the analytical testing. The elevator will deliver the grain to the processor as delivery windows and crush schedules have been established. Upon delivery of grain by the farmer, samples will be analyzed from every truckload by Near Infrared Transmittance (NIT) developed by Monsanto. This will confirm the grain contains high oleic soybean oil as required by the production contract. Upon confirmation of grain that meets specification of high oleic soybean grain, the processor or elevator will approve the premium payment to the farmer.

   In the event that high oleic soybean do not meet the minimum specifications established for oil quality, the soybean would be isolated from other high oleic or commodity soybean and blended with an appropriate quantity of high oleic soybean to meet the specifications required for a food application. Monsanto has been conducting field trials with high oleic soybean since 2005 and has considerable experience with trait performance in various genetic backgrounds and under various climatic conditions. Trait performance has been consistent over several years of breeding (See Table 10). All soybean varieties that Monsanto will introduce must meet specifications for agronomic performance and oil quality. While it is not envisioned that any of the high oleic soybean varieties will underperform, blending with other high oleic soybean is the most likely remedy.

Grain Elevator. Grain elevators play an important role in specialty programs with their long term storage of the grain. Since processing facilities crush soybeans throughout the calendar year, soybeans used to supply these crush plants need to be stored year round. Farmers typically prefer to empty their storage prior to planting of the new crop and prior to temperature warm up in the spring. The warm spring and summer weather present challenges as condensation can build up in the bins creating moisture related issues and grain eating insects become more active. Farmers prefer to avoid these high management grain conditions. Commercial elevators have expert grain managers on staff to monitor grain quality and keep grain in condition in all weather situations presented throughout the year.

Commercial grain elevators are also better equipped to ship grain to processors during times of severe weather or when farmers cannot get to their bins when roads are impassable.

Processors will therefore enter into supply contracts with commercial grain elevators for these reasons. Contracts will be “acre” based, established to fill bin capacity that has been agreed upon by both parties. Grain elevators will then contract with farmers directly, providing harvest storage terms to the farmer with premiums to be paid that have been agreed upon with the processor. The elevator pays the farmer the specialty grain premium upon successful analytical testing by NIT performed at the elevator location. NIT testing equipment will be provided by Monsanto to participating elevators identical to the equipment provided to processors.

In order for the elevator to be reimbursed for the premiums paid out to farmers that have delivered to them, the elevator must in turn preserve the identity of the grain as it is delivered to the processor.

Every load delivered to the processor by the elevator will be analyzed using NIT technology. Processors will approve the premium payment to the elevator after analysis of the grain confirms high oleic soybean oil.

Processing Oil and Meal. Specialty high oleic soybean grain will be introduced into the processing plant as it is running commodity soybean grain. Upon the transition from commodity soybeans in the plant, the processor will ensure that the equipment is lined out and operating within normal and acceptable limits and parameters using commodity soybean. High oleic soybeans will then be moved through the plant continuously until all specialty grain located at the plant is gone. After all of the specialty high oleic soybeans have moved through the seed prep building, the bins and conveyors feeding the seed prep building will be filled with commodity soybeans to keep the plant running continuously. Commodity soybeans will then be processed as normal.

Upon the transition from commodity soybeans to the high oleic soybeans, a sample of crude oil is required to confirm the presence of the appropriate fatty acid composition (FAC) unique to high oleic oil. Until the fatty acid composition of the crude oil exiting the extractor is of the appropriate composition, as determined by the plant manager, off spec crude oil will be sent to a tank that will be designated for flush oil. This will contain all oil before and after the collection of “on-spec” high oleic oil. High oleic crude oil that is collected with the appropriate FAC will be designated for further refining, bleaching, and deodorization. The processor’s lab will be used to aid in identifying the appropriate time to start collecting crude high oleic oil exiting the extractor that will undergo further refining. The lab will use gas chromatography equipment to analyze the crude oil to determine when on spec high oleic oil can be collected from the extractor. A tank approved for high oleic oil will be assigned by a processor employee. After all high oleic grain has been processed, the seed extraction area will be flushed with commodity soybeans, and regular commodity oil will be produced. During the flush, crude oil exiting the extractor will be sampled and analyzed to confirm the equipment has been flushed to an acceptable level, yielding commodity soybean oil.

Processes are established by the processor to ensure the transfer of high oleic oil to the crude oil tank farm to minimize loss and maximize quality. The lab at the processor will utilize appropriate analytical methods to determine when the high oleic oil is of proper quality to send to the main crude tank(s) that will supply oil for further refining. Commodity soybean flush oil prior to and after the crush of the high oleic oil will be collected in tanks designated as flush, and will be blended with commodity soybean oil to bring the flush oil into a specification range necessary to be sold as commodity soybean oil.

Food Company. Oil will be supplied to the food company by oil processors and suppliers. The processor or supplier will test the oil and assure that it meets specific customer requirements including quality factors (e.g. peroxide value, oxidative stability index, color, flavor) and oil composition (customized blends, specified fatty acid composition). Foodservice distributors typically obtain the oil from the oil processors and deliver it to each foodservice outlet (individual stores, caterers, cafeterias, etc). From the time the oil is packaged, until it is utilized at the specific customer’s facility, there is proper identification of the oil through labeling and manufacturing codes allowing for sufficient product traceability if needed. Individual facilities will utilize proprietary inventory and ordering systems that are in place to insure that the appropriate oil is ordered, delivered and utilized.

High oleic soybean oil will be used by the food industry in several ways. One specific type of food company customer will be foodservice operators including quick service restaurants, casual dining and full service restaurants who will use high oleic soybean oil as a fry medium and in meal preparation. Food companies will also use high oleic soybean oil as a food ingredient in a range of food products including as spray oil on crackers and snacks, or as a component of oil blends used in shortenings and other foods. Each individual food company has in place systems for ingredient (oil) ordering, receipt, storage, access and lot identification at specific manufacturing locations, as well as finished product (the food which incorporates high oleic soybean oil) batch identification, manufacturing facility, storage, shipment to distribution centers, customer order picking, customer order shipment and receipt. Appropriate procedures are currently in place to insure traceability from receipt of the ingredient through distribution to a specific retailer's facility. Food companies routinely conduct mock recalls including use of the media should the need arise. Food manufacturing facilities also comply with federal and state requirements for good manufacturing practices and product traceability. Supply chain consultants can be employed to confirm appropriate systems have been established that meet ingredient and product traceability requirements.

5. Stewardship of High Oleic Soybean

Monsanto is committed to product stewardship and to implementing BIO's "Excellence through Stewardship" program and Product Launch Stewardship Policy[11]. Monsanto considered Annex 2 "Special Use traits in Commodity Crops" [12] to develop launch plans for high oleic soybean oil including: (1) identifying relevant stakeholders for the trait and crop and engaging them in dialogue regarding use of high oleic soybean oil and potential impacts to vegetable oil markets, (2) conducting a market and trade assessment, including securing regulatory approvals in key export countries prior to full commercial launch, (3) developing a risk mitigation plan, and (4) undertaking appropriate outreach, necessary to educate stakeholders and implement the management plan for high oleic soybean oil. These actions protect against adverse impacts to trade of soybean due to the introduction of a new biotechnology improved soybean.

Stakeholder Dialogue

Monsanto is committed to dialogue with key industry stakeholder groups and has held several meetings with the National Oil Processors Association (NOPA) as well as other key industry associations such as the North American Export Grain Association (NAEGA), National Grain and Feed Association (NGFA), North American Milling Association (NAMA), American Bakers Association (ABA), and Grocery Manufacturers Association (GMA). Soybean grower organizations: American Soybean Association (ASA), United States Soybean Board (USB), and many state soybean associations. In addition QUALISOY, a collaborative program sponsored by the USB that serves as an independent, third part resource for information on trait-enhanced soybean oils, has been kept informed on the plans for this product, along with leaders in dietary and nutrition fields.

Market and Trade Assessment

Monsanto has conducted a market and trade assessment to determine the impact of the introduction of high oleic soybean oil. Soybean is a globally traded commodity with the U.S. being the top global producer (Soyatech, 2010). Biotechnology-derived crops and their use as food and feed are subject to regulation in many countries. In order to support continued trade in soybean, Monsanto is pursuing regulatory approval for MON 87705 in all key soybean import countries with a functioning regulatory system to support the flow of international trade.

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[11] http://www.monsanto.com/ourcommitments/Pages/product-stewardship.aspx

[12] http://www.bio.org/letters/Product_Launch_Stewarship_12_10_09.pdf;

International regulatory authorities are evaluating the biotech component as well as the modified oil fraction. It is expected that uses of high oleic oil soybean will be similar on a global basis.

There would be no impact to human heath or to the use of any of the other processed fractions produced from soybean due to comingling of high oleic soybean with commodity soybean. Monsanto has completed a GRAS assessment of the high oleic soybean oil (MON 87705 in a Vistive background)[13] and has completed the biotechnology consultation on MON 87705 with the U.S. FDA[14]. The GRAS assessment has been evaluated by FDA and the agency had no further questions. The biotechnology consultation considered the food and feed safety impacts due to the genetic modification process, RNAi suppression of two endogenous enzymes resulting in modification to fatty acid metabolism, as well as exposure to the CP4 EPSPS protein. The GRAS assessment considered the nutritional impact of total replacement of commodity soybean oil with high oleic soybean oil. High oleic soybean oil is similar to other high oleic vegetable oils that are commonly consumed producing no harmful effects to humans. Hence, Monsanto as well as a panel of qualified scientific experts have concluded that high oleic soybean oil is generally recognized as safe.

Information provided to USDA showed that the impact due to the suppression of the two endogenous enzymes is restricted to seed. With the exception of the intended changes in fatty acid composition and presence of the CP4 EPSPS protein, the soybean meal and other processed fractions used for animal feed and human food applications are compositionally equivalent to commodity processed soybean fractions[15]. Monsanto provided information to USDA in the petition demonstrating that the composition of the meal was compositionally equivalent to meal derived from conventional soybean and safe and wholesome for food or feed applications.

Monsanto has assessed the impact of the introduction high oleic soybean oil on commodity and other vegetable oils. In response to stakeholder dialogue, Monsanto was specifically requested by NOPA to address the impact of comingling of commodity soybean oil with high oleic soybean oil to bottled oils (100% commodity soybean oil) and severe heat processing (e.g. impact to frying applications and sensory properties of prepared foods). This assessment has been shared with key stakeholders such as NOPA, NAEGA, ASA, Qualisoy, USB and GMA. Hypothetical impacts were assessed using the following scenario: (1) high oleic soybean grain or oil went unnoticed and was comingled (e.g. harvest mistake, inadvertent mixing of grain during transport, mistaken delivery of grain, etc…), (2) the comingled soybean were delivered to an oil processor and mixed with commodity grain or soybean oil, (3) the oil or grain was not analyzed for oil composition by anyone in the food supply chain, and (4) the comingled oil was used in the food or feed supply chain. This scenario is highly unlikely given existing critical

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[13]http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm061846.htm#Q1

[14]Biotechnology notice: BNF 121: http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing; GRAS notice: GRN 306 - http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing&page=2

[15] USDA Petition Number 09-201-01p, Section VII.C.

control points embedded in the production handling and processing system and because high oleic soybean oil is expected to be produced in a contractual identity preserved system in order to preserve its premium value. Processors will originate the supply of high oleic soybeans and as they have extensive experience managing, segregating, testing, formulating and blending other sources of high oleic vegetable oils such as high oleic canola and high oleic sunflower oil.

Bottled vegetable oil is not an intended use for high oleic soybean oil. However, bottle oil was used to assess potential impacts at the request of NOPA. It represents a readily measurable impact that could occur if high oleic soybean were comingled with 100% commodity soybean. Mixing high oleic soybean with commodity soybean will impact to the levels of fatty acids in commodity soybean. This effect is measurable and can potentially translate into downstream effects to food labeling, oil quality, and functionality. Even though such comingling is improbable, potential impacts were assessed at several different comingling levels ranging from 4% and up to 30% using four different parameters: (1) food ingredient labeling, (2) nutritional facts panel labeling (3) functionality of the oil, and (4) sensory evaluation.

Food Ingredient Labeling Codex Specification. Effects were assessed on the ability to meet USP Food Chemical Codex (USP FCC) soybean oil labeling specification. In Table 3 the impact of varying amounts of high oleic soybean oil comingled with commodity soybean oil on the ability to meet specifications for major fatty acids is evaluated. The USP FCC is a compendium of internationally recognized standards for the purity and identity of food ingredients and is used as a set of agreed standards between buyers and manufacturers of food ingredients[16]. Based on this analysis the most sensitive fatty acid is 18:2 linoleic acid. If high oleic soybean were co-mingled with commodity soybean oil at levels above 14%, the linoleic acid (C 18:2) content of the resulting oil following processing would fall below the USP FCC specification for commodity soybean oil. At levels above 15% oleic (C 18:1), linoleic acid would be out of the specifications for soybean oil.

To put this into perspective, 15% comingling could occur due to a farmer mistakenly harvesting approximately three acres of high oleic soybean (assuming yield = 43 bushels/acre) and comingling it with commodity soybean in a grain truck hauling the standard load limit with a capacity of 900 bushels. If the grain were delivered to a grain elevator or directly to a processor, it would be mixed with other commodity soybean grain thereby diluting the high oleic soybean considerably with commodity soybean. The capacity of grain elevators or bin storage tanks is highly variable; however, bin capacities up to and exceeding ½ million bushels are quite common. Hence, it would take roughly 83 fully loaded trucks containing 100% high oleic soybean or multiple mistakes during harvest of high oleic soybean to achieve a 15% level of comingling.

Nutrition Facts Panel Labeling. Figure 3 and 4 demonstrate the amount of high oleic soybean oil that would be required to be comingled with commodity soybean oil in order to impact the Nutrition Facts Panel for major fatty acid categories. Based on this analysis,

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[16] http://www.usp.org/fcc/

monounsaturated fat is the most sensitive fatty acid category and comingling up to 5% high oleic soybean oil could be tolerated before the Nutrition Facts Panel label for monounsaturated fatty acids were impacted on retail bottled vegetable oil. Up to 15% high oleic soybean could be comingled with commodity soybean oil before effects to polyunsaturated fatty acid labeling would be impacted.

The threshold for effects is lower than USP FCC labeling situation discussed above. In this case it would take a mistake during harvest of one acre of high oleic soybean comingled with 900 bushels of commodity soybean in a 900 bushel grain truck or 28 fully loaded trucks containing 100% high oleic soybean would need to be delivered to a ½ million bushel grain elevator containing commodity soybean to trigger an effect to the nutritional facts panel labeling.

The impact due to both of the comingling scenario discussed above would be minimal. As discussed previously, there would be no impacts to human health and the changes in fatty acids would benefit consumers from a nutritional perspective. Mandatory labeling is required for saturated fats, in this case comingling levels of up to 28% could be tolerated without impacting the level of saturated fats reported on the label. At 28%, the level of saturated fat would be lower, enhancing the nutritional profile of the product (Figure 4).

Oil Functionality; Severe Heat Processing. High oleic soybean oil has an improved stability profile compared to commodity soybean oil. An assessment of the impact of comingling of high oleic soybean oil with commodity soybean grain and oil was conducted. Information in Figure 5 demonstrates that comingling of high oleic soybean oil with commodity soybean oil increases the OSI stability index for commodity soybean oil. This outcome is expected since soybean oil oxidative stability is drastically influenced by the proportion of monounsaturates to polyunsaturates, and high oleic soybean oils are estimated to have improved oxidative stability compared to conventional soybean oil (Frankel, 2005).

Food Sensory Assessment. A sensory assessment of high oleic soybean oil was performed to evaluate consumer acceptability of high oleic soybean oil. Figure 6 demonstrates the sensory results for high oleic soybean oil in the most challenging environment high temperature food frying. In this experiment, commodity soybean oil and blends (5% to 15%) of commodity and high oleic soybean oil were used to prepare French fries. Food testers were asked to evaluate the quality of the fries using the Sensory Quality System described by King et al (2003). The outcome from the sensory evaluation showed that high oleic soybean oil comingled with commodity soybean oil blends were essentially the same as commodity soybean oil over the six-day period during which the experiment was conducted. Thus, comingling of high oleic soybean oil with commodity soybean oil would have no impact to the sensory profile of commodity soybean oil should inadvertent comingling occur (Figure 6).

The comingling scenarios and impacts above are presented as the most conservative scenarios. Oilseed processors and users of vegetable oils are accustomed to the presence of numerous vegetable oils of differing fatty acid makeup that are available concurrently for blending and use in various food applications. The comingling levels described here where an impact could occur in functionality or labeling would happen only in instances where common control points were ignored. Such levels of comingling are highly unlikely to occur due to economic incentives to growers, legal contracts, stewardship SOP's (seed quality to end user), and demonstrated competency in managing inadvertent comingling with other vegetable oils that have a fatty acid profile similar to high oleic soybean oil. In addition, fatty acid analytical methods are widely available and used currently by oil processors and food manufacturers.

Industry Outreach

Monsanto has held conversations with the soybean and food industry key stakeholders mentioned above regarding the oil composition, stewardship plan and performance of MON 87705. Additionally, Monsanto has consulted with NOPA and industry members of NOPA's biotechnology committee as well as the ASA and USB regarding the fatty acid composition of high oleic soybean oil and potential changes to commodity soybean oil due to comingling. NOPA and members of their biotechnology committee were provided information related to the fatty acid composition of high oleic soybean oil derived from MON 87705 in the Vistive low-linolenic genetic background as well as oil properties and mixing effects information described previously. NOPA and biotechnology committee members agree that potential impacts related to the unintended mixing of commodity soybean oil and high oleic soybean oil could be remedied through blending, a common industry practice. Given the control points in the system and potential market impact of high oleic soybean oil, a risk mitigation plan (as described in Annex 2 of BIO's Product Launch Stewardship Policy) for high oleic soybean is not warranted. NOPA and the committee members continue to provide input on various aspects of the intended commercialization.

6 Summary

High oleic soybean offers an opportunity for soybean growers to recapture markets for vegetable oil previously occupied by soybean oil and create added value for U.S. soybean producers. Given the abundance of vegetable oils on the market and demonstrated ability of the system to adapt to consumer preferences incorporating new oils into existing food manufacturing processes, the market impact of high oleic soybean is expected to be minimal and easily managed. Monsanto has conducted and is implementing a product stewardship plan that is based upon consideration of BIO's Launch Stewardship guidance and upon experience with previous successful product introductions completed by Monsanto. Monsanto continues to engage stakeholders and educate them on the benefits of high oleic soybean and proper stewardship practices.

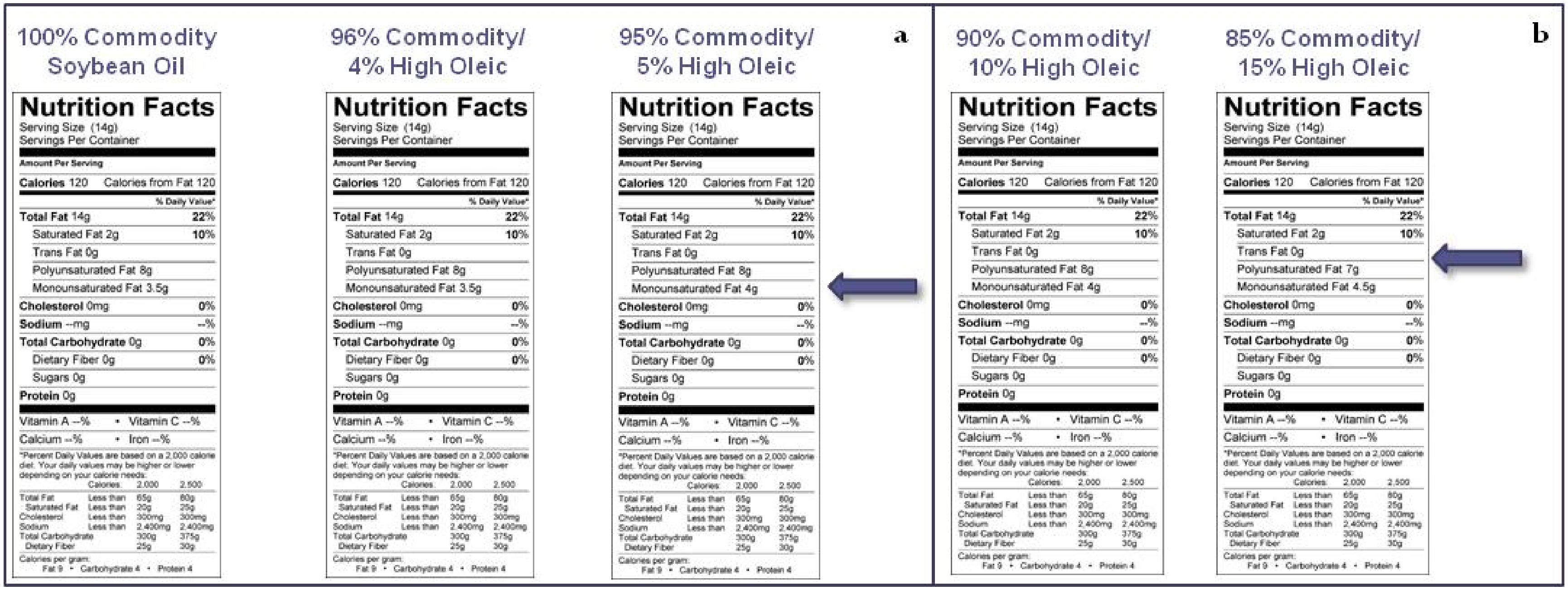
Table 4. Impact of comingling of high oleic soybean oil on Food Codex specifications of commodity soybean oil.

Major Fatty Acids	USP FCC[1] Range SBO min	USP FCC[1] Range SBO max	Typical Soy	Typical HO[2]	5% HO	10% HO	Break Pt 14% HO	15% HO
C16:0	**7**	**12**	10	2.49	10.071	9.672	**9.3528**	**9.273**
C18:0	**2**	**5.5**	4.64	3.34	4.575	4.51	**4.458**	**4.445**
C18:1	**19**	**30**	22.85	72.8	25.3475	27.845	**29.843**	**30.3425**
C18:2	**48**	**65**	52.7	16.6	50.895	49.09	**47.646**	**47.285**
C18:3 n3 ALA	**5**	**10**	6.97	3	6.7715	6.573	**6.4142**	**6.3745**

[1]FCC – Food Chemical Codex specification for named vegetable oils
[2]HO – Oil profile represents high oleic MON 87705 Soybean bred into a low linolenic soybean background.

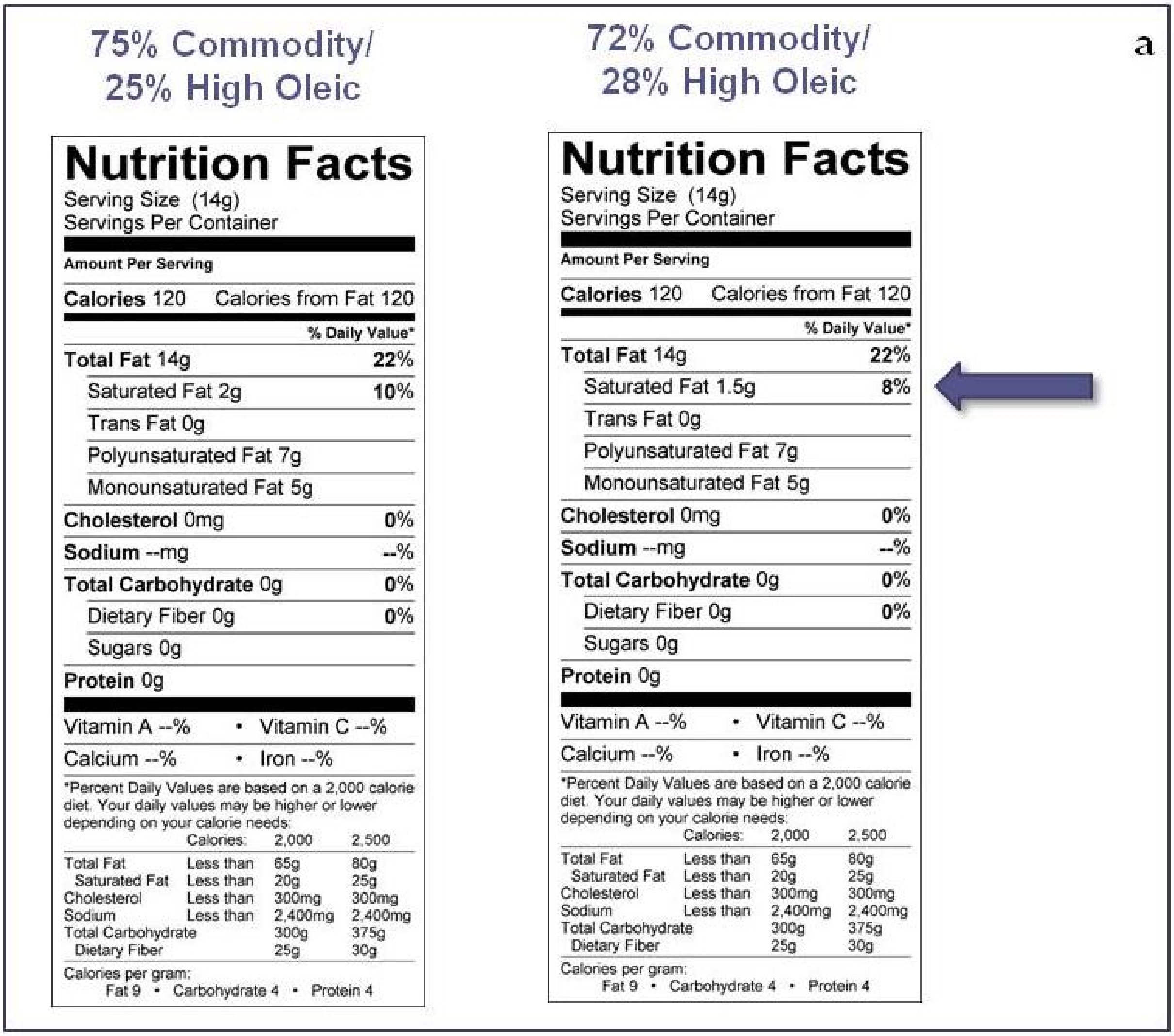
Legend. The impact of mixing high oleic soybean oil on the fatty acid profile of commodity soybean oil is depicted in the table above. The impact to the fatty acid profile was assessed at various percentages of high oleic soybean oil mixed with commodity soybean oil. The "break point" reflects the percentage of high oleic soybean oil at which the fatty acid levels in soybean oil would no longer be in the USP FCC specification range for soybean oil.

Figure 3. Impact of comingling high oleic soybean oil with bottled commodity soybeal oil on nutritional facts labeling to mono and polu unsaturated fatty acids.



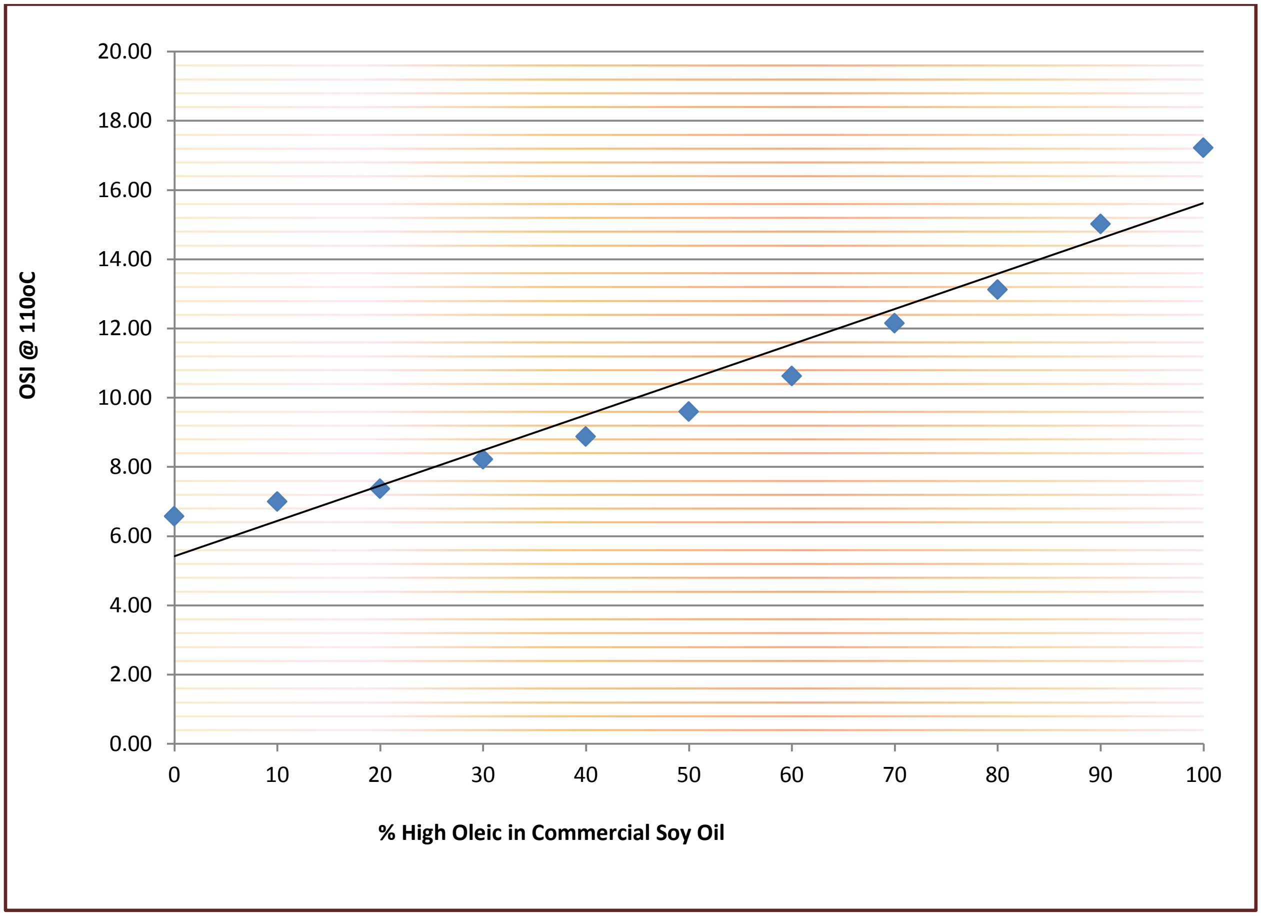
Legend. The impact of mixing high oleic soybean oil on nutritional facts labeling for bottled soybean oil is depicted in the figure above. The impact to nutritional facts panel labeling was assessed at various percentages of high oleic soybean oil mixed with commodity soybean oil. The blue arrows indicate the levels of high oleic soybean oil that would impact the nutritional facts labeling.

Figure 4. Impact of comingling high oleic soybean oil with bottled commodity soybeal oil on nutritional facts labeling to saturated fatty acids.



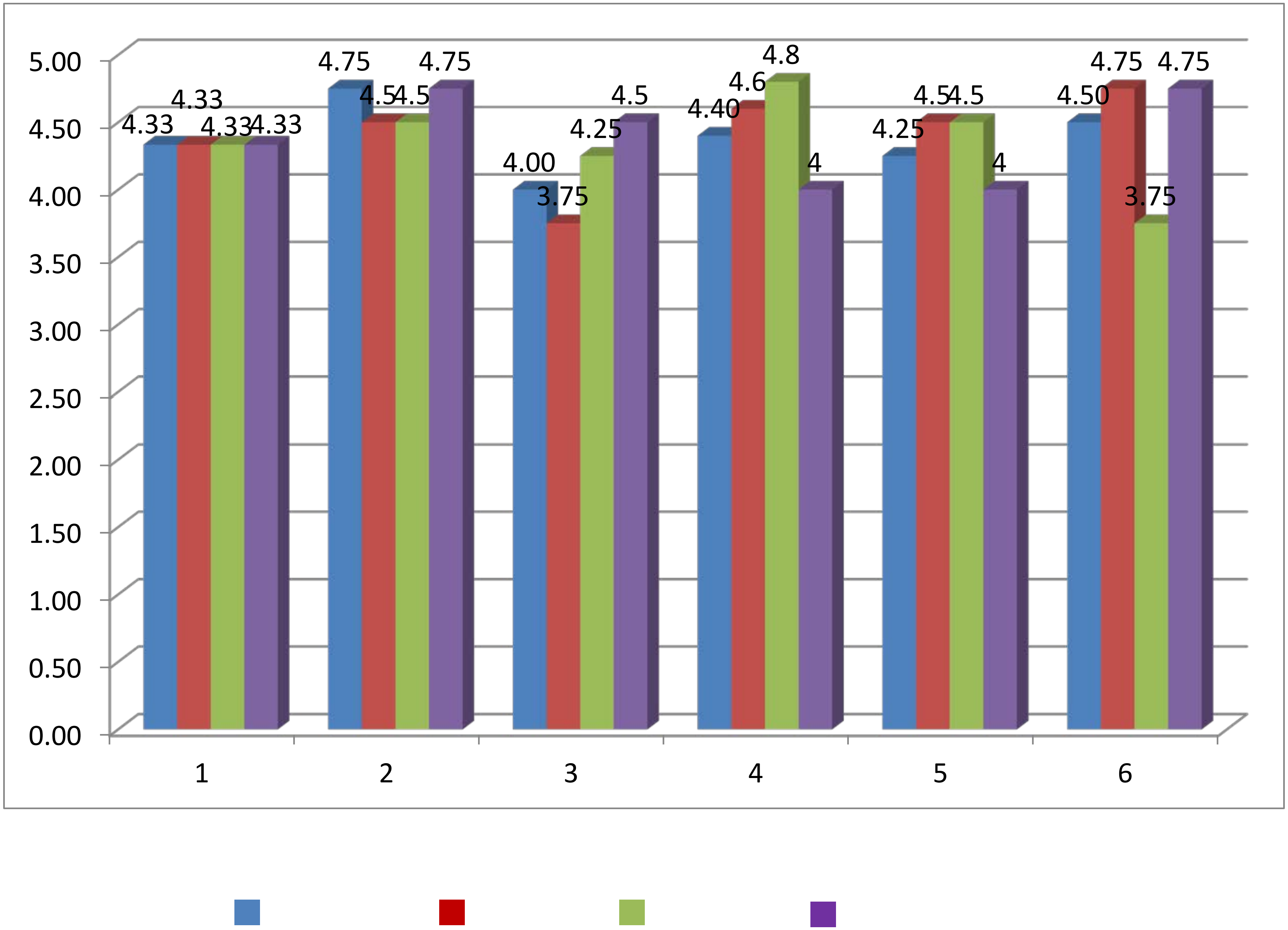
Legend. The impact of mixing high oleic soybean oil on nutritional facts labeling for bottled soybean oil is depicted in the figure above. The impact to nutritional facts panel labeling was assessed at various percentages of high oleic soybean oil mixed with commodity soybean oil. The blue arrows indicate the levels of high oleic soybean oil that would impact the nutritional facts labeling for mandatory fatty acid reporting (saturated fats).

Figure 5. Oxidative stability index of high oleic soybean blended with commodity soybean oil.



Legend. The impact of comingling of high oleic soybean oil was assessed on the oxidative stability index of the blended oil. The OSI stability index is an indicator of soybean oil stability. All oils and fats have a resistance to oxidation, which depends on the degree of saturation, antioxidant and prooxidant concentration, and prior abuse. Oxidation is slow until this resistance is overcome, at which point oxidation accelerates and becomes more rapid. The length of time prior to the acceleration of oxidation is referred to as the 'induction period,' and the point of maximum rate change is referred to as the Oxidative Stability Index or Oil Stability Index (OSI), and is reported in hours (Frankel, 2005).

Figure 6. Sensory assessment of high oleic soybean oil compared to other vegetable oils.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Legend. A sensory assessment of the quality of French fries prepared in blends of high oil/commodity soybean oil was conducted over a period of six days. A modification of the procedure described by King et al (2002) was used for the evaluation. The sensory qualities of the oil blends tested were essentially the same over the six-day period. Scale: 5 = no difference, 4 = very slight difference, 3 = slight difference, 2 = different, 1 = very different.

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ATTACHMENT I

THE MARKET POTENTIAL FOR A HIGH OLEIC SOYBEAN OIL

CONFIDENTIAL BUSINESS INFORMATION

CBI Deleted

Pages 25 through 127 have been deleted