Monsanto Petition (11-202-01p) for Determination of Nonregulated Status of Event MON 87712-4 Soybean

OECD Unique Identifier:
MON 87712-4

Draft Environmental Assessment

June 2013

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ACRONYMS AND ABBREVIATIONS

°C	degrees Celsius
°F	degrees Fahrenheit
AIA	advanced informed agreement
AMS	Agricultural Marketing Service
ANZFS	Australia and New Zealand Food Standards Agency
AOSCA	Association of Official Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
ARMS	Agricultural Resource Management Survey
ARS	Agricultural Research Service
BRS	Biotechnology Regulatory Service’s
C	carbon
CAA	Clean Air Act
CFR	Code of Federal Regulations
CH_4	methane
CO	carbon monoxide
CO_2	carbon dioxide
CWA	Clean Water Act
DNA	deoxyribonucleic acid
EA	Environmental Assessment
ECOS	Environmental Conservation Online System
EFSA	European Food Safety Agency
EIS	Environmental Impact Statement
EO	Executive Order
EPA	Environmental Protection Agency
ERS	Economic Research Service
ESA	Endangered Species Act
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FFP	food, feed, or processing
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
GE	genetically engineered
GHGs	greenhouse gases
HRAC	Herbicide Resistance Action Committee
IP	Identity Preservation
IPPC	International Plant Protection Convention
lb/A	pounds per acre
LMO	living modified organisms
MGs	maturity groups
MT	metric tons
N_2O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NAPPO	North American Plant Protection Organization
NASS	National Agricultural Statistics Service

ACRONYMS AND ABBREVIATIONS (continued)

NEPA	National Environmental Policy Act
NHPA	National Historic Preservation Act
NH_3	ammonia
NMFS	National Marine Fisheries Service
NO_2	nitrogen dioxide
NOP	National Organic Program
NPDES	National Pollutant Discharge Elimination System
NRC	National Research Council
NRCS	Natural Resources Conservation Service
O_3	ozone
OSHA	Occupational Safety and Health Administration
Pb	lead
PDP	Pesticide Data Program
PIPs	plant-incorporated protectants
PM	coarse particulate matter
$PM_{2.5}$	fine particles less than 2.5 micrometers in diameter
PM_{10}	particles greater than 2.5 micrometers and less than 10 micrometers in diameter
PRA	Plant Risk Analysis
ROW	rest of world
SDWA	Safe Drinking Water Act of 1974
SIP	State Implementation Plan
SO_2	sulfur dioxide
SOM	soil organic matter
SSA	Sole Source Aquifer
TES	threatened and endangered species
TMDL	total maximum daily loads
TSCA	Toxic Substances Control Act
U.S.	United States
U.S.C.	United States Code
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
WHO	World Health Organization
WPS	Worker Protection Standard

1 PURPOSE AND NEED

1.1 Background

Monsanto Company of St. Louis, MO (henceforth referred to as Monsanto) submitted petition 11-202-01p to the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) September 16, 2011 (Monsanto, 2011). The purpose of the petition is to support a determination of nonregulated status for Monsanto 87712 soybean (henceforth referred to as MON 87712). The 87712 variety is currently regulated under Title 7 of the Code of Federal Regulations (7 CFR) part 340. Interstate movement and field trials of MON 87712 soybean have been conducted under permits issued or notifications acknowledged by APHIS since 2006. These field trials were conducted within selected soybean growing areas in the U.S., including Illinois, Indiana, Ohio, Iowa, Kansas, Nebraska, Missouri, Texas, Florida and Kentucky. Data resulting from these field trials are described in the MON 87712 petition (Monsanto, 2011; Pioneer, 2011) and analyzed for plant pest risk in the USDA-APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2011a)

The petition stated that APHIS should not regulate MON 87712 soybean because it does not present a plant pest risk. If a determination of nonregulated status is made, it would include MON 87712 soybean, any progeny derived from crosses between MON 87712 soybean and conventional soybean, and crosses of MON 87712 soybean with other biotechnology-derived soybean lines that are no longer subject to the regulatory requirements of 7 CFR part 340 promulgated under the authority of the Plant Protection Act of 2000 (PPA).

1.2 Purpose of the Product

The purpose of MON 87712-4 soybean is to provide a trait that potentially increases soybean yield using a single gene strategy. Increased soybean productivity in the United States has historically been accomplished through conventional breeding with genetic selection and subsequent yield increases per unit area, likely deriving from multigene mechanisms of inheritance. U.S. soybean yield increases can also be attributed to agronomic innovations as well as better control of pests and diseases that provide producers effective tools to meet production demands (Specht et al., 1999). Continuing infusions of genetic resources including those from germplasm centers have also been a major source in soybean for yield stability and growth (USDA-ERS, 2006a). The potential commercial use of MON87712-4 soybean might provide a more efficient method to increase soybean yield for seed producers and for farmers, additional access to potentially high yielding soybean varieties.

1.3 Coordinated Framework Review and Regulatory Review

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

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA APHIS, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). A summary of each role follows:

1.3.1 USDA-APHIS

APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the PPA, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (i.e., importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340, when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under 7 CFR 340, when 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 for a determination that a particular regulated article is unlikely to pose a plant pest risk, and therefore, is no longer regulated under the plant pest provisions of the PPA or the regulations at 7 CFR 340. Under § 340.6(c)(4), the petitioner must provide information related to plant pest risk that the agency can use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk

1.3.2 Environmental Protection Agency

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

Under FIFRA (7 U.S.C. 136 *et seq.*), EPA regulates the use of pesticides, and requires registration of all pesticide products for all specific uses prior to distribution for sale. EPA examines: the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, EPA must determine through testing that the pesticide does not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions. EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide may only be legally used in accordance with directions and restrictions on its label. The overall intent of the label is to provide clear directions for effective product performance, while minimizing risks to human health and the environment. The Food Quality Protection Act (FQPA) of 1996 amended FIFRA, enabling EPA to implement periodic registration review of pesticides to ensure they are meeting current scientific and regulatory standards of safety and continue to have no unreasonable adverse effects (US-EPA, 2011d).

EPA also sets tolerances (maximum residue levels) or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA). A tolerance is the amount of pesticide residue that can remain on or in food for human consumption or animal feed. Before establishing a pesticide tolerance, EPA is required to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the FQPA. FDA enforces the pesticide tolerances set by EPA.

1.3.2 Food and Drug Administration

FDA regulates GE organisms under the authority of the FFDCA (21 U.S.C. 301 *et seq.*). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, on May 29, 1992 (57 FR 22984). Under this policy, FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of bioengineered food. This voluntary consultation process provides a way for developers to receive assistance from FDA in complying with their obligations under Federal food safety laws prior to marketing.

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

1.4 Purpose and Need for This APHIS Action

As noted in the previous section any party can petition APHIS to seek a determination of nonregulated status for a GE organism that is regulated under 7 CFR 340. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of

GE organisms, including GE plants such as MON 87712 corn. When a petition for nonregulated status is submitted, APHIS must determine if the GE organism is unlikely to pose a plant pest risk. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS must respond to the petition from Monsanto requesting a determination of nonregulated status for MON 87712 soybean. APHIS has prepared this draft Environmental Assessment (EA) to consider the potential environmental effects of an agency determination of the nonregulated status of MON 87712 soybean. This action is consistent with regulations for the National Environmental Policy Act (NEPA) established by the Council of Environmental Quality (CEQ), and the USDA APHIS NEPA-implementing regulations and procedures (40 CFR parts 1500-1508, 7 CFR part 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from a determination of nonregulated status for MON 87712 soybean.

1.5 Public Involvement

APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. APHIS does this through a notice published in the *Federal Register*. On March 6, 2012, APHIS published a notice[2] in the *Federal Register* advising the public that APHIS is implementing changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for GE organisms to allow for early public involvement in the process. As identified in this notice, APHIS will publish two separate notices in the *Federal Register* for petitions for which APHIS prepares an EA. The first notice will announce the availability of the petition, and the second notice will announce the availability of APHIS' decision making documents. As part of the new process, with each of the two notices published in the *Federal Register,* there will be an opportunity for public involvement:

1.5.1 First Opportunity for Public Involvement

Once APHIS deems a petition complete, the petition is made available for public comment for 60 days, providing the public an opportunity to raise issues regarding the petition itself and give input that will be considered by the Agency as it develops its EA and PPRA. APHIS publishes a notice in the *Federal Register* to inform the public that APHIS will accept written comments regarding a petition for a determination of nonregulated status for a period of 60 days from the date of the notice. This availability of the petition for public comment will be announced in a *Federal Register* notice.

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

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

1.5.2 Second Opportunity for Public Involvement

Assuming an EA is sufficient, the EA and PPRA are developed and a notice of their availability is published in a second *Federal Register* notice. This second notice follows one of two approaches for public participation based on whether or not APHIS decides the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues:

Approach 1: GE organisms that do not raise substantive new issues. This approach for public participation is used when APHIS decides, based on the review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition, that the petition involves a GE organism that *does not raise new biological, cultural, or ecological issues because of the nature of the modification or APHIS' familiarity with the recipient organism.* After developing its EA, finding of no significant impact (FONSI), and PPRA, APHIS publishes a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the EA, FONSI, and PPRA for a 30-day public review period.

If APHIS determines that no substantive information has been received that would warrant APHIS altering its preliminary regulatory determination or FONSI, substantially changing the proposed action identified in the EA, or substantially changing the analysis of impacts in the EA, APHIS' preliminary regulatory determination becomes final and effective upon public notification through an announcement on its website. No further *Federal Register* notice is published announcing the final regulatory determination.

Approach 2. For GE organisms that raise substantive new issues not previously reviewed by APHIS. A second approach for public participation is used when APHIS determines that the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues. This could include petitions involving a recipient organism that has not previously been determined by APHIS to have nonregulated status or when APHIS determines that gene modifications raise substantive biological, cultural, or ecological issues not previously analyzed by APHIS. Substantive issues are identified by APHIS based on our review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition.

APHIS solicits comments on its draft EA and draft PPRA for 30 days through the publication of a *Federal Register* notice. APHIS reviews and evaluates comments and other relevant information, then revises the PPRA as necessary and prepares a final EA. Following preparation of these documents, APHIS approves or denies the petition, announcing in the *Federal Register* the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, National Environmental Policy (NEPA) decision document (either a FONSI or NOI to prepare an EIS), and regulatory determination.

Enhancements to public input are described in more detail in the *Federal Register* notice[3] published on March 6, 2012.

APHIS has determined that this EA will follow Approach 2 following an APHIS-BRS decision tree, in this case because the trait is a new one, and not previously determined as nonregulated. The issues discussed in this EA were developed by considering the public concerns, including public comments received in response to the *Federal Register* notice (77 F.R. 41354-6) announcing the availability of the petition (i.e., the first opportunity for public involvement previously described in this document), as well as issues noted in public comments submitted for other EAs of GE organisms, and concerns described in lawsuits and expressed by various stakeholders. These issues, including those regarding the agricultural production of soybean using various production methods and the environmental and food/feed safety of GE plants, were addressed to analyze the potential environmental impacts of MON 87712 soybean.

The public comment period for MON 87712 soybean petition closed on September 11, 2012. At its closing, the docket file contained a total of 4,665 public comments. Some of the submissions to the docket contained multiple attached comments gathered by organizations from their members. The majority of the comments expressed a general dislike of the use of GE organisms or was form letters sent to all of the dockets which were open at the time that this docket was open. The form letter expressed a concern that there were too many dockets published on the same day. It also referenced other open dockets and potential effects from the use of the subjects of those petitions. These issues are outside the scope of this EA. The issues that were raised in the public comments which were related to the Monsanto 87712 soybean petition included:

- Outcrossing with other soybean lines that are nontransgenic can negatively impact their salability and also consumer choice in GE-sensitive markets
- Increased production of soybean reduces plant and subsequent animal diversity
- Food and feed impacts are conducted and evaluated by the seed developer and need peer review along with FDA review
- Increased yield will result in increased supply and lower prices to both US and foreign soybean producers
- Concerns that there are economic impacts of cross pollination from MON 87712 soybean to organic soybeans for some organic growers. According to the comment organic growers have experienced rejection rates of 0.25%.
- Concerns that MON 87712 soybean is not approved in all export markets, and if this variety arrived at a market without specific approval, trade disruptions and economic losses could occur. The developer needs binding stewardship mechanisms in place to prevent potential trade economic impacts as well as compensation mechanisms if these mechanisms fail to be observed.

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

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

1.6 Issues Considered

The list of resource areas considered in this draft EA was developed by APHIS through experience in considering public concerns and issues raised in public comments submitted for other EAs of GE organisms. The resource areas considered also address concerns raised in previous and unrelated lawsuits, as well as issues that have been raised by various stakeholders in the past. The resource areas considered in this EA can be categorized as follows:

Agricultural Production Considerations:

- Acreage and Areas of Soybean Production
- Agronomic/Cropping Practices
- Soybean Seed Production
- Organic Soybean Production

Environmental Considerations:

- Soil
- Water Resources
- Air Quality
- Climate Change
- Animals
- Plants
- Gene Flow
- Microorganisms
- Biological Diversity

Human Health Considerations:

- Consumer Health
- Worker Safety

Animal Feed Considerations:

Socioeconomic Considerations:

- Domestic Economic Environment
- Trade Economic Environment

2 AFFECTED ENVIRONMENT

The Affected Environment Section provides a discussion of the current conditions of those aspects of the human environment potentially impacted by a determination of nonregulated status of MON-87712 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 Agricultural Production of Soybean

Soybean (*Glycine max* (L.) Merr.) is an economically important leguminous crop, providing oil and protein. Soybean plants are grown for their seed, which is further processed to yield oil and meal. Soybean in 2013 is ranked number one for oil production (58%) among the major oil seed crops production in the world (USDA-FAS, 2013). Other expanding uses for soybeans in the United States include soy biodiesel, animal agriculture, exports, and edible soybean oil (USB, 2012).

2.1.1 Acreage and Area of Soybean Production

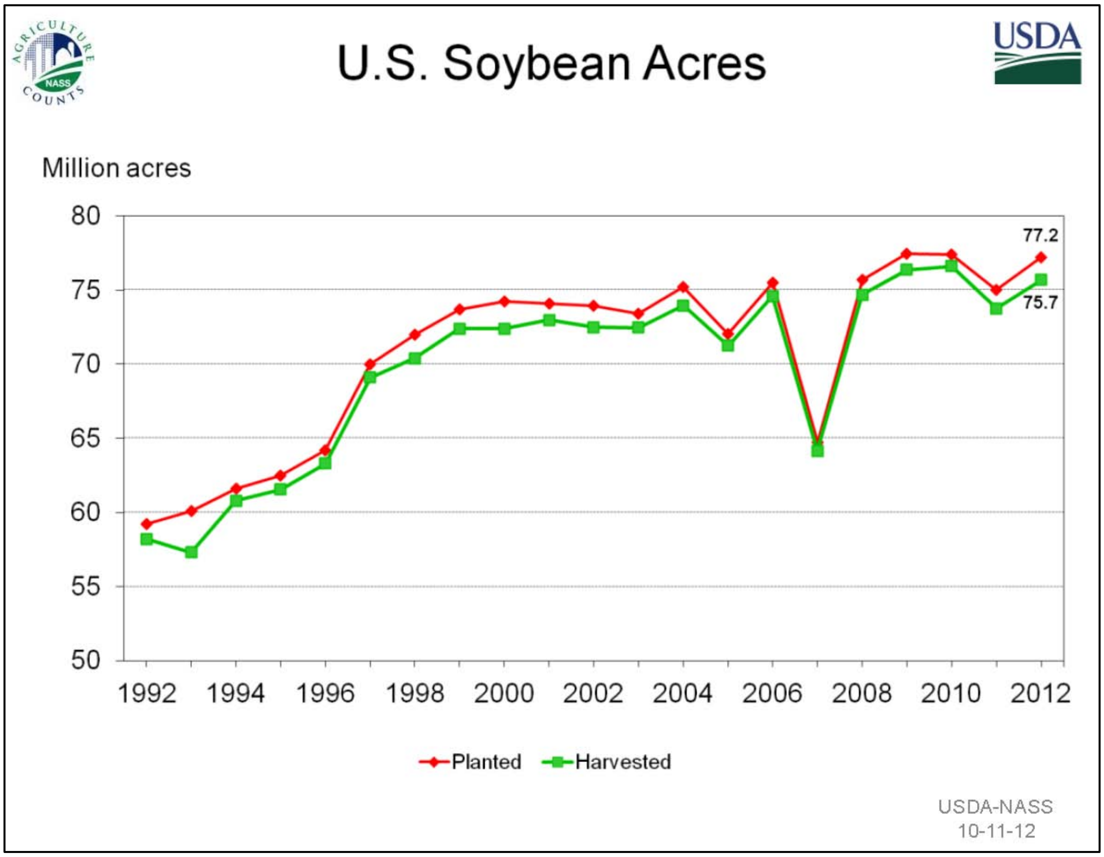
As of 2007, there were about 406 million acres of cropland in the United States, of which approximately 332 million acres (including harvested, failed crops, and cultivated fallow) were used for crop production (USDA-NASS, 2009). The remaining cropland was either idle or was used for pasture. In 2007, total U.S. cropland reached its lowest level since 1945, attributed to large swings in production levels and in land idled under Federal acreage reduction programs (USDA-ERS, 2012a). Peaks in total cropland occurred in 1949, again in the late 1970s, and decreased again in 2007, mostly due to a 26-million-acre decline in cropland pasture and partly due to methodological changes in the 2007 Census of Agriculture that reclassified some cropland pasture to permanent grassland pasture and range (USDA-ERS, 2011e).

Soybean acreage rose rapidly from the end of World War II to the late 1970s, based on increased demand for vegetable oil and higher meat consumption (USDA-ERS, 2006c). U.S. soybean acres stagnated in the 1980s largely due to farm programs for other crops. In the 1990s, changes in farm programs, overseas demand, lower production costs associated with herbicide-resistant crops, increased yields and increased rotations with corn resulted in increased acreage planted to soybeans (USDA-ERS, 2006). From 1992 to 2012, acreage planted with soybean increased 31% from just over 59.1 million acres to approximately 77.2 million acres (Figure 1, Table 1) (USDA-NASS, 2012l; USDA-NASS, 2012j). The combined acreage planted to the two largest U.S. crops, corn and soybeans, was at an all-time high of 168.8 million acres in 2011 (USDA-ERS, 2011f). This was achieved through maximization of existing cropland, reduction of acreage sown to other grain crops and hay, and an increase in the rate of double-cropping (raising two crops in one year on the same land) (USDA-ERS, 2011f). Approximately 75.7 million acres of soybean were harvested in the United States in 2012, up nearly 1.9 million acres or 2.5% from 2011 (USDA-NASS, 2012g). USDA projections to 2021/2022 estimate U.S. soybean acreage will remain relatively steady at approximately 76 million acres (USDA-OCE, 2012)

The majority of soybeans produced in the United States are grown in 31 states (Figure 2, Table 1). The top producing states are Iowa, Illinois, Minnesota, Indiana, and Nebraska, commonly growing soybean in rotation with corn (Soyatech, 2011). U.S. soybean acreage is concentrated where soybean yields are highest, namely the Midwest (USDA-ERS, 2006c). More recently, soybean acreage has expanded to the northern and western parts of the country due to stagnant yields in wheat and improvements in better yielding short-season soybeans adapted to the climate in these areas (USDA-ERS, 2010b), increasing the overall acreage devoted to soybean production in the U.S.

Over the last 20 years, soybean production has increased 35.6%, from nearly 2.2 billion bushels (59.88 million metric tons[MT]) in 1992 to approximately 3.0 billion bushels (81.7 million MT) in 2012 (USDA-NASS, 2012j). From 1991 to 2011, average yield increased approximately 17.6% from 34.2 bushels per acre in 1991 to 41.5 bushels per acre in 2011, but declined nationally in 2012 to 39.3 bushels per acre compared to 2011 average yields (USDA-NASS, 2012j).

USDA agricultural projections for 2021/2022 estimate about 3.6 billion bushels (97.99 million MT) will be produced, of which approximately 2.1 billion bushels (57.16 million MT) of soybean will be produced for domestic consumption and 1.6 billion bushels (43.55 million MT) for export in that year (USDA-OCE, 2012).



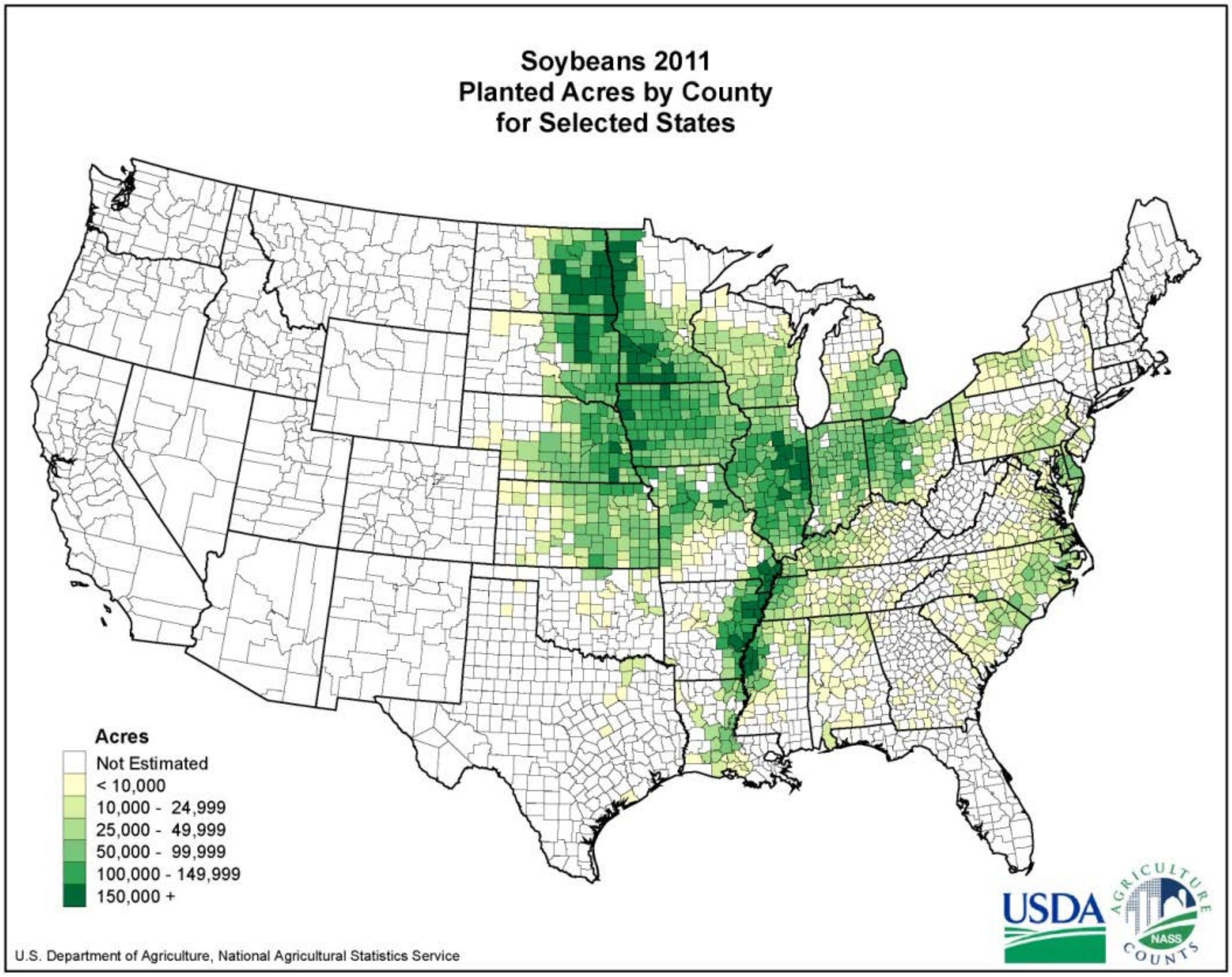
Source: (USDA-NASS, 2012h)

Figure 1. Planted and harvested acreage of soybeans in the United States. (1992-2012).

Table 1. U.S. soybean production in 2011 and 2012.

State	**Acres Planted (x 1,000)**		**Acres Harvested (x 1,000)**	
	2011	**2012**	2011	**2012**
Alabama	300	330	295	325
Arkansas	3,330	3,250	3,270	3,200
Delaware	170	180	168	178
Florida	18	25	16	23
Georgia	155	190	135	180
Illinois	8,900	8,600	8,860	8,570
Indiana	5,300	5,000	5,290	4,990
Iowa	9,350	9,500	9,230	9,440
Kansas	4,000	3,600	3,750	3,550
Kentucky	1,490	1,400	1,480	1,390
Louisiana	1,020	1,140	980	1,110
Maryland	470	480	465	475
Michigan	1,950	2,000	1,940	1,990
Minnesota	7,100	7,000	7,020	6,920
Mississippi	1,820	2,130	1,800	2,100
Missouri	5,350	5,300	5,200	5,250
Nebraska	4,900	5,100	4,830	5,050
New Jersey	88	95	86	93
New York	280	340	277	337
North Carolina	1,380	1,670	1,360	1,630
North Dakota	4,000	4,600	3,950	4,550
Ohio	4,550	4,600	4,540	4,590
Oklahoma	440	410	265	380
Pennsylvania	500	530	490	520
South Carolina	370	420	360	410
South Dakota	4,100	4,500	4,070	4,450
Tennessee	1,290	1,330	1,250	1,290
Texas	165	100	90	85
Virginia	560	550	550	540
West Virginia	20	20	19	19
Wisconsin	1,610	1,690	1,600	1,680
United States	74,976	76,080	73,636	75,315

Source: USDA-NASS (2012b)



Source: USDA-NASS (2012k)

Figure 2. Soybean planted acres by county for selected states, 2011.

Large scale field testing of GE crops began in the 1980s, but it was not until ten years later the first generation of GE varieties became commercially available (Fernandez-Cornejo and Caswell, 2006). Since GE soybeans' initial commercial availability in 1996 (Fernandez-Cornejo and Caswell, 2006; USDA-ERS, 2011a), their use had expanded to 94% of the total U.S. soybean acreage by 2011, which was slightly reduced to 93% in 2012 (Table 2) (USDA-ERS, 2012e). Currently, most commercially available GE soybean varieties are herbicide-resistant (USDA-ERS, 2012e).

2.1.2 Agronomic Practices

Conventional farming in this document includes any farming system where synthetic pesticides and fertilizers may be used. Conventional farming practices cover a broad scope of activities, ranging from only occasional use of synthetic pesticides and fertilizers to regular pesticide and fertilizer inputs. This definition of conventional farming also includes the use of GE varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

Table 2. Percentage of soybean acreage planted with GE herbicide-resistant soybean varieties by state and for the United States.

State	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Arkansas	43	60	68	84	92	92	92	92	94	94	96	95	94
Illinois	44	64	71	77	81	81	87	88	87	90	89	92	90
Indiana	63	78	83	88	87	89	92	94	96	94	95	96	93
Iowa	59	73	75	84	89	91	91	94	95	94	96	97	97
Kansas	66	80	83	87	87	90	85	92	95	94	95	96	94
Michigan	50	59	72	73	75	76	81	87	84	83	85	91	91
Minnesota	46	63	71	79	82	83	88	92	91	92	93	95	91
Mississippi	48	63	80	89	93	96	96	96	97	94	98	98	95
Missouri	62	69	72	83	87	89	93	91	92	89	94	91	91
Nebraska	72	76	85	86	92	91	90	96	97	96	94	97	95
North Dakota	22	49	61	74	82	89	90	92	94	94	94	94	98
Ohio	48	64	73	74	76	77	82	87	89	83	86	85	86
South Dakota	68	80	89	91	95	95	93	97	97	98	98	98	98
Wisconsin	51	63	78	84	82	84	85	88	90	85	88	91	92
Other States[1]	54	64	70	76	82	84	86	86	87	87	90	92	93
United States	54	68	75	81	85	87	89	91	92	91	93	94	93

Source: USDA-ERS (2012e)

[1] Includes all other states in the soybean estimating program

Cultivation

Soybean (*Glycine max* L.) is a member of the legume family that grows as an erect, bushy herbaceous annual (OECD, 2000). It is a quantitative short-day plant, flowering more quickly under short days (OECD, 2000). As a result, photoperiod and temperature responses are important in determining areas of specific cultivar adaptation. Soybean cultivars are identified based on geographic bands of adaptation that run east-west, determined by latitude and day length. In North America, there are 13 maturity groups (MGs) described, ranging from MG 000 in the north (45° latitude) to MG X near the equator. Within each maturity group, cultivars are described as early, medium, or late maturing (OECD, 2000).

The soybean seed will germinate when the soil temperature reaches approximately 50 degrees Fahrenheit (°F) (10 degrees Celsius [°C]) and, under favorable conditions, seedlings will emerge within a five to seven day period. In new fields of soybean production, an inoculation with *Bradyrhizobium japonicum*, a nitrogen fixing bacterium that develops a symbiotic relationship with soybean, dramatically increases plant productivity (Pedersen, 2007; OMAFRA, 2011; Missouri-University-of-Science-and-Technology, No Date). Inoculation is necessary for optimum efficiency of the nodules that form on the root system (Berglund and Helms, 2003; Pedersen, 2007). In the 1990s, row spacing for planting soybean narrowed to seven inches to achieve greater yields and then more recently expanded to 15 inches to promote greater air circulation to reduce increased incidence of disease that impacts yields (USDA-ERS, 2010b).

Soybeans require more moisture to germinate than corn, and seed-to-soil contact is important for good early-season soybean growth. Adequate water supply is most important at planting time, during pod-filling, and seed filling (Hoeft et al., 2000). Soybeans require approximately 20- to 25 inches of water during the growing season (Hoeft et al., 2000) to produce a relatively high yield of 40- to 50 bushels per acre (University of Arkansas, 2006). In regions of the United States that experience low amounts of rainfall during the growing season or during drought, soybean yields benefit from proper irrigation. In 2008, only 9% of harvested soybean acreage, approximating 12 million acres, was irrigated primarily in Nebraska, Arkansas, Mississippi, Missouri, and Kansas, states with 85% of the irrigated acres. A majority (approximately 73%) of U.S. irrigated soybean farms occur in the Missouri and Lower Mississippi Water Resource Regions (USDA-NASS, 2010; USDA-ERS, 2011b; USDA-NASS, 2011). In 2006, approximately 8.4 inches of water per irrigated acre was used, producing an average of over 51 bushels per irrigated acre (USDA-ERS, 2011b). This yield was approximately 19.8% higher than the national average (42.9 bushels per acre) for that year (USDA-NASS, 2011).

Soybean can grow in a diversity of environments, but the optimum soil pH is from 5.8 to 7.0 (NSRL, No Date). Adequate levels of phosphorus, potassium, calcium, and magnesium, as well as other minor nutrients, are required for maximum soybean growth and yield. Given the ability of soybean to fix nitrogen from the air due to its symbiotic relationship with *Bradyrhizobium*, fertilizer nitrogen is not always needed for soybean production. In areas with increased amounts of salt or carbonates, or that have no past history of soybean production, nitrogen amendments prior to or at the time of planting have been shown to increase yield if soil tests reveal levels are not adequate (Franzen, 1999; Berglund and Helms, 2003). A common practice is to fertilize the previous year's corn crop with enough phosphorus and potassium to allow for the subsequent soybean crop to be grown with no supplemental fertilizer (Franzen, 1999; Berglund and Helms, 2003; Ebelhar et al., 2004). Calcium and magnesium are normally present in an adequate supply if the soil is near the optimum pH or recently treated with dolomitic limestone (Frank, 2000; Harris, 2011).

Crop Rotation

Crop rotation is the successive planting of different crops in the same field over a particular period of years. Crop rotation has the two primary goals of sustaining the productivity of the agricultural system and maximizing economic returns (Hoeft et al., 2000). Sustaining the agricultural system is achieved by rotating crops that may improve soil health and fertility with more commercially beneficial "cash crops." Since soybean fixes nitrogen in soil, the yield of some crops following soybean, such as corn or wheat, may increase; moreover, the rotation of crops can effectively reduce disease, pest incidence, weediness, and selection pressure for weed resistance to herbicides (USDA-ERS, 1997; Berglund and Helms, 2003). Crop rotation may also include fallow periods, or sowing with cover crops to prevent soil erosion and to provide livestock forage between cash crops (Hoeft et al., 2000; USDA-NRCS, 2010a). Maximizing economic returns is realized by rotating crops in a sequence that efficiently produces the most net returns for a producer over a single or multi-year period. Many factors at the individual farm level affect the crop rotation system chosen, including the soil type present in an individual field, the expected commodity price, the need to hire labor, the price of fuel, the availability of funding to buy seed, and the price of agricultural inputs (Langemeier, 1997; Hoeft et al., 2000; Duffy, 2011).

Soybeans are often rotated with such crops as corn, winter wheat, spring cereals, and dry beans (OECD, 2000), the selection of which varies regionally. Cropland used for soybean and corn production is nearly identical in many areas, such as Illinois, where over 90% of the cropped area is planted in a two-year corn-soybean rotation (Hoeft et al., 2000). As of 2006, the USDA identified approximately 94% of U.S. soybean acres as grown under a rotation system (USDA-ERS, 2013c). With the recent high corn prices, many producers are turning to a corn-corn-soybean rotation (Hart, 2006), but returns for producers are variable, dependent upon the price and projected yield of both corn and soybean for an individual operator (Stockton et al., 2007). Studies have found soybean yield tends to increase under this rotation sequence, attributed to an effective break in the soybean disease and pest cycle (Nafziger, 2007; Al-Kaisi, 2011). Soybean itself may be a cover crop in short rotations for its nitrogen contributions (Hoorman et al., 2009a). Continuous soybean production is undertaken, but yield can be reduced the second or later years, and pest and disease incidence may increase (Pedersen et al., 2001; Monsanto, 2010c). Double-cropping soybeans is also an option to increase returns. Soybean is frequently planted in winter wheat stubble to produce a crop in the same growing season.

More recently, Monsanto evaluated soybean rotational practices using 2008 USDA-NASS crop production data (Monsanto, 2010a). They found the majority of U.S. soybean acreage (68.6%) was rotated to corn. Other major crops following soybean were soybean (approximately 14.5% of soybean acreage) and wheat (approximately 11.2% of soybean acreage), with cotton, rice, and sorghum the next largest rotational crops (combined 4.6% of soybean acreage). Summaries of the total rotation percentage is complicated by agency inclusion or exclusion of soybean that is double-cropped following wheat, and of the specific states included within the summary. Figure 3 charts the acreage of major rotational crops following soybean in the United States Midwest (Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, North

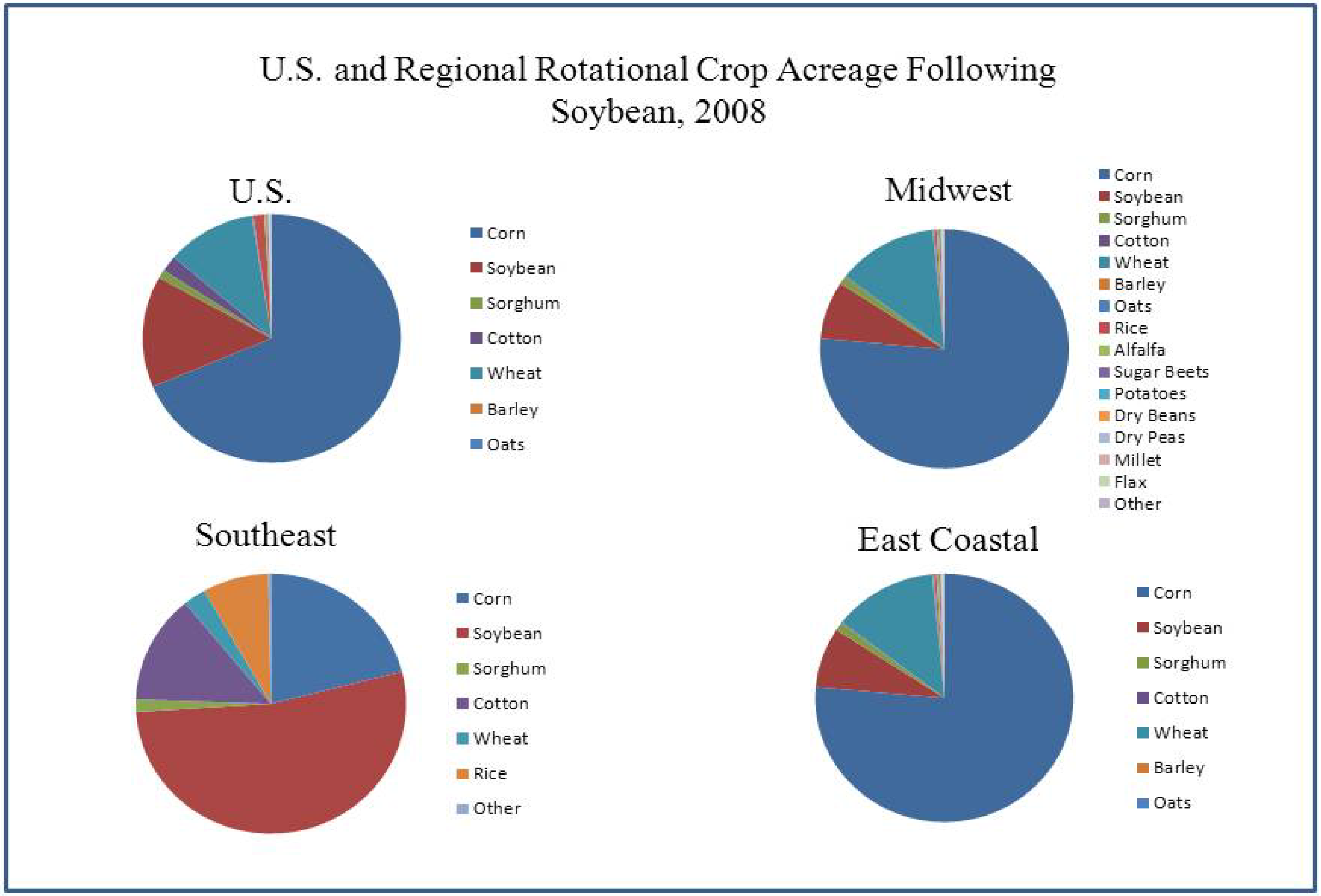
Dakota, Ohio, South Dakota, Wisconsin), Southeast (Alabama, Arkansas, Georgia, Louisiana, Mississippi, North Carolina, Tennessee, South Carolina), and East Coastal (Delaware, Maryland, New Jersey, Pennsylvania, Virginia) regions in 2008. In the Midwest, where 82% of U.S. soybean was grown in 2008, the crops planted most often after soybean included corn, wheat, and soybean. Soybean most frequently followed soybean in the Southeast, with corn and cotton the next most prevalent rotational crops. Corn was most often rotated after soybean in the East Coastal region, with wheat and then soybean the other most frequently planted rotational crops (Monsanto, 2010a).

Double-cropping maximizes profits if high commodity prices can support it, but careful management to achieve uniform stands to sustain high yields is needed: the selection of appropriate varieties, a higher seeding rate, closer row spacing, and adequate moisture for germination are important variables affecting profitability (McMahon, 2011).

Tillage

Tillage in soybean production systems is used to prepare a seedbed, address soil compaction, incorporate fertilizers and herbicides, manage water movement both within and out of a production field, and control weeds (Heatherly et al., 2009), depending on tillage type. Field preparation is accomplished through a variety of tillage systems, with each system defined by the remaining plant residue on the field. Types of tillage systems include conventional, reduced, conservation (including mulch-till, strip-till, ridge-till, and no-till), and deep. Multiple definitions of these tillage systems are abundant (Heatherly et al., 2009); however, the primary purpose of conservation tillage is to reduce soil erosion.

In conventional tillage, post-harvest crop residue is plowed into the soil using moldboard plows, heavy disks, and chisel plows to prepare a clean seedbed for planting and to reduce the growth of weeds, leaving less than 15% of crop residue on the surface (Heatherly et al., 2009; Towery and Werblow, 2010). Conservation tillage employs tools that disturb soil less and leave more crop residues on the surface (at least 30%), whereas no-till farming only disturbs the soil for planting seed (USDA-NRCS, 2005; Towery and Werblow, 2010). Crop residues are materials left in an agricultural field after the crop has been harvested, including stalks and stubble (stems), leaves and seed pods (USDA-NRCS, 2005). These residues aid in conserving soil moisture and reduce wind and water-induced soil erosion (USDA-ERS, 1997; USDA-NRCS, 2005; Heatherly et al., 2009). According to USDA Agricultural Resource Management Survey (ARMS) data (USDA-ERS, 2006b), conservation tillage ranging from no-till to reduced-till conserving 15 to 30% of residues was utilized on 88% of planted soybean acres in 2006. No-till systems are not meant to control weeds or deal with compaction issues, necessitating the addition of other strategies such as herbicidal weed control and track management of heavy machinery use in no-till fields to address these problems.



Source: Monsanto (2010a)

Note: Midwest is defined as Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin. Southeast is comprised of Alabama, Arkansas, Georgia, Louisiana, Mississippi, North Carolina, Tennessee, and South Carolina; and East Coastal region consists of Delaware, Maryland, New Jersey, Pennsylvania, and Virginia

Figure 3. Major rotational crops following soybean in 2008 in the United States and the Midwest, Southeast, and East Coastal regions.

Since 1996, the use of a no-till system has increased more than any other reduced tillage system; nearly all of the growth in adoption has occurred in herbicide-resistant crop production (i.e., soybean, cotton, canola) (Fawcett and Towery, 2002). In a survey conducted in 1997, it was found that farmers using no-till practices were more likely to adopt herbicide-resistant soybeans as an effective weed control practice, although the study also found that the commercialization of herbicide-resistant soybean did not encourage the adoption of no-till practices at that time. Another survey conducted between 1996 and 2001 found that producers using herbicide-resistant seed varieties were more likely to both use conservation tillage practices over conventional methods and practice conservation tillage to a greater degree than producers that did not use herbicide-resistant crops (Fawcett and Towery, 2002). A survey of 1,195 producers conducted by Givens et al. (2009) between November 2005 and January 2006 revealed that 25% of farmers that had been using conventional tillage switched to no-till and 31% switched to reduced-till after adopting GE crops that were glyphosate resistant.

With the increase in production of glyphosate-resistant soybeans, there has been a corresponding increase in the use of no-till production practices (Carpenter et al., 2002; Sankula, 2006). From the introduction and commercial availability of glyphosate-resistant soybeans in 1996 to 2004, the use of no-till practices increased by 64% (Sankula, 2006). Use of conservation tillage practices by U.S. soybean growers increased by 12 million acres (4.9 million hectares) from 51% in 1996 to 63% in 2008 (NRC, 2010).

No-till soybean production is not suitable for all producers or areas. For example, no-till soybean production is less successful in heavier, cooler soils more typical of northern latitudes (Kok et al., 1997; NRC, 2010) where the potential for increased weed and insect pests and disease requires careful management (Peterson, 1997; Pedersen et al., 2001).

Agronomic Inputs

Agronomic inputs, including water, soil and foliar nutrients, inoculates, fungicides, pesticides, and herbicides, are used in soybean production to maximize yields (Hoeft et al., 2000; OECD, 2000; Clevenger, 2010; OMAFRA, 2011). Irrigation provides essential water for growth where rainfall is insufficient or erratic. This issue is discussed in detail in Subsection 2.2.2, Water Resources, and the corresponding impacts analysis in Subsection 4.3.1, Soil Quality. Soil and foliar macronutrient applications to soybean primarily include nitrogen, phosphorous (phosphate), potassium (potash), calcium, and sulfur, with other micronutrient supplements such as zinc, iron, and magnesium applied as needed (Whitney, 1997; USDA-NASS, 2007a; NSRL, No Date).

Nutrients, Fertilizer

Fertilizer and nutrients may be applied to the soil or sprayed on foliage in soybean production. Soil fertilizers have differential availability to plants based upon soil characteristics and moisture. For example, in a drought year, potassium may become fixed between clay layers until water moves through the soil again (Corn and Soybean Digest, 2012). Fertilizer such as nitrogen, potassium and phosphorous may be incorporated into the soil at soybean planting by tillage or drilling (Vitosh et al., 2007). Fertilizer may be purposefully concentrated in bands at varying depths in the soil to enhance nutrient availability at different growth stages (Vitosh et al., 2007; Fernandez and White, 2012). In conservation tillage crop production, phosphorous and potassium may become vertically stratified from use of surface broadcast fertilizers that minimize soil disturbance; hence, more farmers are turning to strip till practices to enhance nutrient availability to sustain higher yields (Fernandez and White, 2012).

The amount of nutrients removed from the soil by soybean production depends upon the planting population and yield. On average, soybean removes 0.85 1bs of phosphate (phosphorous) and 1.2 lbs of potash (potassium) per bushel of seed produced (CAST, 2009a). Table 3 presents removal rates of nitrogen, phosphate and potassium for soybean, and corn and wheat that are commonly rotated with soybean, as reported by the Michigan State University Extension (Silva, 2011). Although the data presented show soybean removes more nitrogen, potassium and phosphorous than either corn or wheat, a typical corn yield is 180 bushels per acre as opposed to a typical soybean yield of 42 bushels per acre and 46 bushels per acre for wheat. Table 4 compares soybean nutrient removal at different bushels per acre yield rates, indicating the higher the yield, the more nutrients are removed from the soil (Snyder, 2000). As discussed in Section 2.1.2.1, Cultivation, soybean fixes nitrogen in the soil in symbiosis with rhizobium bacteria. Recent research summarized by the Council for Agricultural and Science Technology indicates nitrogen supplementation supplants rather than supplements natural cost-free nitrogen production in soybean cultivation, as the size, weight, and number of nitrogen-producing nodules formed on soybean roots are actually reduced (CAST, 2009a). Application of nitrogen under drought conditions, in acid subsoil conditions, in soils having low residual nitrogen, in a high-yield environment, or in late or doublecrop plantings has raised soybean yields but not enough to offset the added cost. Phosphorous should be applied at least at the crop removal rate and based upon regular soil testing. Soil test levels of potassium may change considerably from one testing time to the next, and so it too should be regularly monitored to continuously support optimum yields (CAST, 2009a).

Soybean is often grown in rotation with corn and the nutrient supplements applied to corn are often adequate to produce soybean the following year without additional supplementation (Bender et al., 2013), making it more economical to apply nutrients such as nitrogen, potassium and phosphorous ahead of the corn crop in two-year corn-soybean rotations (CAST, 2009a). Other research has found that annual supplementation of potassium and phosphorous is most beneficial in the south where soybean to soybean rotation is more common (Heatherly, 2012). Corn and soybean take up nutrients and both localize each mineral nutrient in different parts of the plant cell (Mallarino et al., 2011). In plants, potassium is located mainly in the cytoplasm of cells and cell vacuoles where it activates enzymes, regulates stomata functions, and assists in transfer of compounds across membranes. In contrast, most phosphorous is located in cell membranes and nucleic acids, is incorporated into plant organic matter, and is a major component of the energy compounds that drive photosynthesis and plant metabolism in general. Much more potassium than phosphorous is absorbed by plants, and a larger proportion

Table 3. **Nutrient removal rates per unit of yield by soybean and grain crops commonly rotated with soybean.**

Crop	Nitrogen	Potash	Phosphate
	Pounds Removed per Bushel Produced		
corn	0.9	0.37	0.27
soybean	3.8	0.8	1.4
wheat	1.2	0.63	0.37

Source: Silva (2011)

Table 4. **Soybean nutrient removals at differing rates of grain bushels per acre yields.**

Bushels Per Acre Yield	Nitrogen	Potash	Phosphate	Magnesium	Sulfur
	Pounds Per Acre Removed From Soil				
40	220	38	140	16	14
55	290	53	190	22	18
70	360	67	220	28	22

Source: Snyder (2000)

of phosphorous is found in the grain than potassium.

Some portion of these nutrients taken up by the crop from the soil may be returned by retaining plant residue such as corn stalks and soybean foliage in the field (Mallarino et al., 2011). However, by maturity, soybean seed contains approximately 65% of the nitrogen, 73% of the phosphorous, and 55% of the potassium taken up during the season (Snyder, 2000); thus, harvesting the seed removes considerable portions of nutrients from the field.

Bender et al. (2013) have recently evaluated the nutrient uptake of modern, higher yielding transgenic insect-resistant corn varieties in Iowa and found average applications of phosphorous to these modern varieties would deplete this nutrient to inadequate levels for following soybean crops if not supplemented. Further research by the International Plant Nutrition Institute has indicated an increasing percentage of United States and Canadian soils have dropped to levels near or below critical phosphorous, potassium, sulfur and zinc levels in the last five years (Fixen et al., 2010), attributed to producing increased yields of field crops. Another study has shown micronutrient (manganese, boron, zinc) depletion may be higher with increased soybean yields but the amounts documented were highly variable, reflective of management and environmental factors, and were insignificant in comparison to potassium and phosphorous removal (Mallarino et al., 2011).

Table 5 presents summary data of the latest available USDA chemical fertilizer usage statistics from a 2006 survey reported by USDA National Agricultural Statistics Service (NASS) (USDA-NASS, 2007a). The survey found that among 19 select states, nitrogen was applied to 18% of the planted soybean acreage in those states at an average rate of 16 pounds per acre (lb/A) per year, and phosphate was applied to 23% of the planted acres at an annual average rate of 46 lb/A. Potash was applied to 25% of the planted acreage at an average annual rate of 80 lb/A, and sulfur was applied to 3% of the planted acres at an average annual rate of 11 lb/A (USDA-NASS, 2007a). These supplements were applied on average only once per crop year. The relatively low rate of soybean nutrient supplementation is likely a function of most soybean being rotated after corn that has had sufficient nutrients applied to sustain the subsequent soybean crop.

Table 5. Soybeans: total fertilizer primary nutrient applications in program states, 2006.

Primary Nutrient	Area Applied (Percent)	Applications (Number)	Rate per Application (Pounds per Acre)	Rate per Crop Year (Pounds per Acre)	Total Applied (Million Pounds)
Nitrogen	18	1.1	15	16	212.40
Phosphate	23	1.0	45	46	772.80
Potash	25	1.0	79	80	1,454.70
Sulfur	3	1.1	10	11	20.00

Source: USDA-NASS (2007a)

Inoculates

As mentioned above, inoculates of the bacteria *B. japonicum* can increase soybean yields, estimated at an average of a bushel per acre (Conley and Christmas, 2005). Historically, a nonsterile peat powder applied to the seed at planting had been the carrier for the inoculant into the field. More recently, improvements have been made in inoculant manufacturing, such as the use of sterile carriers, the addition of adhesives for inoculates to stick to seed, the introduction of liquid carriers, the use of concentrated frozen products, the introduction of new organism strains, the use of pre-inoculants, and the introduction of inoculants with extended biofertilizer and biopesticidal properties (Conley and Christmas, 2005). Industry has estimated that about one-third of U.S. soybean acreage was inoculated in 2009 (Seed Today, 2009).

Pesticides

A wide variety of pests can hinder soybean production and many require agricultural pesticidal inputs for their control. Several groups and types of insects can feed on the foliage, seed pods and roots of the soybean plant, and can reduce yield if not adequately controlled (Lorenz et al., 2006; Whitworth et al., 2011). A major pest for soybean producers are soybean nematodes that have no effective pesticidal treatment, especially the soybean cyst nematode (Nelson, 2003). Nematodes are microscopic organisms, some of which feed on the roots of various plants, including soybeans. There are several races or different groups of nematodes and their control is difficult. Some soybean varieties have resistance to some of the races, but often these resistant varieties have yielded less than other commercially available soybean varieties. A combination of crop rotation to a non-susceptible host and the use of resistant varieties can help alleviate the problem (Nelson, 2003).

Insect infestation thresholds have been established to indicate when control measures are actually necessary (Higgins, 1997). The thresholds are commonly based on number of insects found in field sampling surveys and in established standard defoliation thresholds, such as those provided by the National Information System of the Regional Integrated Pest Management Centers in pest management strategic plans (USDA, 2011). Table 6 presents summary data of the latest available USDA NASS chemical insecticide usage statistics for U.S. soybeans from a 2006 survey (USDA-NASS, 2007a). The survey found that insecticides were applied to 16% of the 72.9 million soybean acres planted in surveyed states in 2006. Of the 12 reported insecticides, the three most common, lambda-cyhalothrin, chlorpyrifos, and esfenvalerate, were applied to 6%, 5%, and 3% of the planted acres, respectively (USDA-NASS, 2007a). Other methods of addressing insect infestations include crop rotation and tillage as discussed above, and efforts to conserve natural enemies that prey on principle insect pests.

Table 6. Soybeans: insecticide chemical applications in program states, 2006[1].

Insecticide	Area Applied (percent)	Applications (number)	Rate per Application (pounds per acre)	Rate per Crop Year (pounds per acre)	Total Applied (Million pounds)
Acephate	1	1.3	0.72	0.934	0.546
Benzoic acid	<0.5	1.1	0.051	0.056	0.009
Carbaryl	<0.5	1	0.633	0.633	0.091
Chlorpyrifos	5	1.1	0.454	0.48	1.663
Cyfluthrin	<0.5	1.1	0.028	0.03	0.01
Diflubenzuron	<0.5	1.7	0.037	0.062	0.01
Esfenvalerate	3	1.1	0.035	0.037	0.07
Gamma-cyhalothrin	<0.5	1	0.011	0.011	0.003
Lambda-cyhalothrin	6	1.1	0.02	0.021	0.097
Methyl parathion	<0.5	1.1	0.529	0.565	0.066
Permethrin	<0.5	1	0.065	0.065	0.012
Thiodicarb	<0.5	1	0.32	0.32	0.039

Source: USDA-NASS (2007a)

[1] Program states surveyed - Arkansas, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Ohio, South Dakota, Tennessee, Virginia, and Wisconsin totaling 72.9 million planted acres.

<u>Fungicides</u>

Several plant diseases can also reduce soybean yield, many of which are addressed by planting disease resistant cultivars, and relatively few that may be treated with fungicides. Diseases that afflict soybean include fungal, bacterial, and viral (Jardine, 1997). Diseases of major concern in soybean are *Cercospora* foliar blight, purple seed stain, aerial blight, soybean rust, pod and stem blight, and anthracnose (Padgett et al., 2011). Besides selecting cultivars with resistance to diseases prevalent in a producer's particular region (Hershman, 1997), a healthy soybean crop starts with planting disease-free seed (Jardine, 1997), implementing best management practices such as crop rotation to reduce disease carryover from crop to crop, and providing adequate nutrients and water for growth (Nelson, 2011). Additionally, a grower may also purchase seed treated with various chemicals, such as fungicide, to enhance soybean seed germination success (Jardine, 1997).

When disease does occur in soybean, despite taking such measures, chemical treatment options are fairly limited to those of fungal origin (Jardine, 1997; Padgett et al., 2011). USDA NASS (2007a) found that the most commonly applied fungicides on soybean (azoxystrobin, propiconazole, pyraclostrobin, tebuconazole, and trifloxystrobin) were applied to only 4% of the 2006 U.S. soybean planted acreage in the 19 states surveyed. Pyraclostrobin and azoxystrobin were the only two applied on more than 0.5% of the planted acres. Pyraclostrobin was applied to 2% of the planted acres at an average rate of 0.112 lb/A per year, whereas, azoxystrobin was applied to 1% of planted acres at an average rate of 0.106 lb/A per year (USDA-NASS, 2007a).

Herbicides

The presence of weeds in soybean fields is a primary detriment to soybean productivity. Weeds have been estimated to cause a potential yield loss of 37% in world-wide soybean production (Heatherly et al., 2009). Weeds compete with soybean for light, nutrients, and soil moisture; can harbor insects and diseases; and, can also interfere with harvest, causing extra wear on harvest equipment (Loux et al., 2008). In addition to weed density, the time period that weeds compete with the soybean crop influences the level of yield loss. The later the weeds emerge, the less impact they will have on yield. Soybean plants withstand early-season weed competition longer than corn, as the soybean canopy closes earlier (Boerboom, 2000). The extent of canopy closure restricts the light available for weeds and other plants growing below the soybean. In addition, canopy closure occurs more quickly when soybean is drilled or planted in narrow rows (Boerboom, 1999); however, in some studies it has also been observed that, depending on factors such as weed species, environmental conditions (i.e., rainfall amounts), and soybean cultivar, soybeans are able to compete with weeds with no resulting yield reduction (Krausz et al., 2001). Place et al. (2011) have determined that larger soybean seeds produce a larger canopy more quickly and are, therefore, more successful at outcompeting weeds.

Herbicides have been the primary tactic to manage weed communities in soybeans since the mid-1960s and will continue to be an important feature of row crop weed management for the foreseeable future. One study looked at aggregate data on crop yield losses and herbicide use and estimated that even if additional tillage and hand weeding labor replaced the use of herbicides, U.S. crop production would decline by 20% with a $16 billion loss in value if herbicides were not used (Gianessi and Reigner, 2007).

In selecting an herbicide, a grower must consider, among other factors, whether an herbicide can be used on the crop (herbicides are registered by the EPA for specific uses and crops, the potential adverse effects on the crop, residual effects that can limit crops that can be grown in rotation, effectiveness on expected weeds, and cost. Herbicides have different ways of acting on plant physiology (i.e., modes of action) to affect the health of a given plant. Some common modes of herbicide action include auxin growth regulators like 2,4-D; amino acid inhibitors such as glyphosate; photosystem II inhibitors such as metribuzin; lipid biosynthesis inhibitors like quizalofop; and inhibition of protoporphyrinogen oxidase (PPO) inhibitors like fomesafen (University of Wisconsin, No Date). Herbicides may be applied pre-plant (or "burndown" in no-till), pre-emergence post-emergence and post-harvest.

Table 7 presents the most commonly applied herbicides to soybean in 1995, 2001, and 2006, the latest year with available national statistics and the corresponding percent of acres treated (USDA-NASS, 2007b). Figure 4 graphs the usage trends of the top 10 herbicides included in Table 7 in terms of percent planted acres treated. Glyphosate has become the most often-used herbicide on U.S. soybean, while the use of other herbicides has decreased. In 2006, nearly 92 million lbs of glyphosate were applied to 92% of the planted acres, compared to only 21% of planted soybean acres in 1995. Prior to 1995, glyphosate was primarily used for pre-plant weed control in soybean (Young, 2006). After 1995, annual glyphosate usage increased due to post-emergence application on Monsanto's Roundup Ready® Soybean (GTS 40-3-2), which became commercially available to growers in 1996.

Table 7. Percent of U.S. soybean acres[1] treated with herbicides in 1995, 2001, 2006 and 2012.

Herbicide	1995	2001	2006	2012	Herbicide	1995	2001	2006	2012
2,4-D[2]	10	4	3	4	Fomesafen	4	7	2	8
2,4-D 2HE	1	--[3]	7	11	Glufosinate	--	--	--	3
Acetamide	--	<1	<1	--	Glyphosate	21	73	92	98
Acifluorfen	--	3	<1	1	Imazamox	--	5	<1	--
Alachlor	4	<1	<1	--	Imazaquin	15	2	1	--
Acifluorfen	--	3	<1	1	Imazethapyr	4	9	3	5
Atrazine	--	--	--	--	Lactofen	5	1	<1	2
Bentazon	12	1	<1	--	Linuron	2	--	--	--
Butoxy ester 2,4-D	--	--	<1	--	Metolachlor	7	<1	--	--
Carfentrazone	----	----	<1	--	Metribuzin	11	2	2	3
Chlorimuron	16	5	4	11	Paraquat	2	--	1	3
Clethodim	5	4	3	9	Pendimethalin	26	10	3	2
Clomazone	4	<1	--	--	Quizalofop	6	--	--	2
Cloransulam	--	5	1	4	S-Metolachlor	--	<1	1	7
Dimethenamid	1	--	--	1	Saflufencil	--	--	--	4
Ethalfluralin	1	--	--	--	Sethoxydim	7	1	<1	--
Fenoxaprop	6	3	<1	<1	Sulfentrazone	--	5	1	8
Fluazifop	10	3	1	3	Sulfosate	--	3	1	--
Flumetsulam	2	<1	<1	<1	Thifensulfuron	12	2	1	5

Herbicide	1995	2001	2006	2012	Herbicide	1995	2001	2006	2012
Flumiclorac	--	<1	<1	1	Tribenuron	--	--	1	1
Flumioxazin	--	--	--	11	Trifluralin	20	7	2	2
Fluthiocetmethyl	--	--	--	2					

Source: USDA-NASS, (2007b); USDA (2013)

[1] Survey states:

1995: Arkansas, Georgia, Illinois, Indiana, Iowa, Kentucky, Louisiana, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, Ohio, and Tennessee.

2001: Arkansas, Illinois, Indiana, Iowa, Minnesota, Missouri, Nebraska, and Ohio.

2006: Arkansas, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Ohio, South Dakota, Tennessee, Virginia, and Wisconsin.

[2] Dimethylamine salt formulation of 2,4-D

[3] -- = No value

The next herbicide most frequently applied to soybean acres was 2,4-D in several formulations, with just over 3.5 million lbs (1.6 million kg) applied to 10.5% of the planted soybean acres in 2006, and the majority of the herbicide was for preplant burndown (USDA-NASS, 2007a). Applied 2,4-D increased slightly to 15% of acres in 2012 (Figure 8). Figure 4 also shows that, while glyphosate-applied acres increased for the period, the number of acres on which other herbicides were applied significantly declined, as has been noted previously by others (Young, 2006; NRC, 2010). The widespread adoption of the glyphosate-resistant soybean cultivar, in tandem with an increased reliance on glyphosate, has been related to the ability to grow no-till soybean cultivation while effectively controlling weeds, simplifying weed control compared to past practices, reducing input and labor costs associated with the cultivar and glyphosate use, and allowing increased flexibility in timing herbicide applications to resistant soybean (Young, 2006). In 2006, based on soybean farmers surveyed in selected states, it was estimated that 98% of the planted soybeans were treated with at least one type of herbicide, ranging from 0.004 to 1.931 lb/A per crop year (Table 8) (USDA-NASS, 2007a).

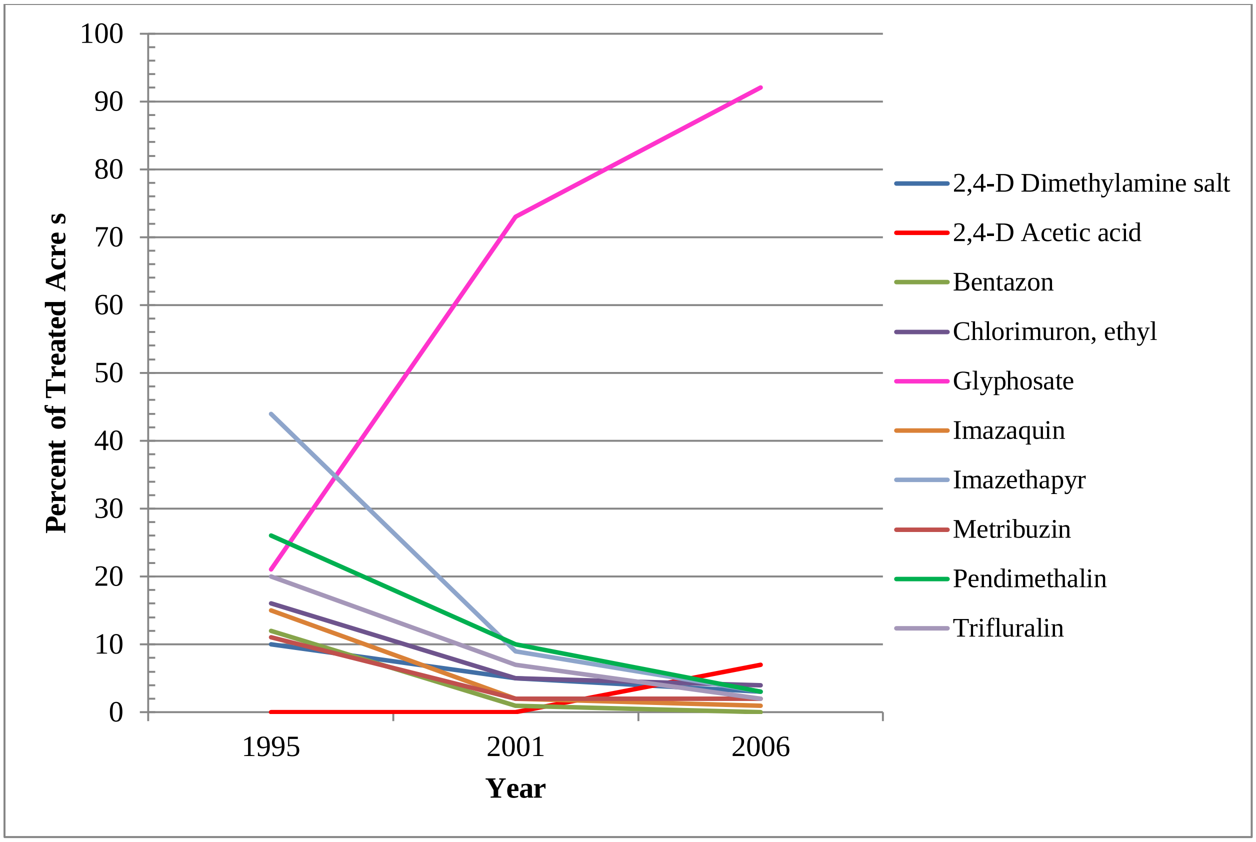


Figure 4. **Percent of U.S. soybean acres in program states[1] treated with 10 most used herbicides in 1995, 2001 and 2006.**

Source: USDA-NASS (2007b)

[1] Survey states:

1995: Arkansas, Georgia, Illinois, Indiana, Iowa, Kentucky, Louisiana, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, Ohio, and Tennessee.

2001: Arkansas, Illinois, Indiana, Iowa, Minnesota, Missouri, Nebraska, and Ohio.

2006: Arkansas, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Ohio, South Dakota, Tennessee, Virginia, and Wisconsin.

Table 8. Soybeans: total herbicide applications, 2006[1].

Herbicide	Area Applied (percent)	Applications (number)	Rate Per Application (pounds per acre)	Rate Per Crop Year (pounds per acre)	Applied (thousand pounds)
2,4-D, 2-EHE	7	1	0.493	0.503	2,505
2,4-D, BEE	<0.5	1.1	0.426	0.459	68
2,4-D, dimeth. salt	3	1	0.462	0.475	953
Acifluorfen, sodium	<0.5	1	0.287	0.296	47
Alachlor	<0.5	1	1.931	1.931	485
Bentazon	<0.5	1	0.687	0.687	70
Carfentrazone-ethyl	<0.5	1.2	0.038	0.046	10
Chlorimuron-ethyl	4	1	0.017	0.017	52
Clethodim	3	1.1	0.096	0.102	190
Cloransulam-methyl	1	1	0.019	0.019	17
Dicamba, digly salt	<0.5	1	0.25	0.25	16
Fenoxaprop	<0.5	1	0.031	0.031	9
Fluazifop-P-butyl	1	1	0.099	0.099	43
Flufenacet	<0.5	1	0.265	0.265	80
Flumetsulam	<0.5	1	0.048	0.048	8
Flumiclorac-pentyl	1	1.4	0.02	0.028	17
Flumioxazin	3	1	0.066	0.066	138
Fomesafen 2	1.2	0.19	0.233	330	
Glyphosate	4	1.5	0.63	1.044	2,841
Glyphosate amm. salt	<0.5	1.7	0.489	0.745	142
Glyphosate isop.salt	92	1.5	0.802	1.33	88,903
Imazamox	<0.5	1	0.03	0.03	9
Imazaquin	1	1	0.061	0.062	66
Imazethapyr	3	1	0.053	0.053	100
Imazethapyr, ammon	<0.5	1	0.048	0.048	5
Lactofen	<0.5	1	0.11	0.11	23
Metribuzin	2	1	0.255	0.26	437
Paraquat	1	1	0.492	0.511	335
Pendimethalin	3	1	0.92	0.926	1,894

Table 8. Soybeans: total herbicide applications, 2006[1] (continued).

Herbicide	Area Applied (percent)	Applications (number)	Rate Per Application (pounds per acre)	Rate Per Crop Year (pounds per acre)	Applied (thousand pounds)
Quizalofop-P-ethyl	<0.5	1.1	0.038	0.041	14
S-Metolachlor	1	1	1.023	1.023	837
Sethoxydim	<0.5	1	0.153	0.153	10
Sulfentrazone	1	1	0.087	0.091	70
Sulfosate	1	1.8	0.967	1.701	970
Thifensulfuron	1	1.1	0.004	0.004	3
Tribenuron-methyl	1	1	0.008	0.008	5
Trifluralin	2	1	0.818	0.818	1,454

Source:USDA-NASS (2007a)

[1] Program states surveyed - Arkansas, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Ohio, South Dakota, Tennessee, Virginia, and Wisconsin; totaling 72.9 million planted acres.

Herbicide usage trends since the adoption of GE crops are the subject of much debate, with initial assessments indicating a decline in herbicide use in the early years of herbicide-resistant crop production (Carpenter et al., 2002) that some argue was then followed by an increase in the volume of herbicide usage as the technology spread (Benbrook, 2009). Others report a continuing decline in herbicide use with the adoption of GE crops (Fernandez-Cornejo and Caswell, 2006), or relative stability in the amount of herbicide active ingredients applied to soybeans (Brookes and Barfoot, 2010). The contradictory findings have been attributed to the different measurement approaches used by researchers, how different factors affecting pesticide use such as weather or cropping patterns were controlled for, and how the collected data was statistically analyzed (NRC, 2010).

Not unlike all agronomic practices, herbicides may impart selection pressures on weed communities resulting in shifts in the weed community that favor weeds that no longer respond to the herbicide used (Owen, 2008). In many instances, these weed community shifts are attributable to the evolution of herbicide-resistant weed biotypes. The shift to herbicide resistance in plants is largely a function of the natural selection of herbicide-resistant traits and is strongly related to the repeated use of one or a limited number of herbicides (Durgan and Gunsolus, 2003; Duke, 2005). Both the increased selection pressure resulting from the extensive use of glyphosate associated with glyphosate-resistant crops with subsequent reductions in the use of other herbicides and changes in weed management practices (i.e., conservation tillage or no-till) have resulted in weed population shifts and increasing glyphosate resistance among some weed populations (Duke, 2005; Owen, 2008). Glyphosate-resistant crops themselves do not influence weeds any more than non-transgenic crops. It is the weed control tactics chosen by growers that create selection pressure that ultimately over time change these weed communities and may result in the evolution of herbicide-resistant weeds (Owen, 2008). Herbicide-resistant weeds are discussed in more detail in Subsection 2.3.2, Plant Communities.

Currently, there are 396 herbicide-resistant weed biotypes described, which are represented in 210 plant species (WSSA, 2013). The first herbicide-resistant biotypes were described in the 1950s but the number of weeds resistant to herbicides increased dramatically in the 1980s and 1990s, and currently evolved resistance to 21 different herbicide mechanisms of action is described (Heap, 2011). The management of glyphosate-resistant weeds has become a substantial issue for U.S. agriculture and in particular, soybean production, especially given reduced number of economically acceptable alternative management tactics (Powles, 2008a; Powles, 2008b; Owen, 2011).

A variety of strategies have been proposed to help farmers avoid new development of glyphosate-resistant weeds (Boerboom, 1999; Beckie, 2006; Sammons et al., 2007; Frisvold et al., 2009), including:

- The rotation of herbicides with different modes of action;
- Site specific herbicide applications;
- Use of full labeled application rates;
- Crop rotation;
- Use of tillage for supplemental weed control;
- Cleaning equipment between fields;
- Controlling weed escapes;
- Controlling weeds early; and
- Scouting for weeds before and after herbicide applications.

Volunteer soybean is not a widespread problem, and when they occur, it is most often in parts of the Delta and the southeast United States. In production systems where soybean is rotated, it has shown up as a volunteer weed, yet was not generally seen as a substantial problem by farmers (Owen and Zelaya, 2005). Volunteer soybean is not considered difficult to manage, as soybean seeds rarely remain viable the following season and any interference they may pose to subsequent crops are minimal; furthermore, herbicides usually used for weed control in corn are also effective at controlling volunteer soybean (Owen and Zelaya, 2005). Conversely, volunteer glyphosate-resistant corn in soybean is a greater concern (Owen and Zelaya, 2005). Glyphosate had been used to control all weeds, including corn in soybean, yet, the increase in cultivation of glyphosate-resistant corn has created problems for growers in the Midwest managing volunteer corn with glyphosate. Growers must now often include graminicides (herbicides to control weedy grasses) as part of their weed management strategy (Owen and Zelaya, 2005).

Soybean Yield

Soybean production has increased 35.6%, from nearly 2.2 billion bushels (59.88 million MT) in 1992, to approximately 3.0 billion bushels (81.66 million MT) in 2012 (USDA-NASS, 2012j). Increased soybean production in the United States has been accomplished by both increasing the area under cultivation and through yield increases per unit area. Based on recent trends in farm production and land area, soybean farmers will have the future challenge of expanding agricultural output by raising productivity on a stable or reduced land area (OECD-FAO, 2008). Much of the projected expansion in soybean production in the future is expected to come from increased yield rather than increased area under production (OECD-FAO, 2008).

Egli (2008) recently compared historical trends in U.S. corn and soybean yields from the early 20th century to 2005. Soybean yield data was first available in 1924. He found soybean yield steadily increased over the period, as substantiated by data analyzed from 1924 to 2012, showing an average annual rate of 0.35 bushels per acre (Phillion, 2013 pers. comm.) (Figure 5). Beginning about 1945, U.S. agriculture entered into a high input era of improved hybrids of corn and soybean (among other crops), manufactured nitrogen fertilizer (important to corn yield increases), herbicide use, and higher plant populations that continue in today's practices. In the study states (Iowa, Illinois, Indiana, Kentucky, Missouri, and Tennessee), corn yield increased faster than soybean yield in the early high input era, but from 1950 to 2005, corn and soybean yields grew at comparable respective rates of 1.8% and 1.4% annually. Changes in soybean cultivars contributing to increased yields included longer seed filling periods, decreased lodging, shorter plants, and increased disease resistance. Beneficial improved management practices such as mechanization, narrow-row planting, earlier planting, adoption of conservation tillage, increased weed control, and decreased harvest loss also contributed to increased yields (Egli, 2008). Agricultural biotechnology has further enhanced crop yields through the introduction of new genetic elements that use or modify existing constituents or pathways in the plant. For example, De Bruin and Pedersen (De Bruin and Pedersen, 2008; De Bruin and Pedersen, 2009) estimate soybean cyst nematode resistance of recent and currently available soybean cultivars produced yields ranging from 17% to 19% higher than comparative new non-resistant cultivars.

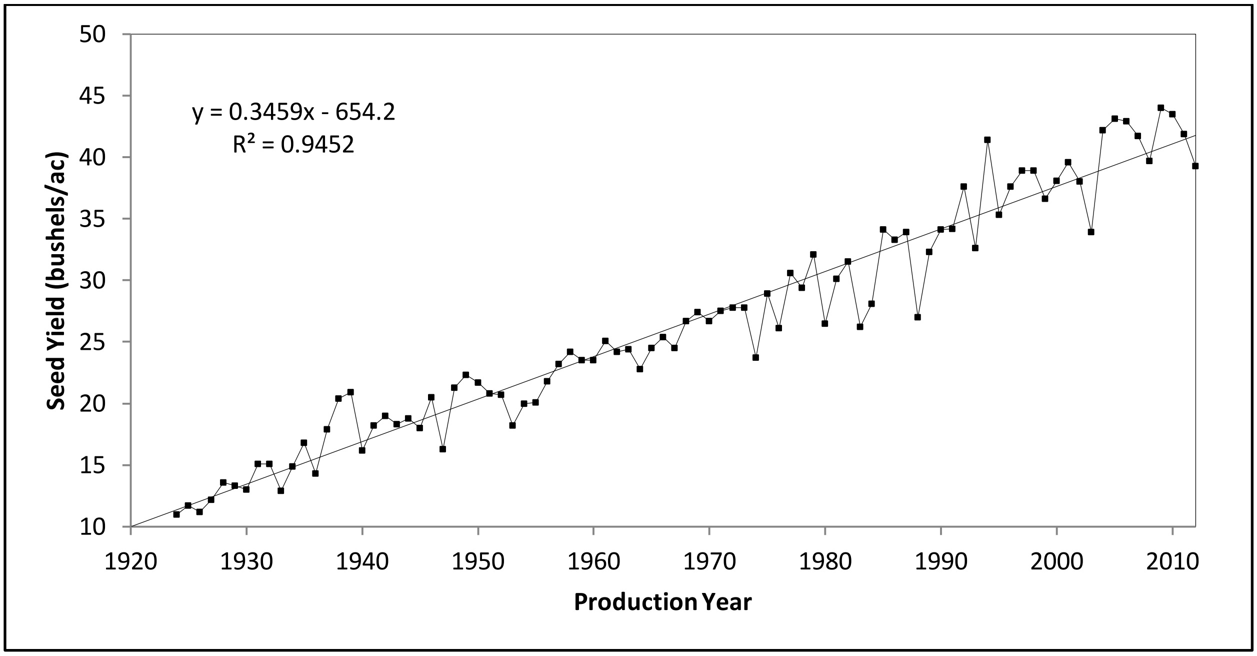


Figure 5. Soybean yield rose at an annual average rate of 0.35 bushels per acre between 1924 – 2010. Linear regression analysis was conducted by Monsanto on data from the USDA-NASS (Phillion, 2013 pers. comm.).

Soybean maximum yield is determined by soybean genetics and this genetic yield potential is only achieved when environmental conditions are perfect. The concept of yield potential of soybean is defined as the yield of a cultivar when grown in environments to which it is adapted, with non-limiting amounts of nutrients and water, and with pests, diseases, weeds, lodging, and other stresses effectively controlled (Evans and Fischer, 1999; Specht et al., 1999). Some researchers have determined substantial gains in soybean yields is still possible through careful management practices, including selecting the right variety for a given field, taking steps early to manage cyst nematodes, optimizing planting time, proper row spacing, sound weed management, controlling pests, and ensuring appropriate soil fertility (Specht et al., 2006; Pedersen, 2008). Research has shown an important factor in soybean yield is determined early in development by biomass production: row closure must be achieved by beginning pod set (R3) to maximize light interception during the critical pod and seed filling period to maximize yield (Pedersen, 2008). This is achieved by reducing stress from weeds, insects and pathogens and then planting early and in narrow rows. Early row closure is also critical to achieving higher yield because it reduces soil moisture loss. Other research evaluating the role of superoptimal seeding rates, narrow row spacing, seed inoculants, fungicide and insecticide seed treatments, additional soil fertilizers, foliar fertilizers, and foliar fungicides has found the single most important factor in achieving high soybean yields was row spacing (Naeve, 2012). Foliar fungicide applications were also important, and pre-plant supplementation of soil fertility was significantly beneficial in fields that tested with suboptimal fertility levels (Heatherly, 2012). While the study found that biennial application of potassium and phosphorous was beneficial in areas where corn is most often rotated with soybean, annual supplementation is recommended in the south where soybean to soybean rotation is more common (Heatherly, 2012).

Conventional high-yield soybean varieties are currently available from several seed companies such as Advantage Seeds’ ADV Heartbeat and OAC Quinte; Albert Lea Sheyenne and Viking lines; several D.F. Seeds’ varieties; and eMerge Genetics’ 348.TCS, e3782s, e45120s, and e5110 varieties (Advantage Seeds, 2005; D.F. Seeds, 2011; Albert Lea Seeds, 2012; eMerge, 2012). Much of the breeding of conventional soybean varieties is accomplished by State University Extension Services such as The Ohio State University, Kansas State University, North Carolina State University, University of Arkansas, and University of Missouri (Pierzynski, 2009; North Carolina Soybean Producers Association, 2010; Shannon et al., 2010; The Ohio State University, No Date; University of Arkansas, No Date). There are also high yielding soybean cultivars available having herbicide or pest resistance or the combination of the two traits and include varieties such as Genuity Roundup Ready 2 Yield® (Monsanto), Liberty Link® (Bayer), and Y Series® (Pioneer), to name a few.

A world record maximum yield for soybean was achieved in Missouri in 2010 of 160.6 bushels per acre for irrigated soybean and 98.9 bushels per acre for non-irrigated soybean, where the statewide average yield in 2010 was 42 bushels per acre (Alsager, 2010). USDA projections through 2021/2022 show an average annual rate of increased average yields of 0.45 bushels per acre for the period 2012/2013 to 2021/2022, which results in an average U.S. yield of 46.05 bushels per acre for the period (USDA-OCE, 2012). While USDA projects increasing yields, the projected rate of increase is lower than the past rate (for example, see USDA-OCE (2012)). Current and future factors that negatively affect yield increases are the expansion of soybean production into northern and western parts of the country, where yields are typically lower than in the core Midwestern production area, and a shift in some areas away from narrow rows to improve air circulation, which helps combat disease (USDA-ERS, 2012m). The U.S. average in 2012 (a drought year in the Midwest) of 39.3 bushels per acre (USDA-NASS, 2012j) was substantially below the current estimate of yield potential, suggesting that there is an opportunity to close the gap between average annual yield performance and yield potential.

Actual yield performance is a complex outcome that is dependent on a number of genetic and environmental factors that influence a crop's opportunity to realize its full yield potential. As shown in Figure 5, soybean yields can be highly variable from year to year, and yield varies geographically (Table 9) due to planting decisions and weather. From 1991 to 2011, average yield increased approximately 17.6% from 34.2 bushels per acre in 1991 to 41.5 bushels per acre in 2011, but declined nationally in 2012 to 39.3 bushels per acre compared to 2011 average yields (USDA-NASS, 2012j). In 2012, soybean average yields ranged as low as 23 bushels per acre in the Midwest and Great Plains to as high as 47 bushels per acre there and in the eastern coastal United States (USDA-NASS, 2012j) (Table 9), likely due to the drought impacting large areas of the central United States that year.

Table 9. 2012 average U.S. soybean productivity by region.

Region	2012 U.S. Soybean Acreage[1]	2012 Average Yield (bushels per acre)	Range of Average State Yields (bushels per acre)
Midwest/Great Plains[1]	64.3	38.2	23 – 47
Southeast[2]	10.1	38.8	32 – 44
Eastern Coastal[3]	2.2	43	40 – 47

Source: USDA-NASS (2012j)

[1] U.S. soybean acreage – million acres

[2] Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota Wisconsin

[3] Alabama, Arkansas, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee

[4] Delaware, Maryland, New Jersey, New York, Pennsylvania, Virginia

Within a state there is considerable local variability, as, for example, in southern Nebraska, where the 2012 yields for Harlan and Kearney counties were 48 bushels per acre and 62 bushels per acre, respectively (USDA-NASS, 2012j). For another example, in two adjacent counties in Iowa, Plymouth and Cherokee, in 2012 the average soybean yield in Cherokee County (50.7 bushels per acre) was 39% greater than the 2012 average yield in Plymouth County (36.4 bushels per acre) (USDA-NASS, 2012f). In 2011, on the other hand, the average soybean yield in Plymouth County had previously been 50.7 bushels per acre. Within each county between 2011 and 2012, the average yield in Plymouth County decreased by 28% while the average yield in Cherokee decreased by only 4% (USDA-NASS, 2012f; USDA-NASS, 2012j). Since these values represent averages over counties, variation from farm to farm and within a farm from year to year would be expected to be even greater. Thus, even with the positive management decisions that were previously discussed, observed yield is highly variable, is dependent on many factors and likely rarely reaches the theoretical maximum yield potential.

2.1.3 Soybean Seed Production

In 2012, nearly 77.2 million acres of soybean required seed for planting in the United States (USDA-NASS, 2012j). Several factors influence optimal planting rate for soybean such as row spacing, seed germination rate, soil conditions, climate, disease and pest pressure, past tillage practices and crop rotation (Robinson and Conley, 2007). Seeding rate is also determined by the plant population desired by the grower. In Iowa, the recommended planting rate for soybean ranges from 150,000 to 200,000 seeds per acre or between 37.5 and 100 lbs of seed per acre depending on seed size (Whigham, 1998). Seed sizes range from 2,000 to 4,000 seeds per pound (Whigham, 1998). Growers may plant certified soybean seed, uncertified seed, and "binrun" soybean seed that is grown and stored on individual farms (Oplinger and Amberson, 1986). Since 93% of the soybean acres planted in the United States in 2012 were GE varieties (see Table 2) (USDA-ERS, 2012e), about 71.8 million acres were planted with certified seeds. Using a conservative planting rate of 150,000 seeds per acre, an estimated 1.3 to 2.7 million tons of certified soybean planting seeds were required in 2012.

Between 1996 and 2006, corn and soybean seeds accounted for 55% of total seed expenditures; within that timeframe, expenditures for soybean seed increased from 15% to 23% of total seed expenditures (Roucan-Kane and Gray, 2009). In addition, from 1985 to 2005, real seed costs per acre have steadily increased, with significant increases since 2000, likely due to new seed technologies that express plant protection traits (e.g., herbicide and insect resistance). From 2000 to 2007, conventional, single-traited GE, and stacked GE seed cost trends were similar (Figure 6); however, prices for conventional seeds were less expensive than GE seed (e.g., $0.36/lb and $0.58/lb in 2007 respectively) (Shi et al., 2009).

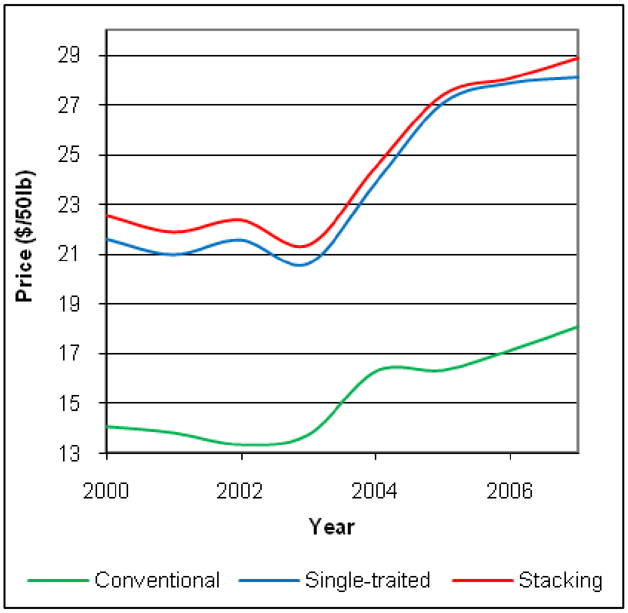


Figure 6. Nominal price trend of U.S. soybean seeds, 2000-2007(Shi et al., 2009).

Seed production differs from grain production due to additional biological, technical, and quality control factors required to maintain varietal purity. Genetic purity in the production of commercial soybean seed is regulated through a system of seed certification which ensures the desired traits in that particular seed remain within purity standards (Bradford, 2006). The production and certification of foundation, registered, certified, or quality assurance seeds are administered by state and regional crop improvement associations, several of which are chartered under the laws of the state(s) they serve (e.g., see Mississippi Crop Improvement Association, 2008; Illinois Crop Improvement Association, 2013; SSCA, No Date-a; Virginia Crop Improvement Association, No Date). These agencies certify varietal purity and identity, while issues concerning germination and mechanical purity are governed under state and federal seed laws. Seed quality includes a variety of attributes, including genetic purity, vigor, weed seed content, seed borne diseases, and the presence of foreign material such as dirt or chaff (Bradford, 2006). The genetic purity of the seed must be maintained to maximize the value of the new variety or cultivar (Sundstrom et al., 2002). Procedures required during seed production include such actions as maintaining seed tags as proof of seed origin and class; fields meeting cropping history, weed, and isolation requirements prior to planting; cultivation, transportation, and storage equipment meeting cleanliness requirements; field inspections accomplished by certified crop inspectors; inspection and laboratory analysis of harvested seeds from approved fields; and separating harvested seeds in storage (Mississippi Crop Improvement Association, 2008; South Dakota Crop Improvement Association, 2011; Illinois Crop Improvement Association, 2013; SSCA, No Date-a; Virginia Crop Improvement Association, No Date). In addition, there are also crop specific field, inspection, isolation, and harvested seed purity (e.g., percentage of pure seed, inert matter, weed seeds, other crop seeds, other variety seeds, and germination) standards in order to meet certification requirements (South Dakota Crop Improvement Association, 2011; Virginia Crop Improvement Association, 2013; SSCA, No Date-b)

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 seed. States have developed laws to regulate the quality of seed available to farmers (Bradford, 2006). Most of the laws are similar in nature and have general guidelines for providing information on the label for the following:

- Commonly accepted name of agricultural seed;
- Approximate total percentage by weight of purity;
- Approximate total percentage of weight of weed seeds;
- Name and approximate number per pound of each kind of noxious weed seeds;
- Approximate percentage of germination of the seed; and
- Month and year the seed was tested.

Various seed associations have standards to help maintain the quality of soybean seed. The Association of Official Seed Certifying Agencies (AOSCA) (AOSCA, No Date) defines the classes of seed as follows:

- *Breeder* seed is directly controlled by the plant breeder that developed the variety.
- *Foundation* seed is the progeny of Breeder or Foundation seed that is handled to most nearly maintain specific genetic identity and purity.
- *Registered* seed is a progeny of Breeder or Foundation seed that is so handled as to maintain satisfactory genetic identity and purity.
- *Certified* seed is the progeny of Breeder, Foundation, or Registered seed that is so handled as to maintain satisfactory genetic identity and purity.

Seed certification systems should be distinguished from Identity Preservation (IP) systems for certain agricultural commodities. IP refers to a system of production, handling, and marketing practices used in order to maintain the integrity and purity of crop products throughout the food supply chain (Sundstrom et al., 2002). IP systems are utilized to meet the demands for specialized grains products, including those from crops with output-specific traits (e.g., high oleic oil), without specific traits or attributes (e.g., non-GE crops), grown under specific production methods (e.g., organic crops), and requiring rigorous safeguards and confinements practices (e.g., pharmaceutical and industrial crops) (Elbehri, 2007).

Soybean is self-pollinated, propagated commercially by seed (Hoeft et al., 2000; OECD, 2000). In the United States, there are no *Glycine* species found outside of cultivation, and the potential for outcrossing is minimal (OECD, 2000). Additionally, Minimum Land, Isolation, Field, and Seed Standards (7 CFR part 201.76) specify that isolation distances for the production of Foundation, Registered and Certified soybean seeds from any potential contaminating source must be adequate to prevent mechanical mixing.

2.1.4 Organic Soybean Production

In the United States., 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, 2008). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced.

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

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

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

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

> A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant deoxyribonucleic acid (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 (USDA-AMS, 2008).

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 (NCAT, 2003). Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2008). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche, 2006; USDA-AMS, 2008).

Organic soybean production practices include crop rotation, use of cover crops, green and animal manures, application of rock minerals such as lime, other soil additives, mechanical weed control, biological control of pests, and disease control primarily through management practices (Kuepper, 2003; Heatherly et al., 2009; USDA-AMS, 2011). Utilizing 2006 ARMS data, McBride and Greene (2008) determined that more than 90% of organic soybean producers planted in standard rows (22-30", (Coulter et al., 2010)), as compared to 60% of other soybean producers; further, organic soybean operations rotated crops more often, and 40% of the farmers incorporated a one-year fallow into their organic soybean rotation.

Weed control in organic systems is accomplished with delayed seeding to avoid spring weeds, applying fertilizer to growing plants to outcompete weeds, increasing seeding rates, sowing cover crops, crop rotation, intercropping, flame weeding, hand weeding, and mechanical means (e.g., tillage) (Kuepper, 2003; Heatherly et al., 2009; Place et al., 2011). Organic crop production historically employed mulch and ridge tillage practices (NCAT, 2003); however, no-till may be unsustainable in some long-term organic systems because of increasingly poor weed control (Teasdale et al., 2007). The latter cited study conducted field evaluations of several tillage systems over nine years, finding that in the organic system evaluated, factors contributing to poor weed control included uneven seeding beds produced by chisel-tilling in a cover crop and animal manure, variable ground cover occurring in mowed cover crop residue, insufficient disruption of weed roots by sweep-type cultivators, and the short grain crop rotation system used was unsuitable for maintaining a low weed seedbank (Teasdale et al., 2007).

Pest control in organic systems is accomplished with application of natural pesticides, integrated pest management techniques such as introduction of beneficial organisms in the form of soil predator and parasitic organisms, and some of the practices described for weed control, such as crop rotation, intercropping, and use of cover crops (NCAT, 2003).

Diseases are primarily controlled in organic systems by planting disease-resistant varieties and with management practices that promote healthy soil, rotating crops, diligently removing diseased plant material, and plant canopy management (NCAT, 2003). When physical, mechanical, or biological controls are not sufficient for controlling weeds, pests, or disease, only a biological, botanical, or synthetic substance approved on the national list may be used (USDA-AMS, 2011).

USDA-NASS recently reported the organic crop production data collected in 2011 (USDA-NASS, 2012a) . In that year, 96,080 acres of organic soybeans in 28 states were harvested (Table 10), compared to approximately 73,636 million harvested acres of conventionally produced soybean (USDA-NASS, 2011). In 2011, organic soybean production consisted of about 0.09% of total U.S. soybean production and was valued at approximately $49.4 million, capturing roughly 0.14% of the overall soybean crop value for that year (USDA-NASS, 2012i; USDA-NASS, 2012a). Organic soybean producers generally harvest lower yields than other producers (McBride and Greene, 2008; Heatherly et al., 2009). McBride and Greene (2008) also found total operating costs averaged $30 more per acre and capital costs averaged $60 per acre higher for organic soybean producers than for other conventional soybean producers.

Table 10. U.S. certified organic soybean harvested acres by state, 2011[1].

State	Soybeans (acres)	State	Soybeans (acres)
Illinois	6,633	North Dakota	3,288
Indiana	945	Ohio	5,634
Iowa	12,659	Pennsylvania	1,280
Kansas	1,311	South Dakota	3,962
Maryland	1,090	Vermont	527
Michigan	11,699	Virginia	150
Minnesota	16,150	Wisconsin	7,622
Missouri	5,505		
Nebraska	6,211		
New York	8,621		

Source: USDA-NASS (2012a)

[1] Table does not include certain states with confidential values due to low number of farms producing organic soybean.

2.2 Physical Environment

2.2.1 Soil Quality

Soil consists of solids (minerals and organic matter), liquids, and gases. This body of inorganic and organic matter is home to a wide variety of fungi, bacteria, and arthropods, as well as the growth medium for terrestrial plant life (USDA-NRCS, 2004). Soil is characterized by its layers that can be distinguished from the initial parent material due to additions, losses, transfers, and transformations of energy and matter (USDA-NRCS, 1999b). It is further distinguished by its ability to support rooted plants in a natural environment. Soil plays a key role in determining the capacity of a site for biomass vigor and production in terms of physical support, air, water, temperature moderation, protection from toxins, and nutrient availability. Soils also determine a site's susceptibility to erosion by wind and water, and a site's flood attenuation capacity.

Soil properties change over time; temperature, pH, soluble salts, amount of organic matter, the carbon-nitrogen ratio, numbers of microorganisms and soil fauna all vary seasonally, as well as over extended periods of time (USDA-NRCS, 1999b). Soil texture and organic matter levels directly influence its shear strength, nutrient holding capacity, and permeability. Soil taxonomy was established to classify soils according to the relationship between soils and the factors responsible for their character (USDA-NRCS, 1999b). Soils are organized into four levels of classification, the highest being the soil order. Soils are differentiated based on characteristics such as particle size, texture, and color, and classified taxonomically into soil orders based on observable properties such as organic matter content and degree of soil profile development (USDA-NRCS, 2010b). The Natural Resources Conservation Service (NRCS) maintains soil maps on a county level for the entire United States and its territories.

Soybeans are normally grown in agricultural fields managed for crop production and are best suited to fertile, well-drained medium-textured loam soils, yet can be produced in a wide range of soil types (Berglund and Helms, 2003; NSRL, No Date). Soybeans need a variety of macronutrients, such as nitrogen, phosphorus, potassium, calcium, magnesium, and sulfur, at various levels (NSRL, No Date). They also require smaller amounts of micronutrients such as iron, zinc, copper, boron, manganese, molybdenum, cobalt, and chlorine. These micronutrients may be deficient in poor, weathered soils, sandy soils, alkaline soils, or soils excessively high in organic matter. As with proper nutrient levels, soil pH is critical for soybean development. Soybeans grow best in soil that is slightly acidic (pH 5.8 to 7.0); soil with a pH that is too high (7.3 or greater) negatively affects yield (Cox et al., 2003; NSRL, No Date). Similarly, soils that are high in clay and low in humus may impede plant emergence and development (NSRL, No Date). Soils with some clay content may increase moisture availability during periods of low precipitation (Cox et al., 2003). Soybean yield is highly dependent upon soil and climatic conditions. In the United States, the soil and climatic requirements for growing soybean are very similar to corn. The soils and climate in the Midwestern, Eastern, and portions of the Great Plains regions of the United States provide sufficient water under normal climatic conditions to produce a soybean crop. Soil texture and structure are key components in determining water availability in soils. Medium-textured soils hold more water, allowing soybean roots to penetrate deeper in medium-textured soils than in clay soils (Berglund and Helms, 2003; Cox et al., 2003).

Land management practices for soybean cultivation can affect soil quality. While practices such as tillage, fertilization, the use of pesticides and other management tools can improve soil health, they can also cause substantial damage if not properly used. Several concerns relating to agricultural practices include increased erosion, soil compaction, degradation of soil structure, nutrient loss, increased salinity, change in pH, and reduced biological activity (USDA-NRCS, 2001).

As discussed in Subsection 2.1.2, Agronomic Practices, conventional and conservation tillage may be used for the cultivation of soybean. Reducing excessive tillage through practices such as conservation tillage minimizes the loss of organic matter and protects the soil surface by leaving plant residue on the surface. Management of crop residue is one of the most effective conservation methods to reduce wind and water erosion, and also benefits air and water quality and wildlife (USDA-NRCS, 2006a). Residue management that uses intensive tillage and leaves low amounts of crop residue on the surface may result in greater losses of soil organic matter (SOM). Intensive tillage turns the soil over and buries the majority of the residue, stimulating microbial activity and increasing the rate of residue breakdown (USDA-NRCS, 1996). The residues left after conservation tillage increase organic matter and improve infiltration, soil stability and structure, and soil microorganism habitat (Fawcett and Caruana, 2001; USDA-NRCS, 2006b). Organic matter is probably the most vital component in maintaining quality soil; it is instrumental in maintaining soil stability and structure, reduces the potential for erosion, provides energy for microorganisms, improves infiltration and water holding capacity, and is important in nutrient cycling, cation exchange capacity[4], and the breakdown of pesticides (USDA-NRCS, 1996).

The residue left over from conservation tillage practices increases SOM in the top three inches of the soil and protects the surface from erosion while maintaining water-conducting pores. Soil aggregates in conservation tillage systems are more stable than that of conventional tillage due to the products of SOM decomposition and the presence of soil bacteria and fungal hyphae (filamentous structures that compose the main growth) that bind aggregates and soil particles together (USDA-NRCS, 1996). Although soil erosion rates are dependent on numerous local conditions such as soil texture and crop, a comparison of 39 studies contrasting conventional and no-till practices illustrates that, on average, no-till practices reduce erosion 488 times over conventional tillage (Montgomery, 2007). This reduction is enough to bring soil production more in line with losses from erosion. From 1982 through 2003, erosion on U.S. cropland dropped from 3.1 billion tons per year to 1.7 billion tons per year (USDA-NRCS, 2006a). This can partially be attributed to the increased effectiveness of weed control through the use of herbicides and the corresponding reduction in the need for mechanical weed control (Carpenter et al., 2002). Conservation tillage also minimizes soil compaction due to the reduced number of tillage trips.

Other methods to improve soil quality include careful management of fertilizers and pesticides; use of cover crops to increase plant diversity and limit the time soil is exposed to wind and rain; and, increased landscape diversity with buffer strips, contour strips, wind breaks, crop rotations,

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[4] Cation Exchange Capacity is the ability of soil anions (negatively charged clay, organic matter and inorganic minerals such as phosphate, sulfate, and nitrate) to adsorb and store soil cation nutrients (positively charged ions such as potassium, calcium, and ammonium).

and varying tillage practices (USDA-NRCS, 2006b). In addition, the practice of using cover crops has been getting recent attention not only for limiting the time soil is exposed to wind and rain, but also for increasing plant diversity, reducing compaction, suppressing disease, controlling weeds, and enhancing soil nutrients (Hoorman et al., 2009b; USDA-NRCS, 2011b; MDA, 2012; NWF, 2012; SARE, 2012; USDA-NASS, 2012e; Corn and Soybean Digest, 2013; Lee et al., No Date)

While conservation tillage does have several benefits for soil health, some management concerns are associated with its use. Under no-till practices, soil compaction may become a problem as tillage is useful for breaking up compacted areas (USDA-NRCS, 1996). Likewise, not all soils (such as wet and heavy clay soils) are suited for no-till. Also, no-till practices may lead to increased pest occurrences that conventional tillage is better suited to managing (NRC, 2010).

There are a multitude of organisms associated with soils ranging from microorganisms to larger organisms, such as worms and insects. The microorganisms that make up the soil community include bacteria, fungi, protozoa, and nematodes. These organisms are responsible for a wide range of activities that impact soil health and plant growth. Decomposers, such as bacteria, actinomycetes (filamentous bacteria), and saprophytic fungi, degrade plant and animal remains, organic materials, and some pesticides (USDA-NRCS, 2004). Other organisms, such as protozoa, mites and nematodes, will consume the decomposer microbes and release macro- and micronutrients, making them available for plant usage. Another important group of soil microorganisms are the mutualists. These are the mycorrhizal fungi, nitrogen-fixing bacteria, and some free-living microbes that have co-evolved with plants that supply nutrients to and obtain food from their plant hosts (USDA-NRCS, 2004). The *B. japonicum* bacteria associated with soybeans is a nitrogen-fixing rhizobium bacteria found in plant root nodules (Franzen, 1999). Since neither soybean nor *B. japonicum* is native to North America, if a field has not been planted with soybean within three to five years, either the seed or seed zone must be inoculated with the rhizobium bacteria prior to soybean planting (Elmore, 1984; Pedersen, 2007).

Pesticide use has the potential to affect soil quality due to the impact to the soil microbial community and is discussed further in Subsection 2.3.4, Microorganisms. The length of persistence of herbicides in the environment is dependent on the concentration and rate of degradation by biotic and abiotic processes (Carpenter et al., 2002). Persistence is measured by the half-life or dissipation time (DT_{50}), which equates to the length of time needed for the herbicide to degrade to half of its original concentration. The degradation of pesticides and herbicides may be dependent on mineralization by microbes in soil, photodegradation in water, leaching (US-EPA, 2005). In soil, pesticide persistence may be strongly influenced by moisture, temperature, organic matter content and pH (FAO, 1997; Senseman, 2007).

2.2.2 Water Resources

Water is essential for life and plays a vital role in the proper functioning of the Earth's ecosystems. Water pollution has a substantial impact on all living creatures, and can negatively affect the use of water for drinking, household needs, recreation, fishing, transportation and commerce. Surface water in rivers, streams, creeks, lakes, and reservoirs supports everyday life through the provision of water for drinking and other public uses. Surface runoff from rain, snowmelt, or irrigation water can affect surface water quality by depositing sediment, minerals, or other contaminants into surface water bodies.

Surface water quality is determined by the natural, physical, and chemical properties of the land that surrounds the water body. The topography, soil type, vegetative cover, minerals, and climate all influence water quality. Surface runoff is affected by meteorological factors such as rainfall intensity and duration, and physical factors such as vegetation, soil type, and topography. When land use affects one or more of these natural physical characteristics of the land, water quality is almost always impacted to some extent. These impacts may be positive or negative, depending on the type, duration and extent of land use. Agricultural practices have the potential to substantively impact water quality due to the vast amount of acreage devoted to farming nationwide and the physical and chemical demands that agricultural use imposes on the land. The most common types of agricultural pollutants include excess sediment, fertilizers, animal manure, pesticides and herbicides. Agricultural nonpoint source pollution is the leading source of impacts to surveyed rivers and lakes, the third largest source of impairment to estuaries, and a major source of impairment to groundwater and wetlands (USDA-NRCS, 2011c).

The principal law governing pollution of the nation’s water resources is the Federal Water Pollution Control Act of 1972, better known as the Clean Water Act (CWA). The EPA utilizes water quality standards, permitting requirements, and monitoring to protect water quality. The EPA sets the standards for water pollution abatement for all waters of the United States under CWA programs, but, in most cases, gives qualified states the authority to issue and enforce permits. The CWA provides the authority to establish water quality standards, control discharges into surface and subsurface waters (including groundwater), develop waste treatment management plans and practices, and issue permits for discharges under the National Pollutant Discharge Elimination System (NPDES). Section 303(d) of the CWA established a process for states to identify those waters within its boundaries that do not meet minimum water quality standards. Waters that do not meet clean water standards are classified under the CWA as “Impaired Waters.” Impaired Waters cannot support one or more designated uses (e.g., swimming, the protection and propagation of aquatic life, drinking, and agricultural or industrial supply). Common pollutants evaluated include sediment, chemicals, fuels, biological contaminants and pathogens, and characteristics such as oxygen availability, water temperature, and water clarity. Once a waterbody or stream segment is listed as impaired, the state must complete a plan to address the issue causing the impairment. States then develop total maximum daily loads (TMDLs) for priority waters that identify the amount of a specific pollutant from various sources that may be discharged to a water body, but still ensure that water quality standards are met for that body of water. Completion of the plan is generally all that is required to remove the stream segment from the 303(d) impaired water list and does not mean that water quality has changed. Once the TMDL is completed and approved by EPA (US-EPA, 2012b), the stream segment is placed on the 305(b) list of impaired streams with a completed TMDL.

Groundwater is water that flows underground and is stored in natural geologic formations called aquifers. It is ecologically important because it sustains ecosystems by releasing a constant supply of water into wetlands and contributes a sizeable amount of flow to permanent streams and rivers. Currently, the largest use of groundwater in the United States is irrigation, representing approximately 67.2% of all the groundwater pumped each day (McCray, 2012).

In the United States, approximately 47% of the population depends on groundwater for its drinking water supply. Drinking water is protected under the Safe Drinking Water Act of 1974 (SDWA) (Public Law 93-523, 42 U.S.C. 300 *et seq*.). SDWA and subsequent amendments authorize the EPA to set national health-based standards for drinking water from source water to the tap to protect against both naturally-occurring and man-made contaminants that may be found. In an effort to protect source water, the Sole Source Aquifer (SSA) Program was developed to protect drinking water supplies in areas where there are few or no alternative sources to the groundwater resource for drinking water and other needs. EPA defines a SSA as an aquifer that supplies at least 50% of the drinking water consumed in the area overlying the aquifer. There are 77 designated SSAs in the United States and its territories (US-EPA, 2011e). The designation protects an area's ground water resource by requiring EPA to review certain proposed projects receiving Federal funds or approval within the designated area to ensure that they do not endanger the water source.

The water needs of soybean are recounted in Section 2.1.2.1, along with the acreage that is irrigated and the states in which irrigation is common. Also previously noted is the important role of irrigation water in increasing soybean yield in those areas of marginal yearly snow- and rain-fall.

The presence of weeds in soybean fields is a primary detriment to soybean productivity. Weeds compete with soybean for light, nutrients, and soil moisture; can harbor insects and diseases; and, can also interfere with harvest, causing extra wear on harvest equipment (Loux et al., 2008). Herbicides have been the primary tactic to manage weed communities in soybeans since the mid-1960s and will continue to be an important feature of row crop weed management for the foreseeable future. Field crop production use of pesticides can introduce these chemicals to water through spray drift, cleaning of pesticide equipment, soil erosion, or filtration through soil to groundwater. Whether an herbicide has the potential to find its way into ground or surface water is dependent on a number of factors such as a chemical’s solubility (whether it readily dissolves in water), its adsorptive qualities (how tightly it binds to clay and humus particles in the soil), and its degradation (how fast it breaks down into harmless components) (WSU, 2010).

Approximately 93% of the soybean acreage in the United States is planted with GE herbicide-resistant soybean varieties (USDA-ERS, 2012e) (see Table 2, Subsection 2.1.1, Acreage and Area of Soybean Production). Farms planting GE herbicide-resistant soybean varieties are more likely to use conservation tillage and no-till practices over conventional agricultural practices (Dill et al., 2008; Givens et al., 2009). This shift has resulted in reduced surface water runoff and soil erosion (Locke et al., 2008). As discussed in Subsection 2.2.1, Soil Quality, reduced tillage agricultural practices result in improved soil quality having high organic material that binds nutrients within the soil. An increased amount of plant residue on the soil surface reduces the effects of pesticide usage on water resources by forming a physical barrier to erosion and runoff, allowing more time for absorption into the soil, and slowing down soil moisture evaporation (Locke et al., 2008). The use of GE herbicide-resistant soybean varieties has also allowed a shift to herbicides that have lower environmental impact, such as glyphosate (Fernandez-Cornejo and McBride, 2002).

Nutrient applications to soybean primarily include nitrogen, phosphorus (phosphate), potassium (potash), calcium, and sulfur, with other micronutrient supplements such as zinc, iron, and magnesium applied as needed (Whitney, 1997; USDA-NASS, 2007a; NSRL, No Date). Runoff from cropland areas receiving manure or fertilizer contributes to increased phosphorous and nitrogen delivery to streams and lakes. Phosphorus in fresh water systems is a limiting factor for eutrophication; therefore, an increase in phosphorus frequently leads to increased eutrophication[5]. Ammonium loss into surface waters can result in the poisoning of aquatic organisms. Nitrate in runoff from fields is carried into rivers and lakes. Elevated nitrate levels in the Gulf of Mexico contribute to the hypoxia zone, an area depleted of oxygen and marine life. Conservation tillage and other management practices are used to trap and control sediment and nutrient runoff. Water quality conservation practices benefit agricultural producers by lowering input costs and enhancing the productivity of working lands (USDA-NRCS, 2012).

2.2.3 Air Quality

The Clean Air Act (CAA) requires the maintenance of National Ambient Air Quality Standards (NAAQS). The NAAQS, developed by the EPA to protect public health, establish limits for six criteria pollutants: ozone (O_3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO_2), lead (Pb), and inhalable particulates (coarse particulate matter [PM] greater than 2.5 micrometers and less than 10 micrometers in diameter [PM_{10}] and fine particles less than 2.5 micrometers in diameter [$PM_{2.5}$]). The CAA requires states to achieve and maintain the NAAQS within their jurisdiction. Each state may adopt requirements stricter than those of the national standard and each is also required by EPA to prepare a State Implementation Plan (SIP) containing strategies to achieve and maintain the national standard of air quality within the state. Areas that violate air quality standards are designated as non-attainment areas for the criteria pollutant(s), whereas areas that comply with air quality standards are designated as attainment areas. Emissions contributing to greenhouse gases (GHGs) associated with global warming are discussed in Subsection 2.2.4, Climate Change.

Primary sources of emissions associated with crop production include exhaust from motorized equipment such as tractors and irrigation equipment, soil particulates from tillage and wind induced erosion, particulates from burning of fields, and sprayed herbicides and pesticides.

As mentioned in Subsection 2.1.2, Agronomic Practices, the majority of soybean grown in the United States is rotated with corn on a two-year rotation. Soybean fields typically are tilled if under conventional tillage and the new rotation crop is planted in the following year. Use of herbicide-resistant soybeans has facilitated conservation tillage or no-till soybean production, as it diminishes the need to till for weed control. Decreased tillage with the consequence of minimized earth disturbance reduces fuel use by emission-producing equipment. This is illustrated in Table 11using the NRCS Energy Estimator: Tillage Tool (USDA-NRCS, 2011a; USDA-NRCS, 2013a). The tool estimates potential fuel savings of 3,010 gallons or 60% savings per year based upon producing 1,000 acres of no-till soybean compared to conventional till soybean in the Urbana, Illinois postal code[6]. NRCS is careful to note that this estimate is only approximate, as many variables could affect an individual operation’s actual savings. Reduced

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[5] Eutrophication is the process by which a body of water becomes enriched in dissolved nutrients (as phosphates) that stimulate the growth of aquatic plant life usually resulting in the depletion of dissolved oxygen.

[6] Postal codes are used in the NRCS Energy Estimator to estimate diesel fuel use and costs in the production of key crops for an area.

tillage also generates fewer particulates (dust) and potentially contributes to lower rates of wind erosion releasing soil particulates into the air, benefitting air quality (Towery and Werblow, 2010).

Table 11. Total farm diesel fuel consumption estimate (in gallons per year).

Estimate for 1,000 Acre Soybean Crop (Urbana, Illinois-61801)	Tillage Method			
	Conventional Tillage	Mulch-till	Ridge-till	No-till
Total fuel use	5,239	4,369	3,460	2,330
Potential fuel savings over conventional tillage	--	870	1,779	2,909
Total savings	--	17%	34%	56%

Source: USDA-NRCS (2013a)

Volatilization of fertilizers, herbicides and pesticides from soil and plant surfaces also introduces these chemicals to the air. The USDA Agricultural Research Service (ARS) is conducting a long-term study to identify factors that affect pesticide levels in the Chesapeake Bay region airshed (USDA-ARS, 2011). This study has determined volatilization is highly dependent upon exposure of disturbed unconsolidated soils and variability in measured compound levels is correlated with temperature and wind conditions. Another ARS study of volatilization of certain herbicides after application to fields has found moisture in dew and soils in higher temperature regimes significantly increases volatilization rates (USDA-ARS, 2011).

Prescribed burning is a land treatment, used under controlled conditions, to accomplish resource management objectives. Open combustion produces particles of widely ranging size, depending to some extent on the rate of energy release of the fire (US-EPA, 2011a). The extent to which agricultural and other prescribed burning may occur is regulated by individual State Implementation Plans (SIPs) to achieve compliance with the NAAQS. Prescribed burning of fields would likely occur only as a pre-planting option for soybean production based on individual farm characteristics.

Pesticide and herbicide spraying may impact air quality from drift and diffusion. Drift is defined by EPA as “the movement of pesticide through air at the time of application or soon thereafter, to any site other than that intended for application” (US-EPA, 2000). Diffusion is gaseous transformation to the atmosphere (FOCUS, 2008). Factors affecting drift and diffusion include application equipment and method, weather conditions, topography, and the type of crop being sprayed (US-EPA, 2000). EPA is currently evaluating new regulations for pesticide drift labeling and the identification of best management practices to control such drift (US-EPA, 2009b), as well as identifying scientific issues surrounding field volatility of conventional pesticides (US-EPA, 2010b).

Other conservation practices, as required by USDA to qualify for crop insurance and beneficial Federal loans and programs (USDA-ERS, 2009a), effectively reduce crop production impacts to air quality through the employment of windbreaks, shelterbelts, reduced tillage, and cover crops that promote soil protection on highly erodible lands.

2.2.4 Climate Change

Climate change represents a significant and lasting statistical change in climate conditions that may be measured across both time and space. The EPA has identified carbon dioxide (CO_2), methane (CH_4), and nitrous oxide (N_2O) as the key GHGs affecting warming temperatures. While each of these gases occurs naturally in the atmosphere, human activity has significantly increased the concentration of these gases since the beginning of the industrial revolution. The level of human produced gases accelerated even more so after the end of the Second World War, when industrial and consumer consumption flourished. With the advent of the industrial age, there has been a 36% increase in the concentration of CO_2, 148 % in CH_4, and 18 % in N_2O (US-EPA, 2011b).

U.S. agriculture may influence climate change through various facets of the production process (Horowitz and Gottlieb, 2010). The major sources of GHG emissions associated with crop production are soil N_2O emissions, soil CO_2 and CH_4 fluxes, and CO_2 emissions associated with agricultural inputs and farm equipment operation (Robertson et al., 2000; Del Grosso et al., 2002; West and Marland, 2002; Adler et al., 2007). Over the twenty-year period of 1990 to 2009, total emissions from the agricultural sector grew by 8.7%, with 7% of the total U.S. GHG emissions in 2009 generated from this sector (US-EPA, 2011b).

CH_4 and N_2O are the primary GHGs emitted by agricultural activities. Emissions from intestinal (enteric) fermentation and manure management represent about 20% and 7% of total CH_4 emissions from anthropogenic activities, respectively. Agricultural soil management activities including fertilizer application and cropping practices were the largest source of N_2O emissions, accounting for 69% of all U.S. N_2O emissions (US-EPA, 2011b). Agricultural practices that produce CO_2 emissions include liming and the application of urea fertilization to agricultural soils. The use of lime and urea fertilizers resulted in an increase of 11% of CO_2 in 2009 relative to 1990 emissions (US-EPA, 2011b). The agricultural sector is also responsible for CO_2 emissions from fossil fuel combustion by farm equipment such as tractors, as discussed in Subsection 2.2.3, Air Quality.

Since CO_2 and CH_4 are two of the key gases most responsible for the “Greenhouse Effect,” scientists and policy makers are interested in carbon (C) gases and how they may be removed from the atmosphere and stored. The process of C moving from the atmosphere to the earth and back is referred to as the carbon cycle. Simplified components of the carbon cycle are:

- Conversion of atmospheric C to carbohydrates through the process of photosynthesis;
- The consumption of carbohydrates and respiration of CO_2;
- The oxidation of organic carbon creating CO_2; and
- The return of CO_2 to the atmosphere.

Carbon can be stored in four main pools other than the atmosphere: (1) the earth’s crust, (locked up in fossil fuels and sedimentary rock deposits); (2) the oceans where CO_2 is dissolved and marine life creates calcium carbonate shells; (3) in soil organic matter; and (4) within all living and dead organisms that have not been converted to soil organic matter. These pools can store or sink C for long periods, as in the case of C stored in sedimentary rock and in the oceans. Conversely, C may be held for as short a period as the life span of an individual organism.

Humans can affect the carbon cycle through activities such as the burning of fossil fuels, deforestation, or releasing soil organic carbon through land disturbing activities. The process of storing C in the ecosystem is termed carbon sequestration. Carbon sequestration includes storing C in trees, plants and grasses (biomass) in both the above ground and the below ground plant tissues, and in the soil. Soil C can be found in the bodies of microorganisms (fungi, bacteria, etc.), in non-living organic matter, and attached to inorganic minerals in the soil.

Between 1990 and 2008, crop conservation tillage practices increased from approximately 30% of soybean acreage to 63% of soybean acreage in the United States (CTIC, 2011). Tillage is one agricultural practice that contributes to the release of GHG because of the loss of soil CO_2 to the atmosphere; conversely, reductions in GHG emissions from lower exposure and oxidation of soil organic matter are often attributed to conservation tillage practices (Adler et al., 2007; CAST, 2009b; US-EPA, 2009a; Towery and Werblow, 2010). Expected reductions in GHG emissions associated with the production of GE soybeans result from a reduction in fuel use due to less frequent herbicide applications and soil cultivation (Brookes and Barfoot, 2006).

As noted by EPA, the increase of conservation tillage is contributing to soil C sequestration (US-EPA, 2011b); however, there is no evidence in EPA data that reductions or downward trends in overall GHG emissions have occurred as a result of GE soybeans becoming commercially available in the mid-1990s.

The impacts of GE crop varieties on climate change are dependent on many variables including cropping systems, production practices, geographic distribution of activities, and individual grower decisions. Agriculture influences emissions that may contribute to climate change, and climate change, in turn, potentially affects agriculture. In a review of several studies on corn, rice, sorghum, soybean, wheat, common forages, cotton, some fruits, and irrigated grains, Field et al. (2007) found that most studies projected likely climate-related yield increases of 5 to 20%; however, this positive impact would not be observed evenly across all regions as certain areas of the United States are expected to be negatively impacted by substantially reduced water resources. In addition, the current range of weeds and pests of agriculture is expected to change in response to climate change (USGCRP, 2009).

2.3 Biological Resources

2.3.1 Animal Communities

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

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

As discussed in Subsection 2.1.2, Agronomic Practices, a shift from conventional agricultural practices to conservation tillage and no-till practices has occurred on farms planting GE herbicide-resistant soybean varieties (Dill et al., 2008; Givens et al., 2009). This increased use of conservation tillage practices has benefitted wildlife through improved water quality, availability of waste grain, retention of cover in fields, and increased populations of invertebrates (Brady, 2007; Sharpe, 2010). Conservation tillage practices that leave greater amounts of crop residue serve to increase the diversity and density of birds and mammals (USDA-NRCS, 1999a). Increased residue also provides habitat for insects and other arthropods, consequently increasing this food source for insect predators. Insects are important during the spring and summer brood rearing season for many upland game birds and other birds, as they provide a protein-rich diet to fast growing young, as well as a nutrient-rich diet for migratory birds (USDA-NRCS, 2003).

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

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

2.3.2 Plant Communities

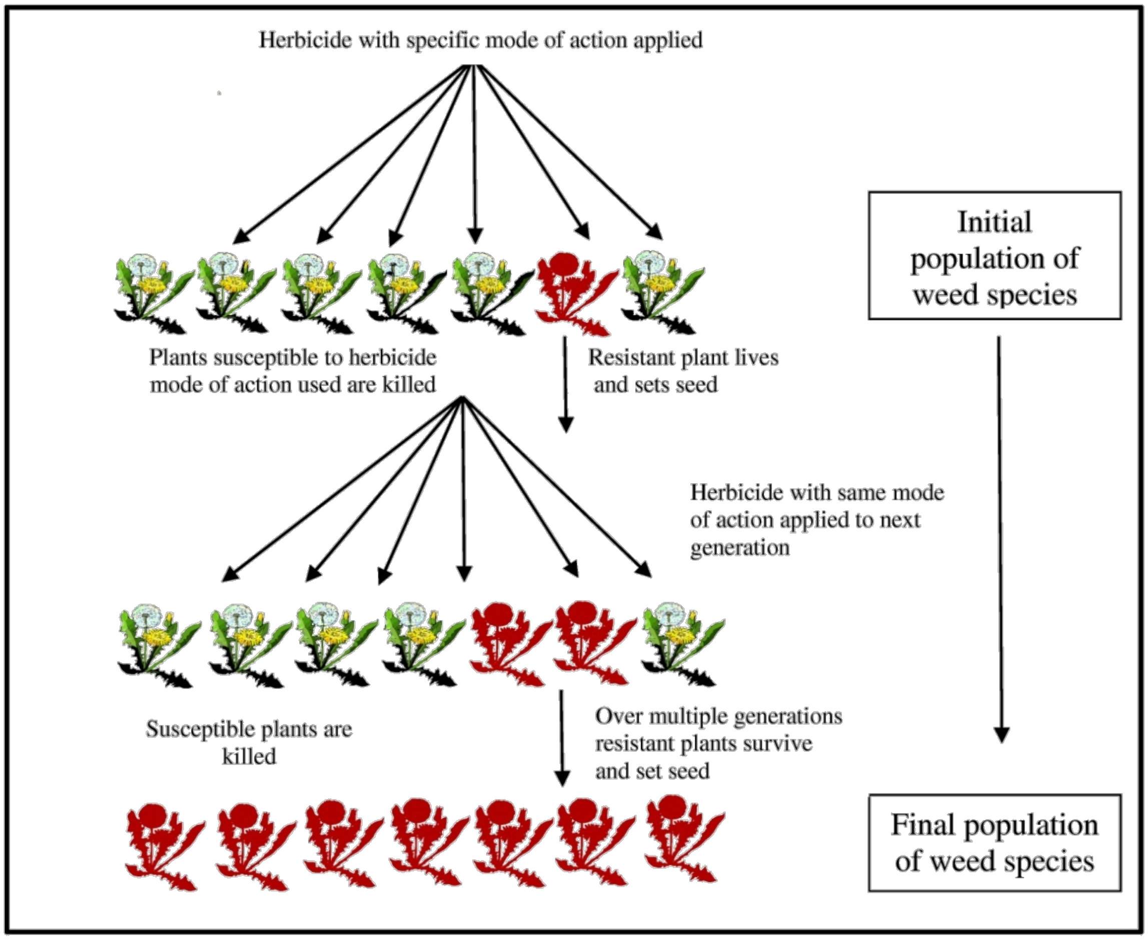
Soybeans are grown in 31 states (USDA-NASS, 2012b) throughout the Midwest, Delta, Mid-Atlantic, and Southeast regions of the United States (see Table 1, Figure 2), encompassing a wide range of physiographic regions, ecosystems, and climatic zones. The types of vegetation, including the variety of weeds, within and adjacent to soybean fields can vary greatly, depending on the geographic area in which the field occurs. Non-crop vegetation in soybean fields is limited by the extensive cultivation and weed control programs practiced by soybean producers. Plant communities bordering soybean fields can range from forests and woodlands to grasslands, aquatic habitats, or residential areas. Adjacent crops frequently include other soybean varieties, corn, cotton, or other crops.

Weeds are classified as annuals or perennials. An annual is a plant that completes its lifecycle in one year or less and reproduces only by seed. Perennials are plants that live for more than two years. Weeds are also classified as broadleaf (dicots) or grass (monocots). Weeds can reproduce by seeds, rhizomes (underground creeping stems), or other underground parts. Annual grass and broadleaf weeds are considered the most common weed problems in soybeans (Krausz et al., 2001; DAS, 2010); however, with increased rates of conservation tillage, increases in perennial, biennial, and winter annual weed species are being observed (Durgan and Gunsolus, 2003); (Green and Martin, 1996). Winter perennials are particularly competitive and difficult to control, as these weeds re-grow every year from rhizomes or root systems. At least 55 weed species have been identified as commonly occurring in soybean production (DAS, 2010; Monsanto, 2010b) including common lambsquarter (*Chenopodium album*), morning glory species (*Ipomoea* spp.), velvetleaf (*Abutilon theophrasti*), pigweed, (*Amaranthus* spp.), common cocklebur (*Xanthium strumarium*), foxtail (*Setaria* spp.), ragweed species (*Ambrosia* spp.), crabgrass (*Digitaria* spp.), barynyard grass (*Echinochloa crus-galli*), Johnsongrass (*Sorghum halepense*), and thistle (*Cirsium* spp.). Recent surveys of U.S. agronomic crop producers suggest that pigweed species, Johnsongrass, foxtail species, and velvetleaf are among the most problematic weeds (Heatherly et al., 2009).

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

Herbicide resistance is described by the Weed Science Society of America as the “inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type” (WSSA, 2011b). The first reports of weed resistance to herbicides were in the 1950s (WSSA, 2011a). Individual plants within a species can exhibit different responses to the same herbicide rate. Initially, herbicide rates are set to work effectively on the majority of the weed population under normal growing conditions. Genetic variability, including herbicide resistance, is exhibited naturally in normal weed populations, although at very low frequencies. When only one herbicide is used year after year as the primary means of weed control, the number of weeds resistant to that herbicide compared to those susceptible to the herbicide may change as the surviving resistant weeds reproduce (Figure 7). With no change in weed control strategies, in time, the weed population may be composed of more and more resistant weeds (WSSA, 2011a).

The adoption of glyphosate-resistant crops, including soybean, resulted in growers changing historical weed management strategies and relying on a single herbicide, glyphosate, to control weeds in the field (Owen et al., 2011; Weirich et al., 2011). Reliance on a single management technique for weed control resulted in the selection for weeds resistant to that technique (Owen et al., 2011; Weirich et al., 2011). The development of glyphosate-resistant weeds has necessitated a diversification of weed management strategies by growers. Faced with glyphosate-resistant weeds, growers have responded to the problem by applying herbicides with different modes of action, using tank mixes, increasing the frequency of glyphosate applications, and returning to tillage and other cultivation techniques to physically control these species when a specific herbicide proves to be ineffective (CAST, 2012).



Source: Adapted from (Tharayil-Santhakumar, 2003)

Figure 7. The evolution of herbicide resistance.

As previously discussed in Subsection 2.1.2, Agronomic Practices, the widespread adoption of glyphosate-resistant GE crops has resulted in the increased use of glyphosate after 1995, and a decrease in the diversity of other herbicides applied in crop production to control weeds (Weirich et al., 2011). Glyphosate-resistant crops do not influence weeds any more than nontransgenic crops. It is the weed control methods selected by growers that create the ecological selection pressure that ultimately changes the weed communities (Owen, 2008). The recurrent and exclusive use of glyphosate in the production of many GE crops has resulted in the selection for weed populations (e.g., *Amaranthus tuberculatus*) that are resistant to glyphosate. Currently world-wide, 24 weed species, 14 in the United States, have evolved herbicide-resistant biotypes to the Glycines (G/9) herbicide group which includes glyphosate (Table 12); furthermore, weeds that had previously been agronomically unimportant (e.g., *Commelina communis* L. or Asiatic dayflower) but had natural tolerance to glyphosate have become major regional problems (Owen, 2008; Heap, 2013b; Heap, 2013a). Glyphosate, however, is not the only herbicide to which weeds have developed resistance. There are currently 396 unique herbicide resistant biotypes with herbicide resistance in 21 Herbicide Resistance Action Committee (HRAC) herbicide groups (Heap, 2013a). In the United States, there are 142 unique herbicide resistant biotypes with herbicide resistance with a majority (approximately 89%) in eight herbicide groups (Heap, 2013a).

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

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

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

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

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

Conversely, volunteer glyphosate-resistant corn in soybean is a greater concern (Owen and Zelaya, 2005). Glyphosate has been used to control all weeds, including corn in soybean; yet, the increase in cultivation of glyphosate-resistant corn has created problems for growers in the Midwest managing volunteer corn with glyphosate. Growers must now often include graminicides (herbicides to control weedy grasses) as part of their weed management strategy (Owen and Zelaya, 2005).

Table 12. Summary of world-wide herbicide-resistant weeds by herbicide group

HRAC Group[1]	Herbicide Group	Example Herbicide	Total
A	ACCase inhibitors	Diclofop-methyl	42
B	ALS inhibitors	Chlorsulfuron	129
C1	Photosystem II inhibitors	Atrazine	69
C2	Ureas and amides	Chlorotoluron	22
C3	Nitriles and others	Bromoxynil	4
D	Bipyridiliums	Paraquat	28
E	PPO inhibitors	Oxyfluorfen	6
F1	Carotenoid biosynthesis inhibitors	Flurtamone	3
F2	4-HPPD inhibitors	Isoxaflutole	2
F3	Triazoles, ureas, isoxazolidiones	Amitrole	5
G	Glycines	Glyphosate	24
H	Glutamine synthase inhibitors	Glufosinate-ammonium	2
K1	Dinitroanilines and others	Trifluralin	11
K2	Mitosis inhibitors	Propham	1
K3	Chloroacetamides and others	Butachlor	4
L	Cellulose inhibitors	Dichlobenil	1
N	Thiocarbamates and others	Triallate	8
O	Synthetic Auxins	2,4-D	30
Z	Arylaminopropionic acids	Flamprop-methyl	2
Z	Organoarsenicals	MSMA	1
Z	Unknown	(chloro) - flurenol	2
Total Number of Unique Herbicide Resistant Biotypes			396

Source: Heap (2013a)

[1] Herbicide Resistance Action Committee (HRAC)

2.3.3 Gene Flow and Weediness

Gene flow is a biological process that facilitates the production of hybrid plants, introgression of novel alleles (i.e., versions of a gene) into a population, and evolution of new plant genotypes. Gene flow to and from an agroecosystem can occur on both spatial and temporal scales. In general, plant pollen tends to represent the major reproductive method for moving across areas, while both seed and vegetative propagation tend to promote the movement of genes across time and space.

The rate and success of gene flow is dependent on numerous external factors in addition to the donor and recipient plant. General external factors related to pollen-mediated gene flow include the presence, abundance, and distance of sexually-compatible plant species; overlap of flowering phenology between populations; the method of pollination; the biology and amount of pollen produced; and weather conditions, including temperature, wind, and humidity (Zapiola et al., 2008). Seed-mediated gene flow also depends on many factors, including the presence, and magnitude of seed dormancy, contribution and participation in various dispersal pathways, and environmental conditions and events.

Soybean is not native to the United States and there are no feral or weedy relatives. Soybean is considered a highly self-pollinated species, propagated by seed (OECD, 2000). Pollination typically takes place on the day the flower opens. 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. 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. Additionally, soybean's reproductive characteristics (e.g., flower orientation that reduces its exposure to wind, internal anthers, and clumping and stickiness of the pollen) decreases the dispersion ability of pollen (Yoshimura, 2011).

As a highly self-pollinated species, cross-pollination of soybean plants to adjacent plants of other soybean varieties occurs at a relatively low frequency (0 to 6.3%) (Caviness, 1966; Ray et al., 2003; Yoshimura et al., 2006; USDA-APHIS, 2011b). A study of soybeans grown in Arkansas found that cross-pollination of soybeans in adjacent rows averaged between 0.1% and 1.6%, but may be as high as 2.5% (Ahrent and Caviness, 1994). Abud et al. (2007) illustrated that as distance is increased from the soybean pollination source, the chance of cross-pollination is decreased. This study found that at a distance of 1 meter (3.28 feet), outcrossing averaged about 0.5%, at 2 meters (approximately 6.5 feet) outcrossing averaged about 0.1%, at 4 meters (approximately 13 feet) it declined to approximately 0.05%, and at 10 meters (approximately 33 feet) the potential for outcrossing was less than 0.01%.

Generally, gene flow by seed is dependent on natural dispersal mechanisms, such as water, wind, or animals, or by human actions and is favored by characteristics such as small and lightweight seed size, prolific production, seed longevity and dormancy, and long distance seed transport (Mallory-Smith and Zapiola, 2008). Soybean seeds do not possess the characteristics for efficient seed-mediated gene flow. Soybean seeds are heavy and, therefore, are not readily or naturally dispersed by wind or water (Mallory-Smith and Zapiola, 2008). Similarly, soybean seeds and seedpods do not have physical characteristics that encourage animal transport (OECD, 2000). In addition, soybeans lack dormancy, a characteristic that allows dispersal in time by maintaining seeds and their genes within the soil for several years (OECD, 2000; Mallory-Smith and Zapiola, 2008). As already mentioned, there are no wild populations of soybean within the United States. Crop seeds that remain on the field after harvest and remain viable to germinate the following year in rotation crops are termed volunteers (Carpenter et al., 2002). Volunteer soybeans are limited by the geography in which soybean is planted. Soybean requires specific environmental conditions to grow as a volunteer (OECD, 2000). Mature soybean seeds are sensitive to cold and rarely survive in freezing winter conditions (Raper and Kramer, 1987); however, if temperature and moisture conditions are suitable, seeds may remain viable, germinate and become volunteers (Mallory-Smith and Zapiola, 2008). Volunteer soybeans can occur in regions with warmer climates where conditions for germination can occur year round, such as the Mississippi Delta and the southeast United States, but as discussed in Subsection 2.1.2, Agronomic Practices, volunteer soybeans do not easily compete with other crops and are easily controlled with common agronomic practices. In addition, as discussed above, since soybean is principally self-pollinating, the potential for transgene movement from volunteers as a result of pollen movement is negligible (Owen and Zelaya, 2005).

Horizontal gene transfer and expression of DNA from a plant species to bacteria is unlikely to occur (Keese, 2008). Many bacteria (or parts thereof) that are closely associated with plants have been sequenced, including *Agrobacterium* and *Rhizobium* (Kaneko et al., 2000; Wood et al., 2001; Kaneko et al., 2002). There is no evidence that these organisms contain genes derived from plants; further, in cases where review of sequence data implied that horizontal gene transfer occurred, these events are inferred to occur on an evolutionary time scale on the order of millions of years (Koonin et al., 2001; Brown, 2003). The FDA has also evaluated horizontal gene transfer from the use of antibiotic resistance marker genes, and concluded that the likelihood of transfer of antibiotic resistance genes from plant genomes to microorganisms in the gastrointestinal tract of humans or animals, or in the environment, is remote (US-FDA, 1998).

2.3.4 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 et al., 2004). They also suppress soil-borne plant diseases and promote plant growth (Doran et al., 1996). Estimates of the number of bacterial species that may be found in a gram of soil range from 6,000 to 50,000 (Curtis et al., 2002). In a study of soil suppressive to *Rhizoctonia solani*, a fungal pathogen in crops such as potatoes, sugar beets, and rice, Mendes et al. (2011) found that over 33,000 prokaryotic[7] species were present in the rhizosphere. The soil microbial community include nitrogen-fixing microbes such as the soybean mutualist *B. japonicum*, mycorrhizal fungi, and free-living bacteria[8]; bacteria, actinomycetes (filamentous bacteria), and saprophytic fungi responsible for decomposition; denitrifying bacteria and fungi; phosphorus-solubilizing bacteria and fungi; as well as pathogenic and parasitic microbes (USDA-NRCS, 2004).

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

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

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

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

Soybeans

An important group of soil microorganisms associated with legumes, including soybean, are the mutualists. These include mycorrhizal fungi, nitrogen-fixing bacteria, and some free-living microbes that have co-evolved with plants that supply nutrients to and obtain food from their plant hosts (USDA-NRCS, 2004). Legumes have developed symbiotic relationships with specific nitrogen-fixing bacteria in the family *Rhizobiaceae* that induce the formation of root nodules where bacteria may carry out the reduction of atmospheric nitrogen into ammonia (NH_3) that is usable by the plant (Gage, 2004). *Bradyrhizobium japonicum* is the rhizobium bacteria specifically associated with soybeans (Franzen, 1999). Since neither soybean nor *B. japonicum* is native to North America, if a field has not been planted with soybean within three to five years, either the seed or seed zone must be inoculated with *B. japonicum* prior to soybean planting (Berglund and Helms, 2003; Pedersen, 2007).

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

GE crops

Identifying and gauging the effects of GE crops on soil microbes in the rhizosphere can be challenging, as agricultural soils are complex and dynamic and numerous other factors can potentially influence the soil-borne ecosystem. Changes in agricultural practices and inputs and natural variations in season, weather, plant development stages, geographic location, soil type, and plant species or cultivars can all impact the microbial community (Kowalchuk et al., 2003; US-EPA, 2009c). It is assumed that direct impacts may include changes to the structure (species richness and diversity) and function of the microbial community in the rhizosphere due to the biological activity of the inserted gene(s). Indirect impacts may result from changes in the composition of root exudates, plant litter, or agricultural practices (Kowalchuk et al., 2003; US-EPA, 2009c). Several reviews of the investigations into the impact of GE plants on microbial soil communities found that most of the studies examining distinctive microbial traits concluded there was either minor or no detectable non-target effects (Kowalchuk et al., 2003; Hart, 2006; US-EPA, 2009c).

Herbicides

Herbicides have a wide variety of formulations, constituents, and recommended uses and concentrations that play a role in how herbicides affect microorganism communities. Understanding and quantifying the effects of their use is further compounded by differences in environment factors, including the main factors affecting microbial population size and diversity listed in Subsection 2.3.4, Microorganisms. As mentioned previously, some types of soil micro-organisms share metabolic pathways with plants, and might be negatively affected by herbicides. Alternatively, many microorganisms feed on herbicides or produce enzymes that break-down herbicides (Tu et al., 2001; Haney et al., 2002; Araujo et al., 2003; Senseman, 2007; US-EPA, 2008). This microorganism activity is instrumental to herbicide degradation in the soil. As a result, herbicides have both positive and negative effects on microorganism groups that may increase the population of some while reducing the population of others.

Identifying and quantifying the specific impacts of herbicides on the soil microbial community is difficult and is subject to a multitude of variables. Several studies have documented an array of potential impacts associated with 2,4-D ranging from no detectable impact to substantial changes to the microbial community (Breazeale and Camper, 1970; Rai, 1992; Xia et al., 1995; FAO, 1997). Field studies have determined there were no differences in agronomic performance (i.e., plant growth and phenotypic characteristics, disease and insect susceptibility) between 2,4-D and glufosinate sprayed and unsprayed control soybean genetically modified to resist these two herbicides (DAS, 2010; USDA-APHIS, 2010), suggesting no meaningful changes to the microbial community that influence soybean growth and health. Similarly, investigations of the impact of glyphosate on microorganisms are mixed (Weaver et al., 2007). Haney et al. (2002) and Araujo et al. (2003) report that glyphosate is mineralized by microorganisms which leads to an increase in their population and activity, while Busse et al. (2001) and Weaver et al. (2007) found little evidence of changes to soil microorganism's population and activity and any declines recorded were small and not consistent throughout the season. It also has been reported that the use of glyphosate increases the colonization of soil borne fungal pathogens such as *Fusarium* spp. (Fernandez et al., 2009; Kremer and Means, 2009; Huber, 2010); however, peer reviewed research that report a direct correlation of glyphosate use to an increase in plant disease is limited and any connection to impacts on yield has not been established (Camberato et al., 2011).

2.3.5 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, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals

(Altieri, 1999). The loss of biodiversity can result in a need for costly management practices in order to provide these functions to the crop (Altieri, 1999).

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

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

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

Crop Diversity

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

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

Farm-scale Diversity

As noted previously, agricultural practices have the potential to impact diversity at the farm level by affecting a farm's biota, including birds, wildlife, invertebrates, soil microorganisms, and weed populations. For example, an increase in adoption of conservation tillage practices is associated with the use of GE herbicide-resistant crops (Givens et al., 2009). Less tillage provides more wildlife habitat by allowing other plants to establish between crop rows in either stubble or weeds. Conservation tillage also leaves a higher rate of plant residue and increases soil organic matter (Hussain et al., 1999), which benefit soil biota by providing additional food sources (energy) (USDA-NRCS, 1996) and increase the diversity of soil microorganisms, as discussed in Subsection 2.3.4, Microorganisms. In addition, invertebrates that feed on plant detritus and their predators and, in turn, birds and other wildlife that prey on them, may benefit from increased conservation tillage practices (Towery and Werblow, 2010; Carpenter, 2011). Ground-nesting and seed-eating birds, in particular, have been found to benefit from greater food and cover associated with conservation tillage (SOWAP, 2007).

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

Landscape-scale Diversity

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

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

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

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

2.4 Human Health

2.4.1 Consumer Health

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

Non-GE soybean varieties, both those developed for conventional use and for use in organic production systems, are not a subject for mandatory evaluation by any regulatory agency in the United States for human food or animal feed safety prior to release in the market. Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. As a GE product, however, food and feed derived from MON 87712-4 soybean must be in compliance with all applicable legal and regulatory requirements.

GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far, all applicants who have wished to commercialize a GE variety that would be included in the food supply have completed a consultation with the FDA. In such 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. This process includes: (1) an evaluation of the amino acid sequence introduced into the food crop to confirm whether the protein is related to known toxins and allergens; (2) an assessment of the protein's potential for digestion; and (3) an evaluation of the history of safe use in food (Hammond and Jez, 2011). FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require. Several international agencies also review food safety associated with GE-derived food items, including the European Food Safety Agency (EFSA) and the Australia and New Zealand Food Standards Agency (ANZFS).

Foods derived through biotechnology also undergo a comprehensive safety evaluation before entering the market, including reviews under the Codex Alimentarius, the EFSA, and the World

Health Organization (WHO) (FAO, 2009; Hammond and Jez, 2011). Food safety reviews frequently will compare the compositional characteristics of the GE crop with nontransgenic, conventional varieties of that crop; moreover, this comparison also evaluates the composition of the modified crop under actual agronomic conditions, including various agronomic inputs (Aumaitre et al., 2002; FAO, 2009). Composition characteristics evaluated in these comparative tests include moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and antinutrients.

There are multiple ways in which organisms can be genetically modified through human intervention. Traditional methods include breeding or crossing an organism to elicit the expression of a desired trait, while more contemporary approaches include the use of biotechnology such as genetic engineering to produce new organisms (NRC, 2004). As noted by the National Research Council (NRC), unexpected and unintended compositional changes arise with all forms of genetic modification, including both conventional hybridizing and genetic engineering (NRC, 2004). The NRC also noted that at the time, no adverse health effects attributed to genetic engineering had been documented in the human population. Reviews on the nutritional quality of GE foods have generally concluded that there are no significant nutritional differences in conventional versus GE plants for food or animal feed (Faust, 2002; Flachowsky et al., 2005).

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

2.4.2 Occupational Health and Safety

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

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

EPA labels for herbicides include use restrictions and safety measures to mitigate exposure risks. Growers are required to use registered pesticides consistent with the application instructions provided on the EPA-approved pesticide labels. Worker safety precautions and use restrictions are clearly noted on pesticide registration labels. These restrictions provide instructions as to the appropriate levels of personal protection required for agricultural workers to use herbicides. These may include instructions on personal protective equipment, specific handling requirements, and field reentry procedures. EPA labels for registered herbicides have been designed to reduce the risks of illness or injury resulting from workers' and handlers' occupational exposures to pesticides used in the production of agricultural plants on farms or in nurseries, greenhouses, and forests and also from the accidental exposure of workers and other persons to such pesticides.

2.5 Animal Feed

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

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

Similar to the regulatory oversight for direct human consumption of soybean under the 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 comply with all applicable legal and regulatory requirements, which in turn protects human health. To help ensure compliance, GE organisms used for feed may undergo a voluntary consultation process with FDA before release onto the market, which provides the applicant with any needed direction about the need for additional data or analysis, and allows for interagency discussions regarding possible issues.

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. A developer who intends to commercialize a bioengineered food consults 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. Monsanto began the process of consultation, and received questions from FDA on July 18, 2012, and responded to those on August 9, 2012. When complete, the decision memo will be published as BNF No. 131.

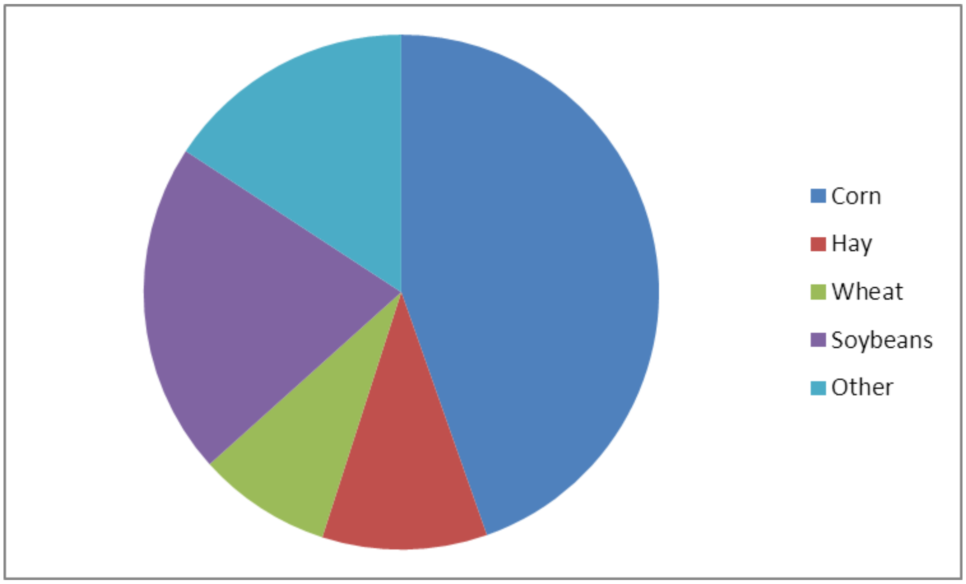
Growers must adhere to EPA label use restrictions for pesticides used to produce a soybean crop before using it as forage, hay, or silage. Under Section 408 of FFDCA, EPA regulates the levels of pesticide residues that can remain on food or food commodities from pesticide applications (US-EPA, 2010a). These tolerances are the maximum amount of pesticide residue that can legally be present in food or feed, and if pesticide residues are found to exceed the tolerance value, the food is considered adulterated and may be seized.

2.6 Socioeconomic

2.6.1 Domestic Economic Environment

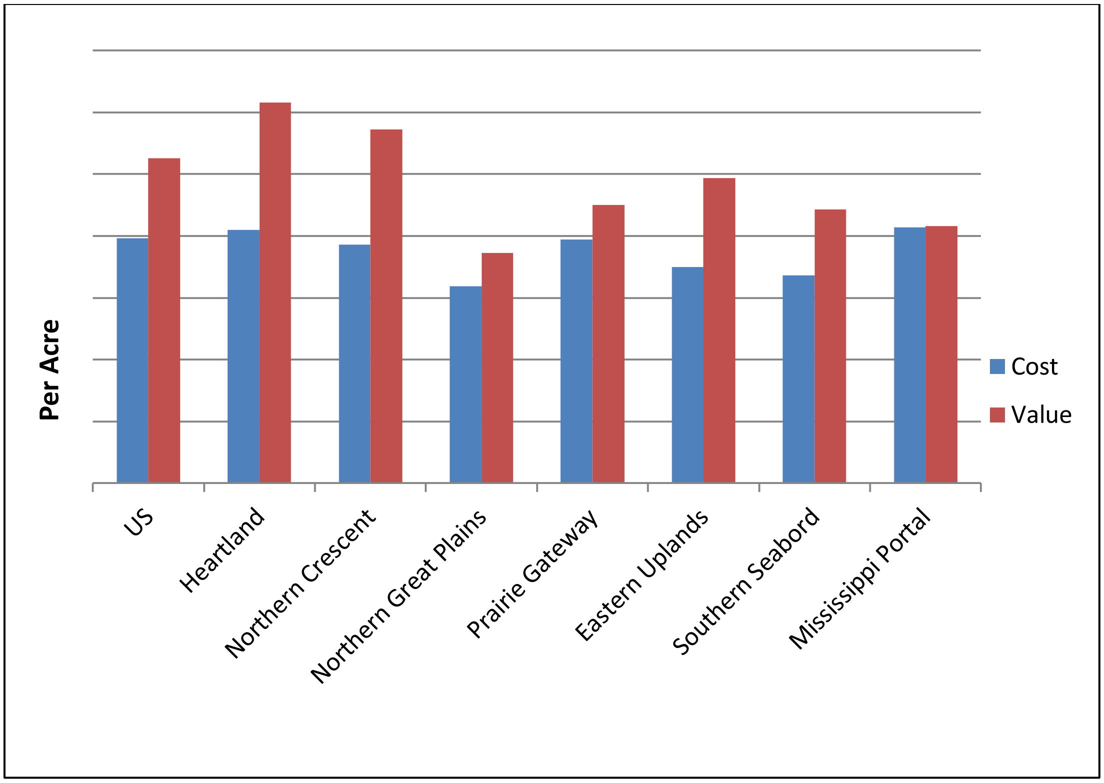
The value of U.S. soybean production exceeded $35.8 billion in 2011, which was 20.8% of the value of all field crops (USDA-NASS, 2012j; USDA-NASS, 2012c) (Figure 8). The top ten producing states (Iowa, Illinois, Minnesota, Nebraska, Indiana, Ohio, Missouri, South Dakota, Arkansas, and North Dakota) accounted for approximately 80% of this production (Table 13). These North Central states fall into the USDA-ERS's Heartland (Iowa, Illinois, Indiana, Minnesota, Missouri, Nebraska, Ohio, and South Dakota), Northern Crescent (Minnesota and Ohio), Northern Great Plains (Nebraska, Minnesota, North Dakota, and South Dakota), Prairie Gateway (Nebraska), and Eastern Uplands (Missouri and Ohio) resource regions (Fernandez-Cornejo and McBride, 2002), which vary in terms of land productivity and cost of production (Figure 9). The most productive of these regions are the Heartland and Northern Crescent. While these regions have higher production cost, their higher productivity still results in greater profitability. In 2011, the U.S. total gross average value of soybean production per planted acre was $525.36 and the average price of a bushel of soybeans at harvest was $11.94 (USDA-ERS, 2012k).

Production cost data are provided by USDA-ERS and collected in surveys conducted every four to eight years for each commodity as part of the annual ARMS (USDA-ERS, 2011c). In 2011, typical operating costs are reported in dollars per planted acre and included purchased seed ($55.55), fertilizer and soil amendments ($22.84), other chemicals ($16.42), and irrigation water ($0.15) (USDA-ERS, 2012k). Total 2011operating costs were $136.87 per planted soybean acre (USDA-ERS, 2012k). In comparison, forecasted 2012 typical U.S. soybean production operating costs per planted acre total $143.16, including $59.87 for purchased seed, $23.41 for fertilizer and soil amendments, and $17.25 for other chemicals; costs for irrigation water were not estimated (USDA-ERS, 2011d; USDA-ERS, 2012d).



Source: USDA-NASS (2012c)

Figure 8. Distribution of crop value in 2012.



Source: USDA-ERS (2012c)

Figure 9. U.S. soybean cost and value of production estimates for 2011 (excluding government payments).

Table 13. Soybean crop value by state.

State	Crop Value (1,000,000 dollars)			State's Percent of Total U.S. Soybean Crop Value		
	2009	2010	2011	2009	2010	2011
Alabama	172	100	110	0.5	0.3	0.31
Arkansas	1,185	1,246	1,491	3.7	3.2	4.17
Delaware	74	66	75	0.2	0.2	0.21
Florida	12	8	5	0.04	0.02	0.01
Georgia	155	76	35	0.5	0.2	0.10
Illinois	4,215	5,779	4,955	13.1	14.9	13.85
Indiana	2,612	3,050	2,761	8.1	7.8	7.72
Iowa	4,627	5,806	5,500	14.4	14.9	15.37
Kansas	1,506	1,658	1,154	4.7	4.3	3.23
Kentucky	675	572	693	2.1	1.5	1.94
Louisiana	354	456	408	1.1	1.2	1.14
Maryland	190	188	204	0.6	0.5	0.57
Michigan	759	1,012	990	2.4	2.6	2.77
Minnesota	2,674	3,717	3,108	8.3	9.6	8.69
Mississippi	713	846	835	2.2	2.2	2.33
Missouri	2,216	2,546	2,259	6.9	6.5	6.31
Nebraska	2,459	3,026	2,972	7.7	7.8	8.30
New Jersey	34	25	37	0.1	0.1	0.10
New York	99	147	137	0.3	0.4	0.38
North Carolina	571	496	469	1.8	1.3	1.31
North Dakota	1,075	1,564	1,283	3.3	4.0	3.59
Ohio	2,171	2,600	2,566	6.8	6.7	7.17
Oklahoma	114	132	40	0.4	0.3	0.11
Pennsylvania	192	245	259	0.6	0.6	0.72
South Carolina	132	120	102	0.4	0.3	0.28
South Dakota	1,615	1,762	1,717	5.0	4.5	4.80
Tennessee	671	507	480	2.1	1.3	1.34
Texas	44	56	21	0.1	0.1	0.06
Virginia	198	166	247	0.6	0.4	0.69
West Virginia	7	7	10	0.02	0.02	0.03
Wisconsin	623	938	861	1.9	2.4	2.41
United States	32,145	38,915	35,784	100	100	100

Source:USDA-NASS (2012c)

Almost all of the U.S. soybean supply is either exported or crushed for meal and oil (Table 14). In any given year, the resulting meal and oil is modestly supplemented with carryover stocks and imports before being consumed domestically or exported. In the United States, almost all of the soybean meal is used for animal feed (97.5% in 2002/03) (Soybean Meal Information Center, 2011). The vast majority of the oil (79% in 2011) is used for human consumption, with the balance going to industrial products. Soybean oil represents almost 70% of the oils consumed by U.S. households. It is notable that higher petroleum prices and an increased interest in biofuels are increasing the demand for soybean-based biodiesel. From 1999 to 2009, the consumption of soybean biodiesel has increased from 0.5 to 1,070 million gallons (ASA, 2012a).

Table 14. U.S. soybean supply and disappearance[1] 2011/12.

	Soybeans[2]	**Soybean Meal (Million Metric Tons)**	**Soybean Oil**
Total	81.94	35.47	8.52
		Supply	
Beginning Stocks	5.85	0.32	1.1
Production	83.17	35.28	8.440
Imports	--[3]	0.15	0.08
		Disappearance	
Crush	43.95	--	--
Feed, Seed & Residual	3.29	--	--
Domestic	--	27.40	7.98
Exports	34.69	8.07	0.54
Ending Stocks	7.48	0.27	1.10

Source: USDA-ERS (2012f; USDA-ERS, 2012g; USDA-ERS, 2012h)

[1] Disappearance is the consumed supply

[2] Total supply includes imports

[3] No data

There is consistent evidence that farmers obtain substantial financial and non-financial benefits as a result of adoption of GE crops. These benefits include an opportunity to increase income from off-farm labor; increased flexibility and simplicity in the application of pesticides; an ability to adopt more environmentally friendly farming practices; increased consistency of weed control; increased human safety; equipment savings; and labor savings (Fernandez-Cornejo and McBride, 2000; Fernandez-Cornejo and McBride, 2002; Marra et al., 2004; Fernandez-Cornejo et al., 2005; Duke and Powles, 2009; Hurley et al., 2009).

According to a USDA-Economic Research Service (ERS) analysis, total economic costs for organic soybean operations are substantially higher than for conventional operations (see Section 2.1.4, Organic Soybean Production). Nevertheless, organic soybeans are more profitable because price premiums paid for organic soybeans compensate for higher production costs (USDA-ERS, 2009b). The USDA-ERS (2012i) reports that consumer demand for organic foods has shown double-digit growth for well over a decade. As discussed in Section 2.1.4, organic soybean production accounted for 0.09% of total U.S. production, and accounted for about 0.14% of the overall soybean crop value in 2011. The majority of organic soybeans were produced in midwestern states (see Table 10, U.S. certified organic soybean acres by state, 2011) (USDA-NASS, 2012i; USDA-NASS, 2012a).

Consumers attitudes towards GE products are driven by three main elements: perceived risks and benefits, individual values, and knowledge of the product (Costa-Font et al., 2008). In some countries, such as the United States, a majority of consumers find that the benefits of GE foods potentially outweigh the risk. In other countries such as much of the EU-27, the perceived risks outweigh any potential benefits (USDA-ERS, 2001; Costa-Font et al., 2008). From a review of surveys taken between 1992 and 2000, USDA-ERS found that consumer attitudes in the United States ranged between 51% and 75% favorable towards the use of biotechnology to improve foods, make foods taste better, stay fresh longer, or prevent crop disease (USDA-ERS, 2001). A 2010 survey of U.S. households found that 93% of respondents believe that GE food should be labeled and 60% are willing to consume GE vegetables, fruits, and grains (Thomson-Reuters, 2010).

2.6.2 Trade Economic Environment

Soybean exports in the form of bulk beans, meal, and oil are a major share of the total agricultural exports for the United States, representing 20.1% of the total value of U.S. exports. The value of U.S. agricultural exports was $135.8 billion in 2012 (USDA-ERS, 2012n). Bulk soybeans accounted for $19.8 billion of this total, ranking first among all agricultural commodities, and soybean meal, at a value of $3.8 billion, ranked 10th (USDA-ERS, 2012l). Table 15presents the United States and the rest of the world's soybean supply and disappearance for 2011/12. The United States was responsible for 38.2% of the world's bulk soybean exports, 13.4% of the world's soybean meal exports, and 6.4% of the world's soybean oil exports (USDA-ERS, 2012b).

Table 15. United States and rest of world (ROW) soybean supply and disappearance[1] 2011/12.

	Soybeans		Soybean Meal		Soybean Oil	
	U.S.	ROW	U.S.	ROW	U.S.	ROW
	(Million Metric Tons)					
	Supply					
Beginning Stocks	5.85	62.90	0.32	7.75	1.10	1.90
Imports	0.41	88.85	0.15	57.76	0.08	8.07
Production	83.17	161.89	35.28	142.60	8.44	33.59
	Disappearance[1]					
Crush/Domestic Use	47.24	207.66	27.40	148.85	7.98	34.09
Exports	34.7	56.19	8.08	52.12	0.54	7.84
Ending Stocks	7.49	49.80	0.27	7.13	1.10	1.64

Source: USDA-ERS (2012b)

[1] Disappearance is the consumed supply

In the 2012/13 market year, soybean meal represented 68% of the protein meal produced worldwide, though soybean ranked behind palm in terms of worldwide vegetable oil production (USDA-FAS, 2013). Similarly, soybean held the largest share of protein meal consumed worldwide mainly as animal feed (USDA-FAS, 2013), with soybean oil again coming in second behind palm oil in terms of worldwide vegetable oil consumption (USDA-FAS, 2013). In 2011/12, the United States, Brazil, and Argentina were the major producers of soybean, producing 190.8 million metric tons (80.0%) of the world's soybeans Table 16). The United States was responsible for 33.9% of the world's soybean production, 19.8% of world's soybean meal production, and 20.1% of the world's soybean oil production (USDA-ERS, 2012b). The United States, China, Argentina, and Brazil are the major producers of soybean meal and soybean oil.

Table 16. World soybean production in 2011/12.

Location	Soybean	Soybean Meal (Million Metric Tons)	Soybean Oil
Argentina	40.1	27.9	6.8
Brazil	66.5	28.6	7.1
Canada	4	--[1]	--
China	14.5	48.2	10.9
EU-27[2]	--	9.6	2.2
India	11.0	7.7	1.7
Mexico	--	2.8	0.6
Paraguay	4.4	--	--
United States	84.2	37.2	9.0
Other	13.8	17.2	4.0

Source:USDA-FAS (2013)

[1] No Data

[2] European Union 27 member countries

The United States, along with Brazil, Argentina, Paraguay, and Canada, account for 96.1% of the bulk soybean exported, while Argentina, Brazil, the United States, India, and Paraguay account for 90.4% of the soybean meal exported Table 17). Argentina, the European Union 27 member countries (EU-27), and Brazil are the dominant countries in terms of soybean oil exports accounting for 75.4% (Table 17). Table 18presents the top 10 U.S. export markets for soybean by volume in two periods spanning 2011 and 2012, of which China, Mexico, and EU-27 countries are the top three importers (USDA-ERS, 2013d). In FY 2012, U.S. exports of soybean were valued at $19.80 billion, soybean meal approximately $3.88 billion, and soybean oil approximately $0.83 billion (USDA-ERS, 2012j).

China, the EU-27, Mexico, and Japan are the major importers of world bulk soybean, accounting for 82.9% of total imports, whereas the EU-27, Indonesia, Thailand, Japan and Vietnam are the largest importers of soybean meal with a world share of 55.0% (USDA-FAS, 2013). For soybean oil, China and India are the major importers with a world share of 35.8% (USDA-FAS, 2013). U.S. soybean exports are projected to increase to approximately 1.6 billion bushels (43.4 million MT) for the 2021/22 market year (USDA-OCE, 2012).

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Table 17. World soybean exports in 2011/12.

Location	Soybean Bulk	Soybean Meal	Soybean Oil
		(Million Metric Tons)	
Argentina	7.4	26.0	3.8
Bolivia	--[1]	--	0.3
Brazil	36.3	14.7	1.9
Canada	2.9	--	--
EU-27[2]	--	--	0.7
India	--	4.5	--
Paraguay	3.2	0.7	0.2
Russia	--	--	0.1
United States	37.1	8.8	0.7
Other	3.5	4.0	0.8

Source: USDA-FAS (2013)

[1] No Data

[2] European Union 27 member countries

Table 18. Top 10 U.S. soybean export markets in 2011/12.

Location	January-November 2011	January-November 2012	November 2011	November 2012
	(Million Metric Tons)			
China	17.76	23.09	3.91	4.95
Mexico	2.98	3.08	0.22	0.23
EU-27	1.50	2.12	0.18	0.47
Japan	1.54	1.81	0.15	0.21
Indonesia	1.56	1.64	0.14	0.06
Taiwan	1.20	1.24	0.09	0.20
Egypt	0.58	1.23	0.01	0.09
Turkey	0.20	0.65	0.02	0.09
Thailand	0.31	0.65	0.08	0.16
South Korea	0.43	0.58	0.01	0.05
World Total	30.26	38.30	5.01	6.91

Source:USDA-ERS (2013d)

[1] European Union 27 member countries

[2] No data

Worldwide prices for grain and oilseed crops such as soybean are influenced not only by supply and demand forces, but also a multitude of other factors. In 2008, world market prices on food commodities such as grains and vegetable oils rose sharply (Trostle, 2008b). There were many factors that contributed to the rise in prices, including an increased growth in demand outpacing the growth in production that tightened world balances of grain and oilseeds, increased demand for biofuel feedstocks, weather conditions, the value of the U.S. dollar, increasing costs for energy, increasing costs for agricultural production, a rise in foreign exchange holdings by major food-importing countries, and policies adopted by exporting and importing countries to relieve food price inflation. Later in 2008, however, soybean prices declined considerably, influenced by factors such as a larger yield than expected after floods in the Midwest and problems with the

United States and world credit markets (Trostle, 2008b; Trostle, 2008a; Irwin and Good, 2009). The recent influx of hedge, index, and sovereign wealth fund investors and the increased practice of trend-following trading practices by some of these fund managers has increased agricultural product price volatility (Trostle, 2008a). Other factors contributing to grain and oilseed price includes competition for plantings from other crops, fluctuations in livestock production, world population growth, per capita income, water availability, the influx of new seed varieties and new biotechnology, and climate change (Trostle, 2008b; Irwin and Good, 2009; USDA-OCE, 2012).

Between 1996 and 2011, 28 countries, besides the United States, adopted the use of GE crops, the largest being Brazil, Argentina, India, and Canada (Clive, 2011). Prior to exporting MON 87712-4 soybean, Monsanto would seek biotechnology regulatory approvals in all major import countries that have a functioning regulatory system to assure global compliance and support of international trade (Monsanto, 2011). Furthermore, all trade actions will be consistent with the Biotechnology Industry Organization's Guide for Project Launch. Some countries will not allow the seed availability for GE crop production from U.S. companies until a non-regulated status has been approved by APHIS; however, APHIS does not influence in which countries a particular crop will be marketed.

3 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of MON 87712-4 soybean. To respond favorably to a request for a determination of nonregulated status, APHIS must determine that MON 87712-4 soybean is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2011a), APHIS has concluded that MON 87712-4 soybean is similar to its antecedent A3525 and other commercially available soybean cultivars, and is unlikely to pose a plant pest risk. Therefore APHIS must determine that MON 87712-4 soybean is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

Two alternatives are evaluated in this EA: (1) no action and (2) determination of nonregulated status of MON 87712-4 soybean. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section.

3.1 No Action Alternative: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the request. MON 87712-4 soybean and progeny derived from MON 87712-4 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 87712-4 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 that unconfined cultivation of MON 87712-4 soybean does not pose a plant pest risk.

This alternative is not the Preferred Alternative because APHIS has concluded through a Plant Pest Risk Assessment that MON 87712-4 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2011a). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the request for nonregulated status.

3.2 Preferred Alternative: Approve the Request for Nonregulated Status to MON 87712-4 Soybean

Under this alternative, MON 87712-4 soybean and progeny derived from it would no longer be regulated articles under the regulations at 7 CFR part 340. MON 87712-4 is unlikely to pose a plant pest risk (USDA-APHIS, 2011a). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87712-4 soybean and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a request 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 87712-4 is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87712-4 soybean is a response that is consistent with the plant pest provisions of the Plant Protection Act, 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 87712-4 soybean and progeny derived from this event if the developer decides to commercialize MON 87712-4 soybean.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for MON 87712-4 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 87712-4 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 87712-4 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-87712-4 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 87712-4 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2011a).

In enacting the Plant Protection Act, Congress found that

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

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order (EO) 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 EO 13563 and, consistent with that EO, 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 the PPRA (USDA-APHIS, 2011a) and the scientific data evaluated therein, APHIS concluded that MON 87712-4 soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87712-4 soybean.

3.3.2 Isolation Distance between MON 87712-4 Soybean and Non-GE Soybean Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating MON 87712-4 soybean from conventional or specialty soybean production. However, because APHIS has concluded that MON 87712-4 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2011a), 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 87712-4 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' PPRA for MON 87712-4 soybean, there are no geographic differences associated with any identifiable plant pest risks for MON 87712-4 soybean (USDA-APHIS, 2011a). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 87712-4 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 request for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. However, individuals might choose on their own to geographically isolate their non-GE soybean production systems from MON 87712-4 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 87712-4 soybean is available from AOSCA (AOSCA, 2010).

3.3.3 Requirement of Testing for MON 87712-4 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 87712-4 soybean does not pose a plant pest risk (USDA-APHIS, 2011a), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for MON 87712-4 soybean would not meet APHIS' purpose and need to respond appropriately to the request in accordance with its regulatory authorities.

3.4 Comparison of Alternatives

Table 19presents 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, Environmental Consequences of this EA.

Table 19. Summary of issues 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, 2011a)
Management Practices		
Acreage and Areas of Soybean Production	Current trends in cultivation and the proportion of crop acreage planted with soybean would continue. The majority of soybean produced in the United States would be in the same 31 states as today. The trend of planting primarily GE soybeans would likely continue. Average U.S. soybean yield is expected to continue to increase without expansion of soybean acreage.	The acreage and area of production would remain unchanged from that of the No Action Alternative. There are no substantial agronomic or phenotypic differences between MON 87712-4 soybean and its comparators and it is subject to the same variables that influence yield in other varieties. The increased yields are the result of changes during the reproductive growth stages that lead to an increased number of seeds and seed weight. Soybean acreage is expected to remain relatively stable through 2021/2022 while soybean yield is expected to increase by about 11% over the same period.
Agronomic Practices	Soybean management practices and methods that increase yield such as tillage methods, fertilization, crop rotation, irrigation, pest management, and plant residue management would be expected to continue.	Testing indicates the agronomic characteristics and cultivation practices used for the production of MON 87712-4 soybean are essentially the same as those used for the cultivation of other commercially available soybean and would remain unchanged from the No Action Alternative. MON 87712-4 soybean does deplete higher amounts of potassium and phosphorus from the soil, yet the need for fertilization would be similar to those of other high-yield varieties or the production strategies used by growers to maximize the yields of any typically average yielding conventional or GE varieties.
Pesticide Use	Pest management practices would continue to rely on the use of pesticides and fungicides to control insect, fungal, and weed pests. It is expected the use of glyphosate on glyphosate-resistant soybeans would remain the principle method for weed management	Testing shows MON 87712-4 soybean is vulnerable to the same pests that effect other commercially available conventional and GE soybean varieties and as such pest management practices would not change from those used under the No Action Alternative.

Attribute / Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Soybean Seed Production	The production of foundation, registered, certified, or quality control seed would still require biological, technical, and quality control factors to ensure varietal purity.	Practices to ensure varietal purity would remain the same as those of the No Action Alternative. Tests would be available and easily accomplished to determine the presence of the gene which conveys the increased yield traits of MON 87712-4 soybean.
Organic Soybean Production	The methods applied in certified seed production systems designed to maintain soybean seed identity and meet National Organic Standards as established by the NOP would continue to be practiced by farmers producing organic soybean. The availability of GE soybean is unrelated to proportion of organic soybean market share.	Measures used by organic soybean producers to manage, identify, and preserve organic production systems would not change. Similar to other commercially available GE soybean varieties, MON 87712-4 soybean does not present any new or different issues or impacts for organic soybean producers or consumers.
Physical Environment		
Soil Quality	Cropping practices that impact soil such as tillage, contouring, cover crops; agricultural chemical management, and crop rotation would continue. The fertility of some U.S. cropland is declining as a result of increasing crop yields without proper fertilization.	Production of MON 87712-4 soybean is not expected to change cropping practices. Root exudates from MON 87712-4 soybean are not expected to change soil physicochemical characteristics. Similar to current high yield production strategies, increased depletion of nutrients such as phosphorus and potassium from the production of MON 87712-4 soybean can be mitigated through the common practices of regular testing of soil fertility and application of nutrients as needed.
Water Resources	Agronomic practices that could impact water resources (e.g., irrigation, tillage practices, and the application of pesticides and fertilizers) would be expected to continue. The use of pesticides in accordance with EPA-approved label directions assure no unreasonable risks to water quality from their use. The historic trend of increased soybean yields on existing cropland would likely continue, minimizing potential impacts to water resources from expanding cultivation.	The production of MON 87712-4 soybean is not expected to change current agronomic practices, acreage, or range of production that may impact water resources.

Attribute / Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Air Quality	Soybean agronomic practices having potential to impact air quality such as tillage, the application of pesticides and fertilizer, and use of particulate- and pollutant -emitting agricultural equipment would continue. The use of pesticides in accordance with EPA-approved labels minimizes drift and reduces environmental impacts. Conservation tillage or no-till practices associated with the adoption of herbicide-resistant soybean is expected to continue.	No changes to agronomic practices for the production of MON 87712-4 soybean are expected that would impact air quality. The application of pesticides and use of conservation tillage and no-till practices would likely be similar to the No Action Alternative.
Climate Change	Agronomic practices having the potential to impact climate change, such as the release of CO_2 to the atmosphere from tillage, machinery powered by fossil fuel, and NO_2 emissions associated with nitrogen fertilizers would continue. The trend towards conservation tillage practices that contribute to carbon sequestration and application of more phosphorous and potassium associated with high yield soybean production would also likely continue.	The production of MON 87712-4 soybean is not expected to change current soybean cropping practices that may impact GHG emissions. The potential increased application of phosphorus and potassium associated with the production of high yield soybean would not impact climate change.
Biological Resources		
Plant Communities	The majority of soybean acres would likely continue to be planted with GE varieties. Plant species typically competing with soybean production would be managed through the use of mechanical, cultural, and chemical control methods. Multiple herbicides would likely continue to be used for weed control in soybean fields and glyphosate would continue to be the primary herbicide applied in the near term; however, diversification of herbicide use and agronomic measures to deter development of herbicide-resistant weeds would likely increase. Herbicide use in accordance with EPA-approved labels containing measures to reduce herbicide drift and volatilization potentially impacting plant communities minimize potential adverse impacts to plant communities. Soybean volunteers would continue to be	No changes to agronomic practices potentially impacting plant communities would be needed to cultivate MON 87712-4 soybean. Field trials and laboratory analyses show no differences between MON 87712-4 soybean and other GE and non-GE soybean in growth, reproduction, or interactions with pests and diseases that may impact plant communities. Volunteers of MON 87712-4 soybean would be managed similar to other nonregulated soybean varieties.

Attribute / Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	controlled with mechanical and herbicidal practices. Weeds competing with soybean production would be managed through the use of mechanical, cultural, and chemical control methods. Multiple herbicides would likely continue to be used for weed control in soybean fields and glyphosate would continue to be the primary herbicide applied in the near term; however, diversification of herbicide use and agronomic measures to deter development of herbicide-resistant weeds would likely increase. Herbicide use in accordance with EPA-approved labels containing measures to reduce herbicide drift and volatilization potentially impacting plant communities minimize potential adverse impacts to plant communities. Soybean volunteers would continue to be controlled with mechanical and herbicidal practices.	
Animal Communities	Conventional and nonregulated GE soybean have been determined to have no allergenic or toxicity to animal communities. Soybean agronomic practices such as such as tillage, cultivation, pesticide, herbicide and fertilizer applications, and the use of agricultural equipment would continue to impact animal communities. The use of EPA-registered pesticides and herbicides in accordance with EPA-approved labels minimize potential impacts to animal communities.	Testing demonstrates consumption of MON 87712-4 soybean poses no allergenic or toxicity risk to animal communities. As field trials demonstrate growth and disease characteristics of MON 87712-4 are similar to other conventional soybean. No change to soybean agronomic practices that may impacting animal communities would be needed to cultivate MON 87712-4 soybean.

Attribute / Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Gene Movement	MON 87712-4 would continue to be cultivated only under regulated conditions. The availability of GE, non-GE and organic soybeans would not change as a result of the continued regulation of MON 87712-4 soybean. Because soybean is highly self-pollinated and its pollination rate significantly decreases with distance, it is not frost tolerant, does not reproduce vegetatively, its seed is not easily dispersed, any volunteers that persist in warmer U.S. climates can be easily controlled with common agronomic practices, and there are no wild soybean species or near relatives in the U.S., gene flow and introgression from soybean to wild or weedy species are highly unlikely.	Field and laboratory tests demonstrate no significant differences among the parameters that may lead to an increased potential for gene flow or weediness between MON 87712-4 soybean and the conventional control. MON 87712-4 soybean would not persist in unmanaged environments and does not demonstrate a competitive advantage compared to conventional soybean. The trait for increased yield is not expected to contribute to increased weediness without changes in a combination of other characteristics associated with weediness.
Soil Microorganisms	MON 87712-4 soybean would remain under APHIS regulation. The availability of GE, non-GE and organic soybeans would not change as a result of the continued regulation of MON 87712-4 soybean. Agronomic practices used for soybean production, such as soil inoculation, tillage and the application of agricultural chemicals (pesticides and fertilizers) that potentially impact microorganisms would continue.	Nonregulated status of MON 87712-4 soybean is not expected to result in changes in current soybean cropping practices that may impact microorganisms. Field and greenhouse tests show no significant differences from other nonregulated soybean varieties in the parameters measured to assess the symbiotic relationship of MON 87712-4 and rhizobia or its responses to abiotic stressors, suggesting no different impact to the microbial community.
Biological Diversity	MON 87712-4 would remain under APHIS regulation; the availability of GE, non-GE and organic soybeans would not change. Agronomic practices used for soybean production and yield optimization, such as tillage, the application of agricultural chemicals (pesticides and fertilizers), timing of planting, row spacing, and scouting would be expected to continue. Agronomic practices that benefit biodiversity both on cropland (e.g., intercropping, agroforestry, crop rotations, cover crops, and no-tillage) and on adjacent non-cropland (e.g., woodlots, fencerows, hedgerows, and	Nonregulated status of MON 87712-4 would not cause changes in current soybean cropping practices that may impact biodiversity as field and laboratory testing demonstrate its growth, reproduction, and interactions with pests and diseases are similar to other nonregulated varieties. MON 87712-4 soybean poses no potential for naturally occurring, pollen-mediated gene flow and transgene introgression and as such is not expected to affect genetic diversity.

Attribute / Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
	wetlands) would continue.	
Human and Animal Health		
Human Health	MON 87712-4 soybean would remain under APHIS regulation and no change to human exposure to existing GE and non-GE soybean varieties would occur. Compositional and nutritional characteristics of nonregulated GE soybean varieties have been determined to pose no risk to human health. A variety of EPA-approved pesticides would continue to be used for pest management in both GE and non-GE soybean cultivation. Use of registered pesticides in accordance with EPA-approved labels protects human health and worker safety. EPA also establishes tolerances for pesticide residue that give a reasonable certainty of no harm to the general population and any subgroup from the use of pesticides at the approved levels and methods of application.	Testing shows the MON 87712-4 BBX32 protein has no amino acid sequence similar to known allergens, lacks toxic potential to mammals, and was degraded rapidly and completely in simulated gastric fluid. Monsanto has initiated a food/feed safety consultation on MON 87712-4 soybean with the FDA and a final decision from FDA is pending. Laboratory and field testing also demonstrate no biologically meaningful differences for compositional and nutritional characteristics between the MON 87712-4 soybean and conventional soybean varieties. Field testing shows MON 87712-4 is similar in growth and habit to other conventional soybean and no change to agronomic practices would be required for its cultivation. No change to human health or worker safety would occur from determining MON 87712-4 nonregulated.
Animal Feed	MON 87712-4 would remain regulated and not be allowed for distribution to the animal feed market. Soybean-based animal feed would still be available from currently cultivated soybean crops, including both GE and non-GE soybean varieties. Nonregulated GE soybean varieties used as animal feed have been previously determined to pose no risk to animal health.	Safety testing of MON 87712-4 soybean BBX32 protein shows it has no amino acid sequence similar to known allergens, lacks toxic potential to mammals, and was degraded rapidly and completely in simulated gastric fluid, indicating no potential risk for its use as animal feed. Monsanto has initiated a food/feed safety consultation on MON 87712-4 soybean with the FDA and a final decision from FDA is pending. Testing shows compositional and nutritional characteristics of MON 87712-4 soybean grain and forage are similar to currently available soybean varieties and no adverse impacts to animal feed would occur upon its nonregulated status. Impacts to animal feed safety would therefore be similar to the No Action Alternative.
Socioeconomic		

Attribute / Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Domestic Economic Environment	MON 88712-4 soybean would remain regulated by APHIS. Domestic growers would continue to utilize GE and non-GE soybean varieties based upon availability and market demand. U.S. soybeans would likely continue to be used domestically for animal feed, with lesser amounts and byproducts used for oil or fresh consumption. Agronomic practices and conventional breeding techniques using GE herbicide- and pest-resistant cultivars currently used to optimize yield and reduce production costs would be expected to continue. Average soybean yield is expected to continue to increase without expansion of soybean acreage while grower net returns are estimated to increase.	Field tests show the performance and composition of MON 87712-4 is not substantially different from that of other conventional soybean reference varieties. Although yield potential is increased, it would be similar to other commercially available soybean varieties with a multigenic high yield trait; both are subject to the same variables affecting agronomic practices and yields as other varieties. MON 87712-4 soybean would likely replace other varieties of GE soybean on existing cropland and not impact organic soybean production or markets. As MON 87712-4 is a GE soybean variety potentially increasing soybean productivity without altering soybean's nutritional value, potential allergenicity, or toxicity. If planted in favorable environments, soybean growers could potentially have greater yield for similar inputs. No change to U.S. consumer attitudes towards GE crops is expected. No adverse impact to the domestic economic environment would occur under this alternative.
Trade Economic Environment	U.S. soybeans will continue to play a role in global soybean production, and the United States will continue to be a supplier in the international market if MON 87712-4 remains regulated by APHIS. Although U.S. global exports are expected to increase overall, increasing foreign competition is expected to reduce U.S. export share by 5% in the next 20 years.	A determination of nonregulated status of MON 87712-4 soybean is not expected to adversely impact the current trends affecting the trade economic environment. However, the determination may have an impact through increased yields and higher US production of soybean. Any impact to soybean market prices from the potential increase to yield from the production of MON 87712-4 soybean would likely be small because the increased yield of MON 87712-4 is similar to production of other high yielding soybeans already in the market, and is subject to the same variables that affect yield in other commercially available cultivars. If however, there is an immediate and general incorporation of the trait into much of the developer's varieties, and a

Attribute / Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
		uniform positive yield response across many environments, there may be an important increase in U.S. soybean production. However, because there are presently high yield varieties available, and these have not resulted in an apparent or large incremental increase in soybean productivity, APHIS does not expect that nonregulated status for MON 87712 will importantly increase overall bulk soybean production, at least not one that greatly exceeds the general annual trend for increased soybean yield. Monsanto plans to seek biotechnology regulatory approvals for MON 87712-4 soybean from all key soybean import countries that have a functioning regulatory system.
Other Regulatory Approvals		
U.S.	Unchanged for existing nonregulated GE organisms	FDA consultation pending
Other countries	Unchanged	China, Japan, Canada, Mexico, European Food Safety Authority
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	Fully compliant

4 ENVIRONMENTAL CONSEQUENCES

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for MON 87712-4 soybean are described in detail throughout this section. An impact would be the result of any change, positive or negative, from the existing (baseline) conditions of the affected environment (described for each resource area in Section 2.0). Impacts may be categorized as direct, indirect or cumulative. A direct impact is an effect that results solely from a proposed action without intermediate steps or processes. Examples include soil disturbance, air emissions, and water use. An indirect impact may be an effect that is related to but removed from a proposed action by an intermediate step or process. Examples include surface water quality changes resulting from soil erosion due to increased tillage, and worker safety impacts resulting from an increase in herbicide use.

A cumulative impacts analysis is also included for each environmental issue and is presented in Section 5. A cumulative impact may be a consequence for the human environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. Examples include breeding MON 87712-4 soybean with other events previously approved for nonregulated status. If there are no direct or indirect impacts identified for a resource area, then there can be no cumulative impacts. Cumulative impacts are discussed in Section 5.

Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential impacts. Certain aspects of the MON 87712-4 soybean and its cultivation may be no different between the alternatives; those are described below.

4.1 Scope of Analysis

For the discussion of environmental consequences, this section addresses the following principal areas of potential environmental concern:

- Agricultural Production of Soybean (Subsection 4.2);
- Physical Environment (Subsection 4.3);
- Biological Resources (Subsection 4.4);
- Human Health (Subsection 4.5);
- Animal Feed (Subsection 4.6); and
- Socioeconomic Impacts (Subsection 4.7).

Under the Preferred Alternative, MON 87712-4 soybean could be planted anywhere in the United States; however, APHIS has limited the environmental analysis to those areas that currently support soybean production. According to USDA annual crop statistics, soybean-producing states in the United States include 31 states that largely encompass the southeast and midwest regions (USDA-NASS, 2012l) (see Subsection 2.1.1, Acreage and Area of Soybean Production, Table 1).

The environmental consequences of the different alternatives described above are analyzed under the assumption that farmers who produce conventional soybean, MON 87712-4 soybean or 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 potential environmental impacts will also include the assumption that some farmers do not follow these best management practices.

Monsanto plans to stack varieties of soybean wherein the MON 87712-4 soybean is combined using traditional hybridization techniques with other non-GE traits or previously nonregulated GE soybean varieties. The range of potential stacked varieties could include stacked hybrids incorporating glyphosate herbicide resistance, or other defensive traits. APHIS does not have jurisdiction under the PPA and Part 340 to review such hybrids expressing stacked traits from nonregulated articles developed using conventional hybridization techniques where there is no evidence of a plant pest risk. APHIS considers the future development of these stacked hybrids a speculative event, and, accordingly, evaluates these stacked varieties only in the cumulative impacts analyses where appropriate. Issues associated with potential future stacking are presented and discussed in the cumulative impacts analyses where appropriate.

4.2 Agricultural Production of Soybean

Best management practices are commonly accepted, practical ways to grow soybean, regardless of whether the soybean farmer is using organic practices or conventional practices with non-GE or GE varieties. 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 management practices that are available through state Cooperative Extension Service offices and their respective websites[9].

4.2.1 Acreage and Area of Soybean Production

<u>No Action Alternative</u>

Under the No Action Alternative, MON 87712-4 soybean would remain regulated and would not be commercially available for production. Soybeans will continue to be a major crop in the United States for the foreseeable future (USDA-OCE, 2012). Existing trends related to the cultivation and proportions of crop acreage planted with soybean in the United States are expected to continue as discussed in Section 2.1.1, Acreage and Area of Soybean Production and below. Soybean is a quantitative (facultative) short-day plant, flowering more quickly under short days (OECD, 2000), thus responses to photoperiod and temperature are important in determining where specific cultivars will be adapted. Soybean cultivars are identified based on geographic bands of adaptation that run east-west, determined by latitude and day length. In North America, there are 13 maturity groups within which cultivars are described as early, medium, or late maturing (OECD, 2000).

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[9] For example, see the soybean crop management websites of Purdue University (http://www.agry.purdue.edu/ext/soybean/index.html), the University of Illinois-Urbana Crop Science and Research Education (http://web.extension.illinois.edu/csrec/), and Mississippi State University (http://msucares.com/crops/soybeans/index.html).

Under the No Action Alternative, the majority of soybean is expected to continue to be commercially produced in the same 31 states as today. U.S. soybean acreage is concentrated where soybean yields are highest, primarily in the Midwest (USDA-ERS, 2006c). More recently, soybean acreage has expanded to the northern and western parts of the country. Stagnant yields in wheat coupled with better yielding short-season soybeans adapted to the climate in these areas are newly available to growers (USDA-ERS, 2010b). These factors have increased the overall acreage devoted to soybean production in the U.S. Soybean production acreage increased 31% from 1992 to 2012, but has remained relatively level the last several years at approximately 75 million acres (USDA-NASS, 2012h). The USDA projects U.S. soybean acreage will remain relatively steady at approximately 76 million acres from 2013/2014 to 2021/2022. While US exports will be decreasing because of increased foreign competition, rising domestic demand for soybean oil to manufactured biodiesel is noted (USDA-OCE, 2012); the trend is also balanced by increasing foreign demand because of rising income and population in Latin America and other parts of the world (USDA-OCE, 2012).

Since the introduction of GE soybeans in the United States in 1996 (Fernandez-Cornejo and Caswell, 2006; USDA-ERS, 2011a), the proportion of GE soybean planted has increased to 93% of all planted soybean acreage (USDA-ERS, 2012e) because of the benefits gained from improved weed control from herbicide and pest-resistant varieties. The trend of planting primarily GE soybeans in the United States will likely continue under the No Action Alternative as new cultivars are developed with new traits or that combine traits desired by growers and consumers. For example, petitions submitted to APHIS for approval of nonregulated status of cultivars that combine resistance to multiple herbicides, provide insect resistance, or change nutritional properties of soybean are currently pending (USDA-APHIS, 2013).

With continuation of these trends, the number of states and areas of the United States involved in soybean cultivation is not expected to change. Additionally, acreage devoted to U.S. soybean production is expected to remain relatively stable for the foreseeable future, and the majority of soybeans planted would likely remain GE.

Preferred Alternative

Monsanto conducted phenotypic, agronomic, and environmental interaction trials with MON 87712-4 soybean and its non-transgenic soybean control parental line having a genetic background similar to MON 87712-4 soybean, but without the *BBX32* gene (variety A3525) (Monsanto, 2011). Multiple commercial reference varieties were also included in the study to provide a range of comparative values representative of existing commercial soybean varieties for phenotypic, agronomic, and environmental interaction measurements. Tests included a combination of field, greenhouse, and laboratory studies and encompassed seven general data categories: (1) seed germination, dormancy, and emergence; (2) vegetative growth; (3) reproductive development (including pollen characteristics); (4) seed retention on the plant and lodging; (5) plant response to abiotic stress and interactions with diseases and arthropods; (6) plant-symbiont interactions; and, (7) volunteer potential and persistence outside of cultivation characteristics (Monsanto, 2011; USDA-APHIS, 2011b).

MON 87712-4 soybean has been genetically modified to extend its diurnal activity that allows it to increase nutrient assimilation and production of plant compounds, such as starches, as well as increased days to senescence (terminal events in development) that result in increased yield.

Increased yields are the result of these changes during the reproductive growth stages (R1 through R7) that lead to an increased number of seeds and seed weight. The results of the combined trials, however, demonstrated that overall there were no substantial agronomic or phenotypic differences between MON 87712-4 soybean and its comparator control or other commercial soybean varieties. No statistically significant differences were detected ($\alpha = 0.05$) between MON 87712-4 soybean and the conventional control A3525 except for early stand count, days to 50% senescence, days to physiological maturity, final stand count, and yield (52.6 vs. 49.0 bushels per acre) (Monsanto, 2011). Although significantly different from the conventional control A3525, the mean values of MON 87712-4 soybean for early stand count and final stand count were within the range of commercial reference varieties for each characteristic. Differences in days to 50% senescence, days to physiological maturity, and yield were consistent with the mode of action of the introduced trait in MON 87712-4 soybean (Monsanto, 2011; USDA-APHIS, 2011b).

The increased yield of MON 87712-4 is within the range of variability of other conventionally high-yield varieties, is subject to the same variables that influence yield as other varieties, and would continue to have similar variability from year to year, as described in Section 2.2.2, Agronomic Practices. The increased stand count found during test trials was not a factor in the increased yield (Monsanto, 2011). Although MON 87712-4 soybean has extended diurnal activity compared to other soybean varieties, Monsanto has indicated it will be adopted into existing maturation groups to match the area in which it would be cultivated. No meaningful phenotypic, agronomic, or environmental interaction differences between MON 87712-4 soybean and other commercial varieties were found in test results (Monsanto, 2011), therefore, no change to area of U.S. soybean production is expected from approval of its nonregulated status.

Because MON 87712-4 soybean is anticipated to increase yields, it might be expected to be bred into many varieties of soybean currently grown. Since the mid-20th century, changes in soybean cultivars have contributed to increased yields, as have improved management practices (Specht et al., 2006; Egli, 2008; Pedersen, 2008). From 1991 to 2011, average soybean yield increased approximately 17.6% from 34.2 bushels per acre in 1991 to 41.5 bushels per acre in 2011, and slightly declined nationally in 2012 to 39.3 bushels per acre compared to 2011 average yields (USDA-NASS, 2012j). Since 1991, U.S. soybean production acreage has increased 31%, partly due to new cultivars facilitating expansion into northern and western states, but largely due to soybean replacing other crops, and more double-cropping of soybean (USDA-ERS, 2011f). Since 1949, however, total U.S. cropland has not changed very much, ranging from 478 million acres at the beginning of the period down to 408 million acres in 2007, the lowest of the period (USDA-ERS, 2011e). As explained in Section 2.1.1, Acreage and Area of Soybean Production, the steep decline in soybean acreage in 2007 is partially attributed to a change in land use classification by USDA in the 2007 Agricultural Census (USDA-ERS, 2011e). Based on this data, historically, the majority of the gains in soybean acreage have been at the expense of other crops on existing cropland and increased production from double-cropping, not converting land to new soybean production. As described in the No Action Alternative, the USDA has projected that soybean acreage will remain relatively steady at approximately 76 million acres until 2021/2022, while soybean yield is estimated to increase 11% during the period (USDA-OCE, 2012). Although the yield potential of MON 87712-4 soybean is higher than its comparator, it is well within the range of variation of other commercially available conventional cultivars such as non-GMO high yield varieties developed by Albert Lea Seeds, D.F. Seeds, eMerge Genetics and several State University Extension Services, as well as high yield cultivars that have been conventionally crossed with herbicide- resistant GE varieties by companies such as Monsanto, Bayer, and Pioneer (see Subsection 2.1.2.5, Soybean Yield). Based upon its phenotypic and agronomic similarity to other soybean cultivars, MON 87712-4 soybean is also subject to the same variables affecting yield in other soybean varieties, such as management practices and weather (see Section 2.1.2.4, Agronomic Inputs). If the developer generally incorporates the MON 87112 trait into much of its seed offerings, and the trait responds uniformly to the grower's agro-environment, there may be yield increases in both individual farms and a potential for increase in overall soybean production. If a trend of such increased production becomes evident, and soybean demand does not increase, then there may be the possibility that acreage planted to soybean actually declines. If these assumptions are realized, then under the Preferred Alternative there could be changes that may not occur under the No Action Alternative.

4.2.2 Agronomic Practices

As discussed in Subsection 2.1.2, soybean cultivation requires significant management attention to tillage, rotation strategy, agricultural inputs, and pesticide inputs. Decisions concerning soybean agronomic practice are dependent on grower want and need, and ultimately reflective of external factors including geography, weed and disease pressure, economics of management of yield, and production system (rotation) flexibility (Heiniger, 2000; Farnham, 2001; University of Arkansas, 2006). Increasing yield depends on the optimization of all manageable variables and sound agronomic decisions.

No Action Alternative

Under the No Action Alternative, MON 87712-4 soybean would continue to be subject to the regulatory requirements of 7 CFR part 340 and plant pest provisions of the Plant Protection Act. Growers will continue to have access to existing nonregulated GE soybean varieties, as well as conventional soybean varieties. Current soybean management practices and methods that increase yield would be expected to continue under the No Action Alternative. These include conventional and conservation tillage, soil and foliar fertilization, crop rotation, irrigation, pest (insects and weeds) and disease management with herbicides, pesticides, and fungicides, and crop residue management. Methods to increase soybean yield include selecting the right variety, taking steps early to manage cyst nematodes, optimizing planting time, choosing optimal row spacing, managing weeds carefully, scouting for pests, and ensuring appropriate soil fertility (Pedersen, 2008).

Approximately one third of planted soybean seed in the U.S. is inoculated with *B. japonicum* to increase yield (Seed Today, 2009). In the 1990s, row spacing for planting soybean narrowed to 7 inches to achieve greater yields and then more recently expanded to 15 inches to promote greater air circulation to combat increased disease impacting yields (USDA-ERS, 2010b). The majority of U.S. soybean acreage is rotated to corn except in the south, where soybean is more often rotated to soybean (see Subsection 2.1.2.2, Crop Rotation). With the recent high corn prices, many producers in the Midwest are turning to a corn-corn-soybean rotation (Hart, 2006). Recent higher international demand for soybean (primarily China) and domestic need for soybean oil for producing biodiesel may spur planting of more soybean. Demand may also have prompted more soybean to soybean rotations, and double-cropping of soybean (USDA-ERS, 2011f). Other major crops following soybean are wheat (approximately 11.2% of soybean acreage), with cotton, rice, and sorghum the next largest rotational crops (combined 4.6% of soybean acreage) (Monsanto, 2010a). Approximately 88% of U.S. soybean acreage is under conservation tillage management where tillage is minimized and greater crop residue is maintained (USDA-ERS, 2006b). In regions of the United States that experience low amounts of rainfall during the growing season or during drought, soybean yields benefit from proper irrigation; in 2006 and 2008, approximately 9% of U.S. soybean acreage was irrigated, primarily in the Missouri and Lower Mississippi watersheds (USDA-NASS, 2010; USDA-ERS, 2011b; USDA-NASS, 2011).

A wide variety of pests can hinder soybean production and many require agricultural pesticidal inputs for their control. As discussed in Subsection 2.1.2.4, Agricultural Inputs, pesticides were applied to 16% of the 72.9 million soybean acres planted in certain surveyed states in 2006. Of the 12 reported insecticides, the three most common, lambda-cyhalothrin, chlorpyrifos, and esfenvalerate, were applied to 6%, 5%, and 3% of the planted acres, respectively (USDA-NASS, 2007a). However, a major pest is the soybean cyst nematode which cannot be controlled by pesticides, but transgenic soybean cultivars have been engineered to resist this pest. Other methods to control insect pests include tillage and crop rotation. While augmenting beneficial insect populations that prey on targeted pests would be useful, effectiveness of this strategy has not been demonstrated; thoughtful use of insecticides to conserve beneficials is nevertheless an important strategy. Diseases that afflict soybean include fungal, bacterial, and viral (Jardine, 1997). Diseases of major concern in soybean are *Cercospora* foliar blight, purple seed stain, aerial blight, soybean rust, pod and stem blight, and anthracnose (Padgett et al., 2011). When disease does occur in soybean, despite implementing best management practices, chemical treatment options are fairly limited to those of fungal origin (Jardine, 1997; Padgett et al., 2011). USDA NASS (2007a) found that the most commonly applied fungicides on soybean (azoxystrobin, propiconazole, pyraclostrobin, tebuconazole, and trifloxystrobin) were applied to only 4% of the 2006 U.S. soybean planted acreage in the 19 states surveyed (see Subsection 2.1.2.4, Agronomic Inputs).

Weeds are a major pest in agriculture and a primary detriment to soybean productivity (Heatherly et al., 2009). Herbicides have been the primary tactic to manage weed communities in soybeans since the mid-1960s and are applied to the majority of soybean acres (USDA-NASS, 2007b). Herbicides may be applied to soybean pre-plant (termed “burndown” in no-till), pre-emergence, post-emergence and post-harvest. With the advent of glyphosate-resistant GE soybeans, glyphosate has become the most often-used herbicide on U.S. soybean, while the use of other herbicides has decreased (Young, 2006; NRC, 2010).

In soybean seed production, most of the nutrients taken up from the soil by the plant is removed when harvesting the seed (Snyder, 2000). As described in Section 2.1.2.4, Agricultural Inputs, application of key nutrients such as potassium and phosphorous is not uncommon in U.S. soybean production; nitrogen is also applied, but at a much lower rate than other crops (USDA-NASS, 2007a). These supplements were applied on average only about once per crop year. In the midwestern United States it has been most economical to apply nitrogen, phosphate (phosphorous), and potash (potassium) soil fertilizer prior to planting corn in a two-year rotation with soybean, as usually the soybean crop can be produced the following year without additional soil fertilizer (Bender et al., 2013). However, in the south where soybean to soybean rotation is more common, soil nitrogen fertilizer is applied annually (Heatherly, 2012). Soil fertilizer is often tilled into the soil, or broadcast on the surface, or injected below the surface, with the latter practices used more often in conservation tillage production of soybean. However, because nutrients frequently become stratified in conservation tillage production systems, more farmers are turning to strip tillage to incorporate supplemental nutrients (Fernandez and White, 2012).

Recent research has found the fertility of some U.S. and Canadian cropland is declining in the last five years, with soils dropping to levels near or below critical phosphorous, potassium, sulfur and zinc levels. The decline is attributed to producing increased yields of field crops without proper fertilization (Fixen et al., 2010). As discussed in Subsection 2.1.2.4, Agronomic Inputs, it is widely recognized that the higher the crop yield per acre, the more nutrients are removed from the soil (Snyder, 2000; Specht et al., 2006; Pedersen, 2008; CAST, 2009a; Mallarino et al., 2011; Silva, 2011), and many agricultural extensions recommend regularly testing the soil for nutrients and soybean fertilization levels based upon bushels per acre produced to support increased yields (CAST, 2009a) (for example, see recommendations for Iowa at http://www.extension.iastate.edu/Publications/PM1688.pdf and http://msucares.com/pubs/publications/p2647.pdf for Mississippi) (Pedersen, 2008; Naeve, 2012). Yields in soybean cultivars not bred to be high yielding may be improved by increasing the plant population of a field through increased seeding rates and narrower rows, and the application of fertilizer in undernourished soils, among other measures (Pedersen, 2008).

Bender et al. (2013) have recently evaluated the nutrient uptake of modern, higher yielding transgenic insect-resistant corn varieties in Iowa and found average applications of phosphorous to these modern varieties would deplete this nutrient to inadequate levels for following soybean crops if not supplemented. As discussed in Subsection 2.1.2.4, Agronomic Inputs, soybean yields have steadily increased since first reported in 1924, and have increased 17.6% from 1991 to 2012 (USDA-NASS, 2012j), attributed to improved cultivars and agronomic practices, including those addressing adequate application of fertilizer (Specht et al., 2006; Pedersen, 2008; Naeve, 2012).

Preferred Alternative

A determination of nonregulated status of MON 87712-4 soybean is not expected to result in changes to current soybean cropping practices as described under the No Action Alternative. As discussed in Subsection 4.2.1, Acreage and Area of Production, Monsanto's studies demonstrate MON 87712-4 soybean is essentially the same as other commercial soybean varieties in terms of agronomic characteristics and cultivation practices (Monsanto, 2011; USDA-APHIS, 2011b). While MON 87712-4 soybean did have an approximately 1.6% higher earlier plant stand count, reached senescence 2 days later and physiological maturity 2.5 days later, had an approximately 3.3% higher final plant stand, and a 7.3% higher yield than variety A3525, none of these characteristics are expected to require changes to agronomic practices such as tillage, crop residue management, crop rotation, irrigation, pest (insects and weeds) and disease management, harvest and storage practices for cultivation of MON 87712-4 soybean (Monsanto, 2011; USDA-APHIS, 2011b). Monsanto has also indicated MON 87712-4 soybean will be adopted into existing maturation groups to match the area in which it would be cultivated, thus soybean planting practices would not change. As noted earlier however, successive crops following the MON 87112 may possibly require additional fertilization, but that would depend upon the soil and its typical constituents, as well as the depletion rate of nutrients.

As discussed under the No Action Alternative, producing higher grain crop yields often requires additional fertilization to be applied to replace the nutrients removed from the soil by harvesting the grain. The grain takes up the majority of nutrients, whether or not the cultivar grown is bred to be high yielding. In two-year rotations of corn and soybean, a common practice is to fertilize the previous year's corn crop with enough phosphorus and potassium to allow for the subsequent soybean crop to be grown with no supplemental fertilizer as it is more economical than two separate applications (Franzen, 1999; Berglund and Helms, 2003; Ebelhar et al., 2004). Approximately 68.6% of U.S. soybean is grown in rotation with corn (Monsanto, 2010a). However, as discussed under the No Action Alternative, annual supplementation of nutrients is common in soybean to soybean rotations in the southern United States. Like any other higher yielding soybean variety or production strategy designed to maximize yields utilizing lower yielding conventional or GE varieties, MON 87712-4 soybean would deplete more potassium and phosphorus from the soil (Monsanto, 2011). Levels of these nutrients may need to be checked and corrected if needed prior to MON 87712-4 soybean planting. Regular testing of soil fertility levels and supplementation if needed is already widely recommended in soybean production for achieving optimal yields. Application of additional nutrients to support production of this soybean would not be different from current practices where up to 23% of soybean acreage has been annually supplemented with phosphate (phosphorous) and 25% has been annually supplemented with potash (potassium) (USDA-NASS, 2007a). As soybean yields have been steadily increasing since the 1920s (Egli, 2008), and variations of yields are experienced field-to-field and year-to-year in GE and non-GE soybean production (USDA-NASS, 2012j; USDA-NASS, 2012f), growers are accustomed to harvesting and storing possibly increased yields.

Based upon the above, changes in U.S. agronomic practices such as tillage, crop rotation, irrigation, pest management, soybean cultivation, geographic range, seasonality or insect susceptibility, are not expected to occur under the Preferred Alternative, although growers may need to increase the frequency of soil nutrient augmentation, dependent upon specific needs of specific fields.

4.2.3 Soybean Seed Production

As discussed in Subsection 2.1.3, soybean seed production is conducted under standard procedures specified by AOSCA to prevent gene flow between varieties (AOSCA, No Date). Several best management practices to preserve varietal identity include:

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

Soybean is considered to be highly self-pollinated; therefore, cross-pollination to adjacent soybean plants occurs at a very low frequency (Caviness, 1966; OECD, 2000; Ray et al., 2003; Abud et al., 2007). Other research has also demonstrated that soybean pollen dispersal is restricted to small areas and wind mediated pollination is negligible (Yoshimura, 2011).

No Action Alternative

Under the No Action Alternative, current soybean seed production practices are not expected to change. Several factors influence optimal planting rate for soybean such as row spacing, seed germination rate, soil conditions, climate, disease and pest pressure, past tillage practices and crop rotation (Robinson and Conley, 2007). Seeding rate is also determined by the plant population desired by the grower. Growers may plant certified soybean seed, uncertified seed, and "binrun" soybean seed that is grown and stored on individual farms (Oplinger and Amberson, 1986). Approximately 93% of the soybean acres planted in the United States in 2012 were GE varieties (USDA-ERS, 2012e), about 71.8 million acres were planted with certified seeds, and an estimated 1.3 to 2.7 million tons of certified soybean planting seeds were required in 2012.

As discussed in Subsection 2.1.3, Soybean Seed Production, the production of soybean for foundation, registered, certified, or quality control seed require biological, technical, and quality control factors required to maintain varietal purity above that required for soybean production for grain. The production and certification of soybean seed is regulated by state or regional crop improvement agencies and are chartered under the laws of the state(s) they serve (e.g., see Mississippi Crop Improvement Association, 2008; Illinois Crop Improvement Association, 2013; SSCA, No Date-a; Virginia Crop Improvement Association, No Date). The procedures followed by certified seed producers to ensure varietal purity and identity during the cultivation, harvest, storage, and transportation of soybean seed are not expected to change under the No Action Alternative.

Seed genetic purity is maintained to maximize the value of a new variety or cultivar (Sundstrom et al., 2002), of which a seed certification process ensures the desired traits remain within purity standards (Bradford, 2006) (see Subsection 2.1.3, Soybean Seed Production). Seed producers routinely submit applications to the AOSCA National Variety Review Boards for review and recommendation for inclusion into seed certification programs. For example, in September 2012, AOSCA recommended the inclusion of 60 varieties of soybean expressing high yield traits by three seed producing companies for certification (AOSCA, 2012a; AOSCA, 2012b). It is expected that soybean seed producers would continue to implement measures to preserve the identity of their seed varieties.

Preferred Alternative

Field trials conducted by Monsanto have not demonstrated any agronomic or phenotypic differences between MON 87712-4 soybean and conventional soybean varieties that would require changes to soybean seed production practices (Monsanto, 2011). Based on the data provided, APHIS has concluded that the availability of MON 87712-4 soybean under the Preferred Alternative would not alter the agronomic practices, cultivation locations, seed production practices or quality characteristics of conventional and non-GE soybean seed production (USDA-APHIS, 2011b). Monsanto has also indicated MON 87712-4 soybean will be adopted into existing maturation groups to match the area in which it would be cultivated, thus its adoption would not alter planting practices of soybean grown for seed. Various state agencies affiliated with AOSCA will continue to provide seed certification services. Monsanto has indicated that tests would be available and easily accomplished to determine the presence of the

BBX32 gene in seed stock. The potential impacts to soybean seed production associated with the Preferred Alternative would not be any different than practices under the No Action Alternative.

4.2.4 Organic Soybean Production

Organic production plans prepared pursuant to the NOP include practical methods to prevent the unintended presence of GE materials. Typically, organic growers use multiple methods to prevent unwanted material from entering their fields, many of them following the same system used for the cultivation of certified seed under the AOSCA procedures. These include planting organic seed only, planting at times earlier or later than neighbors, and using field isolation practices (NCAT, 2003).

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 use practices on their farms that protect their crop from unwanted substances. APHIS's baseline for analysis of the alternatives will therefore assume that growers of organic soybean are already using, or have the ability to use, these common practices.

No Action Alternative

Under the No Action Alternative, MON 87712-4 soybean would remain subject to the regulatory requirements of 7 CFR part 340 and the plant pest provisions of the Plant Protection Act. Availability of GE, non-GE and organic soybean seed would not change as a result of the continued regulation of MON 87712-4 soybean. Organic soybean farmers would continue to use the same methods as applied in certified seed production systems designed to maintain soybean seed identity and meet National Organic Standards as established by the NOP. Acreage devoted to organic soybean production is small relative to that of GE varieties and has remained relatively steady, only fluctuating between 96,080 to 126,000 acres between 2005 and 2011 (USDA-ERS, 2010a; USDA-NASS, 2012a). As described in Subsection 2.1.4, Organic Soybean Production, organic soybean production is a very small portion of the soybean market which would not be expected to change under the No Action Alternative. Also, agronomic practices employed to produce organic soybean would remain unaffected by selection of the No Action Alternative.

It is important to note that the current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE 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. These methods to exclude nonorganic methods and avoid certain substances are detailed in the grower's approved organic system plan (Ronald and Fouche, 2006; USDA-AMS, 2008). However, certain markets or contracts may have defined thresholds for content of GE soybean (Non-GMO Project, 2012).

Preferred Alternative

GE soybean lines are already extensively used by farmers, while organic soybean production represents a small percentage (less than 1.0%) of the total U.S. soybean acreage (USDA-NASS, 2012a) . Under the Preferred Alternative, MON 87112 is not likely to substantially increase the ratio of conventional soybean to organic soybean Similar to the No Action Alternative, organic soybean acreage is likely to remain small, regardless of whether new varieties of GE or non-GE soybean varieties, including MON 87712-4 soybean, become available for commercial soybean production.

When compared to other GE varieties of soybean, MON 87712-4 soybean should not present any new and different issues and impacts for organic and other specialty soybean producers and consumers. Organic producers employ a variety of measures to manage, identify and preserve the integrity of organic production systems (NCAT, 2003). Agronomic tests conducted by Monsanto found MON 87712-4 soybean substantially equivalent to the non-GE control variety (Monsanto, 2011); hence, pollination characteristics would be similar to other soybean varieties currently available to growers. Given the largely self-fertilized nature and the limited pollen movement of soybean (Caviness, 1966; OECD, 2000; Ray et al., 2003; Abud et al., 2007; Yoshimura, 2011), it is not likely that organic farmers will be substantially affected by a determination of nonregulated status of MON 87712-4 soybean when organic soybeans are produced in accordance with agronomic practices designed to meet National Organic Standards. The trend in the cultivation of GE soybean, non-GE, and organic soybean varieties, and the corresponding production systems to maintain varietal integrity are likely to remain the same as the No Action Alternative. Accordingly, impacts of a determination of nonregulated status of MON 87712-4 soybean on organic soybean production would be similar to the No Action Alternative.

4.3 Physical Environment

4.3.1 Soil Quality

No Action Alternative

Under the No Action Alternative, current soybean management practices that benefit soil quality would be expected to continue. These agronomic practices include contouring; use of cover crops to limit the time soil is exposed to wind and rain, reduce erosion and compaction, control weeds, and enhance nutrients; careful management of fertilizers and pesticides; crop rotation; and windbreaks (Hoorman et al., 2009b; USDA-NRCS, 2011b; MDA, 2012; NWF, 2012; SARE, 2012; USDA-NASS, 2012e; Corn and Soybean Digest, 2013; Lee et al., No Date) (see Subsection 2.1.2, Agronomic Practices). Tillage has beneficial impacts to soil quality by incorporating organic material and oxygen, but also exposes soil to increased erosion from precipitation and wind, and if done improperly, compacts soil, reduces nutrients, impacts soil structure, and reduces biological activity(USDA-NRCS, 2001). Agronomic practices affecting soil would not change as a result of the continued regulated status of MON 87712-4 soybean.

Growers would continue to choose certain pesticides based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Heiniger, 2000; Farnham, 2001; University of Arkansas, 2006). The environmental risks of pesticide use are assessed by EPA in the pesticide registration process and are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. When used according to label directions, pesticides can be used without posing unreasonable risks to soil quality.

Recent research has found the fertility of some U.S. and Canadian cropland is declining in the last five years, with soils dropping to levels near or below critical phosphorous, potassium, sulfur and zinc levels; these observations are attributed to producing increased yields of field crops without proper fertilization (Fixen et al., 2010). Increased soybean yields may be obtained by increasing the plant population in a field (i.e., more seed in narrower rows) among other management practices, as well as selecting varieties bred to be higher yielding (Pedersen, 2008). Application of key nutrients to soil to replace those taken up by crops is not uncommon in soybean production, fertilization is widely recommended as a means to increase yields of all soybean cultivars, and regular testing of soil fertility is widely recommended (see discussion in Subsection 4.2.2.1, No Action Alternative – Agronomic Practices).

Preferred Alternative

A determination of nonregulated status of MON 87712-4 soybean is not expected to result in changes in current soybean cropping practices that may impact soil quality. Monsanto studies demonstrate MON 87712-4 soybean is essentially indistinguishable from other GE and non-GE soybean varieties in terms of agronomic characteristics and cultivation practices (Monsanto, 2011; USDA-APHIS, 2011b). As MON 87712-4 soybean is essentially equivalent to conventional soybeans, no changes in agronomic practices (other than crop fertilization), cultivation, geographic range, seasonality or insect susceptibility, are expected to occur. Although MON 87712-4 soybean is a higher yielding cultivar and like other commercially available high yielding cultivars or production systems designed to achieve improved yields from lower-yielding conventional and GE cultivars, it would remove phosphorous and potassium from soil at a higher rate. The application of these nutrients is not uncommon in soybean production (USDA-NASS, 2007a) and regular testing of soil fertility is widely recommended in soybean production.

MON 87712-4 soybean and the associated production of the BBX32 protein is not expected to cause an impact to the physicochemical characteristics of the soil. The BBX32 gene, which has been introduced into MON 87712-4 soybean, is derived from *A. thaliana* (mouseear cress) (Monsanto, 2011), a common introduced forb found in all of the soybean producing states except North Dakota (USDA-NRCS, 2013c). The BBX32 protein allows for greater plant nutrient assimilation and utilization to drive yield improvement. Soil quality may be impacted by a soybean crop through direct interaction with soil fauna via the root system and by the degradation of remaining plant tissue after harvest. Compositional analysis of MON 87712-4 soybean forage tissue (i.e., stems and leaves) revealed no significant or consistent differences between it and the conventional control variety A3525 (Monsanto, 2011). In addition, there were no significant differences between MON 87712-4 soybean and the A3525 conventional control variety in plant-environment interactions or plant symbiont interactions (Monsanto, 2011; USDA-APHIS, 2011b). Recognizing the compositional similarities between MON 87712-4 soybean and conventional soybean, and also the examined safety of the MON 87712-4 gene products, it is not anticipated that MON 87712-4 soybean interaction with soil fauna or degradation of its tissue following harvest would significantly impact soil quality compared to conventional soybean.

Based on this information, overall impacts to soil under the Preferred Alternative are expected to be similar to the No Action Alternative.

4.3.2 Water Resources

No Action Alternative

Under the No Action Alternative, current soybean management practices, including irrigation, pesticide use and fertilizer application would be expected to continue. The environmental risks of pesticide use are assessed by EPA in the pesticide registration process and are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. Pesticide use according to EPA-approved label directions would not pose unreasonable risks to water resources.

The trend towards conservation tillage or no-tillage practices with the adoption of GE herbicide-tolerant soybean varieties is expected to continue, resulting in reduced surface water run-off and soil erosion (Dill et al., 2008; Givens et al., 2009). Conservation tillage and other management practices are used to trap and control sediment and nutrient runoff. Water quality conservation practices benefit agricultural producers by lowering input costs and enhancing the productivity of working lands (USDA-NRCS, 2012).

As of 2006, nitrogen was applied to 18%, potassium to 25%, and phosphorous to 23% of soybean acreage in 19 surveyed states (USDA-NASS, 2007a). High yield production practices for any soybean cultivar and cultivars bred for high yield remove more nutrients from soils (Pedersen, 2008). Regular testing of soil fertility is required and application of nutrients is not uncommon in soybean production (USDA-NASS, 2007a). As discussed in Subsection 2.1.2.1, Cultivation, nitrogen is not usually applied to soybean since soybean fixes nitrogen in the soil in symbiosis with rhizobial bacteria (CAST, 2009a).

Preferred Alternative

No differences in morphological characteristics and agronomic requirements were found between MON 87712-4 soybean and its parent A3525 soybean (Monsanto, 2011); therefore, cultivation of MON 87712-4 soybean would not necessitate changes in current agronomic practices for soybean production that may impact water quality. Monsanto evaluated on a site specific basis abiotic stressors such as drought and flood, and found no difference between MON 87712-4 and its comparator (Monsanto, 2011). Also, as previously discussed, the use of MON 87712-4 soybean would not increase the total acres and range of U.S. soybean production areas. For these reasons, a determination of nonregulated status of MON 87712-4 soybean is unlikely to change the current irrigation practices in commercial soybean production.

As discussed in Subsection 2.2.2, Water Resources, runoff from cropland areas receiving manure or fertilizer contributes to increased phosphorous and nitrogen delivery to streams and lakes, and in fresh water systems phosphorus is a limiting factor for eutrophication. However, regular testing of soil fertility levels and supplementation if needed is already a common recommendation in soybean production for achieving optimal yields; additionally, as of 2006, up to 23% of soybean acreage has been annually supplemented with phosphorous (USDA-NASS, 2007a).

The adoption of herbicide-tolerant crops is associated with increased use of no-till and reduced till practices that benefit water quality through reductions in soil, nutrient and herbicide loaded runoff (Dill et al., 2008; Givens et al., 2009). The adoption rate of herbicide-tolerant soybean has steadily increased since its introduction in 1996, comprising up to 93% of the cultivated soybean in the United States in 2012 (see Subsection 2.1.1, Area and Acreage). This trend is not likely to change with the commercial availability of MON-87712-4 soybean. Some farmers practice no-till or reduced till even though they plant soybean varieties with no herbicide tolerance. Also, no-till soybean production is not suitable for all producers or areas. For example, no-till soybean production is less successful in heavier, cooler soils more typical of northern latitudes (Kok et al., 1997; NRC, 2010) where the potential for increased weeds, insect pests, and disease requires careful management (Peterson, 1997; Pedersen et al., 2001) .

Because MON 87712-4 soybean is expected to simply replace soybean varieties already in use and no changes to agronomic practices are required for its cultivation, the effects of the Preferred Alternative on water use and water quality would be the same as the No Action Alternative.

4.3.3 Air Quality

No Action Alternative

Under the No Action Alternative, air quality would continue to be affected by current agronomic practices associated with soybean production, such as tillage, cultivation, pesticide and fertilizer applications, and the use of agricultural equipment. Growers would continue use of agrochemicals such as pesticides and herbicides which are EPA-registered products. Environmental risks of their application are assessed by EPA in the pesticide registration process. Further, each pesticide is regularly reevaluated by EPA to maintain registered status under FIFRA. In this process, steps to reduce pesticide drift are included on a pesticide's label and approved by the EPA. Use of pesticides according to the EPA-approved label would not pose unreasonable risk to air quality. The trend towards conservation tillage or no-till practices with the adoption of GE herbicide-tolerant soybean varieties would likely continue, which could result in reduced emissions from agricultural equipment and fugitive dust from soil disturbance (Dill et al., 2008; Givens et al., 2009).

Preferred Alternative

No differences in morphological characteristics and agronomic requirements were found between MON 87712-4 soybean and its comparator parent A3525 soybean (Monsanto, 2011); therefore, cultivation of MON 87712-4 soybean would not necessitate changes in current agronomic practices for soybean production. Also, as discussed in Subsection 4.2.1, Acreage and Area of Soybean Production, the use of MON 87712-4 soybean would neither increase the total acres nor range of U.S. soybean production areas. Moreover, since no changes to agronomic practices for the cultivation of MON 87712-4 soybean are expected, the trend towards conservation tillage or no-till practices would likely be similar to the No Action Alternative. However, in those areas in which soil fertility does not normally require frequent nutrient augmentation, there may be additional tractor trips to apply fertilizer to the soil. Thus, potential exists for increased amounts of exhaust gases, should the need arise for additional fertilization of soybean fields, but this depends on existing soil resources, and would not be needed in all locations. Routine soil testing would reveal any deficiencies that required soil interventions. It should be noted that fertilization is often done for the previous crop to soybean, such as corn, and that additional tractor trips for soybean rotation would not likely be common.

Between 1990 and 2010, residue burning occurred on less than 0.5% of soybean acreage (US-EPA, 2012a). As discussed in Subsection 2.2.3, Air Quality, prescribed burning would likely only occur as a pre-planting option based on individual farm needs and not the variety produced. For these reasons, a determination of nonregulated status of MON 87712-4 soybean is unlikely to change the effect of commercial soybean production on air quality and the impacts to air quality from a determination of nonregulated status of MON 87712-4 soybean are expected to be similar to the No Action Alternative.

4.3.4 Climate Change

No Action Alternative

Under the No Action Alternative, agronomic practices associated with soybean production contributing to GHG emissions, including tillage, cultivation, irrigation, fertilizer applications, and use of agriculture equipment, are expected to continue. Tillage contributes to the release of GHG as a result of the loss of soil CO_2 to the atmosphere from the oxidation of soil organic carbon. Conservation tillage practices contribute to soil carbon sequestration through the reduction of soil aeration and microbial activity; loss of soil carbon from conventional tillage is estimated to be five times greater than no-till systems (CAST, 2009b) (see Subsection 2.2.4, Climate Change). Conservation tillage also reduces the number of trips across a field which translates into a reduction of fuel usage and GHG emissions from farm equipment. Reduced tillage also contributes to reducing the loss of nutrients from runoff and subsequent reductions in the need for fertilizer (Oregon State University, 2012).

Cropping practices and soil management also account for 69% of U.S. NO_2 emissions, with application of nitrogen fertilizer in particular contributing to NO_2 emissions (US-EPA, 2011b). As of 2006, nitrogen was applied to 18%, potassium to 25%, and phosphorous to 23% of soybean acreage in 19 surveyed states (USDA-NASS, 2007a). High yield production practices for any soybean cultivar and cultivars bred for high yield remove more nutrients from soils (Pedersen, 2008). Regular testing of soil fertility is required and application of nutrients is not uncommon in soybean production (USDA-NASS, 2007a). As discussed in Subsection 2.1.2.1, Cultivation, soybean fixes nitrogen in the soil in symbiosis with rhizobial bacteria, hence, nitrogen is not usually applied to soybean (CAST, 2009a).

The trend towards conservation tillage or no-tillage practices with the adoption of GE herbicide-resistant soybean varieties would continue, which could result in reduced GHG emissions from agricultural equipment (Dill et al., 2008; Givens et al., 2009).

Preferred Alternative

A determination of nonregulated status of MON 87712-4 soybean is not expected to result in changes in the current soybean cropping practices that potentially impact GHG emissions contributing to climate change. Apart from increased yield, no differences in morphological characteristics and agronomic requirements were found between MON 87712-4 soybean and its A3525 parent cultivar (Monsanto, 2011). Similar to other high yield soybean cultivars and soybeans produced using high yield maximization practices, MON 87712-4 soybean would require more potassium and phosphorous than other lower yield cultivars. Application of these fertilizers is not uncommon, and they do not emit GHG.

As MON 87712-4 soybean is essentially equivalent to other GE herbicide-resistant and non-GE soybeans, no changes in agronomic practices (such as crop rotation), cultivation, geographic range, seasonality or insect susceptibility, are expected to occur; therefore, cultivation of MON 87712-4 soybean would not necessitate changes in current agronomic practices for soybean production that may impact GHG emissions. In addition, cultivation of MON 87712-4 soybean would not likely impact the decision by producers to minimize conventional tillage and adopt conservation tillage practices that reduce CO_2 and NO_2 emissions. For these reasons, a determination of nonregulated status of MON 87712-4 soybean is unlikely to change the effect of commercial soybean production on GHG emissions impacting climate change.

4.4 Biological Resources

4.4.1 Animal Communities

No Action Alternative

Under the No Action Alternative, terrestrial (insect, bird, and mammal) and aquatic (fish, benthic invertebrate, and herptile) species would continue to be affected by current agronomic practices associated with soybean production, such as tillage, cultivation, pesticide and fertilizer applications, and the use of agricultural equipment (USDA-NRCS, 1999a; Brady, 2007; Sharpe, 2010; Palmer et al., No Date). Some of these practices may have potential to impact animal communities. For example, if tillage rates were to increase as a means of weed suppression, it could possibly diminish the benefits to wildlife provided by conservation tillage practices. Growers would continue to choose certain pesticides based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Heiniger, 2000; Farnham, 2001; University of Arkansas, 2008). The environmental risks of pesticide use on wildlife and wildlife habitat are assessed by EPA in the pesticide registration process and are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. EPA's process ensures that each registered pesticide, when used according to label directions, can be used with a reasonable certainty of no harm to human health and without posing unreasonable risks to the environment.

Preferred Alternative

A determination of nonregulated status of MON 87712-4 soybean is not expected to result in changes to current soybean cropping practices. Monsanto's studies demonstrate MON 87712-4 soybean is essentially indistinguishable from other soybean varieties in terms of agronomic characteristics and cultivation practices (Monsanto, 2011; USDA-APHIS, 2011b). MON 87712-4 soybean improves the potential for increased yield, and would be another option to assist growers to optimize production. Because MON 87712-4 soybean is essentially equivalent to other GE and non-GE soybeans in terms of agronomic practices (such as crop rotation or weed management, cultivation, geographic range, seasonality), no impacts to wildlife are expected to occur among that use soybean fields for cover and forage (discussed in Subsection 2.3.1, Animal Communities). Similarly, field trials demonstrated that MON 87712-4 soybean does not confer any biologically meaningful increased susceptibility or tolerance to insect pests (Monsanto, 2011).

Monsanto has evaluated the potential allergenicity and toxicity of the BBX32 protein. The developer followed Codex Alimentarius Commission guidelines to assess potential adverse effects to animals from environmental release or consumption of MON 87712-4 soybean (Monsanto, 2011). These evaluations determined that the BBX32 protein does not share any amino acid sequence similarities with known allergens, gliadins, glutenins, or protein toxins (Monsanto, 2011). In addition, the BBX32 protein is degraded rapidly and completely in simulated gastric fluid and simulated intestinal fluid, and the protein makes up only a very small portion (less than 0.001%) of the total plant protein (Monsanto, 2011). The results presented by Monsanto suggest that the BBX32 protein is unlikely to be a toxin in animal diets. Monsanto has initiated a food/feed safety consultation with FDA on MON 87712-4 soybean. FDA has evaluated the submission and responded with questions on July 18, 2012, and Monsanto responded to those on August 9, 2012. When complete, FDA will announce whether it could identify any safety or regulatory issues under the FD&C Act that would require further evaluation. The decision memo will be published as BNF No. 131.

Based on the above information, there are no expected hazards associated with the consumption of MON 87712-4 soybean and therefore it is unlikely to pose a hazard to wildlife species. Further discussion on the potential impacts from the consumption of MON 87712-4 soybean is presented in Subsection 4.6, Animal Feed.

4.4.2 Plant Communities

Plant communities within agroecosystems are generally less diverse than the plant communities that border crop fields. This lack of diversity is attributable to ecological selection that is imposed by crop production practices such as tillage and herbicide use (Owen, 2008). The plant communities that inhabit crop production fields are represented by plants (including weeds) that are able to adapt and thrive in an environment that is directed specifically to the production of crops, such as soybean. In crop production systems, the plant community is controlled using a number of tactics to maximize the production of food, fiber, and fuel (Green and Owen, 2011). However, along with cultivation and tillage, herbicides are a common and frequently adopted tactic to manage plant communities within agroecosystems (Gianessi and Reigner, 2007). The landscape surrounding a soybean field may be bordered by other soybean (or other crop) fields or may also be surrounded by woodland, rangelands, or pasture and grassland areas. These plant communities represent natural or managed plant buffers for the control of soil and wind erosion and also serve as habitats for a variety of transient and non-transient wildlife species. The potential impacts to off-site plant communities are discussed in Subsection 4.4.5, Biodiversity.

Weed control programs are important aspects of soybean cultivation. 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 (US-EPA, 2007). The types of weeds in and around a soybean field will vary depending on the geographic region where the soybean is grown. Common weeds in soybean include grasses, broad-leaf weeds, and sedges (*Cyperus* spp.). Some of these have been discussed in Subsection 2.3.2, Plant Communities.

No Action Alternative

Under the No Action Alternative, MON 87712-4 soybean would remain under APHIS regulation. Soybean production would likely continue as it does today, with the majority of acres being planted with GE soybean. Growers would likely continue to select the agronomic practices such as tillage, irrigation, row spacing, timing of planting, and weed management that optimize soybean yield and efficiency.

Plant species that typically compete with soybean production would be managed through the use of mechanical, cultural, and chemical control methods. Multiple herbicides would likely continue to be used for weed control in soybean fields. Glyphosate, by far, is the most used herbicide in soybean production, followed by 2,4-D, pendimethalin, trifluralin, S-metolachlor and several others (USDA-NASS, 2007a). Runoff, spray drift, and volatilization of herbicides have the potential to impact non-target plant communities growing in proximity to fields in which herbicides are used. The environmental risks of pesticide use are assessed by EPA in the pesticide registration process and are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. In this process, where appropriate, steps to reduce pesticide drift and volatilization are included on a pesticide's label approved by EPA.

Volunteer soybeans are typically not a major problem in agroecosystems and regionally where volunteer soybean populations can develop, the volunteer plants are manageable and do not represent a serious weed threat (York et al., 2005).

Preferred Alternative

A determination of nonregulated status of MON 87712-4 soybean is not expected to result in changes in current soybean cropping practices. Field trials and laboratory analyses conducted by Monsanto showed no differences between MON 87712-4 soybean and other GE and non-GE soybean in growth, reproduction, or interactions with pests and diseases (Monsanto, 2011). The expression of the BBX32 protein in MON 87712-4 soybean is not expected to cause plant disease or affect susceptibility of MON 87712-4 soybean or its progeny to diseases or other pests (USDA-APHIS, 2011b).

Similar to the No Action Alternative, weeds within fields of MON 87712-4 soybean could be managed using mechanical, cultural, and chemical control. There are no differences expected to the use of herbicides or other pesticides in the production of MON 87712-4 soybean when compared to other GE and non-GE soybean varieties (Monsanto, 2011; USDA-APHIS, 2011b). In addition, there were no differences in the occurrence of volunteer soybean between MON 87712-4 soybean and the conventional control A3525; moreover, the herbicides that are effective for the control of volunteer soybean are equally effective for MON 87712-4 soybean (Monsanto, 2011).

Based on the above information, APHIS has determined that the impacts to plant communities from a determination of nonregulated status of MON 87712-4 soybean are similar to those under the No Action Alternative.

4.4.3 Gene Flow and Weediness

No Action Alternative

Under the No Action Alternative, MON 87712-4 soybean would remain under APHIS regulation. The availability of GE, non-GE and organic soybeans would not change as a result of the continued regulation of MON 87712-4 soybean. Because soybean is highly self-pollinated and its pollination rate significantly decreases with distance, it does not have a high outcrossing rate and there are no wild soybean species or near relatives in the U.S., gene flow and introgression from soybean to wild or weedy species are highly unlikely (USDA-APHIS, 2011a). Soybean is not frost tolerant, does not reproduce vegetatively, its seed is not easily dispersed, any volunteers that persist in warmer U.S. climates can be easily controlled with common agronomic practices, and does not establish itself outside of farmed fields. Potential for weediness is non existent in commercial soybean.

Preferred Alternative

A determination of nonregulated status of MON 87712-4 soybean is not expected to pose greater pollen- or seed-mediated gene flow, or increased potential for weediness than that of currently cultivated soybean varieties. There were no significant differences among the parameters that may lead to an increased potential for gene flow or weediness between MON 87712-4 soybean and the A3525 conventional control.

The *BBX32* gene, derived from *A. thaliana*, was inserted into the MON 87712-4 soybean gene sequence and interacts with one or more of the soybean's endogenous transcription factors that regulate day/night processes to increase plant nutrient assimilation (Monsanto, 2011). An increase in nutrient assimilation is believed to increase yield in MON 87712-4 soybean. Assimilates increase as a result of an increased period of photosynthetic activity and evidence of changes in diurnal metabolism during the soybean's reproductive phase compared to the conventional control A3525 (Monsanto, 2011). MON 87712-4 soybean is equally susceptible to all cultural variables affecting yield as other GE and non-GE soybean varieties.

APHIS evaluated information in its PPRA on the inserted genetic material, the potential for vertical and horizontal gene transfer, and weedy characteristics of MON 87712-4 soybean and concluded it would not represent any plant pest risk (USDA-APHIS, 2011b). Field trials and laboratory data collected on MON 87712-4 soybean indicate no plant pathogenic properties or weediness characteristics. Based on agronomic data and compositional analyses, MON 87712-4 soybean was found to be substantially equivalent to conventional soybean and would no more likely become a plant pest than conventional soybean.

The reproductive characteristics of MON 87712-4 soybean are substantially equivalent to other GE and non-GE soybean varieties (Monsanto, 2011). The field study to assess the potential for persistence outside cultivation calculated the replacement value for both MON 87712-4 soybean and the conventional control A3525 (Monsanto, 2011). The replacement value is the ratio of the number of seeds produced to the number of seeds sown; a replacement value less than one indicates that fewer seeds were produced than sown, meaning the plant will not replace itself and not persist; a value greater than one means more seeds were produced than were sown indicating the population has the potential to increase. At three of the four sites the replacement value was zero, whereas one site had replacement values for MON 87712-4 soybean and the conventional control A3525 of 2.72 and 2.63 respectively at the end of the first growing season; however, no plants emerged during the second growing season and as such the replacement value at that site was zero. This study demonstrates that MON 87712-4 soybean would not persist in unmanaged environments and does not demonstrate a competitive advantage compared to conventional soybean. The trait for increased yield is not expected to contribute to increased weediness without changes in a combination of other characteristics associated with weediness, such as hard seed and dormancy, among other characteristics. Given the reproductive nature of soybean, the potential for cross-pollination of MON 87712-4 soybean with other soybean cultivars is highly unlikely.

Studies have indicated horizontal gene transfer and expression of DNA from a plant species to bacteria is unlikely to occur (Keese, 2008). Furthermore, there is no evidence that bacteria closely associated with plants or their constituent parts contain genes derived from plants (Kaneko et al., 2000; Wood et al., 2001; Kaneko et al., 2002) and when horizontal gene transfer has been found to occur, it has been on an evolutionary time scale of millions of years (Koonin et al., 2001; Brown, 2003). Finally, FDA has determined the chance of transfer of antibiotic resistance genes from plant genomes to microorganisms in the gastrointestinal tract of humans or animals, or in the environment, is remote (US-FDA, 1998). Based on this information, APHIS has concluded that horizontal gene flow from MON 87712-4 soybean to other unrelated organisms would be highly unlikely (USDA-APHIS, 2011b).

In the event of a determination of nonregulated status of MON 87712-4 soybean, the risks to wild plants and agricultural productivity from weedy MON 87712-4 soybean populations are low, as volunteer soybean populations can be easily managed and there are no feral or weedy relatives in the United States (Carpenter et al., 2002). If present as volunteer soybean, MON 87712-4 soybean would not be considered difficult to control, as soybean seeds rarely remain viable the following season and are easily managed with cultivation or hand weeding, or the application of herbicides. In addition, since no feral or weedy species of soybean exist in the United States (Ellstrand et al., 1999; OECD, 2000), MON 87712-4 soybean poses no potential for either naturally occurring, pollen-mediated gene flow or transgene introgression (USDA-APHIS, 2011b).

Based on the above information, APHIS has determined that the impacts to other vegetation in soybean fields and the surrounding landscapes from a determination of nonregulated status of MON 87712-4 soybean are similar to those under the No Action Alternative.

4.4.4 Microorganisms

<u>No Action Alternative</u>

Under the No Action Alternative, MON 87712-4 soybean would remain under APHIS regulation. The availability of GE, non-GE and organic soybeans would not change as a result of the continued regulation of MON 87712-4 soybean. Agronomic practices used for soybean production, such as soil inoculation, tillage and the application of agricultural chemicals (pesticides and fertilizers) that potentially impact microorganisms, would continue.

As discussed in Subsection 2.3.4, soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva et al., 2004). They also suppress soil-borne plant diseases and promote plant growth (Doran et al., 1996). One gram of soil may contain upwards of 50,000 bacterial species (Curtis et al., 2002; Mendes et al., 2011). In addition, the composition of the microbial community is dependent on factors such as soil type, plant type, and agricultural practices (Garbeva et al., 2004; Garbeva et al., 2008). It has been demonstrated that plants are able to influence the rhizosphere microbial community through exudates that stimulate or inhibit certain microbes (Berensen et al., 2012).

One main factor affecting microbial population size and diversity is soil type and characteristics, including texture, structure, organic matter, aggregate stability, pH, and nutrient content. Additional factors include plant type (providers of specific carbon and energy sources into the soil), agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva et al., 2004) and cropping history (Garbeva et al., 2008).

Repeated tillage can reduce the amount of SOM that fuels function of the soil ecosystem and possibly by decreasing aggregate size and stability, and changing soil pH, salinity, and sodium concentration; these may impact bacterial populations (University of Minnesota, 2002; FAO, 2013). Inorganic fertilizers do provide some nutrients needed by soil microorganisms and favor those species that can best use the forms of nutrients found in fertilizers; however, the acidity, alkalinity, or salt found in certain fertilizers may reduce populations of fungi, nematodes, and protozoans (USDA-NRCS, 2004). Provided inorganic fertilizers are used carefully, they can benefit soil ecosystem functioning by increasing plant growth and the input of organic matter into the soil. Methods to manage soil biology and mitigate impacts from tillage and other practices would benefit the microbial community, and these include maximizing crop residue, installing cover crops, altering crop rotations, and reducing tillage (University of Minnesota, 2002).

Growers would continue to choose certain pesticides based on weed, insect and disease pressures, along with considering other related costs for seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Heiniger, 2000; Farnham, 2001; University of Arkansas, 2008). The impact of herbicides on microorganisms is dependent on a wide variety of factors such as formulations, constituents, concentrations, and environmental factors (e.g., soil type, plant type, agricultural management practices) (Garbeva et al., 2004; Garbeva et al., 2008). Identifying and quantifying the specific impacts of herbicides on the soil microbial community is difficult and is subject to a multitude of variables (see Subsection 2.3.4, Microorganisms). The environmental risks of pesticide use are assessed by EPA in the pesticide registration process and are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. Pesticide use according to label directions approved by the EPA would have a reasonable certainty of not posing unreasonable risks to the environment, including microorganisms.

In a review of studies of the below ground impacts of GE plants, Kowalchuk et al. (2003) found that GE crops investigated to date had minor to no detectable effects on the size, composition, or activity of important soil microorganisms, and the effects that had been observed were minimal when compared to “normal” sources of variation such as agricultural practices (e.g., tillage, planting, fertilization), season, weather, plant development, location and plant genotype.

As discussed in Subsection 4.2.2.1, agronomic practices used for soybean production, such as soil inoculation, tillage, irrigation and the application of agricultural chemicals (pesticides and fertilizers) that potentially impact microorganisms are expected to continue under the No Action Alternative.

Preferred Alternative

A determination of nonregulated status of MON 87712-4 soybean is not expected to result in changes in current soybean cropping practices that may impact microorganisms.

Similar to other GE crops, MON 87712-4 soybean has the potential to directly and indirectly impact microbial communities. MON 87712-4 soybean could have some impact on the structure of the soil microbial community in which it is planted, which could include nitrogen-fixing bacteria and mycorrhizal fungi; bacteria, actinomycetes (filamentous bacteria), and saprophytic fungi responsible for decomposition; denitrifying bacteria and fungi; phosphorus-solubilizing bacteria and fungi; as well as pathogenic and parasitic microbes (see Subsection 2.3.4, Microorganisms) (USDA-NRCS, 2004). Greenhouse testing by Monsanto revealed no significant differences found in the parameters measured to assess the symbiotic relationship of the legume and its associated rhizobia (e.g., nodule number, shoot percent total nitrogen, shoot total nitrogen, dry weight of nodules, shoot material, and root material) between MON 87712-4 soybean and the conventional control A3525 and six commercial reference varieties (see Section VII.C.4, Symbiont Interactions, Table VII-6, and Appendix J of the Monsanto Petition) (Monsanto, 2011). During comparative field observations, responses of MON 87712-4 soybean to abiotic stressors such as drought, mineral and nutrient toxicity, and temperature stress were similar to the A3525 control. In addition, data collected on plant-disease interactions during environmental assessments indicated that the presence of the BBX32 protein did not alter disease susceptibility of MON 87712-4 soybean compared to conventional soybean, suggesting no different impact to the pathogenic microbial community.

Like other high yielding soybean cultivars and high yield soybean production systems, cultivation of MON 87712-4 may remove more nutrients, particularly phosphorus and potassium, than other varieties. Such depletion necessitates testing and possibly increased soil nutrient amendments. Soil organisms require varying amounts of both macronutrients, including phosphorus, and micronutrients (USDA-NRCS, 2004). Several studies have demonstrated *B. japonicum* activity, root nodulation, and dinitrogen fixation are positively correlated with phosphorus levels (Cassman et al., 1980; Beck and Munns, 1984; Israel, 1987; Mullen et al., 1988; Sa and Israel, 1991; Tsvetkova and Georgiev, 2003). Likewise, potassium is necessary for nodule formation and bacteria-mediated nitrogen fixation in soybean and other nitrogen-fixing legumes (Mengel et al., 1974; IPNI, 1998). As discussed in Subsection 4.2.2, Agronomic Practices, nutrient application to soybean is not an uncommon practice and is widely recommended to sustain the yields of all soybean cultivars.

Based on the above information, overall impacts to microorganisms under the Preferred Alternative are expected to be similar to the No Action Alternative.

4.4.5 Biodiversity

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

No Action Alternative

Under the No Action Alternative, MON 87712-4 soybean would remain under APHIS regulation; the availability of GE, non-GE and organic soybeans would not change. Agronomic practices used for soybean production and yield optimization, such as tillage, the application of agricultural chemicals (pesticides and fertilizers), timing of planting, row spacing, and scouting would be expected to continue. Agronomic practices that benefit biodiversity would continue both on cropland (e.g., intercropping, agroforestry, crop rotations, cover crops, and no-tillage) and on adjacent non-cropland (e.g., woodlots, fencerows, hedgerows, and wetlands).

Preferred Alternative

A determination of nonregulated status of MON 87712-4 soybean is not expected to result in changes in current soybean cropping practices that may impact biodiversity. Field trials and laboratory analyses conducted by Monsanto showed no differences between MON 87712-4 soybean and other GE and non-GE soybean in growth, reproduction, or interactions with pests and diseases (Monsanto, 2011). Similar to the No Action Alternative, weeds within fields of MON 87712-4 soybean could be managed using mechanical, cultural, and chemical control. Growers would determine the best method necessary to manage pests based on individual needs. The environmental risks of pesticide use are assessed by EPA during the pesticide registration process and are regularly reevaluated by EPA to maintain its registered status under FIFRA for each pesticide. Pesticide use in accordance with label instructions approved by EPA would have a reasonable certainty of posing no unreasonable risks to the environment. Under the Preferred Alternative, potential impacts to biodiversity are not expected to be substantially different from those associated with the No Action Alternative, including those from runoff, spray drift, and volatilization of agricultural chemicals such as pesticides, herbicides, and fungicides.

Potential risks to biodiversity from the production of GE crops include the disturbance of biosystems, including the agroecosystem, and changing permanently the species diversity of the habitat or the genetic diversity within a species (Snow et al., 2005). As discussed in Subsection 2.3.5, Biodiversity, the intensive farming practices associated with agricultural lands limit the diversity of plants and animals (Lovett et al., 2003). Diversity in adjacent natural areas, and those areas established to promote biodiversity (e.g., woodlots, fencerows, hedgerows, and wetlands) tend to have greater biodiversity. Agronomic practices for the production of MON 87712-4 soybean are not expected to change from those currently used for other commercially available GE and non-GE soybean; therefore, impacts to species diversity would be similar to that of the No Action Alternative. Moreover, the agronomic practices commonly used to increase farm-scale biodiversity (see Subsection 2.3.5) are likewise not expected to change. As discussed in Subsection 4.4.3, Gene Flow and Weediness, MON 87712-4 soybean poses no potential for naturally occurring, pollen-mediated gene flow and transgene introgression into native or naturalized plants and is not expected to affect genetic diversity.

A determination of nonregulated status of MON 87712-4 soybean is anticipated to have similar effects on crop, farm or landscape level biodiversity as the No Action Alternative. As such, the impacts of biodiversity under the Preferred Alternative are expected to be similar to the No Action Alternative.

4.5 Human Health

4.5.1 Public Health

No Action Alternative:

Under the No Action Alternative, MON 87712-4 soybean would remain under APHIS regulation. Human exposure to existing GE and non-GE soybean varieties would not change under this alternative. Grower and consumer exposure to cultivated MON 87712-4 soybean would be limited to those individuals involved in its cultivation under regulated conditions.

A variety of EPA-approved pesticides would continue to be used for pest management in both GE and non-GE soybean cultivation. When evaluating the potential consequences that may result from a determination of nonregulated status of a GE crop, USDA-APHIS considers the EPA's registration of pesticides. The environmental risks of pesticide use are assessed by EPA in the pesticide registration process and are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. As part of the registration process, the EPA considers human health effects from the use of pesticides and must determine that the pesticide will not cause unreasonable adverse effects on human health. If needed, the EPA will establish label restrictions to mitigate or alleviate potential impacts on human health and the environment. Pesticide registration labels provide the guidelines, application restrictions, and precautions necessary to protect human health. 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).

Similarly, the EPA establishes tolerances to regulate the amount of pesticide residues that can remain on food or feed commodities as the result of pesticide applications (see, e.g., http://www.epa.gov/pesticides/bluebook/chapter11.html) (US-EPA, 2010a), and the FDA and USDA monitor foods for pesticide residues and enforce these tolerances (USDA-AMS, 2011) (see Subsection 2.4.1, Human Health). The tolerance level is the maximum residue level of a pesticide that can legally be present in food or feed. If pesticide residues are found to exceed the tolerance value, the food is considered adulterated and may be seized. The EPA ensures that residue tolerances for pesticides meet FQPA safety standards for the U.S. population and designated sensitive populations (i.e., infants and children). EPA makes a finding that there is a reasonable certainty of no harm to the general population and any subgroup from the use of pesticides at the approved levels and methods of application.

Preferred Alternative

The protein in MON 87712-4 soybean that regulates the plant's day/night processes resulting in increased availability of assimilates is derived from the *BBX32* gene from the plant *A. thaliana*, whose common name is mouseear cress. Mouseear cress is an annual forb belonging to the Brassicaceae (mustard) family that also includes common food plants such as broccoli, cauliflower, cabbage, and canola (USDA-NRCS, 2013c). Mouseear cress is not consumed by humans and is not known to be consumed by animals.

Monsanto conducted safety evaluations based on Codex Alimentarius Commission procedures to assess any potential adverse effects to humans or animals resulting from environmental releases and consumption of MON 87712-4 soybean (FAO, 2009; Monsanto, 2011). These safety studies included: (1) characterization of the physicochemical and functional properties of BBX32; (2) quantification of BBX32 levels in plant tissues; (3) comparison of the amino acid sequence of BBX32 in MON 87712-4 soybean to known allergens, gliadins, glutenins, toxins, and other biologically-active proteins known to have adverse effects on mammals; (4) evaluation of the digestibility of BBX32 protein in simulated gastric and intestinal fluids; (5) documentation of the presence of related proteins in several plant species currently consumed; and (6) investigation of the potential mammalian toxicity through an oral gavage assay. The BBX32 protein was determined to have no amino acid sequence similar to known allergens, lacked toxic potential to mammals, and was degraded rapidly and completely in simulated gastric fluid. Monsanto has initiated a food/feed safety consultation on MON 87712-4 soybean with the FDA (Monsanto, 2011). A final decision from FDA is pending. MON 87712-4 soybean does not express a pesticidal property, and, accordingly, is not regulated by the U.S. EPA.

Monsanto also has evaluated the compositional and nutritional characteristics of MON 87712-4 soybean grain and forage, comparing the composition of the GE soybean with conventional products components in accordance with OECD guidelines (OECD, 2001). MON 87712-4 soybean was compared to several conventional soybean varieties from eight different field trial locations and analyzed for comparable nutritional composition. Compositional elements compared included proximates (protein, fat, carbohydrates, fiber, ash, and moisture), fiber, amino acids, fatty acids, and vitamin E in harvested seed, and proximates and fiber in forage. The anti-nutrients assessed in harvested seed included raffinose, stachyose, lectin, phytic acid, trypsin inhibitors, and isoflavones (Monsanto, 2011). There were no biologically meaningful differences for any of these compositional characteristics between the MON 87712-4 soybean and the conventional soybean varieties.

Based on this information, including field and laboratory data and scientific literature provided by Monsanto (2011) and safety data available on other GE soybean, APHIS has concluded that a determination of nonregulated status of MON 87712-4 soybean would have no adverse impacts on human health. Overall impacts would be similar to the No Action Alternative.

4.5.2 Occupational Health and Safety

No Action Alternative

The availability of GE, non-GE and organic soybeans would not change as a result of the continued regulation of MON 87712-4 soybean. Agronomic practices used for soybean production, such as the application of agricultural chemicals (pesticides and fertilizers), would be expected to continue. Growers will continue to choose agronomic practices based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Heiniger, 2000; Farnham, 2001; University of Arkansas, 2006). Worker safety is taken into consideration by EPA in the pesticide registration process and reregistration process. Pesticides are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. Furthermore, the OSHA requires all employers to protect their employees from hazards associated with pesticides and herbicides. When used according to label directions, pesticides can be used with a reasonable certainty of no harm to human health and without posing unreasonable risks to the environment.

Preferred Alternative

A determination of nonregulated status of MON 87712-4 soybean is not expected to result in changes in current soybean cropping practices. Similar to the No Action Alternative, it is expected that EPA-registered pesticides, fertilizers, and other chemicals that currently are used for soybean production would continue to be used by growers. EPA's core pesticide risk assessment and regulatory processes ensure that each registered pesticide continues to meet the highest standards of safety including all populations of non-target species and humans, and if used in accordance with the label, can be demonstrated to pose "a reasonable certainty of no harm to humans" and "no unreasonable adverse effects to the environment." Growers are required to use pesticides consistently with instructions for application provided on the EPA-approved pesticide label. These label restrictions carry the weight of law and are enforced by EPA and the states (Federal Insecticide, Fungicide, and Rodenticide Act 7 USC 136j (a)(2)(G) Unlawful Acts).

Exposure to MON 87712-4 soybean under the Preferred Alternative is not expected to elicit any change in existing human health status of individuals or populations. Based on the above information, overall impacts to occupational health and safety under the Preferred Alternative are expected to be similar to the No Action Alternative.

4.6 Animal Feed

The majority of the soybean cultivated in the United States is grown for animal feed and is usually fed as soybean meal. Animal agriculture consumes 98% of the U.S. soybean meal produced (Soyatech, 2011). As with human health, the consumption of the inserted genes and proteins in MON 87712-4 soybean is considered the primary concern relative to animal feed, but any changes in composition or nutrition are also relevant to potential impacts of recognizing nonregulated status.

No Action Alternative

Under the No Action Alternative, MON 87712-4 soybean would remain under APHIS regulation and soybean derived from MON 87712-4 would not be allowed for distribution to the animal feed market. Soybean-based animal feed would still be available from currently cultivated soybean crops, including both GE and non-GE soybean varieties. No change in the availability of these crops as animal feed is expected under this alternative.

Preferred Alternative

APHIS' assessment of the potential impacts of the consumption of the BBX32 protein by animals considers the source of the gene and the expressed protein, as well as safety evaluations conducted by Monsanto. The protein in MON 87712-4 soybean that regulates the plant's day/night processes resulting in increased availability of assimilates is derived from the *BBX32* gene from the plant *A. thaliana*, also known as mouseear cress. Mouseear cress is an annual forb belonging to the Brassicaceae (mustard) family that also includes common food plants such as broccoli, cauliflower, cabbage, and canola (USDA-NRCS, 2013c). BBX32 is a protein that has homologs in food plants with a history of safe use.

Monsanto's safety evaluations were based on Codex Alimentarius Commission procedures to assess any potential adverse effects to humans or animals resulting from environmental releases and consumption of MON 87712-4 soybean (Monsanto, 2011). These safety studies included: (1) characterization of the physicochemical and functional properties of BBX32; (2) quantification of BBX32 levels in plant tissues; (3) comparison of the amino acid sequence of BBX32 in MON 87712-4 soybean to known allergens, gliadins, glutenins, toxins, and other biologically-active proteins known to have adverse effects on mammals; (4) evaluation of the digestibility of BBX32 protein in simulated gastric and intestinal fluids; (5) documentation of the presence of related proteins in several plant species currently consumed; and (6) investigation of the potential mammalian toxicity through an oral gavage assay. The BBX32 protein was determined to have no amino acid sequence similar to known allergens, lacked toxic potential to mammals, and was degraded rapidly and completely in gastric fluid. Monsanto has initiated a food/feed safety consultation on MON 87712-4 soybean with the FDA (Monsanto, 2011). A final decision from FDA is pending.

Monsanto also has evaluated the compositional and nutritional characteristics of MON 87712-4 soybean grain and forage, comparing the composition of the GE soybean with conventional products. MON 87712-4 soybean was compared to several conventional soybean varieties from eight different field trial locations and analyzed for comparable nutritional components in accordance with OECD guidelines (OECD, 2001). Compositional elements compared included proximates (protein, fat, carbohydrates, fiber, ash, and moisture), fiber, amino acids, fatty acids, and vitamin E in harvested seed, and proximates and fiber in forage. The anti-nutrients assessed in harvested seed included raffinose, stachyose, lectin, phytic acid, trypsin inhibitors, and isoflavones (Monsanto, 2011). There were no biologically meaningful differences for any of these compositional characteristics between the MON 87712-4 soybean and the conventional soybean varieties.

The results of studies conducted by Monsanto confirm that the crops containing this protein can be safely used as animal feed. There are no differences in feed safety between the MON 87712-4 soybean and other varieties currently available under the No Action Alternative. Based on this information, including field and laboratory data and scientific literature provided by Monsanto (2011), and safety data available on other GE soybean, APHIS has concluded that a determination of nonregulated status of MON 87712-4 soybean would have no adverse impacts on animal health through use as animal feed. Overall impacts would be similar to the No Action Alternative.

4.7 Socioeconomic Impacts

4.7.1 Domestic Economic Environment

No Action Alternative

In 2011, 77 million acres of soybeans were planted in the United States, yielding 3.1 billion bushels (84.4 MMT) at a value of 35.8 billion U.S. dollars (USDA-NASS, 2012g). The majority of soybeans produced in the United States are used domestically for animal feed, with lesser amounts and byproducts used for oil or fresh consumption (GINA, 2013; USDA-ERS, 2013a). From 1924 when recording U.S. soybean production first began, both soybean acreage and yields have steadily increased (Egli, 2008). In comparison, total U.S. cropland has remained relatively level since 1945, except in 2007 when it retracted, in part due to changes in USDA classification procedures for the 2007 Census of Agriculture (USDA-ERS, 2011e). From 1991 to 2011, U.S. soybean acreage expanded 31% and yields increased 17.6% (USDA-NASS, 2012l; USDA-NASS, 2012j) while annual value of production increased approximately 222% from approximately $11.09 billion to approximately $35.8 billion (USDA-NASS, 2012i).

The expansion of U.S. soybean acreage has largely occurred by replacing other crops on existing cropland, and increasing double-cropping (USDA-ERS, 2011f). Yield increases have been achieved by adopting higher yield cultivars conventionally bred with GE herbicide-resistant and pest-resistant varieties, such as Genuity Ready 2 Yield® (Monsanto), LibertyLink® (Bayer), and Y Series® (Pioneer). Herbicide- resistant soybean are grown on 93% of soybean acres (see Subsection 2.1.1, Acreage and Area of Soybean Production) and increase yields through economically reducing weed competition. Improved management practices such as narrow row planting, foliar fungicide application, and fertilization are also factors in achieving increased yields (see Subsection 4.2.2, Agronomic Practices). It is expected that planted U.S. soybean acreage would hold steady at 76 million acres from 2013/2014 to 2021/2022, primarily because of increased foreign competition (less demand), the continued trend of planting more corn (lessened supply), but accompanied by increased demand for domestic soybean oil in biodiesel production (USDA-OCE, 2012).

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

Under the No Action Alternative, MON 87712-4 soybean would remain under APHIS regulation. Growers and other parties who are involved in production, handling, processing, or consumption of soybean would continue to have access to nonregulated GE and non-GE soybean varieties. Domestic growers would continue to use GE and non-GE soybean varieties based upon availability and market demand. As discussed in Subsection 4.2.2, agronomic practices and conventional breeding techniques using GE herbicide- and pest-resistant cultivars currently used to optimize yield and reduce production costs would be expected to continue under the No Action Alternative. Under the No Action Alternative, any potential increase to yield from the production of MON 87712-4 soybean would not be realized.

Preferred Alternative

In field tests accomplished by Monsanto, the performance and composition of MON 87712-4 soybean was determined as not substantially different from that of the non-GE comparator A3525 soybean and other conventional soybean reference varieties (Monsanto, 2011). Field tests in 2010 demonstrated MON 87712-4 soybean did have a statistically higher yield than the conventional control A3525 (7.3%), and its average yield during field trials was 18.9% greater than the average yield for the entire U.S. soybean crop reported for 2010; however, its yield in the study trial was within the range of conventional varieties reported that year of 67.5 bushels per acre to as high as 100 bushels per acre for some locations (Monsanto, 2011), and well below the world record for soybean yield per acre achieved in 2010 in Missouri at 160.6 bushels per acre for irrigated soybean and 98.9 bushels per acre for non-irrigated soybean (Alsager, 2010). MON 87712-4 soybean is subject to the same variables that affect yield of other GE and non-GE soybean varieties such as weather, timing and density of planting, and soil nutrients (see Subsection 2.1.2, Agronomic Practices). Growers are familiar with yield improvements using varieties with increased yield obtained through traditional breeding techniques, and more recently, from better weed control and disease resistance in transgenic soybean varieties. As discussed under the No Action Alternative, soybean yield has increased steadily from 1924 to present, increasing over 30 bushels per acre during this period (USDA-NASS, 2012j).

MON 87712 soybean is expected to be gradually adopted by many of those growers who are already growing biotechnology-derived soybeans. Additionally, Monsanto may only progressively phase in the incorporation of the trait into their soybean varieties. The rate of adoption will depend on the expectation of yield increase, the price of the seed, and other factors. The adoption of MON 87712-4 soybean is expected to be gradual because its yield benefits may not be immediately apparent, as it is subject to variables affecting yield common to all soybean varieties (Monsanto, 2011). Monsanto estimates maximum trait adoption would be approximately 50- 60% (Monsanto, 2011). This estimate assumes that other seed companies will offer soybean varieties that do not contain MON 87712-4 traits and these varieties will compete for market share with varieties that do contain MON 87712-4 soybean traits. In addition, it is assumed that there will be demand for non-GE conventional, organic soybean as well as other specialty soybean and these soybean varieties will also compete for acreage with MON 87712-4 soybean. As variations of yields are experienced field-to-field and year-to-year in GE and non-GE soybean production, growers are already accustomed to harvesting and storing increased yields that may occur following adoption of MON 87712-4 soybean.

It is unlikely the availability of MON 87712-4 soybean would significantly impact the domestic economic environment. As discussed under the No Action Alternative, past and recent growth in U.S. soybean acreage has occurred at the expense of acreage planted to other crops and not by bringing new lands into production. Overall total U.S. cropland has remained relatively stable since the mid-20th century. Since 93% of U.S. soybean acreage is planted with GE soybean varieties, it is likely that MON 87712-4 soybean would replace other varieties of GE soybean on existing cropland. Historically, soybean yields have been increasing for decades, in more recent times as a result of conventionally breeding high yielding cultivars with GE herbicide- and pest-resistant (nematode) traits, in addition to improved management practices. Apart from yield, the phenotypic and agronomic characteristics of MON 87712-4 soybean have been demonstrated in combined trials to be similar to its comparator A3525 soybean and other commercially available reference varieties. Its yields are also similar to other, widely available high yielding soybean varieties that have performed as well as, or even better, than MON 87712-4 soybean's yield in field trials. Further, U.S. soybean acreage is projected to remain relatively steady until 2021/2022, accompanied by an anticipated 8% per acre yield gain. Field price of soybean per bushel is not expected to appreciably increase, remaining between $10.30 and $11.35 per bushel, while annual net value of production is expected to increase. Because yield is highly variable year to year and from field to field, the yield benefits of MON 87712-4 soybean would not be readily apparent, likely slowing its adoption. Finally, MON 87712-4 soybean would also compete with other high yielding soybeans conventionally bred with GE herbicide- and pest-resistant traits, and conventional, and organic soybean varieties, thus its maximum market potential is estimated at 50-60% (Monsanto, 2011).

As discussed in Subsection 2.6.1, Domestic Economic Environment, GE seed is generally more expensive than conventional seed; producers using MON 87712-4 soybean would likely be charged a premium technology fee in addition to those fees for other traits as part of the seed purchase price (NRC, 2010). Technology fees are charged by the product developer to cover research and development, production, marketing and distribution expenses. The amount of the fee is determined by producers' willingness to purchase the seed, the competiveness of the seed market and the pricing behavior of firms that hold large shares of the market (NRC, 2010). APHIS has no control over the establishment of technology fees, but assumes that the fee for MON 87712-4 soybean would be consistent with the fee charges for other GE crops. Growers must make an independent assessment as to whether the benefits of MON 87712-4 soybean would offset higher seed cost. As discussed under the No Action Alternative, an approximately 3% rise in seed and residual costs is projected from 2013/2014 to 2021/2022 (USDA-OCE, 2012).

While the MON 87712 soybean trait has a similar phenotype to conventionally bred traits for increased yield, these other traits are different because they are most likely derived from multi-gene inheritance. Selection and incorporation of such multigenic traits are more complicated for seed developers to develop and incorporate, and therefor, the employment of this Monsanto trait is likely to provide significant benefits in efficiency of seed and trait production. Also, it is possible that when the MON 87712 trait is combined with these conventionally derived traits an additive yield enhancement may be attained, although the opposite or no effect is possible as well. Because of uncertainties in what the developer may do and the unknown yield consequence, it is not possible to predict whether an overall increased yield might be attained in such combinations.

As discussed in Subsection 2.1.4, Organic Soybean Production, only a small portion of the U.S. soybean market is organic. The value of soybean produced from organic-certified farms in the United States in 2011 was about $49.4 million, which was 0.14% of the total soybean crop value (USDA-NASS, 2012j; USDA-NASS, 2012a). Organic production of grain in the United States remains low, with only about 0.20% of corn and soybean crops grown under certified organic farming systems (USDA-ERS, 2009b). Between 1997 and 2005, overall organic crop acreage doubled; however, between 2000 and 2005 acreage for organic grain such as soybean and corn declined (USDA-ERS, 2009b). The lack of growth in organic grain production in the United States has been associated with financial, managerial, transitional, marketing, and several other risk factors (Wolf, 2006; Yeager, 2006; House Hearing -110 Congress, 2007). The availability of MON 87712-4 soybean is another option for farmers to achieve increased productivity and is not expected to influence growers' decisions to pursue organic soybean production.

Recent attitudes towards the production of GE crops in the United States are generally favorable (see Subsection 2.6.1, Domestic Economic Environment) (USDA-ERS, 2001; Thomson-Reuters, 2010). It is not expected that an additional GE soybean variety potentially increasing farm productivity without altering soybean's nutritional value, potential allergenicity, or toxicity would change U.S. consumer attitudes towards GE crops.

Based upon the preceding information, the potential domestic economic impacts from a determination of nonregulated status of MON 87712-4 soybean would be no different than those currently observed for other high yielding soybean varieties under the No Action Alternative.

4.7.2 Trade Economic Environment

No Action Alternative

In 2012, 93% of planted soybean acres were GE varieties (USDA-ERS, 2012e). In the same year, the United States was responsible for 33.9% of the world's soybean production, 19.8% of world's soybean meal production, and 20.1% of the world's soybean oil production (USDA-ERS, 2012b). Global exports of soybeans are expected to increase by approximately 19.3 MMT over the next ten years (FAPRI, 2011). Over the next decade, Argentina, Brazil, and the United States will account for about 88% of the world's exports of soybean and soybean products; however, by 2012, the U.S. share is expected to decline from just over 30% to about 25% (USDA-OCE, 2012). China is expected to account for 68.8% of imports, with the EU-27 having the next greatest demand accounting for 10.0% of imports (FAPRI, 2011). The USDA-OEC (2012) predicts that soybean and soybean-product trade would be maintained throughout the next decade considering ongoing demand for vegetable oil and protein meal, particularly from China and other Asian countries. Under the No Action Alternative, it is unlikely the current soybean market trade trends would change if MON 87712-4 soybean remained regulated. U.S. soybeans will continue to play a role in global soybean production, and the United States will continue to be a supplier in the international market (USDA-ERS, 2013b).

Preferred Alternative

A determination of nonregulated status of MON 87712-4 soybean is not expected to adversely impact the current trends affecting the trade economic environment. Commercial availability of MON 87712 could have an initial but indeterminable impact on the potential for increased yields; these yields could increase gradually as availability and adoption of the trait increased. As discussed in Subsection 4.7.1.2, Preferred Alternative: Domestic Economic Environment, field trials of MON 87712-4 soybean had a statistically higher yield than the conventional control A3525, yet it was similar to yields documented for other high-yield conventional soybean varieties, and is subject to the same variables that impact yield. If the developer frequently incorporates this trait into many varieties, if adoption of the trait is high, and conditions in fields are supportive of additional soybean productivity for MON 87712-4, then there are possibilities for modest increases in overall U.S. soybean production (see Subsection 4.7.1.2, Preferred Alternative: Domestic Economic Environment).

Overall increased farm productivity, such as increased soybean production, may increase U.S competitiveness in the global economy. USDA projects that from 2013/2014 to 2021/2022, the national annual average of U.S. soybean yield is expected to increase approximately 8% without expanding acreage, but the U.S. average farm price per bushel of soybean is predicted to vary only between $10.30 and $11.35. Grower annual net returns per acre are estimated to increase on average approximately 24% over the same period, despite an estimated approximately 3% rise in seed and residual costs, and 10.3% rise in overall per acre cost of production (USDA-OCE, 2012). Adoption of MON 87712-4 soybean would likely be gradual, dependent upon the speed of introduction of the trait by Monsanto, and upon the value growers place on a higher than average yielding soybean cultivar. A gradual increase in soybean production would be beneficial for US competitiveness, but an immediate large increase could potentially reduce world prices for soybean and the return to growers, both domestic and international.

As discussed in Subsection 2.6.2, Trade Economic Environment, there are several factors that influence worldwide prices for oilseed, including soybean and its products. Included in these are energy costs, the value of the U.S. dollar, government policies, population, per capita income, global market conditions, and trends and practices in market trading and speculation (Trostle, 2008b; Trostle, 2008a; Irwin and Good, 2009). Whether any value derived from MON 87712-4 soybean would be distributed between consumers in the form of reduced prices or growers as increased profits would be dependent upon the previously cited global factors. Any impact to soybean market prices from the potential increase to yield from the production of MON 87712-4 soybean, on top of the gradual increase in US soybean yield would likely be difficult to assess or predict.

The Organisation for Economic Co-Operation and Development and the Food and Agriculture Organization of The United Nations anticipate that much of the future expansion of soybean production will derive from methods that increase yield rather than from increased area of production (OECD-FAO, 2008). Exported soybean seed for planting is a small share of U.S. soybean exports; in 2009, the value of soybean planting seed exports were about 0.11% of the value of bulk soybean and soybean product exports ($17.5 million and $17.6 billion respectively) (USDA-FAS, 2009; USDA-ERS, 2012l). MON 87712-4 soybean seed could be of interest to other countries that also produce and export soybean.

Monsanto plans to seek biotechnology regulatory approvals for MON 87712-4 soybean from all key soybean import countries that have a functioning regulatory system (Monsanto, 2011). In order to ensure global compliance and support the flow of international trade, these actions will be in accordance with the Biotechnology Industry Organization Policy on Product Launch[10]. Monsanto has submitted applications to several international agencies, including the regulatory authorities in Canada; the Ministry of Agriculture, People's Republic of China; Japan's Ministry of Agriculture, Forestry, and Fisheries, Ministry of Environment, and the Ministry of Health, Labor, and Welfare; the Intersectoral Commission for Biosafety of Genetically Modified Organisms, Mexico; and the European Food Safety Authority, as well as other soybean importing countries with a functioning regulatory system (Monsanto, 2011). Approval in these export countries is intended to mitigate global sensitivities to GE products and work in

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[10] Available at http://www.excellencethroughstewardship.org/LinkClick.aspx?fileticket=U8SEhLYSZYA%3D&tabid=62

accordance with international regulations. Timely compliance with these agencies will also prevent adverse effects on trade. While some countries do not assess GE crops from the United States until non-regulated status has been determined in the United States, APHIS does not otherwise have an influence on countries to which crops are exported.

It is not expected that the availability of MON 87712-4 soybean would affect world attitudes towards GE crops. While 28 other countries have adopted the use of GE crops (Clive, 2011), consumers in many countries, such as several EU-27 countries, believe the potential risks posed by GE crops outweigh any potential benefits they may provide (Costa-Font et al., 2008). However, the EU has approved GE soybean food and feed products containing traits conferring resistance to glufosinate, glyphosate, and ALS-inhibiting herbicides and certain lepidopteran resistance for import for food and feed use in EU-27 countries (European Commission, 2013). It is expected food and feed derived from MON 87712-4 soybean would likely be approved by the EU as well since the cultivar has been genetically modified for increased yield using only a plant gene from *A. thaliana.* This gene expressing the BBX32 protein has homologs in common food plants such as broccoli, cauliflower, cabbage, and canola with a history of safe use (USDA-NRCS, 2013c).

The adventitious presence of GE products in other food or feed continues to be a concern of internationally traded grain (Demeke et al., 2005). Monsanto performs quality control tests of their products to ensure traits such as MON 87712-4 would not be inadvertently incorporated into commodity soybean before necessary foreign approvals. Similarly, buyers, foreign governments, nongovernmental organizations, and consumer groups may use private testing firms to mitigate against the potential for adventitious presence of GE traits in food or feed products. Monsanto has indicated tests to determine the presence of the BBX32 gene in seed stock would be available and easily accomplished.

In conclusion, the potential impacts to the trade economic environment from a determination of nonregulated status of MON 87712-4 soybean would be no different than those currently observed for other high yield soybean varieties under the No Action Alternative.

5 CUMULATIVE IMPACTS

5.1 Assumptions Used for Cumulative Impacts Analysis

Cumulative effects have been analyzed for each environmental issue assessed in Section 4, Environmental Consequences. In this EA, the cumulative effects analysis is focused on the incremental impacts of the Preferred Alternative taken in consideration with related activities including past, present, and reasonably foreseeable future actions. Certain aspects of this product and its cultivation would be no different between the alternatives; those instances are described below. In this analysis, if there are no direct or indirect impacts identified for a resource area, then APHIS assumes there can be no cumulative impacts. Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential cumulative impacts. APHIS will limit the analysis of cumulative impacts to the areas in the U.S. where soybean is commercially produced.

A potential for reasonably foreseeable cumulative effects is analyzed under the assumption that farmers, who produce conventional or organic soybean and those who plant MON 87712-4 soybean would continue to use reasonable, commonly accepted BMPs for their chosen production method using favored traits. APHIS recognizes, however, that not all farmers will use such BMPs; thus, the cumulative impact analysis will also make the assumption that not all farmers would do so.

Crop varieties that contain more than one GE trait, known as a “stacked” hybrid, are currently found in agricultural production and in the marketplace. If APHIS approves the nonregulated status of MON 87712-4 soybean, it would likely be combined with non-GE and GE soybean varieties through traditional breeding techniques. Stacking of nonregulated GE crop varieties using traditional breeding techniques is common industry practice and is not regulated by APHIS. Stacking would involve combining MON 87712-4 soybean with other soybean varieties having GE traits such as herbicide resistance, non-GE pest resistance, altered nutritional characteristics (e.g. high oleic acid), which are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Such stacked varieties could provide growers with several options such as combining several herbicides with different modes of action for control of weeds; therefore, as part of the cumulative impacts analysis, APHIS will assume that MON 87712-4 soybean would likely be combined with commercially available herbicide-resistant, non-GE pest-resistant, or altered nutritional profile varieties of soybean as a reasonably foreseeable future action. This intention is also provided by Monsanto in the petition for determination of nonregulated status (Monsanto, 2011).

5.2 Cumulative Effects

5.2.1 Past and Present Actions and the Preferred Alternative

In the preceding analysis, the potential impacts from a determination of nonregulated status to MON 87712-4 soybean were assessed. The agronomic characteristics evaluated for MON 87712-4 soybean encompassed the entire life cycle of the soybean plant and included germination, seedling emergence, growth habit, vegetative vigor, days to pollen shed, days to maturity, and yield parameters. The compositional analysis included the proximates (moisture, carbohydrates, protein, fat, and ash), fiber, vitamin E, amino acids, fatty acids, antinutrients and nutritional impact in seed and proximates and fiber in forage. Except for its enhanced yield potential, MON 87712-4 soybean is agronomically and compositionally similar to its non-GE comparator A3525, as well as other GE and non-GE soybean varieties (Monsanto, 2011; USDA-APHIS, 2011a). Although MON 87712-4 soybean yielded 7.3% more that its comparator variety, this yield was still within the range of other high yield conventional soybeans; therefore, as determined in Section 4, Environmental Consequences, the potential impacts under the Preferred Alternative for all the resource areas analyzed would be the same as those described for the No Action Alternative.

Agricultural Production of Soybean

Neither the No Action nor the Preferred Alternative are expected to directly cause a measurable change in agricultural acreage or area devoted to conventional or GE soybean cultivation or soybean grown for seed in the U.S. (see Subsections 4.2.1, Acreage and Area of Soybean Production, and 4.2.3, Soybean Seed Production). Total U.S. cropland has remained relatively steady since the mid-20th century, and growth in soybean acreage has been in place of other crops on existing cropland (USDA-ERS, 2011e). The majority of soybean grown in the U.S. is already GE and herbicide resistant (USDA-ERS, 2012e). Long-term projections show planted soybean acreage would hold steady at 76 million acres from 2013/2014 to 2021/2022 (USDA-OCE, 2012), about the same as the 77.2 million acres planted to soybean in 2012 (USDA-NASS, 2012h). It is expected MON 87712-4 soybean would replace other similar GE cultivars without expanding the acreage or area of soybean production. MON 87712-4 is agronomically and compositionally similar to other commercially available soybean cultivars (including other high yield soybean varieties), is subject to the same variables that influence yield as other varieties, and would continue to have yield variability from year to year similar to other cultivars. There are no anticipated changes to the availability of GE and non-GE soybean varieties on the market under either alternative. The Preferred Alternative, therefore, would have no impacts to acreage or area of soybean production and soybean grown for seed different than the No Action Alternative.

Based upon recent trends, adding GE varieties to the market has no relationship to the ability of organic production systems to maintain their market share (see Subsection 4.2.4, Organic Soybean Production). As described above, the majority of U.S. soybean planted in 2012 was GE and herbicide resistant (USDA-ERS, 2012e). Since 1996, 11 GE soybean events or lines have been determined by APHIS to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (USDA-APHIS, 2013). U.S. organic soybean production acreage grew 53% from 82,143 acres in 1997 to 126,000 acres in 2008, declining 24% to 96,080 acres in 2011 (USDA-ERS, 2010a; USDA-NASS, 2012a), which was approximately 0.09% of total U.S. soybean acreage in 2011 (USDA-NASS, 2012a). Availability of another GE soybean that does not express a herbicide resistant trait or that is a high yield soybean variety, such as MON 87712-4 soybean under the Preferred Alternative, is not expected to impact the organic production of soybean more than any other GE or high yield variety. Under the No Action Alternative, APHIS concludes from past and present empirical evidence that no such impact on organic production has been demonstrated.

Under the Preferred Alternative, extending a determination of nonregulated status to MON 87712-4 soybean is not expected to result in changes to current soybean cropping practices including those for tillage, fertilization, irrigation, pest and disease control measures, crop rotation, or irrigation. Studies conducted by Monsanto demonstrate that, in terms of agronomic characteristics and cultivation practices, MON 87712-4 soybean is similar to other soybean varieties currently grown. However, like any other high yielding soybean or high yield production system utilizing conventional soybean, MON 87712-4 soybean does deplete more potassium and phosphorous in soil (Monsanto, 2011; USDA-APHIS, 2011a). Supplementing soybean with nutrients is not uncommon (USDA-NASS, 2007a). As discussed in Subsection 2.1.2.4, Agronomic Inputs, in 19 states surveyed in 2006, potassium was applied to an average of 25% of planted soybean acres and phosphate to an average of 23% of planted soybean acres (USDA-NASS, 2007a). Approximately 95% of the soybean-planted acreage since 1991 has been in some form of crop rotation (USDA-ERS, 2005). Approximately 68.6% of soybean acreage is rotated to corn in the United States, with the next most frequent rotating crops being soybean and wheat (Monsanto, 2010a). In two-year corn-soybean rotations, enough potassium and phosphorus amendments are commonly applied to the corn crop to sustain the soybean crop the following year without additional supplementation (Bender et al., 2013). By contrast, these nutrients are commonly applied annually in soybean-soybean rotations that predominate in the South (Heatherly, 2012). Soybean typically removes approximately 65 1b/ac of potash (potassium) and 42 1b/ac of phosphate (phosphorus) for a typical 50 bushel per acre yield, while corn removes approximately 50 1b/ac of potassium and 77 1b/ac of phosphorus for a typical 180 bushels per acre yield (Fernandez, 2010), and wheat removes 17 1b/ac of phosphorous and 29 1b/ac of potassium for an average 46 bushel per acre yield (Silva, 2011). Testing soil fertility and supplementing nutrients if indicated is widely recommended in soybean production to achieve optimal yield potential (Snyder, 2000; Specht et al., 2006; Pedersen, 2008; CAST, 2009a; Mallarino et al., 2011; Silva, 2011). Consequently, no changes to current or foreseeable soybean cropping practices such as tillage, crop rotation, or agricultural inputs associated with the adoption of MON 87712-4 soybean are expected (see Subsection 4.2.2, Agronomic Practices), thus, no cumulative impact to the agronomic production of soybean would occur.

Physical Environment

As discussed in Subsection 4.3, Physical Environment, a determination of nonregulated status for MON 87712-4 soybean under the Preferred Alternative would have the same potential impacts to water, soil, air quality, and climate change as that of other nonregulated GE and conventional soybean varieties presently available. Agronomic practices that have the potential to impact soil, water and air quality, and climate change such as tillage, agricultural inputs (fertilizers and pesticides), and irrigation would not change because MON 87712-4 soybean is agronomically and morphologically similar to other GE and non-GE soybean, including high yield varieties. Other practices that benefit these resources, such as contouring, use of cover crops to limit the time soil is exposed to wind and rain, crop rotation, and windbreaks would also be the same between the No Action and Preferred Alternatives. Because of its similarity to other commercially available soybean, including high yield varieties, adoption of MON 87712-4 soybean in place of other similar cultivars would not change the acreage or area of soybean production. As of 2012, 93% of U.S. soybean acreage was already planted with GE varieties, and replacement of one similar variety for another would not additively impact water, soil, air quality, or climate change. No difference would occur in impacts to these resources between the Preferred and No Action alternatives.

Biological Resources

The impacts of the Preferred Alternative to animal and plant communities, microorganisms, and biodiversity as discussed in Subsection 4.4, Biological Resources would be no different than those experienced under the No Action Alternative. MON 87712-4 soybean is both agronomically and compositionally similar to its comparator A3525 and other nonregulated GE and conventional soybean. Further, it would not require any different agronomic practices to cultivate, and does not represent a safety or increased weediness risk different from other currently available soybean varieties.

There are no differences in the potential for gene flow and weediness between the No Action and Preferred alternatives. The reproductive characteristics of MON 87712-4 soybean are substantially equivalent to other GE and non-GE soybean varieties (Monsanto, 2011). The trait for increased yield is not expected to contribute to increased weediness without changes in a combination of other characteristics associated with weediness. Such changes could include expression of hard seed and development of dormancy and of seed shattering, among other traits. Given the self-pollinating nature of soybean and its limited ability to disperse pollen over large distances, the potential for cross pollination of MON 87712-4 soybean with other soybean cultivars is highly unlikely. No feral or weedy species of soybean exist in the United States (Ellstrand et al., 1999; OECD, 2000), and MON 87712-4 soybean poses no potential for either naturally occurring, pollen-mediated gene flow or transgene introgression (USDA-APHIS, 2011a). Gene flow by seed dispersal is equally unlikely. If present as volunteer soybean, MON 87712-4 soybean would not be considered difficult to control, as soybean seeds rarely remain viable the following season and are easily managed with cultivation or hand weeding, or the application of herbicides. The risk of gene flow and weediness of MON 87712-4 soybean is no greater than that of other conventional and nonregulated GE soybean varieties.

Human Health and Animal Feed

Food and feed derived from GE soybean must be in compliance with all applicable legal and regulatory requirements and may undergo a voluntary consultation process with the FDA prior to release onto the market to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food. As discussed in Subsections 4.5, Human Health and 4.6, Animal Feed, MON 87712-4 soybean would have no toxic effect on human health or livestock. Monsanto has submitted a safety and nutritional assessment of food and feed derived from MON 87712-4 soybean to the FDA and their decision is pending. It will be posted on the FDA website Final Biotechnology Consultations http://www.fda.gov/Food/Biotechnology/Submissions/ucm225108.htm when completed. No change in food and feed safety would occur between the Preferred and No Action alternatives.

Socioeconomic

As discussed in Subsection 4.7, Socioeconomic Impacts, it is unlikely the availability of MON 87712-4 soybean would significantly impact the domestic economic environment. Past and recent growth in U.S. soybean acreage has occurred at the expense of other crops and from double-cropping, not by bringing new lands into production (USDA-ERS, 2011f). Overall total U.S. cropland has remained relatively stable since the mid-20th century (USDA-ERS, 2011e) . MON 87712-4 soybean is expected to replace other GE soybean varieties on existing cropland since 93% of U.S. soybean acreage is already planted with GE soybean varieties (USDA-ERS, 2012e), and combined trials have demonstrated it is phenotypically and agronomically similar to other soybean varieties, including high yielding cultivars. Conventional high-yield soybean varieties currently available from several seed companies include Albert Lea Seeds' Sheyenne and Viking lines; several D.F. Seeds' varieties; and eMerge Genetics' 348.TCS, e3782s, e45120s, and e5110 varieties) (Advantage Seeds, 2005; D.F. Seeds, 2011; Albert Lea Seeds, 2012; eMerge, 2012). Selective breeding of conventional soybean varieties also is accomplished through State University Extension Services such as Ohio State University, Kansas State University, North Carolina State University, University of Arkansas, and University of Missouri (Pierzynski, 2009; North Carolina Soybean Producers Association, 2010; Shannon et al., 2010; The Ohio State University, No Date; University of Arkansas, No Date). Currently available high yielding soybean cultivars with herbicide or non GE pest resistance or the combination of traits include Genuity Roundup Ready 2 Yield® (Monsanto), Liberty Link® (Bayer), and T Series® (Pioneer), to name a few. Although field tests conducted by Monsanto found MON 87712-4 soybean had a 7.3% higher yield than its comparator A3525 cultivar (Monsanto, 2011), its productivity is well within the range of other commercially available conventionally bred high yield varieties. For example, the world record for soybean yield was achieved in Missouri in 2010 at 160.6 bushels per irrigated acre and 98.9 bushels per acre for non-irrigated soybean using a conventionally bred soybean cultivar with transgenic herbicide- and pest-resistant traits (Alsager, 2010). Breeding the MON-87712-4 soybean trait into conventional soybean lines may increase soybean production yields for some varieties, but other similar conventional and GE high-producing conventional varieties are already commercially available; no significant cumulative impact to the domestic economic environment is expected.

Historically, soybean yields have been increasing for decades, in more recent times as a result of conventionally bred high yielding cultivars with GE herbicide- and non-GE pest-resistant traits, in addition to improved management practices (Specht et al., 2006; Pedersen, 2008). Further, U.S. soybean acreage is projected to remain relatively steady until 2021/2022, along with an anticipated 8% per acre yield gain. Despite potential increased production, elevator price for soybean per bushel is not expected to appreciably change, remaining between $10.30 and $11.35 per bushel, while annual production net value is expected to increase (USDA-OCE, 2012). Soybean supply is a function of the amount of acreage planted to soybean and yield. While domestic soybean yield has recently increased primarily without increasing production acreage, demand for soybean products has also increased, mitigating any downward pressure on farm soybean prices from potentially increased supply (NRC, 2010).

Nonregulated MON 87712-4 soybean is not expected to adversely impact the current trends affecting the seed, feed or food trade and may have a negligible impact through increased yields. Apart from its increased yield potential, MON 87712-4 soybean is essentially indistinguishable from other soybean cultivars in terms of agronomic, morphologic, and compositional characteristics (Monsanto, 2011). As discussed in Subsection 4.7.2, Trade Economic Environment, increased farm productivity from adoption of MON 87712-4 soybean may increase U.S competitiveness in the global economy, although many other factors affect worldwide prices for soybean, including energy costs, the value of the U.S. dollar, government policies, population, per capita income, global market conditions, and trends and practices in market trading and speculation (Trostle, 2008b; Trostle, 2008a; Irwin and Good, 2009). How any value derived from MON 87712-4 soybean is distributed between consumers in the form of reduced prices and growers as increased profits would be subject to these factors. Based upon the above information, any impact to soybean market prices from the potential increase to yield from the production of MON 87712-4 soybean would be negligible.

Because yield is highly variable year to year and from field to field, the yield benefits of MON 87712-4 soybean may be masked and not be as readily apparent as, for example, an herbicide-resistant soybean; this would likely slow its adoption, further alleviating potentially significant impacts to the domestic socioeconomic environment. MON 87712-4 soybean would also compete with other high yielding soybeans conventionally bred with GE herbicide- and non-GE pest-resistant traits, and conventional, and organic soybean varieties. Maximum market potential has been estimated at 50-60% (Monsanto, 2011).

Additionally, since MON 87712-4 soybean is agronomically and compositionally similar to other commercially available soybean, there would be no major changes to agronomic inputs or practices from approving the nonregulated status of MON 87712-4 soybean. Consequently, no impacts to on-farm costs for soybean producers or the domestic economic environment are foreseen, including none to the organic soybean market. Like any other high yielding soybean cultivar or soybean grown in high yield production systems, MON 87712-4 soybean has been shown to deplete potassium and phosphorous in soil to a greater extent than other varieties. But as discussed above, supplementation of these nutrients in soybean production is not uncommon, and soil fertility testing and supplementation as indicated by tests and known crop soil nutrient removal rates is widely recommended in soybean production to achieve yield potential (Snyder, 2000; Specht et al., 2006; Pedersen, 2008; CAST, 2009a; Mallarino et al., 2011; Silva, 2011). Advances in soybean yield have been attributed to development of conventionally bred higher yield varieties that also have GE herbicide and pest resistance. Empirical evidence shows that yield is also a consequence of good management practices, including early efforts to manage soybean cyst nematodes, optimizing planting time, recognizing optimal row spacing, providing sound weed management, scouting for pests, and ensuring appropriate soil fertility (Pedersen, 2008).

It is expected adoption of MON 87712-4 soybean would not impact the cost of U.S. soybean production any differently than those following the release of other GE soybean seed in the past. GE seed is generally more expensive than conventional seed; and producers using MON 87712-4 soybean would likely be charged a technology fee for this trait, as well as accompanying traits and are all part of the seed purchase price (NRC, 2010). APHIS has no insight into rationales for the establishment of technology fees, but assumes that the fee for MON 87712-4 soybean would be consistent with the fee charges for other GE crops. Growers would make an independent assessment as to whether the benefits of MON 87712-4 soybean would offset higher seed cost. USDA projections from 2013/2014 to 2021/2022 anticipate an approximate 3% rise in seed and residual costs (USDA-OCE, 2012) .

The availability of MON 87712-4 soybean as another option for U.S. farmers to achieve increased productivity is not expected to influence growers’ decision to pursue organic soybean production. As discussed in Subsection 2.1.4, Organic Soybean Production, only a small portion of the U.S. soybean market is organic. Between 2000 and 2005 acreage for organic grain such as soybean and corn declined (USDA-ERS, 2009b), attributed to financial, managerial, transitional, marketing, and several other risk factors (Wolf, 2006; Yeager, 2006; House Hearing -110 Congress, 2007). As discussed above in cumulative impacts to organic soybean production, adding GE varieties to the domestic market is not related to the ability of organic production systems to maintain their market share. A determination of nonregulated status of MON 87712-4 soybean would not impact the organic soybean market any differently than did previously released GE soybean varieties.

Additionally, it is anticipated that an additional GE soybean variety potentially increasing U.S. farm productivity without altering soybean's nutritional value, potential allergenicity, or toxicity would not change U.S. consumer attitudes towards GE crops. Overall, impacts of the Preferred Alternative on the domestic economic environment would therefore be no different than experienced under the No Action Alternative.

Under the No Action Alternative, if the request to determine MON 87712-4 soybean nonregulated were not approved, it would not be available to other countries or to the the United States buyers. This consequence would not likely impact U.S. trade as it has no value-added benefit to purchasers. On the other hand if nonregulated MON 87712-4 soybean gains approval in other countries, it would still be unlikely that this action would impact the U.S. economic trade environment. Other countries are increasing their production of GE herbicide-resistant soybean, and an exceptionally high yield variety may make production costs decline, and thus offer benefits to growers who participate in U.S. international soybean trade. However, there is no assurance that yields from this trait will be markedly larger than that from other varieties with increased yield traits. As of publication of this EA, Monsanto is in the process of submitting applications to other major soybean producing countries for import clearance and production approval of MON 87712-4 soybean.

Under the Preferred Alternative, it is possible MON 87712-4 soybean would not be approved for import into other countries. Because the United States and other countries already have access to other high yield soybean cultivars, and MON 87712-4 soybean presents another option of high yield soybean similar to cultivars already in the marketplace, its availability only to U.S. producers would not likely significantly impact the economic trade environment. In 2011/2012, 42% of domestically produced U.S. soybean was dedicated to the export market (USDA-ERS, 2012f). If MON 87712-4 soybean was not approved for import by other countries but would be approved as nonregulated in the United States, it would not likely affect the supply of U.S. soybean eligible for import to other countries. Likewise, if it were approved both in the United States and for import by other countries, based on its similarity to other high yield soybean cultivars and the likelihood it would replace other such cultivars without increasing the acreage or area of soybean production, MON 87712-4 soybean would still be unlikely to affect the supply of U.S. soybean available for export.

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

5.2.2 Reasonably Foreseeable Actions

In the event of a nonregulated determination, MON 87712-4 soybean could be combined (stacked) with non-GE and GE soybean varieties using traditional breeding techniques. While stacking of nonregulated GE crop varieties using traditional breeding techniques is common practice, stacked varieties of GE soybeans have only recently been developed (i.e., stacked MON 87701 insect-resistant and MON 89788 glyphosate-resistant variety (Intacta® Roundup Ready® 2 Pro) approved for use in several countries beginning in 2010 (ISAAA, 2013)). The first GE soybean (Monsanto GTS 4-30-2 glyphosate resistant) was determined to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act in 1994 and was commercially available in 1996 (see APHIS Petition File 93-258-01p at http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml). As of 2012, 93% of the soybean planted in the United States was GE, all of which was herbicide resistant (USDA-ERS, 2012e).

MON 87712-4 soybean would be a GE improved yield soybean cultivar that could be stacked like other non-GE improved yield varieties. Potential future stacking of MON 87712-4 soybean might include development of hybrids using other currently available nonregulated soybean varieties expressing tolerance to herbicides, varieties expressing resistance to select insect pests, or varieties with improved or modified fatty acid profiles. APHIS regulations under 7 CFR part 340 do not provide for Agency oversight of stacked varieties combining GE varieties with previously approved nonregulated status, unless it can be positively shown that such stacked varieties are likely to pose a plant pest risk. Whether MON 87712-4 soybean would be stacked with any particular nonregulated GE variety is unknown, as company plans and market demands play a significant role in those business decisions. In addition, the adoption level of MON 87712-4 soybean would depend on the extent producers value the traits offered by stacked versions of MON 87712-4 soybean over other available soybean varieties.

Agricultural Production of Soybean

The potential future development and cultivation of MON 87712-4 soybean increased yield soybean stacked with other GE traits is not likely to change the area or acreage of soybean production. The future expansion of soybean production will likely be from methods that increase yield rather than increased area of production (OECD-FAO, 2008). In addition, U.S. soybean production acreage projections to 2021/2022 predict it would remain relatively stable at approximately 76 million acres, close to recent levels (USDA-OCE, 2012).

As discussed in Section 4.2, Agricultural Production of Soybean, MON 87712-4 soybean is essentially the same as other commercial soybean varieties in terms of agronomic characteristics and cultivation practices (Monsanto, 2011; USDA-APHIS, 2011a). As such, it is not expected that stacking MON 87712-4 soybean with other nonregulated GE varieties would change the agronomic practices associated with those GE soybean traits such as herbicide resistance.

Similarly, the majority of U.S. soybean acres are planted with GE varieties while acreage planted with organic soybean has remained small, fluctuating between 96,080 and 126,000 acres between 2005 and 2011 (see Subsection 4.2.4, Organic Soybean Production). The adoption of MON 87712-4 soybean stacked with other GE varieties may replace other GE varieties, but would not be expected to change production of organic soybean.

Like any other high yielding soybean cultivar or soybean grown in high yield production systems, MON 87712-4 soybean has been shown to deplete potassium and phosphorous in soil more than other varieties. But as discussed in Subsection 5.2.1.1, Agricultural Production, supplementation of these nutrients in soybean production is not uncommon (USDA-NASS, 2007a), and soil fertility testing and supplementation as indicated by tests and known crop soil nutrient removal rates is widely recommended in soybean production to achieve yield potential (Snyder, 2000; Specht et al., 2006; Pedersen, 2008; CAST, 2009a; Mallarino et al., 2011; Silva, 2011). Upon adoption it is expected MON 87712-4 soybean would be grown in rotation with other crops such as corn, soybean-soybean in two-year rotations or double-cropping, and with wheat, and other crops depending upon area of the United States (Monsanto, 2010a). To gain economic efficiency, fertilization of a preceding corn crop is usually supplemented at a level that would support the following soybean crop, but recent research has shown higher yielding corn varieties may remove more phosphorous than is applied on average, and soil fertility testing prior to soybean planting is recommended (Bender et al., 2013). In the south where soybean to soybean rotation is more common, soil fertilizer is applied annually (Heatherly, 2012). For double-cropping of soybeans after wheat or the corn-soybean-wheat and corn-soybean-wheat doublecrop soybean, it is recommended phosphorous be supplemented before corn in the two rotations and again before wheat in the four crop rotation (PPI, 2003). In conservation tillage soybean production, Fernandez and White (2012)note an increasing trend to employ strip tillage with deep subsurface fertilizer delivery; soil fertility is improved while the benefits of undisturbed soil as in no-till are preserved (Fernandez and White, 2012). Because recent research has found agricultural soil fertility in the United States and Canada is declining, regular testing and use of improved techniques to attain adequate supplementation is recommended and being accomplished by growers (Fixen et al., 2010). On this basis, the cultivation of MON 87712-4 soybean would not require any change to fertilization practices in soybean production.

Physical Environment

The potential effects from the cultivation of other stacked GE crops (including soybean) to use of pesticides have been evaluated in other EAs by APHIS. For example, glyphosate, glufosinate and other herbicide resistance and resistance to insects have been thoroughly evaluated in other APHIS EAs since the 1994 introduction of a glyphosate-resistant soybean, and since the first insect-resistant crop (potato) in 1994 (see list of pending and previously approved GE crops at http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml). The total amount of the mix of pesticides that may be applied to varieties of MON 87712-4 soybean stacked with herbicide-resistant varieties would be limited by the total application approved by EPA for a registered or exempted herbicide and would be no different than the application rate already approved for use on currently nonregulated varieties of stacked herbicide-resistant soybean cultivars. In addition, MON 87712-4 soybean engineered for higher yield may also be stacked with dicamba-resistant MON 87708 soybean pending determination of nonregulated status (Monsanto, pers. comm. October 2012); however, as stated above, the authorized amount or application rate of dicamba approved for use on MON 87708 soybean would not likely differ in a stacked product containing the MON 87712-4 soybean enhanced yield trait. When used consistent with the label, the potential risks from the application of pesticides to stacked MON 87712-4 soybean varieties to the physical environment could increase. However, substantial impact would not occur because EPA will have determined whether environmental effects of application of an approved herbicide would or would not be likely to cause unreasonable harmful impacts on the environment. In addition, there would be no changes to currently authorized pesticide tolerance levels for stacked varieties of MON 87712-4 soybean.

Biological Resources

As discussed under Physical Resources, the potential impacts from the cultivation of other GE soybean traits with which MON 87712-4 soybean could be stacked have been thoroughly evaluated by APHIS. In addition, the amount of herbicides that may be applied to varieties of MON 87712-4 soybean stacked with herbicide-resistant soybean would be limited to the total application approved by EPA for a registered or exempted herbicide. Potential risks to biological resources from the application of pesticides to stacked MON 87712-4 soybean varieties would be no different than that presented by GE herbicide-resistant soybeans without the MON 87712-4 high yield trait when used in accordance with label instructions.

Under a determination of nonregulated status, MON 87712-4 soybean could potentially be stacked with another herbicide resistant trait. Currently, Monsanto is requesting determination of nonregulated status for a dicamba resistant soybean, and this could be potentially stacked with MON 87712-4 soybean. Other herbicide stacked traits such as glufosinate resistance, are conceivable, although no plans have been described by Monsanto for that option. Stacking could be done in future insect-resistant varieties although that is not the intention of U.S. developers who are presently planning for only the international use of some of these traits, such as that expressed in lepidopteran-resistant DAS-81419-2 soybean. Any insect-resistant trait that may be developed in the future and stacked with MON 87712-4 soybean using standard genetic crosses would be subject to EPA approval. APHIS and FDA would have assessed the traits previously, so that developers would be free to construct new varieties from them. No adverse cumulative effects of stacking the deregulated traits on biological resources are likely. The adoption of stacked MON 87712-4 soybean would be contingent on the extent growers see value in the traits expressed in comparison to other commercially available soybean cultivars with similar traits.

Human Health and Animal Feed

The potential effects to Human Health and Animal Feed from the cultivation of GE herbicide-resistant soybean varieties with a nonregulated status with which MON 87712-4 soybean may be stacked have already been evaluated in previous EAs. Additionally, future GE soybean varieties would be subject to the same process prior to a determination of nonregulated status. As discussed in Section 4.5, Human Health and Section 4.6, Animal Feed, when evaluating the potential consequences that may result from a determination of nonregulated status of a GE crop, USDA-APHIS considers the EPA's registration of pesticides. The environmental risks of pesticide use are assessed by EPA in the pesticide registration process and are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. As part of the registration process, the EPA considers human health effects from the use of pesticides and must determine that the pesticide will not cause unreasonable adverse effects on human health. Worker safety is also taken into consideration by EPA in the pesticide registration process and reregistration process. The application rate of various herbicides that may be applied to MON 87712-4 soybean or subsequent varieties derived from it would be limited to those rates approved by EPA by single application and yearly total. When used consistent with the EPA label, pesticides present minimal risk to human health and worker safety. Pesticide residue tolerances for pesticides are listed in 40 CFR § 180 and include acceptable concentrations for soybean forage, hay, hulls, and seed (US-EPA, 2010a). APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have an adverse impact on human health or animal feed.

In the near term, any additional GE traits that may be stacked with MON 87712-4 soybean have already been assessed by APHIS and determined nonregulated. As such, the production and use of products from these cultivars as food or feed have been assessed as not likely to have a significant negative impact on human health or animal feed analyzed in this EA. As discussed above in Subsection 5.2.1, Past and Present Actions and the Preferred Alternative, food and feed derived from GE soybean must be in compliance with all applicable legal and regulatory requirements and may undergo a voluntary consultation process with the FDA prior to release onto the market. All GE soybean traits with which MON 87712-4 soybean would be stacked have undergone, or are expected to undergo (e.g., MON 87708 dicamba resistant soybean), FDA's premarket consultation process to ensure their safety as food and feed products.

Socioeconomic

MON 87712-4 soybean could be stacked with other commercially available soybean traits that could have domestic economic impacts, such as affecting production costs, consumer prices, and growers' profits, similar to other GE soybean cultivars already on the market. As discussed previously, soybean varieties with single and multiple herbicide resistance are widely available, representing almost 93% of planted U.S. soybean acreage in 2012. The United States' adoption of herbicide-resistant-only soybean has remained relatively steady from the 2010 through the 2012 planting seasons (Table 2). The development of GE insect-resistant soybean is relatively recent, with DAS- 81419-2 soybean petitioned for a nonregulated status in 2012 (USDA-APHIS, 2013) although this trait is not likely to be deployed in the US. High yielding soybean cultivars of elite germplasm have been and will continue to be conventionally bred with nonregulated GE herbicide- and non-GE pest-resistant traits, such as Genuity Roundup Ready 2 Yield® (Monsanto), possibly dicamba resistant soybean if determined to be nonregulated, and soybean cyst nematode and fungal pathogen resistance to name a few. Similarly, other soybean varieties that have been genetically engineered to produce high oleic acid (Event 305423), have a modified fatty acid profile (MON 87715), and produce stearidonic acid (MON 87769) have all received nonregulated status in the last three years.

Past and recent growth in U.S. soybean acreage has occurred primarily at the expense of other crops and double-cropping, not by bringing new lands into production (USDA-ERS, 2011f). (USDA-ERS, 2011f). Overall total U.S. cropland has remained relatively stable since the mid-20th century (USDA-ERS, 2011e). U.S. soybean acreage is projected to remain relatively steady until 2021/2022, but with an anticipated 8% per acre yield gain. Field price of soybean per bushel is expected to remain unchanged, remaining between $10.30 and $11.35 per bushel, while net value of annual production is expected to increase (USDA-OCE, 2012). About 93% of U.S. soybean acreage is already planted with GE soybean varieties (USDA-ERS, 2012e) and combined trials have demonstrated MON 87712-4 soybean is phenotypically and agronomically similar to other soybean varieties (Monsanto, 2011), including high yielding cultivars. MON 87712-4, stacked with herbicide resistance traits and defensive traits, is expected to replace other GE soybean varieties on existing cropland. Although field tests conducted by Monsanto found MON 87712-4 soybean had a 7.3% higher yield than its comparator A3525 cultivar (Monsanto, 2011), its productivity is well within the range of other commercially available conventionally bred high yield varieties. Historically, soybean yields have been increasing for decades, in more recent times as a result of conventionally breeding high yielding cultivars with GE herbicide- and pest-resistant (nematode) traits, in addition to improved management practices (Specht et al., 2006; Pedersen, 2008).

Agronomic practices, including inputs for production of MON 87712-4 soybean stacked with herbicide or pest resistance, or other GE modified traits, would not be substantially different than those needed to cultivate other commercially available soybean with the same resistances or traits. Some of these commercially available traits include those with similar yields that deplete more phosphorous and potassium in soil than other varieties. Therefore, producer costs are not expected to be any different for the cultivation of MON 87712-4 soybean if it were stacked with other readily available GE and non-GE traits. As discussed in Subsection 5.2.2.1, Agricultural Production of Soybean, supplementation of these nutrients in soybean production is not uncommon (USDA-NASS, 2007a), and soil fertility testing and supplementation as indicated by tests and known crop soil nutrient removal rates is widely recommended in soybean production to achieve yield potential (Snyder, 2000; Specht et al., 2006; Pedersen, 2008; CAST, 2009a; Mallarino et al., 2011; Silva, 2011). Upon adoption it is expected MON 87712-4 soybean would be grown in rotation with other crops. Approximately 68% of U.S. soybean acreage is in two-year rotation with corn, followed in frequency of acreage by soybean and wheat (Monsanto, 2010a). To gain economic efficiency, fertilization of a preceding corn crop is usually supplemented at a level that would support the following soybean crop, but recent research has shown higher yielding transgenic herbicide- and insect-resistant corn varieties may remove more phosphorous than is applied on average, and soil fertility testing prior to planting of any soybean variety is recommended (Bender et al., 2013). In the south where soybean to soybean rotation is more common, soil fertilizer is applied annually (Heatherly, 2012). For double-cropping of soybeans after wheat or the corn-soybean-wheat and corn-soybean-wheat-doublecrop soybean rotation, it is recommended phosphorous be supplemented before corn in the two rotations and again before wheat in the four crop rotation (PPI, 2003). In conservation tillage soybean production, some authors note an increasing trend that employs strip tillage with deep subsurface fertilizer banding to support improved soil fertility; the process preserves the benefits of low soil disturbance between rows just as in no-till (Fernandez and White, 2012). Because recent research has found agricultural soil fertility in the United States and Canada is declining, regular testing and adequate supplementation using improved types of tillage and fertilization is recommended (Fixen et al., 2010). No cumulative impact on the agricultural practices for the production of soybean would therefore be expected with the approval of MON 87712-4 soybean as nonregulated.

MON 87712-4 soybean would likely be bred with nonregulated glyphosate-resistant traits. It has been reported that glyphosate appears to interact with manganese in soil by forming insoluble, stable complexes that either immobilize this element, reducing plant uptake, or preventing reduction in the plant, making it unavailable (Eker et al., 2006; Neumann et al., 2006; Ozturk et al., 2008; Cakmak et al., 2009; Huber, 2010). Huber (2010) and Cakmak (2009) also reported that glyphosate is a broad-spectrum chelate for several other nutrients (e.g., iron, calcium, magnesium, copper, iron, nickel, and zinc); however, these assertions are not without debate. Hartzler (2010a) agrees that glyphosate could immobilize essential elements temporarily, but offers that it does not specifically target manganese or any other particular element, but instead targets those cations that are most prevalent in the soil. Hartzler (2010a) also reports that areas in which glyphosate interactions with manganese nutrition are reported are also areas with known soil manganese deficiencies. Camberato (2010) points out that manganese deficiency is not a new phenomenon and is also associated with high pH, low moisture, or high levels of organic matter; furthermore, manganese deficiency is easily recognizable and can usually be resolved through foliar application(s) of manganese fertilizers. Stacking the MON 87712-4 increased yield trait with the glyphosate-resistant trait in soybean would therefore not likely cumulatively impact practices governing the application of manganese supplements to this crop.

For the above reasons, the future cultivation of MON 87712-4 soybean itself or stacked with other GE traits would not require any change to agronomic practices in soybean production or changes to on-farm costs for soybean producers. Neither is there any likely impact to the U.S. domestic soybean market. MON 87712-4 soybean may also be stacked with other nonregulated GE traits; however, predicting potential trait combinations would be purely speculative. Overall, it is unlikely that any cumulative impact to the domestic economic environment would result from a stacked product consisting of MON 87712-4 soybean and other readily-available GE traits.

As discussed in Subsection 4.7.2, Trade Economic Environment, the U.S. share of soybean exports is expected to decline from the current amount of 30% of world exports to approximately 25% over the next decade (USDA-OCE, 2012). While MON 87712-4 soybean had a statistically higher yield than the conventional control A3525, it was within yields documented for other high-yield conventional and GE soybean varieties, most likely because MON 87712-4 soybean is subject to the same variables that impact yield in other varieties. Conventional non-GE high-yield soybean varieties are currently available from several seed companies (e.g., ; Albert Lea Seeds' Sheyenne and Viking lines; several D.F. Seeds' varieties; and eMerge Genetics' 348.TCS, e3782s, e45120s, and e5110 varieties). Breeding of non-GE conventional soybean varieties with high yield may also be accomplished by State University Extension Services such as Ohio State University, Kansas State University, North Carolina State University, University of Arkansas, and University of Missouri (Pierzynski, 2009; North Carolina Soybean Producers Association, 2010; Shannon et al., 2010; The Ohio State University, No Date; University of Arkansas, No Date). As discussed above, nonregulated GE herbicide- and non-GE pest-resistant soybean cultivars are being conventionally bred with elite soybean germplasm to produce high yields, and soybean varieties that combine multiple herbicide resistance with pest resistance are in development (USDA-APHIS, 2013). As discussed in Subsection 4.7.2, Trade Economic Environment, increased farm productivity from adoption of MON 87712-4 soybean in addition to other high yielding soybean cultivars may increase U.S competitiveness in the global economy, and the summation of many other factors affect worldwide prices for soybean. These factors include energy costs, the value of the U.S. dollar, government policies, population, per capita income, global market conditions, and trends and practices in market trading and speculation (Trostle, 2008b; Trostle, 2008a; Irwin and Good, 2009). Global export markets respond to many factors and are unlikely to experience a meaningful change with the commercial availability of a GE improved yield cultivar such as MON 87712-4 soybean alone, or stacked with other currently available traits. Therefore, no cumulative impact to the trade economic environment is expected following determination of MON 87712-4 soybean as nonregulated.

In summary, the potential for impacts that may result from non regulated status of MON 87712-4 soybean on the resource areas analyzed were considered within this EA. This potential was evaluated for both MON 87712-4 cultivated alone and stacked with other previously nonregulated GE or non GE soybean traits. Implementation of the Preferred Alternative would not result in any changes to the resources analyzed compared to the No Action Alternative, and no negative cumulative impacts from foreseeable actions of stacking MON 87712-4 soybean with other soybean traits would occur. No cumulative effects are expected to the resource areas analyzed from determining MON 87712-4 soybean nonregulated, when taken into consideration with related activities, including past, present, and reasonably foreseeable future actions.

6 THREATENED AND ENDANGERED SPECIES

Congress passed the Endangered Species Act (ESA) of 1973, as amended, to prevent extinctions facing many species of fish, wildlife, and plants. The purpose of the ESA is to conserve endangered and threatened species and the ecosystems on which they depend as key components of America's heritage. To implement the ESA, the United States Fish and 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 from 1999 to 2003 to discuss factors relevant to APHIS's regulatory authority and effects analysis for petitions for nonregulated status, and developed a process for conducting an effects determination consistent with the PPA of 2000 (Title IV of Public Law 106-224). This process is described in a Decision Tree document, which is available from APHIS. APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

APHIS' regulatory authority over GE organisms under the PPA is limited to those GE organisms for which it has reason to believe might be a plant pest or those for which APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk (7 CFR § 340.1). After completing a plant pest risk analysis, if APHIS determines that MON 87712-4 soybean does not pose a plant pest risk, then MON 87712-4 soybean would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR Part 340, and therefore, APHIS must reach a determination that the article is no longer regulated. As part of its EA analysis, APHIS is analyzing the potential effects of MON 87712-4 soybean on the environment including any potential effects to TES and critical habitat. As part of this process, APHIS thoroughly reviews the GE product information and data related to the organism (generally a plant species, but may also be other genetically engineered organisms). For each transgene/transgenic plant, APHIS considers the following information, data, and questions:

- A review of the biology and taxonomy of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- 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 impacts;
- 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 and endangered species (TES) of plants or a host of any TES; and
- Any other information that may inform the potential for an organism to pose a plant pest risk.

In following this review process, APHIS, as described below, has evaluated the potential effects that a determination of nonregulated status of MON 87712-4 soybean may have, if any, on Federally-listed TES 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 and reviewed the USFWS list of TES (listed and proposed) for each state where soybean is commercially produced. The list was generated from the USFWS Environmental Conservation Online System (ECOS; at http://ecos.fws.gov/tess_public/). Prior to this review, APHIS considered the potential for MON 87712-4 soybean to extend the range of soybean production and also the potential to extend agricultural production into new natural areas. Monsanto's studies demonstrate that agronomic characteristics and cultivation practices required for MON 87712-4 soybean are essentially indistinguishable from practices used to grow other soybean varieties (Monsanto, 2011; USDA-APHIS, 2011a). Although MON 87712-4 soybean may be expected to replace other varieties of soybean currently cultivated, APHIS does not expect the cultivation of MON 87712-4 soybean to result in new soybean acres planted in areas that are not already devoted to agriculture. Accordingly, the issues discussed herein focus on the potential environmental consequences of the determination of nonregulated status of MON 87712-4 soybean on TES species in the areas where soybean are currently grown.

APHIS focused its TES review on the implications of exposure to the BBX32 protein in MON 87712-4 soybean and the interaction between TES and MON 87712-4 soybean, including the potential for sexual compatibility and the ability to serve as a host for a TES.

6.1 Potential Effects of MON 87712-4 Soybean on TES

6.1.1 Threatened and Endangered Plant Species

The agronomic and morphologic characteristics data provided by Monsanto were used in the APHIS analysis of the weediness potential for MON 87712-4 soybean, and further evaluated for the potential to impact TES. Agronomic studies conducted by Monsanto tested the hypothesis that the weediness potential of MON 87712-4 soybean is unchanged with respect to conventional soybean (Monsanto, 2011). No differences were detected between MON 87712-4 soybean and the conventional control A3525 in assessed agronomic performance characteristics (e.g., germination, dormancy, emergence, vegetative growth, reproductive development, seed retention and lodging, plant-environment interactions, plant-symbiont interactions, volunteer potential characteristics, and persistence outside of cultivation) other than potential for greater yield in MON-87712-4 soybean (Monsanto, 2011; USDA-APHIS, 2011a). Soybean possesses few of the characteristics of successful weeds (OECD, 2000). Soybean cannot survive in most geographic locations of the country without human intervention, and it is easily controlled if volunteers appear in subsequent crops (see Section 2.1.2 Agronomic Practices and 2.3.3 Gene Flow and Weediness discussion). The expression of the BBX32 protein providing the increased yield potential in MON 87712-4 soybean is unlikely to appreciably improve seedling establishment or increase weediness potential without changes in a combination of other characteristics associated with weediness, such as hard seed and increased lodging. APHIS has concluded the determination of nonregulated status of MON 87712-4 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 soybean varieties (USDA-APHIS, 2011a).

APHIS evaluated the potential of MON 87712-4 soybean to cross with a listed species. As previously discussed in the analysis of Plant Communities and Gene Flow and Weediness (see Subsections 4.4.2 and 4.4.3), APHIS has determined there is no risk to unrelated plant species from the cultivation of MON 87712-4 soybean. Soybean is highly self-pollinating and can only cross with other members of *Glycine* subgenus *Soja*. Wild soybean species are endemic in China, Korea, Japan, Taiwan and some eastern regions of Russia; in the United States there are no *Glycine* species found outside of cultivation and the potential for outcrossing is minimal (OECD, 2000). After reviewing the list of threatened and endangered plant species in states where soybean is grown, APHIS determined that MON 87712-4 soybean would not be sexually compatible with any threatened or endangered plant species proposed for listing, as none of these listed plants are in the same genus nor are known to cross pollinate with species of the genus *Glycine*.

Based on agronomic field data, literature surveyed on soybean weediness potential, and no sexual compatibility of TES with soybean, APHIS has concluded MON 87712-4 soybean will have no effect on threatened or endangered plant species.

6.1.2 Threatened and Endangered Animal Species

APHIS considered the possibility MON 87712-4 soybean could serve as a host plant for threatened or endangered animal species. A review of the species list reveals there are no members of the genus *Glycine* that serve as a host plant for any threatened or endangered animal species. Threatened and endangered animal species that may be exposed to the gene products in MON 87712-4 soybean would be those TES that inhabit soybean fields and feed on MON 87712-4 soybean. To identify potential effects to animal TES, APHIS evaluated the risks to threatened and endangered animals from consuming MON 87712-4 soybean. Soybean commonly is used as a feed for many livestock. Additionally, wildlife may use soybean fields as a food source, consuming the plant or insects that live on the plants. However, animal TES generally are found outside of agricultural fields. Few if any animal TES are likely to use soybean fields because they do not provide suitable habitat. Only whooping crane (*Grus americana*), sandhill crane (*Grus canadensis pulla*), piping plover (*Charadrius melodus*), interior least tern (*Sterna antillarum*) occasionally feed in farmed sites (USFWS, 2011a). Bird species may visit soybean fields during migratory periods, but would not be present during normal farming operations (Krapu et al., 2004; USFWS, 2011a). In a study of soybean consumption by wildlife in Nebraska, results indicated soybeans do not provide the high energy food source needed by cranes and waterfowl (USFWS, 2011a). The Delmarva fox squirrel (*Sciurus niger cinereus*), which inhabits mature forests of mixed hardwoods and pines, may be found adjacent to agricultural areas of the Delmarva Peninsula (USFWS, 2011b). The squirrel forages for food in woodlots and openings, such as farm fields, with a diet that mainly includes acorns, nuts/seeds of hickory, beech, walnut, and loblolly pine. They also feed on tree buds and flowers, fungi, insects, fruit, and mature, green pine cones in the summer and early fall (USFWS, 1999). The Louisiana black bear (*Ursus americanus luteolus*), occurring in Louisiana, Mississippi, and Texas (USFWS, 2013), may occasionally forage on soybean; however, other crops such as corn, sugarcane, and winter wheat are preferred by the species (Mississippi State University, No Date).

The BBX32 protein is expressed in MON 87712-4 soybean through the incorporation of the *BBX32* gene which was derived from *A. thaliana*, commonly known as mouseear cress. Mouseear cress is a common forb found in all soybean producing states except North Dakota and belongs to the Brassicaceae (mustard) family that also includes common food plants such as broccoli, cauliflower, cabbage, and canola (USDA-NRCS, 2013c). Monsanto has presented data on the food, feed, and environmental safety of MON 87712-4 soybean, evaluating the agronomic and morphologic characteristics of MON 87712-4 soybean, including compositional analysis of key nutrients and antinutrients, and safety evaluations and toxicity tests, as compared to conventional soybean (Monsanto, 2011). Compositional elements compared included the proximates (ash, carbohydrates, moisture, protein and fat), fiber, amino acids, fatty acids, and vitamin E in seed, and the above proximates and fiber in forage. The antinutrients assessed in seed included raffinose, stachyose, lectin, phytic acid, trypsin inhibitors, and isoflavones (daidzein, genistein, and glycitein) (Monsanto, 2011). As discussed in Section 4.6.1.2, the data collected indicate there is no difference in the composition and nutritional quality of MON 87712-4 soybean compared with conventional soybean varieties, apart from the presence of the BBX32 protein. The results presented by Monsanto show that the incorporation of the *BBX32* gene and the accompanying expression of the BBX32 protein in MON 87712-4 soybean does not result in any biologically-meaningful differences between MON 87712-4 soybean and nontransgenic hybrids (Monsanto, 2011; USDA-APHIS, 2011a).

In addition to evaluating Monsanto's comparisons of MON 87712-4 soybean with the non-transgenic parent (A3525) for potential agronomic and morphologic differences, APHIS also considers the FDA regulatory assessment when evaluating the potential impacts of a determination of nonregulated status of the new agricultural product. As discussed in Subsection 4.4.1, Animal Communities, Monsanto has initiated a food/feed safety consultation with FDA on MON 87712-4 soybean. FDA has evaluated the submission and responded with questions on July 18, 2012, and Monsanto responded to those on August 9, 2012. When complete, FDA will announce whether it has identified any possible safety or regulatory issues under the FD&C Act that would require further evaluation. The decision memo will be published as BNF No. 131.

Monsanto conducted safety evaluations based on Codex Alimentarius Commission procedures to assess any potential adverse effects to humans or animals resulting from environmental releases and consumption of MON 87712-4 soybean (FAO, 2009; Monsanto, 2011). These safety studies included: (1) characterization of the physicochemical and functional properties of BBX32 protein; (2) quantification of BBX32 protein levels in plant tissues; (3) comparison of the amino acid sequence of BBX32 protein in MON 87712-4 soybean to known allergens, gliadins, glutenins, toxins, and other biologically-active proteins known to have adverse effects on mammals; (4) evaluation of the digestibility of BBX32 protein in simulated gastric and intestinal fluids; (5) documentation of the presence of related proteins in several plant species currently consumed; and (6) investigation of the potential mammalian toxicity through an oral gavage assay. The BBX32 protein in MON 87712-4 soybean was determined to have no amino acid sequence similar to known allergens, lacked toxic potential to mammals, and was degraded rapidly and completely in gastric fluid (Monsanto, 2011). MON 87712-4 soybean does not express a pesticidal property, and, accordingly, is not regulated by the EPA.

Because there is no toxicity or allergenicity potential with MON 87712-4 soybean, there would be no direct or indirect toxicity or allergenicity impacts on animal TES that feed on soybean or the associated biological food chain of organisms. Based on Monsanto's findings and the likely concurrence of APHIS with FDA's analyses of data from Monsanto, and that consumption of MON 87712-4 soybean plant parts (seeds, leaves, stems, pollen, or roots) by animal TES would be unlikely, APHIS concludes it would have no effect on any listed threatened or endangered animal species or animal species proposed for listing.

APHIS expects MON 87712-4 soybean to replace some of the presently available soybean varieties, but APHIS does not expect that MON 87712-4 soybean will cause new soybean acres to be planted in areas that are not already devoted to agriculture. TES generally are found outside of agricultural fields. Combining the above information, cultivation of MON 87712-4 soybean and its progeny is expected to have no effect on TES animal species nor is it expected to adversely modify designated critical habitat compared to current agricultural practices. Based on this analysis, there is no apparent potential for significant impact on nontarget organisms from MON 87712-4 soybean, including beneficial organisms and TES animal species, that would result from an APHIS determination of nonregulated status for the petition in whole. If APHIS chooses the No Action Alternative, there would also be no impact on non-target organisms, beneficial organisms and TES animal species.

6.1.3 Summary of Potential Effects of MON 87712-4 Soybean on TES

After reviewing the possible effects of the environmental release of MON 87712-4 soybean, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. APHIS also considered the potential effect of a determination of nonregulated status of MON 87712-4 soybean on designated critical habitat and habitat proposed for designation, and could identify no differences from effects that would occur from the production of other soybean varieties. As discussed above, soybean possesses few of the characteristics of successful weeds and cannot survive in most geographic regions of the country without human intervention. Soybean is not sexually compatible with, nor serves as a host species for, any listed species or species proposed for listing under the ESA. Consumption of MON 87712-4 soybean by any listed species or species proposed for listing will not result in a toxic or allergic reaction. Based on these factors, APHIS has concluded that a determination of nonregulated status of MON 87712-4 soybean, and the corresponding environmental release of this soybean variety, will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the USFWS or NMFS are not required. The APHIS Decision Tree document is used to determine the need for Section 7 consultation under the ESA.

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

7.1.1 Executive Orders with Domestic Implications

The following EOs require consideration of the potential impacts of the Federal action to various segments of the population.

- ***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.

The No Action and Preferred Alternatives were 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 data associated with the BBX32 protein establish the safety of MON 87712-4 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 with nonregulated MON 87712-4 soybean.

Based on the information submitted by the applicant and assessed by APHIS, MON 87712-4 soybean is agronomically, phenotypically, and biochemically comparable to conventional soybean except for the introduced *BBX32* gene and expressed BBX32 protein. The information provided in the petition indicates that the protein expressed in MON 87712-4 soybean is not expected to be allergenic, toxic, or pathogenic in mammals (USDA-APHIS, 2011a). Also, Monsanto began the process of consultation with FDA on the BBX32 protein in the context of food and feeds deriving from MON 87712-4. Monsanto received questions from FDA on July 18, 2012, and responded to those on August 9, 2012 and FDA has not subsequently requested that Monsant address further questions. When FDA's process is complete, the decision memo will be published as BNF No. 131. APHIS assumes that growers will adhere to herbicide use precautions and restrictions. Pesticide labels include use precautions and restrictions intended to protect workers and their families from exposures. As discussed in Subsection 4.5, Human Health, it is expected that EPA-registered pesticides, fertilizers, and other chemicals that currently are used for soybean production would continue to be used by growers on MON 87712-4 soybean using application rates currently approved for other GE and non-GE soybean varieties and determined by the EPA to have no unreasonable adverse impacts to human health when used in accordance with label instructions.

Based on these factors, a determination of nonregulated status of MON 87712-4 soybean is not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

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

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

Soybean is not listed in the United States as a noxious weed species by the Federal government (USDA-NRCS, 2013b) nor is it listed as an invasive species by major invasive plant data bases. Cultivated soybean seed does not usually exhibit dormancy and requires specific environmental conditions to grow as a volunteer the following year (OECD, 2000). Any volunteers that may become established do not compete well with the succeeding planted crop and are easily managed using standard weed control practices. Field trials and laboratory tests indicate MON 87712-4 soybean has no plant pathogenic properties or weediness characteristics. The agronomic, compositional, and reproductive characteristics of MON 87712-4 soybean are substantially equivalent to other GE and non-GE soybean varieties (Monsanto, 2011; USDA-APHIS, 2011a). The trait for increased yield is not expected to contribute to increased weediness without changes in a combination of other characteristics associated with weediness, such as hard seed and increased lodging, among other characteristics. Non-engineered soybean, as well as other herbicide-resistant soybean varieties, are widely grown in the United States. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by APHIS, MON 87712-4 soybean plants are sufficiently similar in fitness characteristics to other soybean varieties currently grown and are not expected to become weedy or invasive.

The following executive order requires the protection of migratory bird populations:

- ***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 with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

Migratory birds may be found in soybean fields. While soybean does not meet the nutritional requirements for many migratory birds (Krapu et al., 2004), they may forage for insects and weed seeds found in and adjacent to soybean fields. As discussed in Subsection 4.4.1, Animal Communities, data submitted by the applicant has shown no difference in compositional and nutritional quality of MON 87712-4 soybean compared with other GE soybean or non-GE soybean, apart from the presence of the BBX32 protein. MON 87712-4 soybean is not expected to be allergenic, toxic, or pathogenic in mammals. In addition, the BBX32 protein is degraded rapidly and completely in simulated gastric fluid and simulated intestinal fluid, and the protein makes up only a very small portion (less than 0.001%) of the total plant protein (Monsanto, 2011). The results presented by Monsanto suggest that the BBX32 protein is unlikely to be a toxin in animal diets. Monsanto has initiated a food/feed safety consultation with FDA on MON 87712-4 soybean. FDA has evaluated the submission and responded with questions on July 18, 2012, and Monsanto responded to the questions on August 9, 2012. When complete, these will be BNF No. 131.Based on APHIS' assessment of MON 87712-4 soybean, it is unlikely that a determination of nonregulated status of MON 87712-4 soybean would have a negative effect on migratory bird populations.

7.1.2 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 United States, its territories, and possessions that result from actions being taken.

APHIS has given this EO careful consideration and does not expect a significant environmental impact outside the United States in the event of a determination of nonregulated status of MON 87712-4 soybean. All 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 87712-4 soybean subsequent to a determination of nonregulated status would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC) (IPPC, 2013). 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, 2013). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (177 countries as of February 2013). In April 2004, a standard for Plant 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 CBD that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which include those modified through biotechnology. The Protocol came into force on September 11, 2003, and 164 countries are Parties to it as of February 2013 (CBD, 2013). Although the United States 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 United States Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (US-EPA, 2013). These data will be available on the United States Regulatory Agencies Unified Biotechnology Website database (http://usbiotechreg.epa.gov/usbiotechreg/).

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the United States, and within the OECD. NAPPO has completed three modules of the *Regional Standards for Phytosanitary Measures 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*, a forum for information exchange and cooperation on agricultural biotechnology issues for the United States, Mexico, and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including Argentina, Brazil, Japan, China, and Korea.

7.1.3 Impacts on Unique Characteristics of Geographic Areas

A determination of nonregulated status of MON 87712-4 soybean is not expected to impact unique characteristics of geographic areas such as park lands, prime farmlands, wetlands, wild and scenic areas, or ecologically critical areas.

Monsanto has presented results of agronomic field trials for MON 87712-4 soybean. The results of these field trials demonstrate there are no differences in agronomic practices between MON 87712-4 soybean and non-GE hybrids needed for their cultivation. The common agricultural practices that would be carried out in the cultivation of MON 87712-4 soybean are not expected to deviate from current practices, including the use of EPA-registered pesticides. The product is expected to be deployed on agricultural land currently suitable for production of soybean and 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 nonregulated status of MON 87712-4 soybean. This action would not convert land use to nonagricultural use and, therefore, would have no adverse impact on prime farmland. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 87712-4 soybean, including the use of EPA-registered pesticides. The Applicant's adherence to EPA label use restrictions for all pesticides is expected to mitigate potential impacts to the human environment.

Based on these findings, including the assumption that label use restrictions are in place to protect unique geographic areas and that those label use restrictions are adhered to, a determination of nonregulated status of MON 87712-4 soybean is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

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

The NHPA of 1966 and its implementing regulations (36 CFR 800) require Federal agencies to: (1) determine whether activities they propose constitute "undertakings" that have 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 87712-4 soybean is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

APHIS' Preferred Alternative 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 it likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of nonregulated status of MON 87712-4 soybean.

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 noise 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 increased noise on the use and enjoyment of a historic property during the operation of tractors and other mechanical equipment 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 87712-4 soybean is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

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