Monsanto Petition (09-SY-2000U) for Determination of Non-regulated Status of (MON 87769) Stearidonic Acid Soybean

OECD Unique Identifier:
MON 87769-7

Final Environmental Assessment

April 2012

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

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACRONYMS AND ABBREVIATIONS

AIA	advanced informed agreement
ALA	*alpha*-linolenic acid
ALS	Acetolactate Synthase
AOSCA	Association of Official Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
BRS	Biotechnology Regulatory Services (within USDA–APHIS)
Bt	*Bacillus thuringiensis* protein
CAA	Clean Air Act
CBD	Convention on Biological Diversity
CFR	Code of Federal Regulations (United States)
CH_4	methane
CLSS	closed loop stewardship system
CO	carbon monoxide
CO_2	carbon dioxide
CT	conservation tillage
DNA	deoxyribonucleic acid
DHA	docosahexaenoic acid
EA	environmental assessment
E. coli	*Escherichia coli*
ECOS	Environmental Conservation Online System (USFWS)
EIS	environmental impact statement
EO	Executive Order
EPA	eicosapentaenoic acid
EPSPS	5- enolpyruvylshikimate-3-phosphate synthase
ESA	Endangered Species Act of 1973
EU	European Union
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FFP	food, feed, or processing
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FR	Federal Register

g/kg	grams per kilogram
GE	genetically engineered
GHG	greenhouse gas
GLA	*gamma*-linolenic acid
GMO	genetically modified organism
GRAS	generally recognized as safe
HDL	high-density lipoprotein
IP	Identity Preservation
IPCC	Intergovernmental Panel on Climate Change
ISPM	International Standard for Phytosanitary Measure
IPPC	International Plant Protection Convention
ISO	International Organization for Standards
LA	linoleic acid
lb(s)	pound(s)
LDL	low-density lipoprotein
LMO	Living Modified Organism
m	meters
MG	maturity group
mg	milligrams
NO_2	nitrogen dioxide
N_2O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NABI	North American Biotechnology Initiative
NAPPO	North American Plant Protection Organization
Nc.Fad3	*Neurospora crassa* Δ15 desaturase gene
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NMFS	National Marine and Fisheries Service
NOP	National Organic Program
NPS	non-point source
NRC	National Research Council
O_3	ozone

OECD	Organization for Economic Cooperation and Development
PIPs	plant incorporated protectants
Pj.D6D	*Primula juliae* Δ6 desaturase gene
$PM_{2.5}$	particulate matter with an aerodynamic diameter less than or equal to 2.5 micrometers
PM_{10}	particulate matter with an aerodynamic diameter less than or equal to 10 micrometers
POEA	polyethoxylated alkyl amine
PPRA	Plant Pest Risk Assessment
PPA	Plant Protection Act
PRA	Pest Risk Analysis
RNA	ribonucleic acid
SDA	stearidonic acid
SO_2	sulfur dioxide
STS	sulfonylurea soybeans
TES	threatened and endangered species
TSCA	Toxic Substances Control Act
U.S.	United States
USC	United States Code
USDA	U.S. Department of Agriculture
USDA-AMS	U.S. Department of Agriculture-American marketing Service
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service
U.S. EPA	U.S. Environmental Protection Agency
USFWS	U.S. Fish and Wildlife Services
VOC	volatile organic compound
WPS	Worker Protection Standard for Agricultural Pesticides
µm	micrometers
°F	degrees Fahrenheit

1 PURPOSE AND NEED

1.1 Regulatory Authority

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

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

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

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

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

The U.S. EPA regulates plant-incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). U.S. EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act (FFDCA) and regulates certain biological control organisms under the Toxic Substances Control Act (TSCA). The U.S. 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. Because the genes expressed in MON 87769 are not pesticidal, they are not subject to these EPA regulations.

1.2 Regulated Organisms

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

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

1.3 Petition for Determination of Nonregulated Status: MON 87769 Soybean

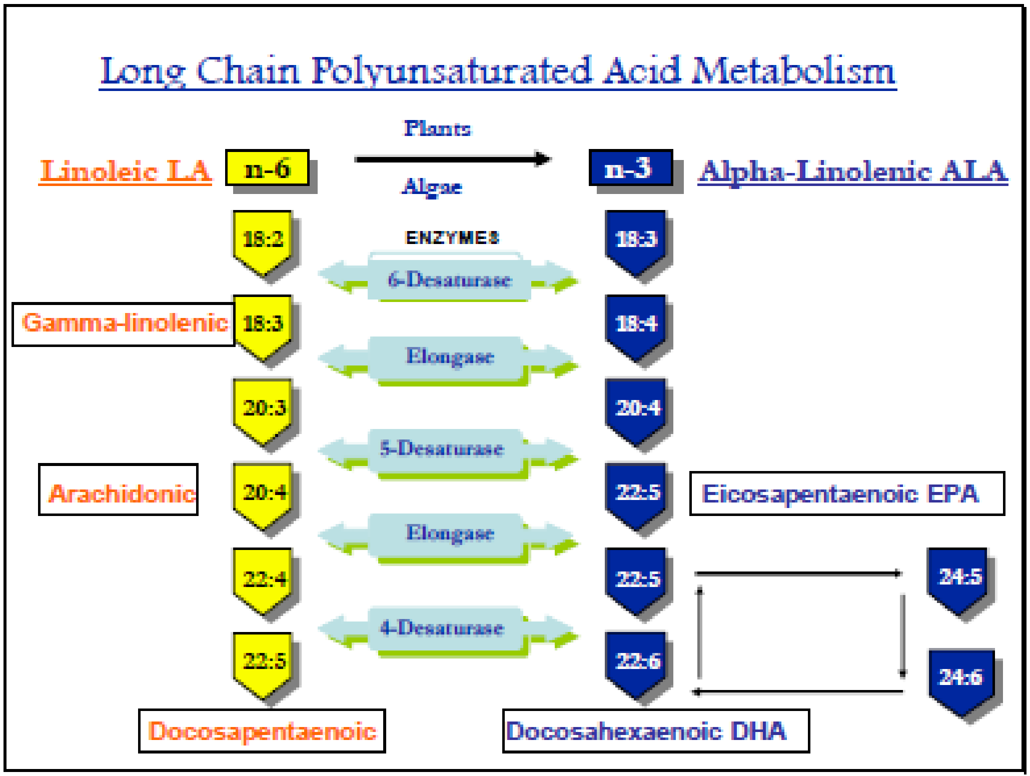
Monsanto Company of St. Louis, MO (Monsanto), submitted a petition (APHIS Number 09-183-01p) to APHIS in 2009 seeking a determination of nonregulated status for Event MON 87769 soybean that is engineered to express high levels of the fatty acid stearidonic acid (SDA) in soybean seed. As detailed in the petition, smaller amounts of three other fatty acids are produced in addition to the SDA, and expression of linoleic acid is reduced (Monsanto, 2010b). In the event of a determination of nonregulated status, the nonregulated status for MON 87769 soybean would include MON 87769 soybean, any progeny derived from crosses between MON 87769 soybean and conventional soybean, and crosses of MON 87769 soybean with other biotechnology-derived soybean that have been determined to be no longer subject to the requirements of Part 340 or the plant pest provisions of the Plant Protection Act. MON 87769 soybean is currently regulated under 7 CFR part 340.

Interstate movements and field trials of MON 87769 soybean have been conducted under permits issued or notifications acknowledged by APHIS from 2003 through 2008. Data resulting from these field trials are described in the petition (Monsanto, 2010b). Notifications acknowledged and permits issued by APHIS are listed in the petition (Monsanto, 2010b). The test sites represent diverse regions of the U.S., including the major growing areas of the Midwest (Wisconsin, Michigan, Minnesota Missouri, Iowa, Illinois, Indiana, Kansas, Kentucky, Nebraska, South Dakota, Pennsylvania, Ohio, and Arkansas), and winter nurseries in Puerto Rico and Hawaii. Field tests conducted under APHIS oversight allow for evaluation in agricultural settings under confinement measures designed to minimize the likelihood of persistence in the environment after completion of the field trial. Under confined field trial conditions, data are gathered on multiple parameters and used by applicants to evaluate agronomic characteristics and product performance. These data are also valuable to APHIS for assessing the potential for a new variety to pose a plant pest risk. The data evaluated for MON 87769 soybean may be found in the APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2010c).

1.4 Purpose of Product

Monsanto seeks a determination of nonregulated status of MON 87769 soybean, a specialty trait soybean characterized by a fatty acid profile containing SDA, an omega-3 fatty acid, which is not found in conventional soybean. SDA (an 18-carbon fatty acid with four double bonds or 18:4) is metabolically converted in humans to eicosapentaenoic acid (EPA; 20:5) and docosahexaenoic acid (DHA; 22:6), both of which may be involved in promoting heart health and other physiologically healthful conditions. These fatty acids may commonly be derived from fish oils, but a soybean source containing SDA that provides a precursor to these would be more efficiently produced in human nutrition. Since SDA has fewer double bonds than the omega-3 fatty acids, EPA (20:5) or DHA (22:6), SDA soybean oil is more stable to oxidation (i.e., less prone to fishy or rancid odors and taste) than fish oils, thereby expanding the potential formulation options for food companies and food products for consumers. The biosynthetic pathways for interconversions of the linoleic, linolenic and SDA to EPA and DHA are shown in Figure 1.

SDA production in MON 87769 soybean is accomplished by inserting two desaturase genes, *Primula juliae* Δ6 desaturase (*Pj.D6D)* and *Neurospora crassa* Δ15 desaturase (*Nc.Fad3)*, into a conventional soybean variety. The PjΔ6D and NcΔ15D proteins found in MON 87769 soybean also produce *gamma*-linolenic acid (GLA), another fatty acid not in conventional soybean. In MON 87769, the NcΔ15D protein converts linoleic acid (LA) to *alpha*-linolenic acid (ALA) and the protein PjΔ6D converts the ALA to SDA and LA to gamma linolenic acid (GLA) (Monsanto, 2010b). Figure 2 shows the existing pathways by which desaturases form fatty acids in conventional soybeans and how the pathways are altered when the two desaturase genes, *Primula juliae* Δ6 desaturase (*Pj.D6D)* and *Neurospora crassa* Δ15 desaturase (*Nc.Fad3)* inserted into MON 87769 soybean form fatty acids.



Source: Source: (Council for Responsible Nutrition, 2005).

Figure 1. Pathways for the synthesis of EPA and DHA from Linoleic and *alpha*-Linolenic Acid.

MON 87769 soybean would not be grown for the commodity soybean market; instead, it is anticipated that a specialty soybean oil from MON 87769 soybean would be produced. Compared to commodity soybean oil, SDA soybean oil contains two additional fatty acids, SDA and GLA. SDA omega-3 soybean oil produced from MON 87769 soybean contains approximately 20 to 30% SDA (weight percent of total fatty acids), 5 to 8% *gamma*-linolenic acid (GLA), and slightly higher levels of *alpha*-linolenic acid (ALA) and palmitic acid than in conventional soybean oil (Monsanto, 2010b). It also contains lower levels of oleic acid and linoleic acid (LA) than those present in conventional soybean oil. Since oleic acid, linoleic acid, and *alpha*-linolenic acid are directly involved in the pathway to SDA, their concentrations are inter-related with those of other fatty acids and, therefore, were expected to be different in MON 87769 soybean seed.

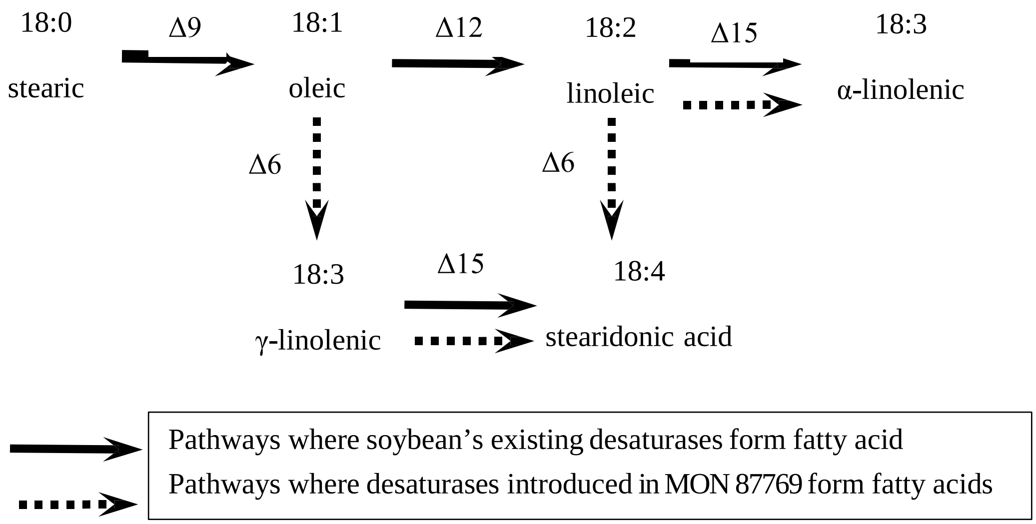


Figure 2. Fatty acid biosynthesis in plants and the introduced changes in MON 87769 soybean

SDA omega-3 soybean oil produced from MON 87769 soybean can be included in a range of food products for health benefits. The use of SDA soybean oil in selected food categories could provide a wide range of dietary alternatives for increasing human omega-3 fatty acid intake. SDA soybean oil is intended for use in a variety of food products including baked goods and baking mixes, breakfast cereals and grains, cheeses, dairy product analogs, fats and oils, fish products, frozen dairy desserts and mixes, grain products and pastas, gravies and sauces, meat products, milk products, nuts and nut products, poultry products, processed fruit juices, processed vegetable products, puddings and fillings, snack foods, soft candy, and soups and soup mixes at levels that will provide 375 milligrams (mg) SDA per serving. Fish and plant oils rich in omega-3 fatty acids also are used in feed applications such as aquaculture and poultry feeds. SDA soybean oil from MON 87769 soybean may eventually be used in aquaculture and feed applications as an alternative to fish oil and other omega-3 rich feed components.

It is anticipated that MON 87769 soybean will have low production acreage (< 5% of total U.S. soybean acreage or up to 3 to 3.5 million acres) in North America. In order to derive commercial value from this product, the SDA soybean crop will be grown a closed-loop production and marketing system in the soybean growing region of the Northern U.S (Monsanto, 2010b).

1.5 APHIS Response to Petition for Nonregulated Status

Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of genetically engineered organisms, including GE plants such as MON 87769 soybean. When a petition for nonregulated status is submitted, APHIS must make a determination if the genetically engineered organism is unlikely to pose a plant pest risk. If APHIS determines based on its PPRA that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

APHIS has prepared this environmental assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality's National Environmental Policy Act (NEPA) regulations and the USDA and 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 of MON 87769 soybean.

1.6 Coordinated Framework Review

1.6.1 U.S. Environmental Protection Agency

The U.S. EPA regulates plant-incorporated protectants (PIPs) under FIFRA (7 U.S.C. 136 *et seq.*) and certain biological control organisms under TSCA (15 U.S.C. 53 *et seq.*). MON 87769 soybean does not express a pesticidal property, and, accordingly, is not regulated by the U.S. EPA.

1.6.2 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 that are GE, in the *Federal Register* 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.

MON 87769 soybean is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced through genetic engineering. Monsanto initiated the consultation process with FDA for the commercial distribution of MON 87769 soybean and submitted a safety and nutritional assessment of food and feed derived from MON 87769 soybean to the FDA on March 23, 2009 (BNF No. 00117) (Monsanto, 2010b). FDA is currently evaluating the submission.

FDA also administers the Generally Recognized as Safe (GRAS) Notification Program (US-FDA, 2011). A substance that will be added to food is subject to premarket approval by FDA unless qualified experts determine its use is generally recognized as safe (GRAS). Under the GRAS program (62 FR 18938), a notification procedure is established whereby FDA is notified by a person that they have made a determination that a particular use of a substance is GRAS. FDA evaluates the submission to determine whether a sufficient basis for a GRAS determination has been provided or issues exist on whether use of the substance is GRAS. Monsanto submitted a GRAS Notice for SDA soybean oil (No. GRN 000283) to FDA on February 25, 2009 (US-FDA, 2009b). FDA issued a response letter on September 4, 2009, indicating the agency has no further questions about the characteristics of the oil, and the safety of its use in foods (US-FDA, 2009a).

---

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

1.7 Public Involvement

APHIS routinely seeks public comment on draft EAs prepared in response to petitions for nonregulated status of GE organisms. APHIS does this through a notice published in the Federal Register. The issues discussed in this EA were developed by considering the public concerns as well as issues raised in public comments submitted for other EAs of GE organisms, concerns raised in lawsuits, as well as those issues of concern that have been raised by various stakeholders. These issues, including those regarding the agricultural production of soybeans using various production methods and the environmental and food/feed safety of GE plants were addressed to analyze the potential environmental impacts of MON 87769 soybean.

This EA, the petition submitted by Monsanto, and APHIS's PPRA will be available for public comment for a period of 60 days (7 CFR § 340.6(d)(2)). Comments received by the end of the 60-day period will be analyzed and used to inform APHIS' determination decision of the regulated status of MON 87769 soybean and to assist APHIS in determining whether an Environmental Impact Statement (EIS) is required prior to the determination decision of the regulated status of this soybean variety.

1.8 Issues Considered

The list of resource areas considered in this draft EA were 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
- Specialty Soybean Production

Environmental Considerations:

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

Human Health Considerations:

- Public Health
- Worker Safety

Livestock Health Considerations:

- Livestock Health/Animal Feed

Socioeconomic Considerations:

- Domestic Economic Environment
    - Implications for Food Use
    - Implications for Industrial Use
- Trade Economic Environment
- Social Environment

2 AFFECTED ENVIRONMENT

The Affected Environment section provides an overview of the use and composition of soybeans, followed by a discussion of the current conditions of those aspects of the human environment potentially impacted by a determination of nonregulated status of MON 87769 soybean. For the purposes of this draft EA, those aspects of the human environment are: soybean production practices, the physical environment, biological resources, human health, animal feed, and socioeconomic issues. Because production of MON 87769 soybean is expected to be limited by actions taken by Monsanto, the affected environment assessed in this EA will primarily focus on those geographical areas where MON 87769 soybean would potentially be planted. As indicated by Monsanto, the area to which production will be limited includes the Northern Tier states of North and South Dakota, Minnesota, Wisconsin, and Michigan (Monsanto, 2010c) and a combination of geographically delimited seed sales, released maturity groups and soybean purchases, and contracts will provide a means to define the production area.

2.1 Soybean Products and Composition

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

2.1.1 Soybean Use

Approximately 50% of the world soybean seed supply in 2009 was crushed to produce soybean meal and oil (Soyatech, 2008). Most of the seed was used to supply the feed industry for livestock use or the food industry for edible vegetable oil and soybean protein products. Another 34% of the world soybean seed supply was traded to other geographies, with China, the European Union (EU), Japan, and Mexico being the top soybean seed importers (SoyStats, 2010h). The remainder of the soybean seed produced was used as certified seed, feed, or stocks. Industrial uses of soybean range from a carbon/nitrogen source in the production of yeasts via fermentation to the manufacture of soaps, inks, paints, disinfectants, and biodiesel (see, e.g., (Cahoon, 2003); (SoyStats, 2010a)).

Soybean oil generally has a smaller contribution to soybean's overall value compared to soybean meal because the oil constitutes just 18 to 19% of the soybean's weight. Nonetheless, soybean oil accounted for approximately 30% of all the vegetable oils consumed globally and was the second largest source of vegetable oil worldwide, slightly behind palm oil representing approximately 32% of global consumption (Soyatech, 2010). Soybean oil also has industrial applications, including feedstock in manufacture of inks, paints, varnishes, resins, plastics, and biodiesel ((Cahoon, 2003); (SoyStats, 2010a)). Soybean meal is used as a supplement in feed rations for livestock. Soybean meal is the world's most important protein feed, accounting for nearly 69% of world protein meal supplies (SoyStats, 2010f).

Soybean is grown as a commercial crop in more than 40 countries (those with greater than 10,000 hectares) (FAO, 2010). Processed soybeans supply the largest world source of protein animal feed and the second largest source of vegetable oil (USDA-ERS, 2010e). U.S. total oilseed production consists of more than 90% by weight of soybeans while the remainder is other oilseeds—such as cottonseed, sunflower seed, canola, and peanuts (USDA-ERS, 2010e).

Soybean Meal

Following solvent extraction of the oil, the remaining solid soybean flakes are toasted and ground to produce soybean meal (Soyatech, 2008). Soybean seed (at 13% moisture) with about 18% oil will contain 34.6 to 36.7% protein, and the derived soybean meal will contain 47.5 to 48.8 % protein by dry weight (Brumm and Hurburgh Jr, 2006). Only a small proportion (1%) of the soybean is consumed directly by humans as protein; most domestic soybean meal is used by the American livestock industry (USB, 2011a). The mixed rations for poultry, hogs, cattle, dairy cows, domestic pets, and farmed fish often are formulated with soybean meal. In 2010, poultry were the largest consumers of soybean meal (49%), followed by hogs (25%) and then cattle (12%) (Soystats, 2011a). Other animal consumers include farmed fish and domestic pets.

Soybean Oil

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

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

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

Table 1. Fatty acid composition of conventional soybean oil.

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

Source: (CODEX, 2010).
Notes: *Fatty acids are identified based on the number of carbon atoms and the number of double bonds in that fatty acid. Hence, oleic acid is identified as C18:1, indicating that this fatty acid is comprised of 18 carbon atoms with a single double bond.
ND – Not detectable

Soybean Food Products

Soybean is used in various food products, including tofu, soybean sauce, soymilk, energy bars, and meat products. A significant fraction of the soybean market is dedicated to production of purified oil for food use and industrial applications (Cahoon, 2003). Food uses include margarines, shortenings, and cooking and salad oils (OECD, 2000).

2.1.2 Soybean Composition

Generally, soybean seed consists of oil (about 20%), protein (about 40%), carbohydrate (about 35%), and ash (about 5%) (Liu, 1997)Various constituents have importance to the health and nutrition value of soybean, such as the isoflavonoids. Others are anti-nutritive, and many of these can be eliminated by the routine heating of the protein or meal fraction during processing for animals or humans. The oil fraction is composed of triglycerides with associated fatty acids, whose profile has significant consequences for human health and nutrition. The protein fraction is the most valued part of the soybean, and represents a complete protein that is important in human diets and feeding of livestock, poultry and farmed fish. The carbohydrate fraction of soybean flours can include both nutritive sugars (glucose, sucrose, galactose and others) and those that cannot be processed by human digestive enzymes (raffinose, stachyose) (see (Eldridge et al., 1979)).

Protein

Soybean is considered to be a source of complete protein. A complete protein is one that contains significant amounts of all the essential amino acids that must be provided to the human body because of the body's inability to synthesize them. The ten essential amino acids are arginine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, and valine (Kuiken and Lyman, 1949). Soybean provides these ten essential amino acids necessary for human nutrition, which is in addition to another 10 which can by synthesized by human metabolism from other nitrogen containing precursors (Kuiken and Lyman, 1949). The essential amino acid composition of soybean and soy-based products is provided in the USDA National Nutrient Database for Standard Reference (USDA-ARS, 2008b).

Isoflavones

Soybeans contain isoflavone compounds, polyphenol compounds closely related to the antioxidant flavonoids found in other plants (Manach et al., 2004). Soybean isoflavones are described as phytoestrogens because they exhibit estrogenic activity similar to estradiol hormones (Rostagno, 2009). These isoflavones may provide both benefits and negative impacts, as they are variously reported to exhibit estrogenic and anti-estrogenic effects, influence cardiovascular disease, impact cancer rates, and possibly slow the rates of osteoporosis. The major soybean isoflavones include genistein and daidzein. Isoflavones are produced primarily by beans and other legumes such as peanuts and chickpeas. (See Higdon and Drake (Higdon and Drake, 2009) for a summary of recent research on soy isoflavones.) The negative impacts of isoflavones are those that have been shown to have some adverse consequences to pest insects that feed on them, such as feeding inhibition for larvae of the moth *Spodoptera litura* among others (Zhou et al., 2011).

Antinutrients

Antinutrients are components of a food product which may be toxic at high concentrations, bind nutrients, or otherwise prevent their digestion. Soybeans contain several key antinutrients, such as oligosaccharides, lectins, phytic acid, and protease inhibitors (OECD, 2001). Protease inhibitors include trypsin and chymotrypsins (OECD, 2001). Lectins are sugar-binding protein inhibitors. The activity of these inhibitors is destroyed during the heat processing of soybean products. The carbohydrates stachyose and raffinose which are oligosaccharides can cause flatulence when consumed (Rackis, 1974). Phytic acid binds most of the phosphorus in soybean, preventing its absorption by an animal. It is common practice to add phytic acid-degrading enzymes to the animal feed formula (Monsanto, 2010b). Protease inhibitors interfere with the digestion of proteins, resulting in decreased animal growth (OECD, 2001). The antinutrients are destroyed during the heat treatment processing of the soybean products (OECD, 2001).

Fatty Acids

Saturated fatty acids in soybean include palmitic and stearic; whereas palmitic acid raises total cholesterol and low density lipoprotein (associated with adverse cardiovascular events) stearic does not (see review in (Micha and Mozaffarian, 2010)). Polyunsaturated fatty acids in soybean include linoleic and linolenic, and the monounsaturated fat is oleic. Evidence from the best human studies show that when polyunsaturated fatty acids replace saturated ones in the diet, the risk of cardiovascular heart disease declines (but not when caloric replacement is carbohydrate) (Micha and Mozaffarian, 2010). When monounsaturated fatty acids (e.g., oleic acid) replace saturated fatty acids, effects are uncertain because of mixed evidence at present (Micha and Mozaffarian, 2010). Trans-fats in the diet are unhealthy; these are produced when soybean fatty acids such as linolenic and linoleic are subjected to hydrogenation because of inherent low stability, or because properties of soybean oils are unsuitable for certain food uses. Incorporation of consequent trans-fats in foods results in known undesirable effects on blood lipid parameters (lowering HDLs, increasing triglycerides, and increasing LDLs). In turn, these measured parameters of human health correlate with adverse effects on cardiovascular health (see review in (Micha and Mozaffarian, 2008)).

2.2 Agricultural Production of Soybean

Soybean (*Glycine max* (L.) Merr.) plants are grown for their seed, which is further processed to yield oil and meal. In the U.S., the majority of soybean is cultivated as a commodity crop for animal feed and soybean meal (Monsanto, 2010b). Soybean is ranked number one in oil production (58 percent) among the major oil seed crops production in the world (ASA, 2011). Recently, there has been an increase in the percentage of the crop dedicated to specialty soybean produced for a specific market or use. These specialty, value-added products may be the whole bean or a fraction, such as the oil (Lee and Herbek, 2004). The production of specialty soybean is discussed in more detail in Subsection 2.2.5.

2.2.1 Acreage and Area of Soybean Production

Soybean production in the U.S. extends over a wide range of geographies and regions, and is grown from North Dakota to Louisiana and from the Great Plains states to the Eastern Seaboard (USDA-NASS, 1997). In the U.S., soybeans were harvested on 76.4 million acres in 2009 and 76.6 million in 2010 (USDA-NASS, 2011a). At least 31 states grew soybean as an annual crop in 2010 (USDA-NASS, 2011a). For the 2010 growing season, more than one million acres of soybeans were grown in each of the following 18 states (from highest to lowest acreage): Iowa, Illinois, Minnesota, Indiana, Missouri, Nebraska, Ohio, Kansas, South Dakota, North Dakota, Arkansas, Michigan, Mississippi, Wisconsin, North Carolina, Tennessee, Kentucky, and

Louisiana (USDA-NASS, 2011a). Harvested soybean is projected to slightly increase to nearly 80 million acres by 2020 (USDA-NASS, 2011b; USDA-OCE, 2012).

Although soybean acreage has increased from 2005 to 2010 by about 7% (USDA-NASS, 2011a), the potential for an increase into uncultivated acreage is low because soybean is profitably grown on high quality agricultural land, not lands of lower productivity (EIA, 2007; USDA-NASS, 2011a). Much of the high quality land in the U.S. is already committed to agricultural production (US-EPA, 2007) and in 2002, USDA- Economic Research Service (USDA-ERS) estimated that only 2.1% of cropland was idle in 2002 (Lubowski et al., 2006). At the same time, U.S. crop and agricultural acreage is declining through replacement by urban and other developed areas (EIA, 2007). It is unlikely that "new" previously uncultivated land will be brought into soybean production, but rather that growth of soybean production will compete with other agricultural uses (EIA, 2007).

Genetically modified plants, including soybeans, have been widely planted, with increasing frequency after their commercial introduction in the late 1990s. GE soybeans currently are planted on the majority of soybean acres in the U.S. (93% of acreage in 2010) (USDA-ERS, 2011a). All these GE soybean varieties are herbicide resistant. Besides genetically modified soybean varieties with crop production traits, such as herbicide tolerance, varieties expressing altered fatty acids are also available to growers (e.g., low linolenic varieties, see Specialty Soybean Production, Soybean Varieties with Altered Fatty Acids in Section 2.2.5 and (Fehr, 2007)). At present, these fatty acid modified lines are non-transgenic products, but new GE varieties are being developed (Cahoon, 2003).

Monsanto plans to channel production of SDA soybean into a limited region using several strategies identified below (Monsanto, 2010c). Constraints on production areas will be imposed by the seed provider (see first bullet below) and, to some extent, also by the biology of the specialty crop (see third bullet). Several measures are currently used in the production of specialty soybeans, including contracts specifying details of production and sales between growers and soybean purchasers (see second bullet). These measures will be used by Monsanto to limit the production area of MON 87769 soybean:

- The relative maturity groups (MG) in which the developer releases the traits. Growers must use varieties which are best adapted to the local season. Day length, temperature and length of the growing season may affect the time of flowering and seed formation (Setiyono et al., 2007) and soybean maturity is affected by the local day length (Cober et al., 1996). Thus, soybean yield, and therefore, commercial value, is a consequence of the MG and planting location.
- The area in which designated elevators and specialty oil crushers are located. Soybean growers will sign contracts with elevators and processors which will be designated in advance by the trait developer. These businesses would have compartmented storage available for specialty oilseed crops, and would agree to conditions specified in Monsanto's management plan, which would be required for segregating the crop. If soybean buyers are located too distant from production sites, cost of transport increases and profits decline; economic penalties further constrain soybean movement.
- The environment in which the soybeans are grown determines desired properties of the soybeans. Monsanto has determined that states located in the northern U.S. provide the

optimal environment for maximal expression of SDA from MON 87769 soybean (Monsanto, 2010b).

Through these means, Monsanto will be able to limit where growers produce MON 87769 soybean which will be the states of North and South Dakota, Minnesota, Wisconsin, and Michigan (Monsanto, 2010c). Some of the largest soybean production areas, such as Illinois, Iowa, Indiana and Missouri, would not be included in Monsanto's targeted production area. The area of production will include the northern-most area of the Heartland (McKnight, 2004). This area south of the Great Lakes encompasses Minnesota, Wisconsin, Michigan, and parts of South Dakota, which is characterized as lowland, level with some hills, and with fertile soils (McKnight, 2004). Corn, soybean, alfalfa, hay, fruit, beef cattle, hogs and dairy cattle are produced here. The other area where Monsanto plans to target production of MON 87769 soybean is the eastern-most fringes of the Great Plains and prairies**,** which includes parts of North and South Dakota. These lands are characterized as flat or sloping land (McKnight, 2004). Wheat, but also corn, soybean, sorghum, canola, sunflower, edible beans and peas, barley and rye, flaxseed, oats and sugar beets are grown here; cattle may be produced in this region; areas that are under irrigation allow vegetable and fruit production for cities (truck crops). These areas targeted by Monsanto for MON 87769 soybean production are areas where considerable commodity soybean is already produced (Tables 2 and 3).

Table 2. U.S. soybean production in Northern Tier states in 2010.

State	Acres Harvested (x 1000)	Production (x 1,000 bushels)	Yield (bushels per acre)
Michigan	2,090	91,960	44
Minnesota	7,310	328,950	45
North Dakota	4,050	149,850	37
South Dakota	4,150	166,000	40
Wisconsin	1,630	79,870	49
Total U.S.	76,823	3,408,211	44

Source: Crop Production. Soybean, October 10, 2010. (USDA-NASS, 2010a)

Table 3. Rank of soybean production in Northern Tier states and the U.S. in 2007 along with other principal crops.

State	First Rank Crop	Rank of Soybean Crop in State	Rank of State Soybean Production in U.S.
Michigan	Corn (for grain)	2	3
Minnesota	Corn (for grain)	2	12
North Dakota	Wheat (for grain)	2	9
South Dakota	Corn (for grain)	4*	34
Wisconsin	Corn (for grain)	3	15

Source: 2007 Census of Agriculture (USDA-NASS, 2009)
Note: *Wheat, forage and soybean acreage nearly equal

2.2.2 Agronomic Practices

In this EA, "conventional farming" includes any farming system where synthetic pesticides or fertilizers may be used. Conventional farming covers a broad scope of farming practices, ranging from farmers who only occasionally use synthetic pesticides and fertilizers to those farmers whose harvest depends on regular pesticide and fertilizer inputs. Conventional farming also includes the use of genetically engineered (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.

Soybean self-pollinates and is propagated by seed (OECD, 2000). Proper seedbed preparation, appropriate variety selection, appropriate planting dates and plant population, and good integrated pest management practices are important for optimizing the yield potential and economic returns of soybean (Barrentine, 1989; USDA-APHIS, 2010b).

Soybean Maturity Groups

Soybean varieties are developed and adapted to certain geographical zones (bands about 100-150 miles north to south) and are separated into ten maturity groups – Group 00 to Group VIII: Group 00 through Group IV soybean varieties are planted in the Midwest and Eastern Coastal regions; Groups IV through VIII are planted in the southern states (Helsel and Minor, 1993; Hodges and French, 1985; Pioneer, 2011). To adapt to the local growing season, producers typically plant seed of an appropriate maturity group so that its development and harvest coordinates with the seasonality of the location. To avoid frosts and maximize yield and oil content, the grower's priority is to plant soybean as early as possible and to use the early maturing varieties (North Dakota) (Berglund and Helms, 2003). In the five Northern Tier states, the 0-2 maturity groups would be generally planted (Zhang et al., 2007), but University of Wisconsin Extension (UW-Extension, 2008) has tested maturity groups between 0.1 and 2.8 in various parts of Wisconsin to match local conditions. In parts of Michigan, a maturity group as high as 3.4 might be planted (MSU-Extension, 2010) and in parts of North Dakota 00 or even 000 might be planted (Kandel, 2008).

Pre-Season Preparation

Crop rotation, tillage system, row spacing, planting equipment, seed or trait selection(s), herbicide choices and details of soil fertility require production decisions well in advance of planting the soybean crop.

Planting and Early Season

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

Highest soybean planting activity begins in mid-May (as early as the 10th in some states) and continues through early June, with Wisconsin planting as late as June 20 (USDA-NASS, 1997). As an example, in Wisconsin, although the highest yield comes from planting before May 20, delayed planting to June 1 could reduce yield to an estimated 89 per cent and by June 10 to 75 percent (with a plant population of 200,000) (Conley and Gaska, 2011).

Recommended herbicide use in Roundup Ready Soybean (NDSU Weed Science):

- Strategy 1: Pre-emergent herbicide or pre-plant incorporated metolochlor, pendimethalin, Fierce, or metribuzin, etc. used. Most require rain for activation.
- Strategy 2: Glyphosate applied to early emerged weeds.
- Strategy 3: Glyphosate applied to 2-4 inch weeds.

For tillage practices in early season, see Tillage section, below.

Mid- to Late Season

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

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

Recommended herbicide use in Roundup Ready Soybean (NDSU Weed Science):

- Strategy 1: Glyphosate applied to soybean post-emergent (follows early pre-emergent soil-applied or -incorporated herbicide).
- Strategy 2: Post emergent herbicide acetochlor, imazamox, bentazon/sethoxydim, acifluorifen (follows glyphosate applied pre- emergent to soybean).
- Strategy 3: Roundup/glyphosate 14-21 days after first application (follows glyphosate applied to pre-emergent soybean).
  For tillage practices in mid and late season, see Tillage section, below.

Harvest Season

At maturity, the seed moisture content is approximately 55 to 60%. At this stage, at least one pod on the plant reaches maturity (Hoeft et al., 2000). Under warm and dry weather conditions, seed moisture content will drop to 13 to 14% in 10 to 14 days from physiological maturity (Hoeft et al., 2000). Soybean is harvested when the moisture content drops below 15%. From preharvest through combining, soybean loss can vary between 3 and 10% and greater, depending upon operating processes and equipment adjustment (Bennett et al., 2011).

Harvesting activity is highest in the five states of South Dakota, North Dakota, Minnesota, Michigan, Wisconsin between late September (North Dakota) and mid- to late-October (Wisconsin: early November) (USDA-NASS, 1997).

Recommended fall herbicide use in Roundup Resistant Soybean for next season soybean (MSU, 2011):

- 1: Burndown without residual activity: glyphosate, gramoxone, 2,4-D.

2: Burndown with residual activity: Authority Assist, Canopy, Autumn, Extreme.

Crop Rotation

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

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

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

Agronomic practices for soybean rotations vary from state to state. Continuous (i.e., non-rotation) soybean production is discouraged by most extension soybean specialists to reduce the risk of diseases and nematodes (Al-Kaisi et al., 2003). In a survey of major corn/soybean production states, corn and soybean were alternated on 72 to 80% of acreage, other rotations were grown on 16 to 20 % of acreage, and soybean was grown continuously on 5 to 12% of acreage during the years 1996-2002 (Sandretto and Payne, 2008). In another analysis, the majority of the U.S. soybean acreage (68.6%) is rotated to corn ((Monsanto, 2010b) at page 157, et seq.). Approximately 14.5% of the soybean acreage is rotated back to soybean the following year. Wheat follows soybean on approximately 11.2% of the U.S. soybean acreage, with cotton, rice, and sorghum the next largest rotational crops following soybean (4.6% of the soybean acreage). Other minor rotational crops that follow soybean production include barley, rice, oats, and dry beans.

In the Northern Tier states where MON 87769 soybean would likely be grown, corn is often grown following soybean, but other crops may be added to the basic rotation, often small grains (Table 4) (UW-Extension, 2004). In eastern South Dakota, a corn-soybean rotation when coupled with a wheat crop is advantageous, since it may reduce yield losses caused by corn-soybean adapted *Diabrotica* species (corn rootworm), soybean cyst nematode, and weeds that proliferate in soybean and corn (Anderson, 2008). In southwestern Michigan, increasing crop diversity in crop rotations has been shown to increase corn grain yield (Smith et al., 2008). Double cropping (i.e., plantings two crops in the same field within one year) of soybean with wheat is discouraged, since a predictable rate of return on late planted soybean cannot be established (Conley et al., 2008).

Table 4. First and second most frequent rotational crop following soybean

State	Rotational Crop Following Soybean	Percentage of rotational crop planted
Michigan	Corn	70
	Wheat	25
Minnesota	Corn	76
	Wheat	18
North Dakota	Corn	30
	Wheat	45
South Dakota	Corn	72
	Wheat	20
Wisconsin	Corn	85
	Alfalfa	4

Source: Table IX-8, column G, based on personal communications with state extension specialists and Monsanto Technology Development Representatives (Monsanto, 2010b).

Tillage

Mechanical weed control by means of tillage is an important aspect of soybean cultivation, and in 2006, no-till production ranged from 9.2 to 47.7% of soybean production in the five Northern Tier states in 2006 (Horowitz et al., 2010). Other types of conservation tillage, reduced and conventional tillage, made up the remainder. Conservation tillage practices have seen increased use throughout the U.S. in recent years, especially in the Midwest where wind and water erosion are often important farm issues. The percentage of planted land in the U.S. managed in conservation tillage increased from 26% in 1990 to 41% in 2004 (Sandretto and Payne, 2008). Soybean tillage has been summarized in five categories, with two groups, one of “conservation tillage” (no-till, ridge-till and mulch-till) or “other tillage practices” (reduced till and intensive till) (CTIC, 2010b). Conventional tillage is associated with intensive plowing and less than 15 percent crop residue; reduced tillage is associated with 15 to 30 percent crop residue; and conservation tillage, including no-till practices requiring herbicide application on the plant residue from the previous season, is associated with at least 30 percent crop residue and substantially less soil erosion than other tillage practices (US-EPA, 2009). Almost 40% of full season soybean acreage is under no-till practice, while another 23% is under a specialized type of conservation tillage. Another 20% of soybean acres are intensively tilled.

In addition to preplant tillage preparations, cultivation for weeds might also be undertaken because a preplant residual herbicide was not activated by precipitation, and immediate control is required (IPMCenters, 2011). Pre-emergence herbicides may also need activation, and failing adequate rainfall, rotary hoes or harrows may be deployed at soybean emergence (IPMCenters, 2011). Weed escapes from herbicide treatment may also be remedied with shallow cultivation (IPMCenters, 2011).

<u>Nitrogen Fertilization</u>

Soybeans remove up to 70 pounds of nitrogen from the soil when a 50-bushel yield of soybean is attained, with only about 35% of that originating from soil (Hoeft et al., 2000). The remaining nitrogen needs of soybean come from symbiotic nodulating bacteria of the families Rhizobiaceae and Bradyrhizobiaceae, and these form a symbiotic relationship with soybean (Gage, 2004). The symbiosis between nitrogen-fixing plant-microbe and the plant results in the formation of root nodules, providing an environment in which differentiated bacteria reduce or fix atmospheric nitrogen. The product of nitrogen fixation, ammonia, then can be used by the plant (Gage, 2004). USDA-ERS (USDA-ERS, 2010e) estimates that less than 40% of soybean acres in the U.S. receive nitrogen fertilizer. Given the important role of these bacteria for meeting nitrogen needs of soybean, commercial sources of inoculants such as multiple strains of *Bradyrhizobium* can be applied to soybean seeds just before planting (Beuerlein, 2005). These bacteria must be supplied if a soybean crop has not been recently grown on the field (Bottomley, 1992), and if nodulation is inadequate, supplemental nitrogen may be required for the developing crop (Ferguson et al., 2006). Maintaining an optimal pH is important to proper initiation of nodulation, and in a typical corn-soybean rotation, pH of about 6 is a good target (Hoeft et al., 2000).

<u>Weed Control</u>

One of the highest priorities in soybean production is weed management (Hoeft et al., 2000). Weeds compete with soybean for water, soil nutrients and light, and may ultimately reduce yield. Growers use cultural methods, cultivation and herbicides to control crop competitors, and, depending on the strategies chosen, different herbaceous annuals, perennials, or even woody species can become established (Hoeft et al., 2000). Weeds present during an entire growing season can result in soybean yield losses ranging from 12 to 80% (Barrentine, 1989).

U.S. soybean farmers began augmenting tillage with herbicides to control weeds in the late 1950s, but tillage in crop production remained an important strategy (Gunsolus, 1990). By the early 1990s, there were over 70 individual herbicides or combination products registered for weed control in soybean (Gianessi et al., 2002). As additional herbicides became available, the possibility of the conservation-enhancing use of reduced tillage or no-till became feasible (Givens et al., 2009). Next, as herbicide-tolerant GE crops were no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act beginning in 1996, a larger number of growers were able to adopt conservation tillage strategies (Givens et al., 2009).

The use of herbicides is directly related to choices made by soybean producers for tillage options. Herbicides can directly substitute for tillage, and their use often offers better management than tillage alone (Gianessi and Reigner, 2007). Consequently, as noted, there has been a trend towards less tillage as a greater number of herbicide choices and options have become available. As herbicide-resistant crops were offered and deployed, increased amounts of conservation tillage began to be practiced, since particularly wide spectrum herbicides (such as glyphosate) could be used on soybean. Although herbicide-tolerant varieties have become the most widely planted soybean in the U.S. (94% of all soybean acreage in 2011 (USDA-ERS, 2011a)), especially Roundup Ready® varieties, the developer of the technology still recommends that growers add tillage or other herbicides, as appropriate, in their Roundup Ready® soybean production methods (Monsanto, 2011).

Foxtail spp., pigweed, velvetleaf (*Abutilon theophrasti*), lambs quarters (*Chenopodium album*), and cocklebur (*Xanthium strumarium*) are common annual weeds in Midwest corn and soybean fields. However, growers consider giant ragweed (*Ambrosia artemisiifolia*), lambs quarters, Canada thistle (*Cirsium arvense*), cocklebur, and velvetleaf to be the top five most problematic weeds in corn and soybean because of the difficulty of controlling these weeds (Nice and Johnson, 2005). For Minnesota soybean, yellow foxtail, common ragweed and common lambsquarters are prominent, with winter annuals such as mustards, horseweed, and biennials such as wormwood important weeds; perennial broadleaf weeds include Canada thistle, common milkweed and hemp dogbane which can be difficult to manage in soybean (Potter and Ostlie, 2003). Eighty-six common weeds of soybean across three growing regions (Midwest, Mid-South, and Eastern Coastal) were identified in another soybean petition for nonregulated status (pages 150-151 in (Monsanto, 2010a)).

Commercial soybean production may require at least one herbicide application for effective weed control. Most commonly, weeds are controlled by planting glyphosate-tolerant soybean varieties, and applying glyphosate at least once during production. In some places glyphosate resistant weeds have been reported, such as pigweed and morning glory (Heatherly et al., 2009; Woodruff et al., 2010). These resistant weeds can be managed by applying herbicide combinations with different modes of action, as well as crop rotation, varying row spacing, and mechanical removal of weeds (Woodruff et al., 2010). In 2002, it was calculated that 96 percent of all planted soybeans were treated with at least one type of herbicide, ranging from 0.04 to 0.71 pounds (lbs) of product per acre. In 2006, herbicides were used on 98 percent of soybean acres of surveyed states (USDA-NASS, 2007b). Table 5 shows principle herbicides used on soybean in two Northern Tier states. Weed species are also discussed in Section 2.4.2, Plant Communities.

Table 5. Principal herbicides used in soybean production and percentage of acres applied—selected states.

State	Herbicide					
	Glyphosate	2,4-D	Imazathapyr	Pendimethalin	Clethodim	Trifluralin
	Percent of total acres applied					
Wisconsin* (2006)	85	11	9	9	--	--
Minnesota** (2007)	91	--	--	--	2	2

Sources:
* NASS, Wisconsin Field Office (USDA-NASS_Wisconsin-Field-Office, 2009 download).
** Minnesota Department of Agriculture (MDA, 2009).

Various other pesticides may also be used for soybean production, including insecticides, fungicides, and nematicides. In 2006, insecticides were used on 16 percent of soybean acres. The three most common insecticides, lambda-cyhalothrin, chlorpyrifos, and esfenvalerate, were applied to 6, 5, and 3 percent of the planted acres, respectively (USDA-NASS, 2007b). In addition to these three insecticides, a total of 10 other insecticides are recommended for use on soybeans for aphid control (UM, 2011).

2.2.3 Soybean Seed Production

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

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

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

Foundation seed, Registered seed, and Certified seed production is controlled by public or private seed certification programs (AOSCA, 2009). Commercially certified soybean seed must meet state and Federal seed standards and labeling requirements. Federal Seed Act regulations are detailed in 7 CFR 201. State seed certification standards may vary slightly from state to state and can be more restrictive than the seed standards of AOSCA (Association of Official Seed Certifying Agencies) (GCIA, 1988; NCCIA, 2011; Seed Certification Department, 2001). The values for certified soybean seed standards from AOSCA are as follows (AOSCA, 2009):

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

In addition to these specific factors, soybean certification standards identify land requirements and field practices that must be followed. Soybeans must be grown on land on which the previous crop grown was of a different type, certified seed of the same variety, or a variety having noticeable characteristic differences. In addition, for every 200 certified soybean plants, only one off-type or other variety is allowed (AOSCA, 2009). Certified seed crop is subject to field inspections by certifying agencies at harvest and other times in order to observe factors related to seed certification and determine genetic purity and identity. Harvested seeds may be inspected and sampled at any time (AOSCA, 2009).

All soybean seed sold may not be officially certified; however, commercial soybean seed sold and planted for normal soybean production is produced predominately to meet or exceed certified seed standards.

Seed certification systems should be distinguished from identity preservation systems for certain agricultural commodities. Soybean Identity Preservation (IP) refers to a system of production, handling, and marketing practices that maintains the integrity and purity of specialty crop products (Sundstrom et al., 2002). MON 87769 soybean is expected to be handled and marketed within the practices of the certified seed system, and is expected to meet all state and federal seed standards and labeling requirements.

2.2.4 Organic Soybean Production

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

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 Section 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 Section 205.2 as:

> A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA [deoxyribonucleic acid] 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, 2010).

Common practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields (Baier, 2008; Bradford, 2006; NCAT, 2003; Sundstrom et al., 2002).

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, 2010). 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, 2010).

The production of organic soybeans represents between 0.17% and 0.22% of total U.S. soybean production (USDA-ERS, 2010d). In 2005 and 2008, 122,217 and 125, 621 acres of soybean in the U.S., respectively, were certified organic (USDA-ERS, 2010d). In the Northern Tier states for 2008, approximately 50,500 acres were certified organic (Table 6), which represents less than 0.3% of the total soybean crop in the region (USDA-ERS, 2010d). Organic soybean markets typically enjoy a market premium offsetting the additional production and record-keeping costs associated with this production method.

Table 6. Certified organic soybean acreage, 2007 and 2008.

State	2007 Acreage	2008 Acreage	Percent of total U.S. organic soybean acreage (2008)
Michigan	11,320	11,251	9.0
Minnesota	25,518	21,229	17
North Dakota	3,308	3,773	3.0
South Dakota	4,531	4,786	3.8
Wisconsin	8,381	9,369	7.5
Total Northern Tier states	53,058	50,408	41
Total U.S.	100,390	125,621	

Source: (USDA-ERS, 2010d).

2.2.5 Specialty Soybean Production

Identity Preservation (IP) refers to a system of production, handling, and marketing practices that maintains the integrity and purity of specialty crop products (Sundstrom et al., 2002). Commodity grains are marketed en masse according to USDA grading standards. Specialty crops require some form of segregation or IP to keep these grains separate from commodity grains (Elbehri, 2007). This segmentation helps preserve a specified purity of the product. With certain specialty crops (e.g., organic or designated industrial-uses), IP is required to prevent accidental or unintended commingling. Should the IP crop be admixed with a different variety, contracts between growers and purchasers define acceptable limits of such admixture. If defined purity is not attained, the buyer can reject the crop, and the grower would not receive the premium price specified by the contract. Thus, financial penalty encourages the grower to maintain standards expected by the buyer and by those users further along in the supply chain.

Comments submitted in previous environmental assessments have identified issues pertaining to management practices designed to prevent accidental or unintended commingling of crops. Many of these practices are already well established in the soybean industry as part of the crop cultivation practices necessary to maintain IP. The need for segregation and IP production systems has increased with the development of specialty crops or crops with special output traits, such as high oil corn, high oleic sunflower, and low-linolenic soybean (Sundstrom et al., 2002). MON 87769 soybean is expected to be handled and marketed within the practices of a Closed Loop IP (see definition in Section 4.2.5) production system (Monsanto, 2010b).

Specialty Soybean Types

The U.S. soybean IP production and distribution systems accommodate differences between commodity and specialty soybean. Production systems designed prior to the introduction of MON 87769 soybean or even prior to the introduction of biotechnology-derived soybean allow for production of specialty soybean varieties to meet varied customer demands. Although soybeans are primarily a commodity crop, there is an existing specialty soybean market. Distinct identity-preserved specialty soybean with such traits as clear hilum or high protein have been grown and successfully marketed for specific food uses in domestic and export markets for many years (Cui et al., 2004).

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

- non-biotechnology-derived,
- certified seed,
- organic food-grade,
- low saturated fat,
- clear hilum,
- tofu,
- natto,
- high sucrose,
- high oleic,
- low linolenic, and
- high protein.

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

The majority of these specialty soybean varieties are offered in Maturity Group II and early Group III varieties which are adapted to the upper Midwest/Great Plains region (Lee and Herbek, 2004). Vistive® soybean with low linolenic traits are offered by Asgrow in Maturity Groups 2.0 to 3.6 (Asgrow, 2011).

Specialty Soybean Production

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

The distinction between the commodity soybean and the specialty soybean involves both certified seed production as well as IP of the harvested crop. The majority of soybean in the U.S. is cultivated and marketed as a commodity for the oil and protein markets (Monsanto, 2010b). The goal of the commodity supply chain is to supply a homogenous product to the end user. Although the grower producing soybean for this chain may choose from many different varieties for cultivation, the harvested soybean is viewed to be the same for all commodity soybean varieties (Monsanto, 2010b).

At harvest, the grower either delivers soybean to a handler or stores them on farm for later delivery. The commodity soybean is not differentiated for later use. Commodity soybean handlers typically have large volume storage capacity, and commodity soybean processors crush large volumes of soybean to produce homogeneous oil and meal products. The commodity system is designed to maximize efficiency at a low profit margin and results in comingling of different sources of soybean. The beneficial consequence of mixing soybean in the initial crush, increased homogeneity, is also one that does not affect the price received for the final product. This production system has been in place in the U.S. since the production of soybean began in earnest in the 1960s (Sonka et al., 2004).

The specialty soybean market produces soybeans that have specific physical or chemical characteristics to meet specific buyer requirements. As a result of these special needs, a separate specialty soybean channel has developed for the specialty soybean product that involves much smaller volumes than commodity soybean (Smyth and Phillips, 2002a; Sonka et al., 2004). Specialty soybean varieties are produced on approximately 12% of the U.S. soybean acreage and, according to the Midwest Shippers Association (MSA, 2009), this acreage could grow to over 25% of the crop acreage in certain states within the next decade. In Iowa, 13.5% of soybean acres were planted to specialty soybean, and about half of these acres were either non-GE crops or for seed production (Goldsmith et al., 2008). Fehr reported that in 2006, about 700,000 acres in the U.S. were planted to low and ultralow linolenic acid varieties (Fehr, 2007).

The specialty soybean supply chain typically start with a firm that contracts production of a specific variety and sets standards for quality of the harvested soybean (Lee and Herbek, 2004). In return, growers receive a premium over the price paid for commodity soybean. Growers may store harvested soybean on farm or deliver the product directly to an approved processor or to special containers for international shipment.

The IP practices used in specialty soybean production require that all equipment and storage facilities for specialty soybean must be clean of seed from other soybean varieties or plants, dirt, pathogens, and other foreign material (Hanna and Jarboe, 2005). Some soybean contracts may require a special inspection of the handling and storage facilities. The specialty soybean for soybean foods may require special harvesting equipment because some of these soybeans are harvested before full maturity (e.g., edamame or vegetable soybean) (Ernst and McNulty, 2011 download).

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

Soybean Varieties and Altered Fatty Acids

The genetic changes in soybeans that resulted in altered soybean oil composition have been achieved by both conventional and genetic engineering techniques. Varieties were improved conventionally by genetic selection and mutagenesis techniques. Among the cultivars currently grown for commercial production are those for reduced palmitic and linolenic acids (Fehr, 2007; Goldsmith et al., 2008). Non-GE soybean breeders also have obtained varieties with greater than 70% oleic acid by selection and intercrossing (Alt et al., 2005).

Nontransgenic lines include those which express low linolenic acid, an oil trait which does not require trans-hydrogenation to improve oil properties and increase product stability. Asoyia formerly offered an ultralow linolenic variety at 1% of fatty acids (Qualisoy, 2011; Wilkes, 2008) and Iowa State has made some lines available to growers (http://www.notrans.iastate.edu/). Low saturated fat soybeans are also available from Iowa Natural (1% linolenic, 7% saturated fats of total oil) (American Heart Association, 2011; NYC-DOH, 2009). Low linolenic soybeans with GE herbicide tolerance are marketed by Monsanto (‘Vistive’) and Pioneer (‘Plenish’) seed companies, with linolenic acid expressed at less than 3%. The Vistive line was planted on 1.5 million acres in 2008 (Monsanto, 2008).

Genetic engineering techniques have been used to increase oleic acid composition in soybean to near 80%, but the first altered fatty acid variety no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (APHIS Petition # 97-008-01p (USDA-APHIS, 1997)) has not been planted on a large commercial scale since 2005 because the developer changed its market strategy. This line is no longer commercially available. Another GE high oleic acid variety, DP-304423-1 with a high oleic phenotype conferred by introduction of the soybean omega-6 desaturase gene 1 (*fad2-1* gene) was no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act, but will not be released commercially until 2012 (Plenish (Pioneer Hi-Bred, 2011)). Other soybean with altered fatty acids have also been petitioned for non-regulated status (MON 87705 high oleic soybean).

Non-herbicide Tolerant Soybean

In the US, non-herbicide tolerant soybean varieties (conventional, nontransgenic) in the U.S. were planted on approximately 8% of the total soybean acres in 2008 (Fernandez-Cornejo et al., 2002), and many of these are specialty soybeans (Lee and Herbek, 2004). Specialty soybean varieties include tofu, natto, bean sprouts, edamame, soynuts, as well as those with unique chemical identities, such as those with modified fatty acid profiles, high protein or high sucrose content. Farm production of these soybeans is essentially the same as for conventional soybeans, although for specific varieties, there may be less tolerance for accidental admixture with weed seeds such as nightshade and pokeweed seeds which can stain the soybean seed (Lee and Herbek, 2004).

2.3 Physical Environment

2.3.1 Water Resources

The typical amount of water required for a high-yielding soybean crop is approximately 20 inches during the growing season (Hoeft et al., 2000). Annual state-wide precipitation data collected for the 5-state region where MON 87769 soybean may be grown (i.e., North and South Dakota, Minnesota, Wisconsin, and Michigan) ranges from approximately 18 to 33 inches (NOAA, 2011 download). While normal climatic conditions may provide sufficient water to produce a soybean crop, precipitation may vary across a state and from year to year and irrigation may be needed to supplement precipitation amounts. Irrigation of soybean acres, according to data from the USDA 2007 Census of Agriculture, is used on 4.6 to 15% of soybean acres in the five-state region where MON 87769 soybean may be cultivated (USDA-NASS, 2007c, 2010). In some limited areas, such as central Minnesota, soybean is usually produced under irrigated conditions (deJensen et al, 2004), and this may be a consequence of the soil characteristics in specific areas. Soybean acres that are irrigated are a small portion of total soybean acres, much less than those acres irrigated for corn (Table 7) (USDA-NASS, 2007c).

Table 7. Irrigation of soybean acres in Northern Tier states.

State	Harvested acres[a]		Irrigated harvested acres[b,c]		Percent of soybean acres irrigated[c]
	All crops	Soybeans	All crops	Soybeans	
Michigan	6,859,081	1,715,427	1,434,358	66,556	4.6
Minnesota	19,267,018	6,273,919	1,416,247	92,347	6.5
North Dakota	22,035,717	3,073,981	233,171	12,513	5.4
South Dakota	15,278,709	3,222,872	358,807	52,661	15

Wisconsin	8,884,628	1,363,124	373,680	24,855	6.6
United States	309,607,601	63,915,821	86,529,391	2,175,069	2.5

a. Table 1, State Summary Highlights: 2007 (USDA-NASS, 2009)
b. Source: Soybean Irrigated Harvested Acres: Table 33, 2007 Census of Agriculture – State Data (USDA-NASS, 2007c)
c. Total acres from (USDA-NASS, 2007c).

In most states, irrigation water comes predominantly from groundwater sources, with comparatively little derived from surface water sources (Table 8).

Table 8. Water sources used for irrigation of soybean acres in Northern Tier states.

State	Irrigated harvested soybean acres[a]	Water Source[a]		
		Acres irrigated with groundwater from wells (% of total)	Acres irrigated with on-farm surface water (% of total)	Acres irrigated with water from off-farm suppliers (% of total)
Michigan	73,986	46,851 (63)	26,155 (35)	1,220 (2)
Minnesota	100,513	100,076 (99)	3,489 (3)	-- (NA)
North Dakota	18,939	15,019 (79)	1,802 (10)	2,738 (14)
South Dakota	79,296	57,533 (72)	5,420 (7)	16,733
Wisconsin	ND (NA)	ND (NA)	ND (NA)	ND (NA)
United States	7,044,546	6,448,846	619,824	136,708

Source:
a. Farm and Ranch Irrigation Survey 2008, Table 29 (USDA-NASS, 2010b).
Notes:
Some farms may obtain water from multiple sources.
-- – No irrigation
NA – Not applicable
ND – No data available.

Agricultural non-point source (NPS) pollution is the primary source of discharge pollutants to rivers and lakes and a major contributor to groundwater contamination. The EPA lists the most important cause of impairment in assessed streams and rivers as pathogens, with sediment second, and nitrogen third; pesticides are only the 16th most important (EPA, 2012). Agricultural management practices that contribute to NPS pollution include the type of crop cultivated, plowing and tillage, and the application of pesticides, herbicides, and fertilizers. Agricultural pollutants released by soil erosion include sediments, fertilizers, and pesticides that are introduced to area lakes and streams when they are carried off of fields by rain or irrigation waters (US-EPA, 2005). Excess sediment can directly affect fish and other wildlife mortality and reduce the amount of light penetration into a body of water. Indirectly, soil erosion-mediated sedimentation can increase fertilizer runoff, and facilitate algal blooms and oxygen depletion in a body of water (US-EPA, 2005).

Agriculture may contribute to several types of chemicals found in water resources. These include nitrogen and phosphorus from applied fertilizers, which, when present at high concentrations, may lead to eutrophication of surface water, resulting in changes in dissolved oxygen concentrations and frequent algal blooms (Carpenter et al., 1998). Other chemicals found in surface water runoff may include various pesticides (both herbicides and insecticides) which, at high concentrations, may impact humans, plants and animals that are exposed to the affected water (Domagalski et al., 2008; Vogel et al., 2008). Some pesticides used on soybeans were detected by Vogel et al. (2008) in rainwater, such as chlorpyrifos (64% of samples in a four state pattern). In addition to direct impacts to surface water, agricultural chemicals may eventually impact groundwater when transported by infiltrating surface or irrigation water. Irrigation with locally pumped water tends to reduce transport of chemicals in ground water because it avoids connecting streams with groundwater (Domagalski et al., 2008).

Ground water and aquifers may be impacted by agricultural chemicals via infiltration as well. In areas where soybean and corn are grown in rotation, such as Nebraska, and where ground water is a principle source of water for human consumption, this can be a critical issue (Stanton et al., 2007). In other areas, surface water movement of contaminants is at issue, and agricultural tile drainage systems have been shown to be a source of nitrate entering streams and rivers (Randall and Mulla, 2001). In areas where water retention in fields is high, periodically impeding crop production, such subsurface drainage systems are commonly employed (Hoeft et al., 2000).

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

2.3.2 Soil Quality

Arable land supports a rich and complex community of below-ground microorganisms and arthropods. The interaction between the below-ground community, plant root suture, and organic residues in the soil is central to a variety of dynamic soil ecological processes, including the decomposition of organic material, subsequent nutrient cycling and release, and the associated maintenance of soil structure and composition.

Soil Type

Soil texture and structure are key components determining water availability in soils which, in turn, affects soybean root depth and density. Soybeans are grown on a variety of soil types, ranging from small particles (clay), medium particles (silt), and large particles (sand). Silt loam particles’ medium size, good aeration, fertility, high water-holding capacity and abundance of organic matter make it the ideal soil for soybean cultivation (Hoeft et al., 2000). As medium-textured soils are able to hold more available water, the soybean roots in medium textured soils are denser and extend to a typical depth of 1.2 meters. By contrast, soils that are more compact (e.g., clayey soils) hold less water and, as a result, the soybean plant root mass is less dense and shallower. The disadvantages of clay soils include their tendency to clump and impede drainage when tilled at too low or too high moisture levels, leading to less aeration and a tendency toward erosion (Hoeft et al., 2000). The ideal pH for soybean growth is 6.0, with yield declining at a pH less than or equal to 5.8 (Heatherly et al., 2009; Hoeft et al., 2000).

The soils found in the Northern Tier states are of varying types but predominately Mollisols and Alfisols. Soil surface layers of Mollisols are generally thick and dark and are among some of the most important soil types in both world and U.S. agriculture (McDaniel, 2011). Alfisols may typically have a layer of clay beneath a surface layer of relatively high fertility (McDaniel, 2011; Soil Survey Staff, 1999, 2010; US-EPA, 2009). Additionally, another type of soils found in the five states of interest are Vertisols which are clay soils that expand when wet and shrink with cracking when drying (Soil Survey Staff, 1999). Also, other soils present in this region include Entisols, many of which are sandy or have very shallow surface layers, and Histosols, having high organic material in upper layers, and which overlay rock, cinders or pumice.

Soil Disturbance/Degradation

Cultivation of soybean directly impacts the qualitative and quantitative attributes of soil. For example, conventional tillage and mechanized harvesting machinery may disturb and expose the top soil surface layer, leaving the land prone to degradation. In turn, degradation of soil structure and composition may lead to decreased water retention, a decrease in soil carbon aggregation and net positive carbon sequestration, and increased emission of radiatively-active gases that contribute to the greenhouse effect (e.g., carbon dioxide (CO_2) and nitrous oxide (N_2O)) (Lal and Bruce, 1999; US-EPA, 2010a). Additionally, land that is prone to degradation is also more likely to negatively affect water resource quality and communities of organisms dependent on those water resources.

Soil Biota

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

In addition to *Rhizobium*, beneficial microorganisms to the soybean plant include mycorrhizal fungi that attach to soybean roots and extend hyphae deep into the soil, effectively increasing soybean access to nutrients and water (Purves et al., 2004). In addition to increasing soybean access to water and nutrients, mycorrhizal hyphae also facilitates pore creation in soil through particle aggregation, an important effect in clay soils that do not aerate well (Heatherly and Hodges, 1999).

Both *Rhizobium* and mycorrhizae aid plant survival during drought. Mycorrhizal-colonized non-irrigated soybeans have shown a 10 percent increase in yield compared to non-colonized non-irrigated soybeans during a drought period. These two mutualistic symbioses have been shown to occur concurrently, with mycorrhizae having a positive impact on *Rhizobium* nodulation and the nitrogen-fixing activity of nodules present on the soybean plant. These soybean plants also provided a greater yield (Heatherly and Hodges, 1999).

2.3.3 Air Quality

Agricultural Air Pollutants and Emissions Sources

Agricultural impacts on air quality can be measured by concentrations of specific air pollutants, such as the Clean Air Act (CAA) National Ambient Air Quality Standards (NAAQS) criteria pollutants, greenhouse gases (GHGs), volatile organic compounds (VOCs), pesticides, odors, and airborne allergens. The seven NAAQS criteria pollutants are carbon monoxide (CO), lead, nitrogen dioxide (NO_2), particulate matter between a nominal 2.5 and 10 micrometers in aerodynamic diameter (PM_{10}), particulate matter less than a nominal 2.5 micrometers in aerodynamic diameter ($PM_{2.5}$), ozone (O_3), and sulfur dioxide (SO_2) (US-EPA, 2010c). The main GHGs that enter the atmosphere because of agricultural activities include: carbon dioxide (CO_2), methane (CH_4), and nitrous oxide (N_2O). In addition to CO_2, ammonia is also another trace gas from agriculture (Krupa et al., 2006).

Emissions from crop agriculture can be broken down into two main categories – emissions related to working fields, such as dust and equipment emissions, and emissions from the soil and plants. Emissions released from agricultural equipment (e.g., irrigation pumps and tractors) include CO, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (US-EPA, 2010b). Agriculture activities (e.g., field preparation, planting, and harvesting) may generate dust plumes (PM_{10} and $PM_{2.5}$) (Holmén et al., 2006). For example, peak levels of particulate concentrations coincide with the peak agricultural harvest season in California's Central Valley (Giles et al., 2006).

Primary agricultural air emission sources of other pollutants include soil particulates associated with tillage; smoke from agricultural burning, pesticide drift from spraying; and aerial application of pesticides which all may cause air quality impacts by drift and diffusion. Atmospheric wet and dry deposition of nitrogen, mineral nutrients, and organic compounds to cropping systems can have feedback effects on trace gas emissions from fields (Krupa et al., 2006). Agricultural pesticides may also enter the atmosphere through volatilization from soil and plant surfaces and through wind erosion and can be returned to the surface through precipitation or dry deposition processes (Vogel et al., 2008).

Primary agricultural air emission sources of GHGs include: CO_2 from agricultural burning; vehicle exhaust associated with equipment used in tillage and harvest; and N_2O emissions from the use of nitrogen fertilizer (Aneja et al., 2009; Hoeft et al., 2000; US-EPA, 2010a; USDA-NRCS, 2006a). Agriculture, including land-use changes for farming, is responsible for an estimated 17 to 32 percent of all human-induced GHG emissions. Herro (Herro, 2008) proposes that if agriculture practices were modified, significant reductions in the release of GHGs would be expected. Compliance and enforcement of emission rules may be regulated at state, local, and federal levels, but for most GHGs there are no applicable regulations of these gases arising from agricultural burning.

Agricultural burning generates smoke that consists of particulate matter, including a complex mixture of carbon, tars, liquids, and different gases that are harmful to the human environment (US-EPA, 2011a) The major pollutants from burning on natural lands are particulates, carbon monoxide, and volatile organics. Nitrogen oxides are emitted at rates of from 1 to 4 grams per kilogram (g/kg) burned, depending on combustion temperatures (US-EPA, 2011a)

Burning of soybean crops is usually not recommended by State Extension Services, but burning of corn preceding a corn crop in a corn-soybean rotation is sometimes indicated (Minnesota (Rehm, 2009); North Dakota, (Franzen and Nowatzki, 2009)). More likely, agricultural fires in soybean acreage occur as accidental events in hot and dry fall conditions (Sawyer, 2000). These fires are more likely to occur in corn, but fires in rotation crops such as wheat and soybean may also occur (Gelderman, 2009). Field burning of corn produces particulate matter of 11.7 g/kg $PM_{2.5}$, defined by EPA as those fine particles ≤ 2.5 micrometers (μm) in diameter (Li et al., 2007). Within the affected area for this EA, there are only two non-attainment areas for $PM_{2.5}$: three-county Milwaukee-Racine, WI area and the seven-county Detroit-Ann Arbor, MI area (US-EPA, 2011b).

Greenhouse Gases

Primary agricultural air emission sources of GHG include: CO_2 from agricultural burning; vehicle exhaust associated with equipment used in tillage and harvest; and nitrous oxide emissions from the use of nitrogen fertilizer (Aneja et al., 2009; Hoeft et al., 2000; US-EPA, 2010a; USDA-NRCS, 2006a). Agriculture, including land-use changes for farming, is responsible for an estimated 6% of all human-induced greenhouse gas (GHG) emissions in the U.S. (US-EPA, 2010a). Agricultural emissions sources of GHGs include:

- Livestock are responsible for the largest fraction of methane emissions (80% of total methane via enteric fermentation and manure management) (US-EPA, 2010a).
- Agricultural equipment (e.g., irrigation pumps and tractors) release carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (US-EPA, 2010a).
- Agricultural soil management practices, including nitrogen-based fertilizer application and cropping practices, are the largest source of U.S. N_2O emissions. Croplands account for 69% of the total N_2O emissions attributable to agricultural land uses (US-EPA, 2010a).
- Carbon dioxide (CO_2) is also a significant GHG gas associated with several agricultural practices, including classes of crops, location and soil types associated with the practices, and energy consumption (Cole et al., 1997; US-EPA, 2010a).

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

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

Tillage, Fertilization, and Greenhouse Gases

Tillage contributes to the release of GHG because of the loss of CO_2 to the atmosphere and the exposure and oxidation of soil organic matter (Baker et al., 2005). Herbicide-tolerant crops may encourage increases in the adoption of conservation tillage programs whose consequences may include reductions of many of these emission concerns. Special conservation tillage field equipment can often perform the equivalent functions of several standard implements, reducing the necessity for multiple passes through the field. Implementing CT practices can lead to both economic and production quality benefits, as well as having positive environmental impacts (USDA-NRCS, 2006b). Tillage contributes to the release of GHG because carbon is lost as CO_2 to the atmosphere, and because of exposure and then oxidation of soil organic matter (Baker et al., 2005).

GHGs and Nitrogen Fertilizer

Nitrous oxide emissions are released following use of nitrogen fertilizer and the action of soil microbes on soil constituents. Massive overuse of fertilizers is the biggest contributor to these emissions within the industry; more than half of all fertilizer applied to fields ends up in the atmosphere or local waterways each year. The equivalent of 2.1 billion tons of carbon dioxide in the form of nitrous oxide, a GHG almost 300 times more potent than CO_2, is emitted because of fertilizer use (Herro, 2008).

Because soybean is able to fix atmospheric nitrogen by means of symbiotic nodulating bacteria, nitrogen fertilization is often not indicated as a good management practice (Rehm et al., 2001; Staton and Warncke, 2009). Less than 40% of soybean acres across the U.S. receive fertilizer application, which is appreciably lower than other major crops, such as corn and cotton (USDA-ERS, 2010e). Considering these observations and recommendations, soybean production is most likely not a large contributor to GHG emission through nitrogen fertilizer application.

Pesticide Application

Aerial application of pesticides may cause impacts from drift and diffusion. Pesticides may volatilize after application to soil or plant surfaces and move following wind erosion (Vogel et al., 2008). Airborne chemicals may partition between gas and particle phase, be transported through wind, and then be deposited again by rainfall or particulate settling. Vogel et al.(Vogel et al., 2008) from measurements of pesticide content in 4 states estimate that 2% of all applied agricultural chemicals are re-deposited via rainfall.

The persistence of pesticides in the atmosphere may be an air quality issue. Air concentrations of pesticides are typically greatest within the immediate treatment area, although, evidence also indicates that airborne chemicals may be detected at distances further from treated fields. When rainwater is sampled, pesticides that were used beyond the local watershed, that is, from the intermediate and larger watersheds may be well represented among the analytes (Vogel et al., 2008). Whether pesticides are applied by ground or aerial spraying or by mechanical application to the plant surface, chemicals move to their intended and unintended targets through air, moving as droplets, dry particles or vapors (Carlsen et al., 2006 ; Ravier et al., 2005). The distance traveled depends upon their chemical and physical nature, method of application, and the atmospheric conditions at time of treatment. All these influence their concentration and ultimate fate (Carlsen et al., 2006).

2.3.4 Climate Change

Climate change represents a statistical change in climate conditions, and may be measured across both time and geographic space. U.S. agriculture may affect climate change through various facets of the crop cultivation process. Combustion of fossil fuels in mechanized farm equipment, fertilizer application, and decomposition of agricultural waste products may all contribute GHGs to the atmosphere (Aneja et al., 2009). GHGs collectively function as retainers of solar radiation, and agricultural related activities are recognized as both direct (e.g., exhaust from equipment) and indirect (e.g., agricultural-related soil disturbance) sources of CO_2, CH_4, and N_2O (US-EPA, 2010a)

As summarized by the Intergovernmental Panel on Climate Change (IPPC) (Technical Summary, Working Group I: The Physical Science Basis (IPCC, 2007)), the atmospheric persistence of long-lived GHGs, including CO_2, CH_4, and NO_2, may lead to extensive climate change because of altered cycling between atmosphere, ocean and land and radiative forcing causing climate change (IPCC, 2007). The U.S. agricultural sector is identified as the second largest contributor to GHG emissions, ranking only behind the energy sector (i.e., electricity production, transportation, and related activities) (US-EPA, 2010a).

Agricultural crop commodities may also affect dynamic geophysical soil processes, such as carbon turnover and sequestration, through tillage and cropping system practices. In general, reduced/conservation tillage practices favor more stable and increased carbon sequestration in the agro-environment (Lal, 2011). The impacts of GE crop varieties on climate change are most likely dependent on the selected cropping systems and production practices, geographic distribution of activities, and individual grower decisions.

<u>Climate Change Impacts on Crop Production</u>

Climate change may also affect agricultural crop production. These potential impacts on the agro-environment and individual crops may be direct, including changing patterns in precipitation, temperature, and duration of growing season, or may cause indirect impacts influencing weed and pest pressure (Hatfield et al., 2011a; Rosenzweig et al., 2002).

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

Climate Change Impacts on Soybean Production

A number of impacts of increased temperature have been inferred from models of climate change. More than one model suggests that soybean yields will decline in the U.S., mediated by increased temperature and declining precipitation during key periods of the growing season (Goldblum, 2009). Besides yield penalties, increased temperatures could result in early season flooding and increased precipitation (which in past seasons may either delay planting, or prevent harvest). The changes in precipitation patterns would lead to crop losses, including soybean, of up to 30% in 2030 and 65% in 2090 (Rosenzweig et al., 2002). Other modeling efforts have suggested that before the end of the century, yields could be decreased 30 to 46%, under the slowest warming scenario, and up to 63 to 82% under a rapid warming scenario (Schlenker and Roberts, 2009).

The cited models suggest that impacts of climate change (specifically, an overall deficit in total soybean yield) would exert pressure for land allocations for new soybean planting. However, the analysis by Mori et al. (Mori et al., 2010) suggests that land use conversion in the U.S. to mitigate the need for additional soybean would be unlikely. Mori et al. (Mori et al., 2010) also suggest that it would be Brazil, China and South America that would likely have large conversions to soybean production in response to lower production efficiencies elsewhere in the world. However, some areas of the U.S. that may experience decreased soybean yield may show small levels of increased production, such as the Midwest states (+1.7%), because of increased CO_2 stimulating plant growth and cultivars with improved water use efficiency (Hatfield et al., 2011b).

Future impacts might be mitigated by selection of varieties that showed decreased responses to the changed climate. As Betzelberger et al. (Betzelberger et al., 2010) note, cultivar sensitivity to parameters such as increased ozone can have substantial deleterious impacts on soybean yield as well. Some tropical soybean is less susceptible than other varieties to the increased O_3 that may typify future environmental concentrations, and the differences are measurable in several parameters of total biomass, crop yield and certain biochemical markers (Singh et al., 2010). In addition, if progress in developing drought resistant crops is maintained, additional soybean lines may be produced that will resist decreased precipitation expected over some U.S. soybean growing areas. Finally, use of different maturity group soybean with higher yield potential may be possible, especially if early spring occurs and the growing season is lengthened, and this and other management strategies could recover possible yield losses (Kucharik, 2008). From an analysis (Goldblum, 2009) of climate change impacts on yield of corn and soybean, timing of increased hot weather and of precipitation can cause county by county differences within a single state. As has been shown in such an analysis in Wisconsin, however, increased warming in spring and fall (producing increased precipitation) versus increased temperature in summer (along with drought) may produce opposite impacts on soybean yield, and empirical evidence is needed to establish overall impacts of the anticipated variations (Kucharik, 2008).

2.4 Biological Resources

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

2.4.1 Animal Communities

Deer and groundhogs feed on soybean and cause soybean damage, while Eastern cottontail, raccoon, Canada geese, squirrels, other rodents (such as ground squirrel) also feed on soybean but their damage is of less importance (MacGowan et al., 2006). Deer in large numbers, by browsing in soybean fields for forage, may significantly damage soybean in site specific circumstances, and in some areas, growers may be issued licenses to kill deer outside the regular hunting season to reduce crop damage (Berk A, 2008; Garrison and Lewis, 1987). Deer may also feed on seed left after harvest. Other animals that feed primarily on soybean include seed-feeding insects and rodents found in agricultural fields. Rodents, such as mice or squirrels, may seasonally feed exclusively on soybean seeds. Thus, these animals may have a diet containing significant amounts of soybean seeds. Migratory birds feed on spilled soybean following crop harvest (Galle et al., 2009) although more birds fed on nearby corn and sunflower seed fields. As many as 28 desirable bird species, as well as another five which can be crop pests in sunflower, have been identified as resident in soybean and corn fields in the Dakotas (Gamble et al., 2002).

The biodiversity of insect predators of a soybean aphid in soybean fields have been studied in four Northern Tier states, and relative to corn and soybean, environments with abundances of crop and non-crop plants provided greater "biocontrol services" than does soybean (Gardiner et al., 2009). Total insect diversity in GE glyphosate tolerant soybean has been compared to that in non-GE soybean, and although mostly similar, some slight decreases of insect diversity and numbers were observed between rows of soybean, but attributed to reduced abundance of weeds in glyphosate treated plots (Imura et al., 2010). Buckelew et al. (Buckelew et al., 2000) also conclude that insect abundance in soybean is more related to effectiveness of weed suppression, rather than use of glyphosate herbicide.

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

2.4.2 Plant Communities

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

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

Generally, the effects of competition increase with increasing weed density (Monsanto, 2010b). The time period that weeds compete with the soybean crop influences the level of yield loss. The later the weeds emerge, the less impact the weeds will have on yield. Soybean plants withstand early-season weed competition longer than corn as the soybean canopy closes earlier in soybean than in corn (Mallory-Smith and Zapiola, 2008). The extent of canopy closure regulates the availability of light to weeds and other plants that grow below the soybean. In addition, canopy closure occurs much sooner when soybean is drilled or planted in narrow rows.

Eighty-six common weeds of soybean across three growing regions were identified in another soybean petition for nonregulated status ((Monsanto, 2010b) (Tables IX-5 and IX-6). Foxtail spp., pigweed, velvetleaf (*Abutilon theophrasti*), lambs quarters (*Chenopodium album*), and cocklebur (*Xanthium strumarium*) are common annual weeds in Midwest corn and soybean fields. However, growers consider giant ragweed (*Ambrosia artemisiifolia*), lambs quarters, Canada thistle (*Cirsium arvense*), cocklebur, and velvetleaf to be the top five most problematic weeds in corn and soybean because of the difficulty to control these weeds (Nice and Johnson, 2005).

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

Herbicides provide effective and economical control of weeds in soybean. Approximately 98% of the soybean acreage received an herbicide application in 2006, indicating the importance of weed control in maximizing soybean yield (USDA-NASS, 2007b). Herbicide-tolerant soybean was introduced to provide growers with additional options to improve crop safety and/or improve weed control. In 2011, herbicide-tolerant soybean varieties represented 94 percent of planted soybeans in the U.S. (USDA-ERS, 2011a). The Roundup Ready® soybean system, i.e., planting Roundup Ready® soybean and applying glyphosate in crop, has become the standard weed control program in U.S. soybean production. In the 2006 crop year, for the surveyed states, 92 percent of the planted soybean acres were treated with glyphosate (USDA-NASS, 2007b).

2.4.3 Gene Flow and Weediness

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

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

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

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

- Presence of feral populations (domestic populations gone wild) and uncontrolled volunteers;
- Presence of a high number of highly compatible relatives;
- Self-incompatibility;
- Large pollen source;
- Large amounts of pollen produced;
- Lightweight pollen;
- Strong winds (wind pollinated);
- Large insect populations (insect pollinated); and
- Long pollen viability.

Additionally, the creation of a hybrid depends on a series of events including:

- A pathway for the gene of interest of one plant species to enter the population of the species to be hybridized (i.e., the parent plant and the receptor plant must be able to produce fertile offspring); and
- The hybridization must confer a fitness advantage that allows the gene, over multiple generations, to develop into a sustainable, reproducing population.

The rate and success of gene flow is dependent on numerous external factors in addition to the donor/recipient plant. General external factors related to pollen-mediated gene flow include the presence/abundance/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 absence/presence/magnitude of seed dormancy; contribution and participation in various dispersal pathways; and environmental conditions and events.

The genus *Glycine* consists of two subgenera, soja and glycine. The subgenus soja consists of three annual species: G. soja Sieb. and Zucc., the wild form of soybean; *G. gracilis* Skvortz., the weedy form of soybean; and G. max, the cultivated soybean. Cultivated soybean, *G. max*, can only hybridize with other members of the *Glycine* subgenus soja (OECD, 2000). The wild and weedy relatives (*G. soja* and *G. gracilis*) of soybean do not occur in the U.S. (USDA-APHIS, 2010c). Consequently, there is no potential for gene flow from cultivated soybean plants to wild relatives in the U.S. (USDA-APHIS, 2010b). *Glycine soja* grows wild in China, Japan, Korea, the Russian Far East, and Taiwan and is commonly found in fields, hedgerows, roadsides, and riverbanks in those countries (OECD, 2000).

Although there are no wild relatives with which soybean can share transgenes, such introduced genes have the potential to move within cultivated varieties of soybean. The potential for outcrossing can be defined as the ability of genes to escape to other soybean populations. Soybean is a highly self-pollinating species with a cross-pollination rate of less than one percent in plants grown in close proximity (Caviness, 1966; OECD, 2000). Cross-pollination at distances greater than 4.6 meters (m) from a pollen source has been rarely observed, although it has been reported that insects can sometimes transfer the pollen that distance or more (Caviness, 1966).

Soybean is not native to the U.S. and there are no feral or weedy relatives. Soybean is a self-pollinated species, propagated by seed (OECD, 2000). 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. As a result, soybean is considered to be a highly self-pollinated species, with cross-pollination to adjacent plants of other soybean varieties occurring at very low frequency (0 to 6.3%) in adjacent plants (Caviness, 1966; Ray et al., 2003; USDA-APHIS, 2010c; Yoshimura et al., 2006).

Potential of soybean for weediness is low, and even if gene flow occurred from this variety to other commercial soybeans, the trait (fatty acid composition changes) would not likely confer a selective advantage to the recipient soybean. Specific traits of soybean also limit their potential as weeds. Mature soybean seeds have no innate dormancy, are sensitive to cold, and are not expected to survive in freezing winter conditions (Raper Jr. and Kramer, 1987). The only known propagation method for soybean is through seed germination. Because there are no reports of vegetative propagation under field conditions in the U.S., human movement of soybean seed is the only possible route to establishing the plant outside growing areas. Volunteer plants that might grow in previously planted fields or from spilled seed under some favorable environmental conditions can be easily controlled mechanically or with herbicides (Zollinger, 2010). Soybean is not weedy (Holm et al., 1977), is not found outside of cultivated areas, and does not compete well with other cultivated plants (Hymowitz and Singh, 1987).

Horizontal gene transfer and expression of DNA from MON 87769 soybean to soil bacteria are unlikely to occur for several reasons (USDA-APHIS, 2010c). First, many genomes (or parts thereof) have been sequenced from bacteria that are closely associated with plants including *Agrobacterium* and *Rhizobium* (Kaneko et al., 2000; Kaneko et al., 2002; Wood et al., 2001). There is no evidence that these bacteria contain genes derived from plants. Second, in cases where review of sequence data suggest that horizontal gene transfer might have occurred, these events are likely to have occurred over an evolutionary time scale, i.e., on the order of millions of years (Brown, 2003; Koonin et al., 2001; USDA-APHIS, 2010b). Third, transgene DNA promoters and coding sequences are optimized for plant expression, not prokaryotic bacterial expression. Thus, even if horizontal gene transfer were to occur, proteins corresponding to the transgenes are not likely to be produced. Fourth, the FDA has evaluated horizontal gene transfer from the use of antibiotic resistance marker genes, and concluded that the likelihood of transfer of antibiotic resistance genes from plant genomes to microorganisms in the gastrointestinal tract of humans or animals (e.g., *E. coli*), or in the environment, is remote (US-FDA, 1998).

2.4.4 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). The main factors affecting microbial population size and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva et al., 2004). Plant roots, including those of soybean, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere. Microbial diversity in the rhizosphere may be extensive and differs from the microbial community in the bulk soil (Garbeva et al., 2004).

Members of the bacterial families Rhizobiaceae and Bradyrhizobiaceae form a highly complex and specific symbiotic relationship with leguminous plants, including soybean (Gage, 2004). The nitrogen-fixing plant-microbe symbiosis results in the formation of root nodules, providing an environment in which differentiated bacteria called bacteroids are capable of reducing or fixing atmospheric nitrogen. The product of nitrogen fixation, ammonia, then can be used by the plant. In soybean, atmospheric nitrogen is fixed into ammonia through a symbiotic association with the bacterium *Bradyrhizobium japonicum*. As a result of this relationship, nitrogen enhancement of soils may only be needed in a limited number of situations for maximal yield of soybean (Ferguson et al., 2006).

It is necessary that an adequate soil population of nodulation-inducing bacteria be found in the soil planted to soybean. As noted in the earlier section on fertilization and effects on air and water, these bacteria must be supplied if a soybean crop has not been recently grown on the field. Although the bacteria persist for several years in soil, their numbers may not be sufficient to insure adequate nodulation (Bottomley, 1992). Various commercial sources of inoculants such as multiple strains of *Bradyrhizobium* can be applied to seeds just before planting, many with similar results (Beuerlein, 2005). From one season to the next, the inoculated bacteria in soil may change characteristics or phenotypes and diverge from traits expressed by the original culture (Farooq and Vessey, 2009), and if nodulation is not adequately accomplished, growers may need supplemental nitrogen after plant growth has begun (Ferguson et al., 2006).

2.4.5 Biodiversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson, 1988). In assessing the plant and animal species of the affected area, the animal and plant sections of this EA named the most common animal species, including mammals, avian species, invertebrates and soil dwelling biota and similarly, plant species that are represented by prominent weeds within the fields and by other non-crop plants at the margins. These are indicators of the overall environment, but do not identify the interaction of all plants, animals, and microorganisms in an ecosystem, which is the definition of biodiversity (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 pests by natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 1999). The loss of biodiversity results in a need for costly management practices in order to provide these functions to the crop (Altieri, 1999).

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

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

Tillage practices may impact biodiversity, and the type of tillage may be dependent upon adoption of a GE herbicide tolerant crop. For example, while production of a non-GE field crop may typically be accomplished using intensive tillage, a GE crop with herbicide tolerance traits may facilitate use of conservation tillage and thus the crop type may lead to the indirect effects observed with planting the GE crop. Thus, comparisons of tillage effects may actually reflect such indirect effects. The majority of soybeans are under some type of conservation tillage (~63% (CTIC, 2010b)); the conservation tillage rates for non-transgenic soybean would likely be substantially less if there were no herbicide tolerance traits facilitating use of this tillage. Weed management with herbicide-tolerant GE crops using over the top herbicides are more efficient than conventional tillage. Tillage alone changes bird species diversity, and in one analysis, four times as many species nested in no-till compared to tilled fields (Basore et al., 1986). Waste soybean seed left in fields after harvest may in some cases be a source of food for birds and other wildlife in fall, winter or spring (Galle et al., 2009), and may total 48 to 63 kg/ha in untilled crops, and 12 kg/ha in tilled crops (Warner et al., 1985).

Species diversity and abundance in soybean agro-ecosystems may differ between the three soybean production methods: conventional with herbicide-tolerant GE varieties (mostly using glyphosate), conventional with non-GE varieties (using a variety of herbicides), and organic (without the use of herbicides). Many studies over the last 10 years have investigated the differences in biological diversity and abundance between GE and non-GE fields, particularly those GE crops that are resistant to insects (e.g., Bt crops) or herbicides (e.g., glyphosate-tolerant or glufosinate-tolerant crops.) Different studies have indicated potential decreases in biological diversity or abundance due to GE crops, or the presence of a pesticidal protein in some GE crops (Bt) (e.g., (Hansen Jesse and Obrycki, 2000; Pilcher et al., 2005; Ponsard et al., 2002). Other studies of GE crops, such as Bt corn, when compared to non-GE crops sprayed with insecticides demonstrate that GE crops do not cause any changes in arthropod abundance or diversity (e.g., (Bitzer et al., 2005; Chen et al., 2008; Marvier et al., 2007; Romeis et al., 2006; Torres and Ruberson, 2005; Wolfenbarger et al., 2008)). While metastudies have noted an increase in abundances and of some species of organisms in organic crops, one conclusion has been that "positive effects of organic farming on abundance were prominent at the plot and field scales, but not for farms in matched landscapes" (Bengtsson et al., 2005). These authors propose that efforts to enhance biodiversity should be focused on landscapes, not smaller sites such as on fields. Given the small number of organic soybean farms, and that MON 87769 soybean will have no impacts on this production system, comparisons of biodiversity effects of organic and conventional agriculture will not be further analyzed in this EA.

Farm-scale comparisons were made of three herbicide tolerant crops with conventionally managed controls—beets, winter oilseed rape and maize (Squire et al., 2003). In two herbicide tolerant crops (beets and winter oilseed rape), weed biomass was significantly reduced over those in the non-GE varieties (Heard et al., 2003). Decreases were detected in invertebrate populations using the weeds as a food source or refuge in the rape and beet herbicide tolerant crops, but not in herbicide tolerant maize (Hawes et al., 2003). As weed biomass was reduced (whether in GE plants or the non-GE control) the herbivores, pollinators and natural enemies generally declined as well (Buckelew et al., 2000; Hawes et al., 2003). Abundance of yellowhammer and granivore birds was also greater on non-GE than herbicide tolerant beet and rape crops (Chamberlain et al., 2007), but herbicide tolerant maize also showed the same pattern. Correlating weed diversity and changes in agricultural practices demonstrates that weeds have a broad role in supporting certain types of biological diversity within farmed fields (Marshall et al., 2003).

Arthropod abundance may not depend upon crop variety (either herbicide-tolerant or non-GE corn) but either variety may increase species diversity during different times of the year (e.g., (Brooks et al., 2005; Haughton et al., 2003; Hawes et al., 2003; Roy et al., 2003; Wolfenbarger et al., 2008)). Biodiversity of insect predators of a soybean aphid in soybean fields have been studied in four Northern Tier states, and relative to corn and soybean, environments with abundant crop types and non-crop plants provided greater "biocontrol services" than does extensively planted soybean (Gardiner et al., 2009). Total insect diversity in GE glyphosate tolerant soybean has been compared to that in non-GE soybean, and although mostly similar, some slight decreases of insect diversity and numbers were observed between rows of GE soybean, but attributed to reduced abundance of weeds in glyphosate treated plots (Imura et al., 2010). Buckelew et al. (Buckelew et al., 2000) also conclude that insect abundance in soybean is more related to effectiveness of weed suppression, rather than use of glyphosate herbicide. For some predator insects (biocontrol organisms) on soybean, the genetic diversity of the host soybean is relevant to predicting predator lifespan, and these impacts are not mediated by weeds (Lundgren et al., 2009). Additionally, the comparator chosen may be quite specific to certain relationships, and subtle impacts may be related to use of one specific herbicide (such as Atrazine) (Brooks et al., 2005), as was demonstrated in the previous farm scale evaluations (Heard et al., 2003).

Soil-inhabiting organisms also respond to changes imposed by constraints of the management system, such as those that include GE glyphosate tolerant crops. In the case of soil microorganisms, variations in number and species can be observed following many 'normal' agronomic interventions (Kowalchuk et al., 2003), but ascertaining those that are relevant to types of production systems require detailed analysis. From 10 years of observations, Kremer and Means (Kremer and Means, 2009) found increased colonization by *Fusarium* of glyphosate tolerant soybean roots following application of glyphosate, and increases of fluorescent *Pseudomonas* spp. Kremer and Means (Kremer and Means, 2009) also summarized findings of theirs and others that showed that GE glyphosate tolerant soybeans reduced nodulation and nitrogen fixation, but did not affect grain yields (Bohm et al., 2009). However, because many of the variations in soil microbial populations or diversity can be produced by many types of impacts, Kowalchuk et al. (Kowalchuk et al., 2003) propose that experimentally, systematic analysis of indicator groups representing different functions be assessed, and that rigorous methods of analysis be required to demonstrate impacts.

Since biological diversity can be defined and measured in many ways, APHIS considers determining the level of biological diversity in any crop to be complex and difficult to achieve concurrence. Another complication with biodiversity studies is separating expected impacts from indirect impacts. For example, reductions of biological control organisms are seen in some Bt-expressing GE crops, but are caused by reduction of the pest host population following transgenic pesticide expression in the transformed crop plant.

2.5 Human Health

2.5.1 Public Health

Public health concerns surrounding GE soybean primarily involve the human consumption of GE soybean products. Non-GE soybean varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for food safety prior to release in the market. Under the FFDCA, it is the responsibility of food manufacturers to ensure that the products they market are safe and properly labeled.

Food derived from GE soybean must be in compliance with all applicable legal and regulatory requirements. GE organisms for food may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far, all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. FDA evaluates the submission and responds to the developer by letter.

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 non-GE versus GE plants for food or animal feed (Faust, 2002; Flachowsky et al., 2005).

Monsanto has provided the FDA with information on the identity, function, and characterization of the genes, including expression of the gene products. The submittal to the FDA included information on the safety of the altered fatty acid profile in MON 87769 soybean oil, including a dietary risk assessment. Monsanto initiated the consultation process with FDA for the commercial distribution of MON 87769 and submitted a safety and nutritional assessment of food and feed derived from MON 87769 to the FDA on March 23, 2009 (BNF No. 00117). FDA is currently evaluating the submission (Monsanto, 2010b). SDA soybean has been accepted as GRAS (GRN No. 000283) after FDA accepted the notice in September 2009 (US-FDA, 2009a); SDA is to be used as an ingredient in baked goods and baking mixes, breakfast cereals and grains, cheeses, dairy product analogs, fats and oils, and so forth that will have 375 mg of stearidonic soybean oil per serving (US-FDA, 2009b).

2.5.2 Human Dietary Health

Soybean protein is used in food production to enhance nutrition and also to supply functional properties. In breakfast cereals and pasta, it enhances protein content (United Soybean Board, 2009). In baked goods, soups, meats and poultry it may emulsify, absorb fats and water, provide adhesion or cohesion properties, and in many other products it may aerate, add texture, assist in film or dough formation, increase shelf life and improve richness. Besides uses of soybean for functional properties, other foods are predominantly soy, such as soy beverages, tofu, textured vegetable protein items (simulated meats), such as burgers, hot dogs, crumbles, nuggets, green vegetable soybeans (edamame), and soy flour as a primary constituent of many foods and numerous other products (USB, 2011c).

Soybean oil achieved prominence as a food oil after cottonseed oil and lard were overtaken in the 1950s and by 2000, and soybean oil was found in almost 61% of the liquid oils, margarines, and shortening by 2000 (O'Brien, 2004). Thus, soybean oil is the principal food oil used in the U.S. The oil has high versatility for food processing and formulating, because it can be processed with low losses, and is high in essential fatty acids (O'Brien, 2004).

Table 9. Percentages of linoleic and linolenic acid in various vegetable oil sources and U.S. consumption.

Oil type	Linolenic acid as % fatty acid - typical value of omega-3	Linoleic acid as % fatty acid - typical value of omega-6	U.S. consumption 2000 (millions pounds)
Soybean	7.6	53.7	16,210
Canola	8.8	21.0	1,744
Canola-High Oleic*	3	14	NA
Corn	1.2	59.6	1,711
Sunflower*	<1	65	--

Coconut	0.0	1.6	968
Cottonseed	0.7	54.4	674
Palm	0.4	10.1	375

Sources: (O'Brien, 2004) and * (Orthoefer, 2005).

Soybean contains two apparently essential polyunsaturated fatty acids, an omega-3 (linolenic: C18:3) and an omega-6 (linoleic: C18:2), in appreciable quantities. Another principle fatty acid constituent is the monounsaturated fatty acid, oleic acid (C18:1). Two other principle fatty acids include saturated ones, stearic (C18) and palmitic (C16).

DHA (22:6 n-4) and EPA (20:5 n-3) are highly beneficial fatty acids that may support good human health or correct health concerns, but are not represented in soy oil. In a review of the literature, Wijendran and Hayes (Wijendran and Hayes, 2004) showed that DHA and EPA are important contributors to good cardiovascular health. Additional benefits may include preventing aging-related cognitive decline according to Cunnane et al. (Cunnane et al., 2009). Hamer et al. (Hamer et al., 2005) summarized additional evidence that these fatty acids when added to the diet may improve health status for other conditions as well. The omega-3 oil, linolenic acid, can be metabolized by human biosynthetic processes to the fatty acids EPA and DHA, but not at sufficiently high rates to provide what may be healthful intake levels of the desirable EPA and DHA (Burdge and Calder, 2005).

The biosynthesis of SDA to EPA in humans has been studied, and it is far more efficient than biosynthesis of EPA from alpha linolenic acid, a typical soybean fatty acid. Thus, James et al. (James et al., 2003) showed that if the incorporation of EPA into erythrocytes and plasma was assigned a value of 1.0, EPA incorporation following SDA administration occurred with an efficiency of 0.3, and incorporation following alpha linolenic acid (soybean constituent), 0.07. To attain recommended intake rates of EPA, populations should consume 1.5 g/day of SDA. These levels could be achieved if all typical vegetable oils consumed, including cooking oil, margarine, salad oil and mayonnaise contained about 10% SDA (James et al., 2003).

While fish oils are a practical source of EPA and DHA for human health, omega-3 fatty acids from vegetable sources are an ecologically sustainable alternative. This source relies on conversion of SDA by human metabolism into the healthful fatty acids. Sourcing these fatty acids from soybean spares fish which may be in reduced supply because of overfishing of resources in world oceans. About 80% of the market for food and supplement use of omega-3 fatty acids is provided by fish oils (Packaged Facts (Market Research Group LLC), cited in (Daniells, 2011)). Krill are also rich in EPA and DHA (some species with around 30% of these as a percentage of fatty acids (Linder et al, 2010) and are becoming an increasing source of these highly unsaturated fatty acids (Starling, 2011). EPA and DHA are also produced by yeast such as *Yarrowia lipolytica* , a species which also synthesizes food grade citric acid (Du Pont, 2011). Algae produced in contained ponds are currently a source of DHA and other fatty acids in foods and supplements (Martek, 2010). SDA is an infrequent fatty acid in plants, but may be found in up to 14% concentrations in *Ribes nigrum*, and *Primula* and *Echium* species (Aitzetmüller and Werner, 1991). Soybean is one of the most economical oil sources, and development of these other plants as a SDA source would not be an option to be taken over a short term, nor likely to produce inexpensive specialty oil. In the U.S., the market for omega-3 fatty acids for functional foods is $4 billion and for supplements is $1.3 billion (Packaged Facts (Market Research Group LLC), cited in (Daniells, 2011)).

One issue that is relevant to human health is the more rapid oxidation of SDA and other polyunsaturated omega-3 fatty acids compared to the less unsaturated fatty acids (Jacobsen et al., 2008). A consequence of this oxidation is development of free radicals and bioactive aldehydes, and the production of off-flavors (Jacobsen et al., 2008). However, the stability of SDA can be improved by formulation with appropriate antioxidants (see review in (Jacobsen et al., 2008)). One such example is the use of citric acid which provided stability to SDA that was similar to that of oleic acid when subjected to 55 and 25 degree heat protocols and then fatty acid analysis (Appendix B-2 (Monsanto, 2009)).

The trend towards increasing use of oil from altered oilseed crops that produce diminished linolenic acid (and omega-3 fatty acid) or with increased oleic acids (high oleic sunflower, canola, safflower and soybean), is noted by Dubois et al. (Dubois et al., 2007); these changes may have consequences for human health (see also Table 9 for omega-3 content in common vegetable oils). The need of food manufacturers for products with reduced linolenic acid has been met by either new sources of oils (reduced linolenic acid varieties in soybean) or trans hydrogenation (which destroys linolenic acid). Although these strategies increase oxidative stability and thus shelf-life (desirable properties for merchandising products containing oils), future trends may not provide for current content of omega-3 fatty acids in human diets, as recommended by multiple nutrition authorities (University of Connecticut, 2011). The essential fatty acid, linolenic acid, should continue to be available in food products to enhance content of healthful DHA and EPA and the longer chain fatty acids, rather than be reduced (Dubois et al., 2007); replacement with another omega-3 fatty acid such as stearidonic may be a useful dietary direction. At present, U.S. National Academy of Sciences (NAS) has not discerned any deficits in current U.S. dietary intake. NAS/Institute of Medicine advises an Acceptable Macronutrient Distribution Range (AMDR) of omega-3 polyunsaturated fatty acids as 0.6 to 1.2% of dietary energy, and ratios of omega-6 to omega-3 fatty acids between 5.1 and 10.1 for adults (Otten et al., 2006). These AMDRs are based on average consumption values for U.S. consumers, and there is no known deficiency of omega-3s in this population.

2.5.3 Worker Safety

Worker hazards in farming are common to all types of agricultural production, and include hazards of equipment, exposures to agricultural chemicals, and to plant materials. Production of soybean exposes workers to herbicides, and acceptable exposures are regulated by U.S. EPA labels. EPA's Worker Protection Standard (WPS) (40 CFR part 170) was published in 1992 requiring actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protection 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.

Grower compliance with all U.S. EPA requirements is required. MON 87769 soybean has no added herbicide tolerance, so its cultivation would be similar to that of non-herbicide tolerant soybean. None of the agricultural chemicals that would be used with MON 87769 soybean differ from those used with other typical commercial soybean varieties. Although an allergenic potential of soybean exists, soybean allergy is typically a response to ingestion. Hull hypersensitivity following inhalation has been observed, as have asthma reactions of workers to soybean dust (Besler et al., 2000). Oils produced by soybean are typical of those produced by many other plants and are generally not allergenic (Hefle and Taylor, 1999), but rather are required human dietary constituents.

2.6 Animal Feed

Animal feed concerns surrounding GE soybean primarily involve the animal consumption of GE soybean products. Soybean meal is a substantial part of animal feed rations in the U.S. In 2009, approximately 39 million tons of soybean meal was produced, 27 million tons of which was marketed for animal feed, with the largest volumes consumed by poultry (48%), swine (26%), and beef (12%) (SoyStats, 2010c, 2010e).

Non-GE soybean varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for feed safety prior to release in the market. Under the FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from GE soybean must be in compliance with all applicable legal and regulatory requirements. GE organisms for feed may undergo a voluntary consultation process with the FDA prior to release onto the market.

Although a voluntary process, thus far all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. FDA evaluates the submission and responds to the developer by letter.

Monsanto has provided the FDA with information on the identity, function, and characterization of the genes, including expression of the gene products in MON 87769 soybean. The submittal to the FDA included information on the safety of the SDA and profile of other fatty acids in MON 87769 soybean oil, including a dietary risk assessment. Monsanto initiated the consultation process with FDA for the commercial distribution of MON 87769 soybean and submitted a safety and nutritional assessment of food and feed derived from MON 87769 soybean to the FDA on March 23, 2009 (BNF No. 00117) (Monsanto, 2010b). FDA is currently evaluating the submission.

2.7 Socioeconomic

2.7.1 Domestic Economic Environment

Soybean first entered North America in the 18th century (Hoeft et al., 2000). Sometime during the 1930s, soybean was processed industrially in the U.S. for edible oil and protein meal.

Currently, the U.S. produces approximately 38% of the global soybean supply (SoyStats, 2010h). In 2009, the U.S. exported 1.3 billion bushels (34.9 million metric tons) of soybean, which accounted for 46% of the world's soybean exports (SoyStats, 2010g). In total, the U.S. exported $16.5 billion worth of soybean and soybean products globally in 2009 (SoyStats, 2010b). China is the largest export market for U.S. soybean with purchases totaling $9.2 billion. Mexico is the second largest export market with sales of $1.3 billion in the same year (SoyStats, 2010b). Other significant markets include Japan and the EU.

Soybean Production Operating Costs

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

Soybean Products

Soy meal typically contains about 50% protein by dry weight, and is the most important product of soybean production. From production and feeding statistics, in 2010 about 67% of the domestic-crushed soybean meal was fed to domestic animals, and 28% of the meal was exported (most likely for animal feed in the international market) ((SoyStats, 2011b); Table 8, 2009/2010 (USDA-FAS, 2011)). Of the domestically crushed soybean, 53% of soybean by weight produces meal and 19% produces oil (SoyStats, 2011b). Thus, only a small proportion of the soybean crop is consumed directly by humans. Human food derives from whole soybean made into soymilk (including tofu), or from meal processed into soy flour (meat substitutes) or into isolates or concentrates (protein powder) or from processed whole soybeans (soynuts) or from fresh soybeans (edamame) (Soyconnection, 2011). The domestic food use of soybean oil is mainly in frying oils, salad and cooking oils, and margarines (SoyStats, 2010d). In 2009, these three categories represented approximately 85% of the soybean oil market in the U.S., with industrial uses consuming the remaining 15% (SoyStats, 2010d; USSEC, 2006). Soybean oil industrial uses include plastics, lubricants, coatings, printing inks and adhesives, emulsifiers, surfactants (industrial detergents and cleaners as well as solvents), resins, and biodiesel, among others (AGRA, 2009; USB, 2010b). Soy-based industrial oil products have many advantages in the marketplace, including being inherently biodegradable, having low ecotoxicity, and being derived from renewable resources (USSEC, 2006). The extraction of oil from soybeans also creates a highly valued solid, soybean meal, which is used for animal food in all sectors (swine, beef, poultry, dairy and fish).

Prices for soybean oil typically are among the lowest among those for all vegetable oils. During the 10-year period 1996-2006 three months out of 12, only Malay palm oil prices were lower than U.S. sourced soybean oil (USDA-FAS, 2008). During the 12-month period October-September 2006/2007 corn oil prices were lower than soybean oil prices in only five months during the same period (USDA-FAS, 2008) Thus, both low cost and usability have led to soybean oil becoming the top choice of food processors and industrial processors for feedstock in these industries.

Changes in fatty acid profile may impact food and industrial uses of the soybean oil. Fatty acid composition of the soybean oil affects melting point, oxidative stability, and chemical functionality, and changes in any of these can impact the market sector of the product (APAG, 2011). Table 10 illustrates several of the key physical properties of the fatty acid constituents of soybean oil.

Table 10. Properties of select fatty acids.

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

Source: (CRC, 2011)

1. As in Table 1, fatty acids are identified based on the number of carbon atoms and the number of double bonds in that fatty acid.
2. ºC = degrees Celsius

Palmitic and stearic acids are considered saturated fatty acids, indicating that they do not have any carbon double bonds. Oleic acid is a mono-unsaturated fatty acid, containing a single double bond, and linoleic and linolenic acids are polyunsaturated fatty acids, containing 2 and 3 double bonds, respectively (Institute of Shortening and Edible Oils, 2006). Generally, the longer the carbon chains for saturated fatty acids, the higher the melting point, and the more unsaturated, the lower the melting point (Berg et al., 2002).

These fatty acid properties influence the market applications for the oil, and various foods and industrial products are formulated to take these properties into consideration. Many of the commercial vegetable oils are a carefully blended mix to take advantage of the properties of the constituent fatty acids (Cargill, 2011). A soy oil with a high content of oleic acid and low content of polyunsaturated fatty acids results in an oil with high oxidative stability, a critical property for industrial lubricants, as well as achieving the food industry needs for a soy-based oil without trans fatty acids (Cahoon, 2003; Soyconnection, 2011).

<u>Soybean Industry Description</u>

Soybean industry comprises two main groups, commodity production businesses and the users of soybean products. The commodity production business begins with the providers and developers of the traits technology and the seed, retailers that sell seed to growers, the growers and their operations. Users of the soybean commodity include those who purchase the soybean seed and then crush, process and sell the basic products of seed, oil and meal, to the next set of soybean processors or users. The downstream purchasers are animal feed producers, food producers, oil users in food and industrial sectors, and industrial product manufacturers, such as those for biodiesel oil.

Commodity Production Industry

Contracts are typically signed with growers when the specialty seed is purchased, obligating the growers to supply harvested seed under given conditions, such as all the soybean from a certain number of committed acres, specifying methods of productions and where the seed may be sold, and establishing standards for the product when delivered. Contracts between the growers and an oil crusher maybe signed, and after oil is crushed, the bulk oil processer companies arrange for sale to food or industrial buyers (ADM, 2006).

In the production of soybean seed for commodity or IP use, two industries are relevant. The first are businesses that sell seed for planting and applied chemicals, and the second are the buyers of soybean grain, the elevators. Both are needed to produce specialty soy products. When a grower purchases specialty seeds, he will be required to produce his soybeans for a designated elevator, and a contract with the elevator may specify means of production, crop performance and seed quality.

Soybean meal is the most important product deriving from soybean seed and meal is the product that drives demand for soybean rather than oil. Oil comprises only 19% by weight of the soybean (Tyson et al., 2004). Thus, oil is a minor product of the crushing industry. As noted earlier, soybean meal is predominantly fed to animals while a small percentage is used for human consumption or industrial uses (see preceding section on "Soybean Products").

Fatty acid composition of soybean oil is affected by many variables, including genetics of the crop, details of the climate including temperature, available water and timing of applied water, and probably other facts about the planting site, including soil components (Lee and Herbek, 2004; Oliva et al., 2006; Primomo et al., 2002). Consequently, a range of values for soybean oil can be distinguished in soybean varieties planted in the U.S. See Table 1 for these ranges and a typical value found in a general textbook about U.S. oils.

Animal Feed Users

Animal feeds are the major use for soybean meal, consuming about 77% of the total meal produced (2007/2008 (USB, 2011a)). Oil from soybean used in animal feed is so limited that it is not summarized. The mixed rations for poultry, hogs, cattle, dairy cows, domestic pets, and farmed fish often are formulated with soybean meal. In 2008/2009, 10.3 million metric tons of meal was used in broiler rations, 9.1 million tons in hog rations and 1.9 million tons in beef rations (USB, 2010a). The other animal industries used 7.7 million tons for feeding operations. A variety of industries prepares, formulates, manufactures and distributes animal feeds.

Fresh and Processed Food Users

Various industries supply all types of processed and fresh foods deriving from soybean (USB, 2011c). Grain products from soy include flours, pasta, bread, waffles, and cereal. Oil products include margarines, salad and frying oils. Simulated 'meats' include soy burgers, hot dogs, nuggets, and tofu. Vegetable uses include edamame, and soynuts. Simulated 'milk products' include soymilk beverage, soy cheese, yoghurt, and ice cream.

Oil Users

In the production of oils from oilseed such as soybean, two general industries can be identified (O'Brien, 2004). The first is the crusher/refiner whose focus may be oil feedstocks deriving from a single source of oilseed, and which processes the oil in a continuous, automated mode. The crushing business, which extracts crude vegetable oil and meal, sends the oil to refiners, or may retain some for industrial and fuel users. The refiners may be separate physically from the crushing business and may subject oil to including degumming, refining, bleaching, dewaxing, fractionating, interesterifying, hydrogenating, changing the melting points of the oil, blending and deodorizing. The refiner may then package the liquid oil, produce margarines, shortening, and bulk fats or oils. In 2007, soybean receipts at oil crushing facilities attained to 54.4 million tons, with slightly more crushed than originating from receipts (US Census Bureau, 2008). Specialty oils when produced at facilities making commodity oils are produced in batches or only semi continuously and supply specialized needs of the food processing or other commercial products industries. The total value of products from the primary soybean processing industry were estimated at $18 billion (US Census Bureau, 2009a).

The second industry comprises the many value-added businesses which may employ starting feedstocks from soyseed or other oilseed sources, and which manufacture products from commodity oil or a variety of specialized oils. These include food and industrial product manufacturers in a wide variety of offerings to businesses, retailers and consumers.

Foods

The properties of oils that are used in foods may vary widely, and these result from the fatty acids that are incorporated into constituent triglycerides. The positions of the fatty acids within the triglycerides also may help determine these properties. Specific fatty acids have associated chemical properties (such as reactivity) and physical properties (such as melting points), as well as other functional properties which are taken into account when they are incorporated into foods. Oils high in unsaturated fatty acids (5-15%. such as those derived from hydrogenated soybean oil, stearin fractions of palm oil, etc.) are useful in making solid fat products such as baking shortenings (O'Brien, 2009a), while oils low in saturated fats (and optimally, high in oleic acid) are useful for salad oils (O'Brien, 2009b). Trans-esterification may be used to change the positions of the fatty acids in the triglyceride, or exchange one for another, all of which can alter oil properties.

When fatty acids are oxidized, flavor is adversely affected, and this is referred to as "reverted" oil. Reverted soybean oil has a "beany" or "grassy" flavor (O'Brien, 2004). Oils that are high in polyunsaturates are the most susceptible to such oxidation among food oils. Linoleic and particularly linolenic in traditional soybean oil are those fatty acids most easily oxidized. Hydrogenation of soybean salad oils reduces the content of linolenic acid, a polyunsaturated oil, and typically, will reduce it from 9% to 3% (O'Brien, 2004). Reducing the unsaturated linolenic acid decreases the possibility that off- flavors will develop. This process also produces "trans" fatty acids, which have been linked to deleterious consequences for human health, and have encouraged the development of other soybean lines with altered fatty acid content.

Industrial (Non-Edible Products) Use

Soybean oil is a feed stock for numerous products used in several domestic industries. Biodiesel provides the largest market for soybean oil (see Table 11), with production at 822,000 metric tons in 2008/2009 (USB, 2011b). Soybean biodiesel in 2007 had a value of $1.09 billion dollars. By comparison, fuel ethanol had a value of $6.6 billion (US Census Bureau, 2009a). Soaps, amines, fatty acids and oleo chemicals is the second largest consumer of industrial soybean oil at 140,000 metric tons (see Table 11) (USB, 2011b). Paints, coatings and inks rank third, with 118,000 metric tons, and polyols and plastics with 115,000 metric tons. Lubricants and working fluids produced a total 26,000 metric tons, and solvents and specialty uses a total of 22,000 tons. A total of 15.8 billion pounds of refined soybean oil was processed in the U.S. in 2008 (US Census Bureau, 2009b).

Table 11. Industrial soybean oil production 2008/2009.

Product	Soybean oil (million metric tons)
Biodiesel	0.822
Soaps, Amines, Fatty Acids & Oleo Chemicals	0.140
Paints, Coatings & Inks	0.115
Polyols & Plastics	0.127
Total Industrial Meal	0.055
Lubricants & Working Fluids	0.026
Solvents & Specialty	0.022
Other Industrial Products	0.010
Total Industrial Whole Bean	<0.001

Source: (USB, 2011b).

2.7.2 Trade Economic Environment

The major producers of soybean are the U.S., Brazil, Argentina, China, and India, which accounted for approximately 91% of the global soybean production in 2007 (Soyatech, 2010) (see Table 12). Soybeans produced in China and India are primarily for domestic use. A significant portion of soybean produced in the U.S., Brazil, and Argentina is traded globally in the form of soybean harvested seed, soybean meal, or soybean oil (Monsanto, 2010b). Globally, the U.S. was the largest soybean seed export country; whereas Argentina led the soybean meal and soybean oil export markets in 2007 (Soyatech, 2010).

Table 12. World soybean production, 2009.

Country	Production (million metric tons)
U.S.	80.7
Brazil	57.0
Argentina	32.0
China	15.5
Canada	9.3
India	9.1
Paraguay	3.9
Other	9.3
Total Production	210.9

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

2.7.3 Social Environment

Data from the 2007 Census of Agriculture indicated that 279,110 U.S. farms raised soybeans in 2007, down from 511,000 in 1982 (USDA-ERS, 2010d; USDA-NASS, 2007). Soybean farms with sales greater than $50,000 totaled 109, 269 (USDA-NASS, 2007). Although acreage planted to soybeans was also lower in 2007 than in 2002 as growers shifted to corn production, harvested soybean acreage per farm increased from 114 acres in 1978 to 229 acres in 2007 (USDA-ERS, 2010d). Although small farms with less than 250 acres accounted for 72% of the farms growing soybeans, these farms produced only 26% of the 2007 crop (USDA-ERS, 2010d). Irrigation was used on 5.2 million acres of soybean, or 8% of U.S. soybean acreage in 2007 (USDA-ERS, 2010d). Individual or family farms accounted for 81% of all soybean farms in 2007 and 69% of soybean production, with the balance identified largely as partnerships and small family-held corporations; corporations accounted for less than 1% of soybean farms and soybean production (USDA-ERS, 2010d).

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

Average acreage of all operated soybean farms is reported as approximately 623 acres; whereas, the average acreage of a more specialized soybean farm operator is reported at 390 acres (USDA-ERS, 2006b). Nearly 60% of these specialty soybean farmers reported annual income less than $40,000; whereas, 76% of commodity soybean farmers reported incomes exceeding $40,000 per year (USDA-ERS, 2006b).

Industrial soybean crushers, as represented by membership in the National Oilseed Processors Association (which includes 90% of the U.S. oilseed crushers), identify 45 oilseed processing plants in 19 states (NOPA, 2011). These may include locations that process oilseed other than soybean. For soybean blending and refining, the U.S. Census Bureau (US Census Bureau, 2007) noted that these operations employ 6,019 people with a total value of products of $19.2 billion. Statistics for other parts of the soybean industry are included in summaries for other oil products; additional details of soybean businesses from these Census Bureau statistics thus cannot be distinguished. To provide perspective about one soybean processor (South Dakota Soybean Processors), this business is a cooperative with 2,200 farmer/members. This crushing/refining business produces refined and bleached soy oil for industrial buyers, soybean meal and hulls and also partly owns an ancillary urethane/resin business   The crusher processes 30 million bushels of soybean per year and has 83 employees (Hoover's, 2011).

About 1.3 million metric tons of soybean derived non-food products were produced in 2009 (see Table 11). APHIS is not aware of data for the numbers of employees engaged in various industrial production sectors using soybean products. However, the largest category of industrial products, biodiesel, was estimated in 2009 to include 1700 manufacturing employees and 160 agricultural workers that were needed to supply the commodity soybean (Cardnoentrix, 2011). The same report identified a total of 21,000 jobs as deriving from 2009 biodiesel production. Food production involving soybean products has reached $4.5 billion in 2009 (SANA, 2011download) and total employment in this industry is not readily available.

3 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of MON 87769 soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that MON 87769 soybean is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2010c), APHIS has concluded that MON 87769 soybean is unlikely to pose a plant pest risk. Therefore APHIS must determine that MON 87769 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 87769 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 petition. MON 87769 soybean and progeny derived from MON 87769 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 87769 soybean and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of MON 87769 soybean.

This alternative is not the Preferred Alternative because APHIS has concluded through a PPRA that MON 87769 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2010c). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

3.2 Preferred Alternative: Determination that MON 87769 Soybean is No Longer a Regulated Article

Under this alternative, MON 87769 soybean and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. MON 87769 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2010c). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of MON 87769 soybean and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that MON 87769 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87769 soybean is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Under this alternative, growers may have future access to MON 87769 soybean and progeny derived from this event if the developer decides to commercialize MON 87769 soybean.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for MON 87769 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 87769 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 87769 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 87769 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 87769 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2010c).

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 13563, to guide the development and implementation of policies for oversight of emerging technologies (such as genetic engineering) at the agency level. In accordance with this memorandum, agencies should adhere to Executive Order 13563 and, consistent with that Executive Order, the following principle, among others, to the extent permitted by law, when regulating emerging technologies:

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

Based on the PPRA (USDA-APHIS 2011) and the scientific data evaluated therein, APHIS concluded that MON 87769 soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of MON 87769 soybean.

3.3.2 Approve the Petition in Part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that MON 87769 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2010c), there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3.3.3 Isolation Distance between MON 87769 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 87769 soybean from non-GE soybean production. However, because APHIS has concluded that MON 87769 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2010c), 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 87769 soybean based on the location of production of non-GE soybean in organic production systems in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' PPRA for MON 87769 soybean, there are no geographic differences associated with any identifiable plant pest risks for MON 87769 soybean (USDA-APHIS, 2010c). This alternative was rejected and not analyzed in detail because APHIS has concluded that MON 87769 soybean does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. However, individuals might choose on their own to geographically isolate their non-GE soybean production systems from MON 87769 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 87769 soybean is available from Association of Official Seed Certifying Agencies (AOSCA, 2010).

3.3.4 Requirement of Testing for MON 87769 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 87769 soybean does not pose a plant pest risk (USDA-APHIS, 2010c), 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 87769 soybean would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

3.4 Comparison of Alternatives

Table 13 presents a summary of the potential impacts associated with selection of either of the alternatives evaluated in this EA. The impact assessment is presented in Section 4 of this EA.

Table 13. 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 – PPRA (USDA-APHIS, 2010c)
Management Practices		
Acreage and Areas of Soybean Production	Unchanged	Unchanged
Seed Production	Unchanged	Unchanged
Organic Farming	Unchanged	Unchanged
Specialty Soybean	Unchanged	Unchanged
Soybean Cultivation Practices	Unchanged	Unchanged
Physical Environment		
Water Resources	Unchanged	Unchanged
Soil and Land Use	Unchanged	Unchanged
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Biological Resources		
Gene Movement and Weediness	Unchanged	Unchanged
Animals	Unchanged	Unchanged
Plants	Unchanged	Unchanged

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Microorganisms	Unchanged	Unchanged
Biological Diversity	Unchanged	Unchanged
Human and Animal Health		
Worker Safety	Unchanged	Unchanged
Risk to Human Health	Unchanged	Unchanged (potential health benefits)
Risk to Animal Feed	Unchanged	Unchanged
Socioeconomic		
Domestic Economic Environment	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged
Other Regulatory Approvals		
Other U.S Regulatory Approvals	Unchanged for existing nonregulated GE organisms	FDA consultation pending, U.S. EPA tolerance exemptions and conditional pesticide registrations not required.
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	Fully compliant

Notes:

1. Unchanged – the current conditions will not change as a result of the selection of this alternative.

4 ENVIRONMENTAL CONSEQUENCES

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, namely taking no action and a determination by the agency that MON 87769 soybean does not pose a plant pest risk and therefore should no longer be regulated under 7 CFR 340. Potential environmental impacts from the No Action Alternative and the Preferred Alternative for MON 87769 soybean are described in detail throughout this section. A cumulative effects analysis is presented for each potentially affected environmental concern. Certain aspects of this product and its cultivation would be no different between the alternatives: those instances are described below.

4.1 Scope of the Analysis

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for MON 87769 soybean are described in detail throughout this section. An impact would be 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 effects analysis is also included for each environmental issue. A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. Examples include breeding MON 87769 soybean with other GE events that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. 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 this product and its cultivation may be no different between the alternatives; those are described below.

Although the preferred alternative would allow for new plantings of MON 87769 soybean to occur anywhere in the U.S., the scope of analysis of the EA focuses on those areas that are expected to support production of MON 87769 soybean. According to the developer (Monsanto, 2010c), cultivation of MON 87769 soybean will be limited to the Northern Tier states of North and South Dakota, Minnesota, Wisconsin, and Michigan.

4.2 Agricultural Production of Soybean

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

Monsanto's field trials have not demonstrated any agronomic or phenotypic differences between MON 87769 soybean and control varieties of soybean (Monsanto, 2010b). Based on the data provided by Monsanto for MON 87769 soybean (Monsanto 2010), as well as previous experience with other GE soybean varieties that have been widely adopted by growers since their introduction in 1996 (USDA-ERS, 2010b), APHIS has concluded that none of the best management practices for agricultural production of soybean are expected to change MON 87769 soybean is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Consistent with the lack of changes to agronomic properties, the potential impacts on agricultural production associated with the No Action and Preferred Alternatives are the same.

4.2.1 Acreage and Area of Soybean Production

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

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

Based on current acreage trends, commodity soybean production with GE varieties will likely continue to dominate. Cultivation of GE soybean increased from 17% of the U.S. soybean acreage in 1997, to over 93% in 2010. The continued cultivation of soybean and the penetration of the soybean market by GE varieties is not expected to change under the No Action Alternative. Soybeans are produced commercially in the Northern Tier states (USDA-NASS, 2011a) and under the No Action Alternative, this range of production is not expected to change.

Preferred Alternative: Acreage and Area of Soybean Production

Monsanto has determined that the SDA content of MON 87769 soybean seed would be greatest when grown in the most northerly areas of soybean production in the US. Both genotype and environment can simultaneously influence ratios of multiple fatty acids in soybean (Hou et al., 2006). The effects of temperature may be most relevant during the final stages of seed maturation (Wilcox and Cavins, 1992). By limiting the proposed production area, Monsanto will keep the yield of SDA at the maximal attainable levels (Monsanto, 2010c).

Production in the Northern Tier states will be encouraged by producing seed only for the lower maturity groups (Monsanto, 2010c). Monsanto currently produces Vistive® low linolenic specialty soybean lines, and has multiple years of experience with IP production of this variety. From a survey of six seed producers selling Vistive® seed, APHIS observed that Monsanto seed is available mostly in maturity groups 2-3.6, although one was a 1.5. By this means, Monsanto has both focused and restricted the growing area for the Vistive® low linolenic varieties (offered through various seed companies). Existing Vistive® varieties are mostly grown in areas where soybean is already extensively produced, while MON 87769 soybean will be grown in the more northerly parts of these areas.

A second means seed companies employ to direct production of soybean varieties lines to a specific region is a contractual one. To produce the soybean crop and receive premium prices, growers must sign a contract with an authorized elevator or processor. For the Vistive® line, Monsanto lists at least 12 states where commodity seed is purchased or crushed with 127 elevators and 21 processors in major soybean production areas including Alabama, Iowa, Illinois, Indiana, Maryland, Minnesota, Michigan, Missouri, Nebraska, New York, Ohio, Pennsylvania, and South Dakota (Monsanto, 2010b). This area is partially coextensive with the five-state region proposed by the developer for MON 87769 soybean. If MON 87769 soybean seed becomes available, Monsanto would provide growers and the public a list of these elevators and crushers, and they will likely be restricted to the five states planned for production of this variety. The area proposed for MON 87769 soybean production will correlate with soybean oil processors capable of accommodating specialty soybean production.

Economic considerations constrain growers from marketing their soybeans at too great a distance from the specialty soybean crusher or elevators. An Indiana survey determined that 80% of growers delivered their soybeans within 25 miles of the growing site. In the northern and central parts of the state, at least 50% of soybeans were delivered within 10 miles (Purdue Extension. 2006). Thus, even if growers purchased the seed for the soybean variety outside of the expected optimal range, the high cost of transport would likely deter movement beyond that of authorized regional buyers. If Monsanto authorizes only certain elevators to receive the MON 87769 soybean, then MON 87769 soybean seed sales and delivery of harvested beans can be carefully constrained by the company.

Monsanto plans to market MON 87769 soybean as a specialty variety for producing the novel constituent SDA by this product (Monsanto, 2010b). Monsanto's field trials have not demonstrated any agronomic or phenotypic differences between MON 87769 soybean and control varieties of soybean (Monsanto, 2010b). The changes in fatty acid composition expressed in MON 87769 soybean do not require changes in cultivation practices when compared with other non-GE soybean varieties (Monsanto, 2010b). MON 87769 soybean does not confer an increase in cold tolerance, heat resistance, or drought tolerance (these issues are discussed again below in the subsection on gene flow) and therefore MON 87769 soybean is not anticipated to be cultivated in new regions outside of the current soybean production areas. MON 87769 soybean is anticipated to fill a small niche for an omega-3 fatty acid easily converted by human metabolism into desirable longer chain fatty acids. MON 87769 soybean is not expected to significantly replace plantings of conventional or existing GE varieties where those growers seek to cultivate a commodity soybean variety (Monsanto, 2010b). Similar to other soybean traits have recently been determined by APHIS to no longer be subject to the plant pest provisions of the Plant Protection Act and 7CFR part 340 that modestly alter fatty acid ratios, MON 87769 has the potential to lead to increases in specialty soybean acreage. Under the Preferred Alternative, a determination of nonregulated status of MON 87769 soybean is not expected to increase soybean production, or result in an increase in overall GE soybean acreage or cultivation in new regions because this trait is one to be grown for a niche specialty oil market, focused on nutritional augmentation. Impacts would be similar to the No Action Alternative.

4.2.2 Agronomic Practices

Crop rotation in soybean is conducted to manage weeds, optimize soil nutrition and fertility, reduce pathogen loads, and control certain soybean pests (Al-Kaisi et al., 2003; University of Illinois, 2006). In crops that have no tolerance to herbicides, such as MON 87769 soybean, various types of cultivation and herbicide use are typically employed by soybean growers. Besides tillage practices not always used in herbicide tolerant crops, herbicide use would generally include burndown, preplant and one or more post plant applications of herbicide (Loux et al., 2008). A more diverse pattern of herbicides would also be used in these situations, rather than principle use of a single herbicide (glyphosate, glufosinate or ALS) applied preplant or over the top, depending on the herbicide tolerant variety planted.

No Action Alternative: Agronomic Practices

Under the No Action Alternative, soybean crop rotation practices and herbicide pesticide use will likely remain as it is practiced today by the farming community. Growers will continue to have access to existing herbicide-tolerant soybean products that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act, as well as conventional soybean varieties. Agronomic practices associated with traditional and existing non-regulated GE soybean production would not be expected to change under the No Action Alternative. As a result, no changes are anticipated from the current agronomic practices associated with soybean production, including tillage, cultivation, fertilization, pesticide applications, fertilizer applications, or the use of agricultural equipment.

Preferred Alternative: Agronomic Practices

Monsanto has determined that the SDA content of MON 87769 soybean seed would be greatest when grown in the most northerly areas of soybean production in the U.S. (Monsanto, 2010c). Both genotype and environment can simultaneously influence ratios of multiple fatty acids in soybean (Hou et al., 2006). The effects of temperature may be most relevant during the final stages of seed maturation (Wilcox and Cavins, 1992). By limiting the proposed production area, Monsanto will attempt to keep the yield of SDA at the maximal attainable levels.

Monsanto will produce seed only for the lower maturity groups (Monsanto, 2010c) which will restrict the potential growing area for the MON 87769 soybean varieties (offered through various seed companies). As with other identity preserved soybeans, growers must sign a contract with an authorized elevator or processor and which will approve the soybean product quality before purchase. Elevators and crushers will be restricted to the five states planned for production of this variety. Many of the growers electing to plant MON 87769 soybean and also elevators and crushers chosen will likely already have extensive experience in strictly observing standard operating procedures (SOPs) to maintain segregation during storage and crush. Otherwise, new growers and producers will be provided with SOPs, and asked to agree to conditions of contracts so as to channel soybean and oil to purchasers seeking the special fatty acids offered by MON 87769 soybean.

Monsanto's studies demonstrate MON 87769 soybean is essentially indistinguishable from other soybean varieties in terms of agronomic characteristics and cultivation practices (Monsanto, 2010b; USDA-APHIS, 2010c). Monsanto did not identify any differences between MON 87769 soybean and conventional A3525 control soybeans in dormancy, germination potential, disease or insect response, seedling vigor, or plant maturity (Monsanto, 2010b; USDA-APHIS, 2010c). The similarity in agronomic and phenotypic characteristics suggests that the changes in fatty acid profile do not impact the ability of soybean to overwinter or become a volunteer.

A determination of nonregulated status of MON 87769 soybean is not expected to alter the use of herbicides currently being used for non-GE soybean production. A preplant burndown herbicide would be used, followed by a pre-emergence residual herbicide, with timely post plant herbicide applications (Sprague, 2006). The use of glyphosate as a post-emergent weed herbicide in other soybean varieties would likely continue to be the pattern for the majority of soybean production. The tillage procedures if used would be those already employed and include those noted in section 2.2.2 (Agronomic Practices). Use of pest control strategies, such as those for insects or pathogens would also be unchanged.

If MON 87769 soybean is not stacked with herbicide tolerant traits, control of herbicide tolerant corn or soybean volunteers from the previous season would not be different from control of such volunteers arising after planting herbicide tolerant crops with typical rotational crops. Numerous other registered soybean herbicides are available to eliminate these volunteers (See Table IX-4 in Petition (Monsanto, 2010b)).

Monsanto's field trial and laboratory analyses demonstrated that the agronomic performance of MON 87769 soybean was functionally identical to its non-transgenic counterpart (Monsanto, 2010b). No increases in fertilizers and pesticides were required, nor were any changes in cultivation, planting, harvesting, and volunteer control required (Monsanto, 2010b). It is expected that similar agronomic practices that are currently used for other commercially available GE soybean will also be used by growers of MON 87769 soybean. Overall impacts would be similar to the No Action Alternative.

4.2.3 Soybean Seed Production

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

No Action Alternative: Soybean Seed Production

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

Preferred Alternative: Soybean Seed Production

Monsanto's field trials have not demonstrated any agronomic or phenotypic differences between MON 87769 soybean and control varieties of soybean (Monsanto, 2010b), other than differences of fatty acid content. Based on the data provided by Monsanto for MON 87769 soybean (Monsanto, 2010b), as well as previous experience with other GE soybean varieties that have been widely adopted by growers since their introduction in 1996 (USDA-ERS, 2010b), APHIS has concluded that the availability of MON 87769 soybean would not alter the agronomic practices, locations, and the production and quality characteristics of conventional and GE seed production (USDA-APHIS, 2010c). The overall impact of a determination of nonregulated status of MON 87769 soybean on the availability of conventional and GE seed, and the production practices used to grow soybean seeds would be similar to the No Action Alternative. Accordingly, there are no differences between the No Action and Preferred Alternatives with regard to seed production.

4.2.4 Organic Soybean Production

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

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

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

No Action Alternative: Organic Soybean Production

Current availability of conventional (both GE and non-GE) soybean varieties, and those soybean varieties that are developed for organic production, are expected to remain the same under the No Action Alternative. Since 2001, GE varieties of soybean have dominated the market, representing 68% of the market in 2001, and 93% of the market in 2010 (USDA-ERS, 2010b). Although organic soybeans have a place in the market, the respective share is small, and the dedicated acreage appears to be steady. Between 2005 and 2008, the total acreage devoted to soybean fluctuated between 72 million and 64 million acres, although organic soybeans ranged from 122,000 to 126,000 acres, less than 1% of the total soybean acreage (USDA-ERS, 2010f). The market share for organic soybean varieties is not expected to change under the No Action Alternative (USDA-ERS, 2010b; USDA-NASS, 2007a, 2010e).

Preferred Alternative: Organic Soybean Production

It is not likely that organic farmers, or other farmers who choose not to plant transgenic varieties or sell transgenic seed, will be substantially impacted by APHIS' determination of nonregulated status of MON 87769 soybean.

GE soybean varieties are currently cultivated on 93% of the U.S. soybean acreage (USDA-ERS, 2010b), and organic varieties comprise less than 1% of the total soybean acreage (USDA-ERS, 2010f). In the affected area, only 0.3% of soybean acreage is organic certified (see Affected Area analysis). MON 87769 soybean should not present any new or different issues and impacts for organic and other specialty soybean producers and consumers.

According to the petition, agronomic trials conducted in 2006 and 2007 at 21 field locations in the U.S. demonstrated that MON 87769 soybean in combined site analysis is not significantly different for plant growth, yield, and reproductive capacity from its nontransgenic counterpart (Monsanto, 2010b; USDA-APHIS, 2010c). No differences were observed in pollen diameter, and viability (Monsanto, 2010b; USDA-APHIS, 2010c). Consistent with the lack of difference in agronomic properties, MON 87769 soybean is not expected to have an increased ability to cross pollinate organic soybean varieties.

The practices currently employed to preserve and maintain purity of organic production systems would not be required to change to accommodate the production of MON 87769 soybean. Common production practices for soybean and the practical methods typically used by soybean farmers under organic conditions (NCAT, 2003) can greatly reduce the likelihood of accidental gene flow between MON 87769 soybean and non-GE soybean fields.

MON 87769 soybean will be marketed by Monsanto as a specialty variety to take advantage of the high content of SDA (Monsanto, 2010b). Consistent with no required differences in agronomic practices, and the intention of Monsanto to produce soybean for a specialty market, MON 87769 soybean is not expected to displace current organic soybean production.

The acreage devoted to organic soybean is expected to remain small regardless of whether new varieties of GE or non-GE soybean varieties, including MON 87769 soybean, become available for commercial soybean production. As noted above for the time period of 2005 to 2008, when the total U.S. acreage dedicated to soybean fluctuated between 72 million and 64 million acres, the acreage devoted to organic soybeans was relatively stable, reported between 122,000 and 126,000 acres (USDA-ERS, 2010f). The percentage of the soybean acreage that was organic in the five state region identified as the affected area is only 0.3% (see affected area). Significant increases in soybean acreage are not expected, so increased GE or conventional soybean acreage adjacent to organic plantings is not expected. Consistent with these cultivation trends, a determination of nonregulated status of MON 87769 soybean is not expected to have a significant impact on organic soybean growers.

4.2.5 Specialty Soybean Production

The soybean industry, supplying both industrial and food products, has numerous products which can meet specialized needs. Established methods of IP have maintained these products, and as more such specialty products are introduced, will continue to provide them for customers willing to pay premiums beyond those prices given to commodity soybean producers.

No Action Alternative: Specialty Soybean Production

Under the No Action Alternative, no changes to soybean production will occur. These products will continue to be produced for a variety of niche markets beyond that of commodity soybean.

Preferred Alternative: Specialty Soybean Production

In the event of a determination of nonregulated status, MON 87769 soybean would become an additional specialty soybean variety that would be produced and marketed as an IP oil. Monsanto plans to exercise product stewardship in a “closed loop” system (Monsanto, 2010b) and would supervise the sale and movement of the soybean from growers to designated buyers, and then after extraction, continue to oversee the product through a system of required SOPs, contracts and agreements to ultimate users. Under a full stewardship plan (see Appendix C of this EA; Appendix 1 (Monsanto, 2010b)) buyers and users of the oil would be given full information about maintaining product segregation, about necessary procedures and equipment, and Monsanto would make themselves available for consulting with entities in the supply chain. To meet market needs, additional procedures would be assessed, to be proposed for adoption by the principle users of the product in the marketplace. Using a “closed loop” system, a product of specified quality is produced by preserving the identity of the product from the seed stock to the processed product until it is purchased by the final customer (Smyth and Phillips, 2002b). Because the closed loop system is a robust one, APHIS has concluded that the mechanism Monsanto has proposed would be capable of implementing effective isolation from other specialty oils, as well as commodity oils. APHIS concludes that other soybean specialty crops would not be affected by the new SDA producing line MON 87769 soybean.

4.3 Physical Environment

4.3.1 Water Resources

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

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

No Action Alternative: Water Resources

Under the No Action Alternative, land acreage and agronomic practices, including irrigation, associated with soybean production would not be affected. Herbicide-tolerant soybeans, cultivated on 93% of the soybean acreage (USDA-ERS, 2010b), have resulted in the adoption of increased conservation practices (Monsanto, 2010b). These conservation practices, including reduced tillage and precision agriculture, play a significant role in water conservation and maintaining water quality by minimizing soil erosion (USDA-NRCS, 2006c). Current application rates of glyphosate for weed control are not expected to change.

Preferred Alternative: Water Resources

The acreage on which MON 87769 soybean is grown might revert to full cultivation tillage if the new variety was not to be stacked with herbicide tolerance, given that such a high percentage of U.S. is currently growing herbicide tolerant soybeans. Conservation tillage, facilitated by herbicide tolerant crops (see Section 2.2.2, Weed Control), may decrease the likelihood of run-off carrying soil or undesirable pollutants into surface water sources (see Section 2.2.2, Tillage, and Section 2.3.1, Water Resources). The consequences of further crossing of MON 87769 soybean to incorporate other expressed traits is considered in Section 5.3 (Cumulative Impacts: Agronomic Practices).

MON 87769 soybean does not change cultivation practices for soybean production, nor would it increase the total acres and range of U.S. soybean production areas. A determination of nonregulated status of MON 87769 soybean will not change water use in soybean production, as the MON 87769 soybean is expected to be used as an alternative crop to GE or non-GE soybean varieties already in use, offering no additional agronomic benefits to growers.

4.3.2 Soil Quality

No Action Alternative: Soil Quality

Agronomic practices associated with traditional and existing non-regulated GE soybean production would not be expected to change under the No Action Alternative. As a result, no impacts to the soil environment are anticipated from the current agronomic practices associated with soybean production, including tillage, cultivation, fertilization, pesticide applications, fertilizer applications, and the use of agricultural equipment.

Preferred Alternative: Soil Quality

Monsanto's field trial and laboratory analyses demonstrated that the agronomic performance of MON 87769 soybean was functionally identical to its non-transgenic counterpart (Monsanto, 2010b). No increases in fertilizers and pesticides were required, nor were any changes in cultivation, planting, harvesting, and volunteer control required (Monsanto, 2010b). It is expected that similar agronomic practices that are currently used for other commercially available GE soybean will also be used by growers of MON 87769 soybean. Therefore, under the Preferred Alternative there are no expected impacts to soil quality.

4.3.3 Air Quality

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

Conservation practices, including conservation tillage associated with GE soybean production, requires fewer tractor passes across a field (Baker et al., 2005; USDA-NRCS, 2006a). This results in a decrease in dust generation and tractor emissions (Baker et al., 2005; USDA-NRCS, 2006a). Surface residues and untilled organic matter physically hold the soil in place thus decreasing wind erosion of soils and pesticide drift in wind-eroded soils (Baker et al., 2005; USDA-NRCS, 2006a). Reduced tillage also increases sequestration rates of potential carbon emissions from soils (Causarano et al., 2006).

No Action Alternative: Air Quality

Under the No Action Alternative, current impacts to air quality associated with land acreage and cultivation practices associated with soybean production would not be affected. Agronomic practices associated with conventional soybean production and current GE soybean varieties and which contribute to air quality and GHG emissions, including tillage, cultivation, irrigation, pesticide application, fertilizer applications and use of agriculture equipment, would not be expected to change.

Preferred Alternative: Air Quality

A determination of non-regulated status of MON 87769 soybean will not change the cultivation or agronomic practices, or agricultural land acreage associated with growing soybean, and is expected to have the same effect on air quality as the No Action Alternative.

4.3.4 Climate Change

No Action Alternative: Climate Change

Under the No Action Alternative, current impacts on climate change associated with soybean production would not be affected. Agronomic practices associated with soybean production such as tillage, cultivation, irrigation, pesticide application, fertilizer applications and use of agriculture equipment would continue on soybeans grown throughout the region.

Preferred Alternative: Climate Change

There is unlikely to be a measurable change in an agricultural practice that might affect climate change in soybean fields where MON 87769 soybean would be grown. Agronomic practices associated with soybean production such as tillage, cultivation, irrigation, pesticide application, fertilizer applications and use of agriculture equipment would continue on soybeans grown throughout the region. Therefore, there would be no change in agricultural activities that might contribute to climate change.

A determination of non-regulated status of MON 87769 soybean is expected to have the same effect on climate change as the No Action Alternative.

4.4 Biological Resources

4.4.1 Animal Communities

Soybean production systems in agriculture are host to many animal species. Mammals and birds may use soybean fields and the surrounding vegetation for food and habitat throughout the year. Invertebrates can feed on soybean plants or prey upon other insects living on soybean plants as well as in the vegetation surrounding soybean fields. The cumulative effects analysis for the potential effects of the production of MON 87769 soybean on plants and animals is found in Sections 5.11 (Animals), 5.12 (Plants), and 5.15 (Biodiversity).

No Action Alternative: Animal Communities

Under the No Action Alternative, conventional and GE soybean production would continue while MON 87769 soybean remains a regulated article. Potential impacts of GE and non-GE soybean production practices on non-target animals would be unchanged.

Preferred Alternative: Animal Communities

Monsanto data indicate that the agronomic practices used to produce MON 87769 soybean will be the same as those used to produce other conventionally grown GE and non-GE soybean. MON 87769 soybean production is not expected to change land acreage or any cultivation practices for soybean production.

MON 87769 soybean provides a modified fatty acid profile based on the introduction of *Primula juliae* Δ6 desaturase (Pj.D6D) and *Neurospora crassa* Δ15 desaturase (Nc.Fad3). Changes in fatty acid composition resulting from the expression of these genes are not expected to cause impacts to animals consuming the soybean. MON 87769 soybean contains two principle new fatty acids, stearidonic (26% of total fatty acids) and gamma-linolenic (7%). MON 87769 soybean contains modestly reduced oleic acid and substantially reduced linoleic fatty acids compared to the typical range of fatty acids found in commodity soybean oil (Table E-16 (Monsanto, 2010b)). MON 87769 soybean has a fatty acid profile that is comparable to commercial high oleic vegetable oils (e.g., high oleic canola, high oleic safflower, high oleic sunflower), traditional oils such as olive oil that has a long-history of consumption in the diet, and canola oil that obtained FDA GRAS (Generally Recognized as Safe) status. Table 14 presents a comparison of fatty acid profiles of several plant sources of vegetable oil, including conventional soybean and MON 87769 soybean.

Table 14. Comparison of fatty acid profiles for oil derived from MON 87769 soybean with several other plant sources

Vegetable Oil Type	% Saturated Fat[1]	% Oleic Acid[1] (18:1)[2]	% Linoleic Acid[1] (18:2)	% Linolenic Acid[1,4] (18:3)	% Stearidonic Acid[3] (18:4)	% PUFAs[1]
Canola	6	57	26	10	0	36
MON 87769 Soybean	13	16	26	11	26	67
MON 87705 Soybean	6	76	10	7	0	17
Conventional Soybean[5]	15	23	53	8	0	60
Olive	13	78	7	1	0	8
Palm	50	38	11	1	0	12
Coconut	92	6	2	0	0	2

Source: Table P-3 and Table VII-2 (Monsanto, 2010b).
Notes:

1. Percent fatty acid presented as a percent (%) of total fatty acids.
2. Ratios presented within parenthesis represent the lipid numbers for the subject fatty acid, one of the more common nomenclature systems. The first number, e.g., 18, indicates the number of carbon atoms in the fatty acid, and the second number, e.g., 1, indicates the number of double bonds in the fatty acid. A fatty acid is considered saturated when there are no double bonds in the carbon chain, hence the 18:3 linoleic acid would be considered a polyunsaturated fatty acid, presenting three double bonds across the 18 carbons.
3. From Table VII-1 (Monsanto, 2010b); (Monsanto, 2010c).
4. Alpha linolenic totals; add 7% additional for gamma linolenic in MON 87769 soybean
5. A3525, the variety originally transformed, a conventional variety.

Monsanto statistically analyzed 42 seed components and seven in forage. The samples were collected at five sites and included a combined site analysis. Some 28 differences between the MON 87795 and control observations for constituents were significantly different, but except for linoleic acid, were either within the published variability of existing commercial cultivars, or were actually within a 99% tolerance limit based on existing commercial cultivar values. Linoleic acid was expected to be different, because it is a substrate for the desaturases introduced into the soybean to make SDA. In seed, statistically significant differences were found in 19 nutrients other than fatty acids including amino acids in combined site analyses, and these were all of less than 10%, but were not outside the 99% tolerance level for commercial soybean properties. Differences in fatty acids (including linoleic acid) in combined-site analyses between MON 87769 soybean and a conventional control included six fatty acids of the eight analyzed.

Except for linoleic acid, a substrate for the introduced desaturases, all of these differences were within the 99% tolerance level for commercial content of these fatty acids (Monsanto, 2010).

Animals are known to forage on soybean foliage and seed. With the exception of the introduction of the desaturase genes, genes to change fatty acid composition, no phenotypic or morphological differences have been identified between MON 87769 soybean and conventional soybeans. Composition of MON 87769 soybean forage was compared to a conventional control (the host variety used in the transformed variety) and analyzed for fiber and no combined site differences were found, although one site of the five showed an increase. For proximates, fat was slightly decreased at one site of five; neither difference was outside the commercial tolerance range. No observable adverse effect of feeding up to 4 g of SDA oil/kg body weight per day was determined in a 90 day, one-generation reproductive rat toxicity study (Hammond et al., 2008). The two new proteins in MON 87769 are homologous to many other desaturases found in food or feed, have no similarity to known toxins, are present at very low quantities in foods, and are readily digestible in simulated gastric and digestive fluids (Monsanto, 2010b).

The potential risks to animals from the consumption of MON 87769 soybean with modified fatty acid composition will be evaluated by the FDA (Monsanto, 2010b). Soybean meal is the most common supplemental protein source in U.S. livestock and poultry rations due to its nutrient composition, availability, and price. Although MON 87769 soybean is intended to be cultivated as a specialty soybean to take advantage of the SDA production, the soybean meal remaining after the extraction of the soybean oil may become a constituent of livestock or poultry food supplements. Monsanto completed a feeding study and a one generation reproduction study on rats using oil derived from the MON 87769 soybeans and fed in substantial quantity. No adverse treatment related effects were determined from either study (Hammond et al., 2008). Monsanto is completing a consultation with FDA on the possible impacts on animals using feed containing MON 87769. The analysis will compare the composition of MON 87769 soybean with the conventional non-transgenic soybean variety A3525 (also the original line used for the transformation), and evaluate the potential impacts to animal diets from the reduced intake of linoleic acid. Although the soybean meal derived from MON 87769 soybean would have reduced levels of linoleic acid, the animal’s requirements for linoleic acid could be met by other ingredients in animal feed.

One important use of MON 87769 will be to enhance the omega-3 fatty acids in animal tissues, either with stearidonic acid itself, or with the elaborated fatty acids, DHA and EPA. Broiler chickens were fed with soy oil from the MON 87769 SDA line, from isogenic lines and with fish oil. Feeding MON 87769 oil increased the incorporation of three desirable fatty acids over the isoline fed animals, and the treatments did not change the intake, weight gain or feed conversion efficiency (Rymer et al., 2011). Similarly, MON 87769 SDA-containing oil when fed to sea bass can increase the DHA concentrations in fish muscle (Bharadwaj (Bharadwaj et al., 2010) et al., 2010). When introduced into the abomasum of dairy cows, MON 87769 oil can increase omega-3 fatty acids five fold over control with no impact on milk production or on milk fat yield (Bernal-Santos (Bernal-Santos et al., 2010).

Based on the above information, APHIS concludes that a determination of nonregulated status of MON 87769 soybean is not expected to have adverse effects on non-target animals.

4.4.2 Plant Communities

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

In this context, weeds are those plants which, when growing in the soybean field, compete with the soybean for space, water, nutrients and sunlight, and may thus include native species. The types of weeds in and around a soybean field will vary depending on the geographic region where the soybean is grown, as is apparent from control recommendations in various states (Aref and Pike, 1998; Byrd et al., 2003; Duke and Powles, 2009; Loux et al., 2009).

No Action Alternative: Plant Communities

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

Preferred Alternative: Plant Communities

In the event of a determination of nonregulated status of MON 87769 soybean, the risks to wild plants and agricultural productivity from weedy soybean populations are low; volunteer soybean populations are easily managed and there are no feral or weedy relatives. Agronomic studies conducted by Monsanto tested the hypothesis that the weediness potential of MON 87769 soybean is unchanged with respect to conventional soybean (Monsanto, 2010b). No differences were detected between MON 87769 soybean and nontransgenic soybean in growth, reproduction, or interactions with pests and diseases, other than the intended effect, which is production of SDA. Volunteer soybean is normally not a concern. Soybean is not winter hardy, and existing mechanical and chemical methods are available to manage the occasional volunteer soybean in cultivation areas (Carpenter et al., 2002; OECD, 2000). Several post-emergent herbicides are also widely used to control the presence of volunteer soybeans in subsequent rotational crops (See Table IX-4 (Monsanto, 2010b; Zollinger, 2010)). Based on these biological limitations, as well as readily available control practices, a determination of nonregulated status of MON 87769 soybean is not likely to result in increased weediness. Overall impacts would be similar to the No Action Alternative.

4.4.3 Gene Flow and Weediness

Two forms of gene flow are evaluated: Vertical gene flow and horizontal gene flow. Vertical gene flow, or hybridization and associated introgression, is the movement of genes to sexually compatible relatives (Ellstrand, 2003; Quist, 2010). The soybean is considered self-pollinating, and has no wild relatives in the U.S. (Monsanto, 2010b; OECD, 2000). Although some cross-pollination can occur, AOSCA identity protection practices have been found adequate to protect against such gene flow (Monsanto, 2010b; OECD, 2000; USDA-APHIS, 2010c). The only relatives of soybean are other varieties currently cultivated. In assessing the risk of gene introgression from MON 87769 soybean to its sexually compatible relatives, APHIS considered two primary issues: 1) the potential for gene flow and introgression to soybean relatives; and 2) the potential impact of introgression. Vertical gene flow is discussed below in the analysis of the Preferred Alternative.

Horizontal gene flow represents the stable movement of genes from one organism to another without reproduction or human intervention (Keese, 2008; Quist, 2010). There is no evidence of naturally occurring transgene movement from transgenic crops to sexually incompatible species (Stewart, 2008). Horizontal gene transfer and consequent expression of DNA from one plant to another sexually incompatible plant or other phyla (e.g., species of bacteria) is unlikely to occur (Keese, 2008). This event would require physical relocation of the functional genetic sequences from the transgenic plant to the new location, including not only the genes which code for the production of specific proteins, but also those portions of the genome which regulate the activity of those genes (Keese, 2008; Stewart, 2008). There are no known naturally occurring vectors (such as plasmids, phages, or transposable elements) that could be responsible for inter-domain gene transfer, and there is little evidence that eukaryotic cells are naturally capable of stably incorporating genes from the environment into their genome (Brown, 2003). Although viruses do move genetic material, all viruses that infect higher plants have small RNA or DNA genomes, usually with fewer than 20 encoded proteins (Keese, 2008). These viruses are, therefore, constrained as to the type and size of novel genetic material which can be acquired by horizontal gene transfer (Stewart, 2008). The development of herbicide resistance, particularly that found in crop fields treated with glyphosate, is thus not a result of gene transfer but is the result of selective pressures associated with herbicide use. This issue is discussed in the subsection on impacts to plant communities.

Two bacteria species commonly associated with plants, *Agrobacterium* and *Rhizobium,* have been evaluated to determine the probability of horizontal gene transfer between the bacterium and their host plants. *Agrobacterium* moves its genes from its bacterial plasmid to the plant causing the plant to produce the gall; *Rhizobium* aids in nitrogen fixation in legume nodules (Stewart, 2008). The genomes of both bacteria have been sequenced, and the sequenced genes evaluated in search of exogenous genes (Kaneko et al., 2000; Kaneko et al., 2002; Wood et al., 2001). Despite what would appear to be millennia of symbiotic relationships between these bacteria and their host plants, there is no evidence that these organisms contain genes derived from plants (USDA-APHIS, 2010c). In cases where review of sequence data implied that horizontal gene transfer occurred, these events are inferred to occur on an evolutionary time scale of millions of years (Brown, 2003; Koonin et al., 2001). Transgene DNA promoters and coding sequences are optimized for plant expression, not bacterial expression (USDA-APHIS, 2010d). Horizontal gene flow, resulting in the relocation of entire transgenes including the regulatory portions of the DNA (those parts of the DNA which code for the production of the specific proteins in that relocated transgene) has never been shown to occur in nature (Clarke, 2007; Stewart, 2008). Thus, even if horizontal gene transfer occurred, proteins associated with these transgenes are not likely to be produced in the new host organism (Stewart, 2008; USDA-APHIS, 2010c). Based on this information, APHIS considers the horizontal gene flow from MON 87769 soybean or other cultivated GE soybean varieties to unrelated species to be unlikely.

No Action Alternative: Gene Flow and Weediness

Under the No Action Alternative, conventional and GE transgenic soybean production will continue to be grown commercially, while MON 87769 soybean will remain a regulated article. Soybean cultivation practices are expected to remain the same. Gene flow from current commercially available GE cultivars to non-GE soybean cultivars is expected to remain unchanged from the current conditions.

Preferred Alternative: Gene Flow and Weediness

APHIS evaluated the potential for gene introgression to occur from MON 87769 soybean to sexually compatible varieties and considered the possibility that such introgression would result in increased weediness. Monsanto's data found no significant difference in pollen morphology and viability from field grown MON 87769 soybean plants and other soybean varieties. The soybean is not identified as a weed in the U.S. (USDA-APHIS, 2010c). Soybeans are not frost tolerant, do not survive freezing temperatures, and do not reproduce vegetatively (OECD, 2000; USDA-APHIS, 2010c).

Some research suggests that fatty acid composition may influence cold tolerance and survivability. Kodama (Kodama, 1994) and Kodama et al. (Kodama et al., 1995) found that increases in levels of certain fatty acids, particularly hexadecatrienoic and linolenic acids, results in an increase in cold tolerance. In MON 87769 soybean, the levels of linolenic acid are within the lower end of the commercial range of fatty acid composition when compared with other varieties (Monsanto, 2010b). Changes in oleic acid or linoleic acid composition and reductions in saturated fatty acids have not been linked to increased cold tolerance. The changes in fatty acid composition MON 87769 soybean are not expected to enhance cold tolerance (USDA-APHIS, 2010c).

In its PPRA, APHIS assessed the weediness potential of MON 87769 soybean based on the introduced *Primula juliae* delta-6 desaturase (Pj.D6D) and the *Neurospora crassa* delta-15 desaturase (Nc.Fad3) genes controlling fatty acid composition (USDA-APHIS, 2010c). The changes introduced in the MON 87769 soybean were deemed to not present a weediness risk (USDA-APHIS, 2010c).

The change in composition of fatty acid in MON 987769 Soybean is due to the activity of the endogenous *Pj.D6D* and the *Nc.Fad3* genes in the soybean. These two genes pose no novel risks from a plant pest perspective (USDA-APHIS, 2010c). The action of these two genes in MON 87769 soybean is not anticipated to give rise to an enhanced weediness or gene flow.

In its petition, Monsanto presented information on phenotypic and agronomic characteristics collected from field studies (Monsanto, 2010b). These data included information on seed dormancy, germination, emergence, seedling vigor, plant height, lodging, days to maturity, shattering, seed weight, yields, disease incidence, and insect damage, among others (Monsanto, 2010b).

APHIS has assessed those parameters including some of those noted above to evaluate the weediness potential of MON 87769 soybean. Monsanto found no biologically significant differences between MON 87769 soybean and the original commercial variety that was transformed for seed dormancy, germination, early stand count, seedling vigor, days to 50% flowering, lodging, pod shattering, and final stand count. All values were within the recommended standards for certified soybean seed (AOSCA, 2009).

To determine whether the variety could be more likely to increase gene flow, Monsanto studied pollen viability and morphology. No statistically significant differences were detected between MON 87769 soybean, the original modified line, and other controls for percent viable pollen or pollen grain diameter (Monsanto, 2010b). No differences in pollen morphology were observed. Thus, differences in gene flow to other soybean are unlikely.

Results from the phenotypic and agronomic assessments indicate that MON 87769 soybean does not possess characteristics that would confer a plant pest risk compared with conventional soybean (USDA-APHIS, 2010c). These data indicate that the engineered plant is not different in any fitness characteristics from its parent that are likely to cause the MON 87769 soybean to become weedy or invasive (USDA-APHIS, 2010c).

Based on the above information, APHIS has concluded that a determination of nonregulated status of MON 87769 soybean will not impact other soybean varieties through gene flow or introgression, nor would it present a greater risk of weediness or invasive characteristics (USDA-APHIS, 2010c). MON 87769 soybean is expected to have the same effect on gene movement as the No Action Alternative.

4.4.4 Microorganisms

Microorganisms in soil are important components that sustain and provide the dynamic aspects of soil associated with critical ecological processes. Nutrient cycling, establishing soil structure contributing to plant growth, metabolism of deleterious components are all dependent on the microbial constituents. The health and growth of these microbes may be influenced by many processes and conditions.

<u>No Action Alternative: Microorganisms</u>

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

<u>Preferred Alternative: Microorganisms</u>

Monsanto conducted field observations to assess potential agronomic differences between MON 87769 soybean and conventional soybean (variety A3525, used for the transformation) over two years and at a total of 21 locations (Monsanto, 2010b). The disease analysis included observations of a wide range of bacterial and fungal pathogens, nematodes, and plant viruses (Table I-4, I-5 (Monsanto, 2010b)). No significant incidence of disease damage was noted between MON 87769 soybean and the comparison variety (Monsanto, 2010b). The lack of difference indicates that the expression of stearidonic and gamma linolenic acid and modified fatty acid content by MON 87769 soybean does not change soybean interactions with microorganisms in the field.

Monsanto also evaluated the potential impacts of these changes on the symbiotic relationship of soybean with the nitrogen-fixing root nodule bacteria *Bradyrhizobium japonicum* (Monsanto, 2010b). In these studies, MON 87769 soybean was compared with the original transformed conventional line, and six conventional soybean varieties as well as the negative isoline for MON 87769 soybean (Monsanto, 2010b). No significant differences were detected between MON 87769 soybean and any of the comparison varieties for nodule number, biomass of nodules, shoot total nitrogen (percent and mass), or shoot and root material (Monsanto, 2010b). These results indicate that the expression of the modified fatty acid composition does not impact the biology of root nodules formation by the symbiotic bacteria.

Consistent with these test results, the impacts of a determination of nonregulated status of MON 87769 soybean on microorganisms is the same as the No Action Alternative.

4.4.5 Biodiversity

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

<u>No Action Alternative: Biodiversity</u>

Under the No Action Alternative, MON 87769 soybean would continue to be a regulated article. Growers and other parties who are involved in production, handling, processing, or consumption of soybean would continue to have access to GE soybean varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act, herbicide-tolerant soybean varieties, and conventional soybean varieties. The implications of agronomic practices associated with soybean production whether traditional or GE varieties with the attendant effects on biodiversity would not change.

<u>Preferred Alternative: Biodiversity</u>

Although soybean fields are cultivated as monocultures to optimize soybean yield, the landscape adjacent a soybean field may harbor a wide variety of plants. Broad spectrum herbicide application has the potential to impact off-site plant communities. The herbicide choices used for cultivation of MON 87769 soybean will not be different from those used by growers for weed control on other non-herbicide tolerant varieties, and acreage is not expected to exceed 100,000 acres in five years (Monsanto, 2010b). Consequently, production MON 87769 soybean is not expected to result in an increase in the application of herbicides or frequency of application over other existing non GE soybean varieties. A determination of nonregulated status of MON 87769 soybean is not expected to change the cultivation or agronomic practices, or agricultural land acreage associated with growing soybean.

The stearidonic and gamma linolenic acid expressed in MON 87769 soybean, which are also expressed in some other plants, fish, and algae, would have no effect on animals that might feed on soybean, because the novel oils have been shown to have no harmful consequences by feeding (see FDA acceptance of GRAS status of oils from this variety). Monsanto has shown that expression of the two new proteins in MON 87769 soybean are homologous to many other desaturases found in food or feed, have no similarity to known toxins, are present at very low quantities in foods, and are readily digestible in simulated gastric and digestive fluids (Monsanto, 2010b). Thus, no potential for allergic response has been demonstrated by consuming the meal deriving from the soybean. Therefore, a determination of nonregulated status of MON 87769 soybean is highly unlikely to have any direct toxic effects on non-target organisms and is likely to be neutral or beneficial to animal and plant biodiversity.

The abundance of diverse beneficial insects was assessed over two years in four states (Tables I-8 and I-10 (Monsanto, 2010b)). No consistent differences were noted in the populations of these insects over three collections spanning reproductive development of the soybean. The insects surveyed included Carabid and ladybird beetles, parasitic wasps, predatory plant bugs and spiders. No differences in insect diversity would be expected under the Preferred Alternative compared to the No Action Alternative.

The cultivation of MON 87769 soybean would not change the use of insecticides to manage the invertebrate pests of soybean since there is no difference in insect damage or populations of pest insects in MON 87769 soybean and conventional control soybean (Monsanto, 2010b). Populations of pest insects were assessed in four states comparing MON 87769 soybean and conventional line A3235, the parental line during two growing seasons (Monsanto, 2010). Aphids, beanleaf beetles, leaf hoppers and three moth pests among others were assessed over three collection periods during the reproductive phase of plant growth. No consistent differences were found in populations of insects in these locations and years. Practices currently employed for the management of conventional and other GE soybean would likely continue for this crop. In this regard, a determination of nonregulated status of MON 87769 soybean would have the same impacts on biodiversity as the No Action Alternative.

4.5 Human Health

4.5.1 No Action Alternative

Public Health

Under the No Action Alternative, MON 87769 soybean would continue as a regulated article. Human exposure to existing traditional and GE soybean would not change under this alternative. Growers and consumers exposure to this product would be limited to those individuals involved in the cultivation of MON 87769 soybean under regulated conditions.

Worker Safety

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

4.5.2 Preferred Alternative: Human Health

Public Health

APHIS considers the FDA regulatory assessment in making its determination of the potential impacts of a determination of nonregulated status of the new agricultural product. Monsanto has submitted the data needed for a full consultation with FDA and has demonstrated the safety of the new proteins. Previous to the submitted FDA new protein consultation, Monsanto submitted a GRAS Notice for SDA soybean oil (No. GRN 000283) to FDA on February 25, 2009 (US-FDA, 2009b). FDA issued a response letter on September 4, 2009, indicating the agency has no further questions about the characteristics of the oil, and safety of its use in foods (US-FDA, 2009a).

Monsanto's intention in developing MON 87769 soybean is to provide a plant source of omega-3 fatty acid that can efficiently be converted to the long chain polyunsaturated fatty acids, DHA and EPA, which are important in prevention or improvement of human health conditions. Oil derived from MON 87769 soybean would be used to enrich a wide variety of foods, including processed foods, margarine, salad dressings, and other selected food categories.

APHIS has considered the human health impacts associated with the new fatty acids expressed in MON 87769 soybean deriving from activity of the two desaturases, PjD6D and Nc.Fad3. The possible impacts of ingestion of the proteins were considered, as were the new fatty acids. Neither desaturase protein formed by the introduced sequences have amino acid segments that are structural or immunologically relevant to human allergens, and both are easily degraded by simulated gastric and intestinal fluids (Monsanto, 2010b). The two proteins were purified from immature soybean seed, and tested for adverse effects on mice (Monsanto, 2010b). A 'No Observed Effect Level' (NOEL) was found for mouse ingestion up to 37.3 mg/kg body weight, which is 29,000 and 47,000 times the concentration expected in human diet when containing oils from MON 87769 soybean.

Monsanto presents data comparing the fatty acid and other nutritional element concentrations with the reported ranges for conventional soybean against commercial tolerance ranges (see summary Table 15, below). MON 87769 soybean fatty acids are compared with conventional soybean and commercial ranges of these fatty acids. In addition to evaluating the targeted fatty acid composition, Monsanto evaluated non-fatty acid nutrients, anti-nutrients, proximate and fiber levels, consistent with the compositional guidance provided by the OECD (OECD, 2001).

Table 15: Comparison of percentage fatty acid in MON 87769 soybean with conventional soybean control (A3525) and commercial range.

Fatty Acid	Total Percent (%)		
	MON 87769 Soybean Mean	Conventional Soybean (A3525) Mean	Commercial Soybean Range
16:0 palmitic	12.1	11.8	9.9-12.3
18:0 stearic	4.2	4.2	3.7- 4.9
18:1 oleic	15.2	19.2	16.7 - 23.2
18:2 linoleic	22.8	54.9	53.4 - 57.4
18:3 alpha-linolenic	11.2	9.2	7.0 – 10.6
18:3 gamma-linolenic	7.1	N/A	N/A
18:4 stearidonic	26.1	N/A	N/A

Source: Table E-12 and Table VII-1 (for percentage of new fatty acids) (Monsanto, 2010b).

From the summary Table 14, total saturated fat (as measured by palmitic and stearic acid percentages) in MON 87769 soybean was similar to that of conventional soybean and olive oil. The mean level of oleic acid decreased 4% in MON 87769 soybean compared to the conventional soybean variety (Table 15). Linoleic acid decreased from 54.9% in conventional soybean to 22.8% in MON 87769 soybean, and this is reflected in the appearance of stearidonic in MON 87769 soybean at 26.1%. There was a 2% increase in *alpha*-linolenic acid in MON 87769 soybean when compared to the conventional variety and the appearance of gamma linolenic acid of 7%. Overall, the total polyunsaturated fatty acids of MON 87769 soybean and conventional soybean are similar.

SDA commonly occurs within the environment, and is found in 17 plant families and over 200 species at more than 1% of fatty acid content (p. 8 (Monsanto, 2010b)) and gamma-linolenic acid is found in at least 13 species (Table X-1 (Monsanto, 2010b)). Many plant species are cultivated as a source of these omega-3 fatty acids, such as *Echium* spp., black currant, and *Borago officinalis*. No adverse effects on human subjects were reported in a study of healthful effects associated with consuming soybean oil from MON 87769 (containing SDA) ((Lemke et al., 2010)). Many fish species have measureable content of SDA (Table X-2 (Monsanto, 2010b)) and fish oil is extensively consumed for the benefit of providing the long chain polyunsaturated fatty acids (Addendum to petition (Monsanto, 2010b)).

Monsanto measured compositional aspects of MON 87769 soybean and compared these data with conventional soybean. As earlier noted, SDA and also gamma linolenic acid are not found in commodity soybean. Although the animal feed consultation with FDA is pending, submitted data showed that these new components are both intermediates in mammalian systems during production of DHA and EPA, and also are found in the environment in numerous other plant and animal sources. Linoleic acid (18:2) is decreased to about 41% of control percentage, and this altered MON 87769 soybean constituent is similar to that found in canola oil. Statistically significant but small differences were observed in the comparisons of the A3525 conventional variety to MON 87769 soybean in the concentrations of several fatty acids (16:0 palmitic, 18:0 stearic, 18:1 oleic, 18:3 alpha linolenic acid, 20:0 arachidic, 22:0 behenic). APHIS evaluated these differences in composition and has determined that those reported for MON 87769 soybean either fall within the typical commercial range for percentage composition or the 99% tolerance interval for commercial soybean composition (Monsanto, 2010b). Several amino acid percentages, % dry weight of proximates (protein and carbohydrate), and two isoflavones were also different from controls, but these also were within either the range of commercial values or the 99% tolerance level for commercial soybean (Monsanto, 2010b).

MON 87769 soybean was produced to make available an additional source of SDA, which is a healthful omega-3 fatty acid that can be obtained from other plant sources, fish and algae on commercial scales (Monsanto, 2010b). Monsanto 87769 stearidonic acid soybean would likely be a lower cost alternative to marine-derived omega-3 oils (Kennedy et al., 2012). The key contribution of SDA is that it is a precursor for the fatty acids DHA and EPA, which have been shown by a variety of clinical and research reports to reduce adverse cardiovascular incidents, reduce inflammatory mediators, reduce cancer risk and inhibit tumor growth (see review in Whelan, 2006). EPA alone may influence these outcomes, but administration of SDA can equal the impacts on these conditions (see review in Whelan, 2006).

The Preferred Alternative impacts to human health differ from the No Action Alternative with regard to potential human health benefits associated with consumption of the oil from this crop. Monsanto's analysis (Monsanto, 2010b) suggests that enhancing food oils with the soybean oil extracted from the MON 87769 soybean may have a positive impact on human health when used in many foods for which it is suitable. The addition of SDA using oil derived from MON 87769 soybean oil may benefit many health conditions, both as preventative and as remedial. The extent to which positive benefits may be observed is contingent upon the market share of the MON 87769 soybean and the types of food products to which manufacturers add the modified oil, but it is likely to begin to be incorporated into processed foods only after a lengthy period of food ingredient adaptation and then marketing to the public to attain acceptance.

Based on APHIS' review of field and laboratory data and scientific literature provided by Monsanto (Monsanto, 2010b), and safety data available on other GE soybean, APHIS has concluded that under this alternative, a determination of nonregulated status of MON 87769 soybean would have no significant impacts on human health.

Worker Safety

If MON 87769 soybean is adopted, growers during the course of production will be exposed to the same pesticides as those typical of other non-herbicide tolerant soybean varieties. As MON 87769 soybean does not require different cultivation practices than currently available glyphosate-tolerant soybean, this level of herbicide exposure is expected to be the same as the No Action Alternative.

Soybean processing and manufacturing will not be altered by use of MON 87769 soybean, and workers will not be exposed to any new equipment or chemicals to which they had not already been exposed. The novel fatty acids stearidonic and gamma linolenic acid derive from two enzymes (desaturases) that are conserved across plant, animal and bacterial kingdoms, and which are ubiquitous in the human diet. Minor amounts of trans-SDA and trans alpha linolenic acid (trans-ALA) are also generated from processing of the novel fatty acids (Monsanto, 2010b). The oils found in MON 87769 soybean, including the novel ones, are also commonly found in other plants. Oils with substantial amounts of the new fatty acids are already being processed by the food and nutrients industries, and are extracted from other plant sources (gamma linolenic acid from borage oil and blackcurrant; SDA from *Echium* spp.) and thus would not provide novel exposures to workers in the edible oil processing and packaging industry. Monsanto submitted a GRAS Notice (for Foods Generally Recognized as Safe) for MON 87769 soybean to the FDA (US-FDA, 2009b). FDA has no further questions about the characteristics of the oil, and safety of its use in foods (see Appendix A; GRAS Notice No. GRN 000283) (US-FDA, 2009a).

4.6 Animal Feed

The majority of the soybean cultivated in the U.S. is grown for animal feed, and is usually fed as soybean meal (Monsanto, 2010b). Soybeans intended for animal feed are generally cultivated as commodity products, although there are some consumers demanding specific physical or chemical characteristics to meet specific feed needs (Monsanto, 2010b). In these cases, the soybean meeting those specialized needs are cultivated as a specialty soybean crop. The cultivation practices necessary to maintain identity protection have been previously discussed in Section 2.2.5.

Under FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from MON 87769 soybean must be in compliance with all applicable legal and regulatory requirements. GE organisms for feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Monsanto initiated the consultation process with FDA for the commercial distribution of MON 87769 soybean and submitted a safety and nutritional assessment of food and feed derived from MON 87769 soybean to the FDA on March 23, 2009 (BNF No. 00117) (Monsanto, 2010b). FDA is currently evaluating the submission.

4.6.1 No Action Alternative: Animal Feed

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

4.6.2 Preferred Alternative: Animal Feed

Monsanto has submitted compositional and nutritional characteristics of MON 87769 soybean to APHIS (Monsanto, 2010b). As part of field trials, samples of MON 87769 soybean and conventional variety A3525 were collected from five different field trial locations during the 2007-2008 growing season (Monsanto, 2010b). These samples were analyzed for comparable nutritional components, including proximate (protein, fat, carbohydrates, fiber, ash, moisture), vitamins, amino acids, fatty acids, and the antinutrient factors of soybean (which included lectin, trypsin inhibitors, isoflavones, and phytic acid) (Monsanto, 2010b). APHIS has reviewed Monsanto's results and has concluded that with the exception of the changes in fatty acid composition, the levels of nutrients, anti-nutrients, and secondary metabolites in MON 87769 soybean are not statistically different from those likely to be expressed by conventional varieties.

The change in fatty acid composition is not expected to impact the value of MON 87769 soybean as an animal feed, The total fat content of the oil is unchanged which is only about 0.5% (minimum) (Iowa Soybean Association, 2010). The total saturated fatty acids and polyunsaturated fatty acids in MON 87769 soybean oil are similar to those found in conventional soybean. FDA has agreed that the soybean oil produced with MON 87769 soybean has GRAS status (US-FDA, 2009a), and thus, these oils are not a risk to animals that consume meal. The desaturase proteins introduced into MON 87769 soybean are similar to those found in a wide variety of plants, fish and animals, and have been shown to have no toxic or allergenic potential (Monsanto, 2010b).

Based on this information APHIS has concluded that a determination of nonregulated status of MON 87769 soybean would have no significant impacts on animal feed or animal health. Overall impacts are similar to the No Action Alternative.

4.7 Socioeconomic Impacts

4.7.1 Domestic Economic Environment

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

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

No Action Alternative: Domestic Economic Environment

Under the No Action Alternative, MON 87769 soybean and its progeny would continue to be regulated under 7 CFR part 340. Growers and other parties who are involved in production, handling, processing, or consumption of soybean would not have access to MON 87769 soybean and its progeny, but would continue to have access to GE that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act as well as conventional varieties. Domestic growers will continue to utilize currently available traditional and GE soybean varieties based upon availability and market demand.

Preferred Alternative: Domestic Economic Environment

Monsanto anticipates that MON 87769 soybean will provide a niche product, which in five years, if all demand for SDA were provided by this variety, would equate to about 100,000 acres of MON 87769 soybean being grown in the U.S. (Monsanto, 2010b). Monsanto does not anticipate that MON 87769 soybean would change soybean production practices or increase soybean acreage (Monsanto, 2010b). Properties of MON 87769 soybean are not likely to replace substantial amounts of commodity acreage, and will not require significant additional acreage for the new soybean varieties. New niche food and industrial uses may be found for this oil, but at present, no large requirements for this variety can be foreseen. Existing soybean users will remain users of commodity soy oil, and small scale use of MON 87769 soybean oil may slowly increase in the next five years to that predicted in Monsanto's market analysis (see Appendix C of this EA).

Stewardship of MON 87769 Soybean

Soybean oil users who may have concerns about undesirable changes in standard properties of this modified oil have been identified by Monsanto, and dialogues have begun to solicit both specific issues of importance and to provide these stakeholders with relevant information (Appendix C; Addendum (Monsanto, 2010b)). As noted in Addendum 2 to the MON 87769 soybean petition, these groups include trade organizations representing oil processors, elevators, grain and oilseed processors, agricultural businesses and exporters, bakers, and grocery producers. Issues of commingling have been addressed in Addendum 1 (see for example, impacts to commodity soybean and meal, changes in oxidative and heat stability, acceptability of sensory properties and allowable changes in nutrition facts labeling). The issue of impacts of misdirected MON 87769 soybean was analyzed. Making standard assumptions for the size of a single truck delivery of an IP soybean and for the smallest soybean processor holding tank, the total SDA content of commodity oil would be 0.8% from a single such delivery. Maximal percentage of SDA in an elevator after misdirection would be 0.03-0.16% given standard elevator dimensions. A single truck inadvertently delivering one SDA soybean load to a commodity soybean ship would lead to SDA content of 0.0008%. In all these cases, the relative amount of the admixture would be extremely small, and as we show next, would not affect key properties of commodity oil.

A number of assessments were made that showed to what extent mixture of MON 87769 soybean would affect expected properties of commodity oil. To decrease the oxidative stability (measured by the oxidative stability index falling below the range of that for commodity soybean), the mixture would require up to 12.5% of MON 87769 soybean (Figure 1, Appendix C). Monsanto also determined that commodity oil would tolerate up to 15% MON 88769 Soybean without impact on formation of unacceptable levels of polar materials in commercial fryer conditions (Figure 3, Appendix 2). Commingling of MON 87769 soybean up to 15% content in the commodity oil had no impact on flavor of French fries (Figure 4, Appendix 2).

A key to the acceptability of soybean oil as a feedstock is that the product has a consistent and specific fatty acid composition (Cahoon, 2003). The identity protection system detailed above in Subsection 2.2.5, Specialty Soybean Production, provides controls to ensure that the product traits attained in the field are preserved up through the ultimate user. Monsanto intends to segregate the crop from commodity soybean at all stages, from seed production through and including handling , processing and use in a closed loop process, and to oversee a complete product stewardship plan involving all producers and users (Monsanto, 2010b).

Mechanisms to Maintain Product Identity

Monsanto has developed a Closed Loop Stewardship System (CLSS) that will avoid potential impacts to commodity soybean oil (Appendix 2). Procedures and processes for MON 87769 soybean have been designed for production integrity at all steps of viable seed and grain production, and through storage, grain elevators, oil and meal processors, and downstream entities for product identity assessment (Appendix 2; Addendum 1 (Monsanto, 2010b)). The CLSS will require terms and conditions for quality management systems, quality assurance and quality control. After obtaining international regulatory approvals for MON 87769 soybean, Monsanto will continue to refine and update the stewardship system for long term implementation. Key stakeholders will continue to be consulted as stewardship of MON 87769 soybean continues.

Contract buyers of MON 87769 soybean will be required to identify MON 87769 soybean beginning with delivery at grain elevators; sampling for MON 87769 soybean grain will be required by contract for each arriving truckload. Processors and downstream users will use standard oil analytic procedures to provide oil constituent analysis at critical control points in the CLSS, as well as segregation and adherence to standard protocols required by contracts and agreements.

In addition to contracts and agreements with Monsanto, product identity at all steps will be maintained because soybean sellers and oil processors are motivated to capture premium prices; routine adherence to protocols will also serve to maintain product identity. With these financial incentives and established procedures, the soybean industry will observe best management practices, use appropriate identification procedures, employ proprietary inventory systems and ensure traceability requirements. Using the proposed measures, which would be established by contractual agreements with growers, elevators and processors, Monsanto aims to provide stewardship during all phases of production for stakeholders invested in all uses of soybean oil.

The vegetable oil industry is experienced at handling multiple IP soybean types and the oils extracted from them (Appendix 2 and Addendum 1 (Monsanto, 2010b)). Oil processors and users are able to appropriately characterize, segregate and blend for special functions the identity preserved oils available to them for attaining the final quality needed in specialty products. The

Monsanto Vistive low-linolenic variety has been available to oil users for six years, and is grown extensively in 12 states (Appendix 2, www.vistive.com). Monsanto's oversight mechanisms for production of Vistive low linolenic oil as well as IP mechanisms used for other identity preserved soybean production both have similarities to the plan described here for product stewardship of MON 87769 soybean oil. Monsanto has provided the leadership for production of the low linolenic IP specialty oil, and thus, has multiple years of relevant experience in establishing and maintaining processes of appropriate stewardship for MON 87769 soybean and its oil products. Monsanto demonstrated that they would work with processors to assure adequate testing methods and quality processes were applied.

<u>Market Share/Uses of MON 87769 Soybean</u>

The majority of soybean cultivated in the U.S. is grown as a commodity product intended for animal feed. Specific market uses for specialty soybean products generally require adherence to specialty crop practices to preserve identity from seed production through harvesting, handling, and processing. A premium is paid to growers and processors for delivering product that meets these desired purity and quality standards (Elbehri, 2007; Lee and Herbek, 2004; Muth et al., 2003; Pritchett et al., 2002; Smyth and Phillips, 2002a; Sundstrom et al., 2002). MON 87769 soybean is considered a specialty soybean product and will be marketed in accordance with other high-value specialty food crop products (Monsanto, 2010b). To maintain the identity of the product soybeans, growers cultivating MON 87769 soybean may potentially incur increased costs for production and distribution throughout the supply chain (mostly IP costs). The extent to which MON 87769 soybean displaces other cultivated varieties cannot be predicted, as market segment is contingent on variety acceptance by both growers and consumers.

Monsanto has developed MON 87769 soybean to provide an enriched oil source of SDA, which could be made available for food incorporation and for cooking. Commercial plant sources of SDA are limited and production quantities are difficult to ascertain, and fish oil sources of stearidonic and other long chain polyunsaturated fatty acids may not be acceptable to customers who do not wish to consume fish or to producers who do not favor the organoleptic or stability properties of fish oil. Of the fish oil used in the U.S., about 14% is used in functional foods (Addendum 1 (Monsanto, 2010b)), which is one category to which SDA soybean will contribute. Monsanto proposes that the availability of SDA soybean will allow incorporation of the omega-3 fatty acid into a wider range of food categories than existing SDA sources (Monsanto, 2010b). The increase projected through 2016 for omega-3 oils is 26.6%, about twice the present rate, and Monsanto proposes that the product will get all the increase. Thus, by 2016, Monsanto expects that MON 87769 soybean will be produced on 100,000 acres (Appendix C: Addendum 1 (Monsanto, 2010b)). The MON 87769 soybean modified oil may also be a candidate oil for use in industrial products, since increased unsaturation may be useful in some applications, but the potential for this use cannot easily be estimated.

The main variables that determine outcomes for market share will be consumer acceptance (including that of food and industrial producers) and price of the commodity (Giannakas and Yiannaka, 2010). The greatest impacts will occur if the price of the novel soybean oil is relatively low, and consumer evaluation is highly favorable, which could result in an increasing number of products using oil from MON 87769 soybean. In this event, increased economic benefit would ensue to producers of the novel oil. Because these variables associated with MON

87769 soybean cannot be determined at present, no definitive conclusions can be made about market share impacts on soybean oil producers.

Potential Market Response to MON 87769 Soybean

Changes in total acreage of specific oilseed crop varieties in response to market demand can be readily observed. In 1995, the National Sunflower Association began developing sunflower varieties to take advantage of pending label requirements for trans fatty acids (NSA, 2006). By 2005, it was estimated that 80% of the U.S. sunflower acreage was planted in NuSun™, a conventionally produced high-oleic variety (NSA, 2006). This transition occurred after the food industry conducted extensive studies of food chemistry, supported by human health assessments (NSA, 2006). The usefulness of low linolenic soybean has allowed growth of the market, from 800,000 acres in 2006 (Fehr, 2007) to a total of 3 million acres since 2005 (Monsanto, 2010b). The low linolenic soybean however, has uses as a modified commodity product, and not as a specialty oil that MON 87769 soybean would supply.

The value to the consumer from the changes presented in MON 87769 soybean is a direct function of the chemical changes associated with the changed concentrations of the fatty acids. The beneficial results of incorporating SDA into consumer products and into finished manufactured foods will be a point advanced by food marketers. Enough scientific evidence is available for use of EPA, DHA (SDA is a precursor for these in human metabolism) as a food supplement in a conventional food to make certain health claims (see summary of U.S. Agencies statements,(Council for Responsible Nutrition, 2005)), and these should not exceed FDA statements for reducing the risk of coronary heart disease, “Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease” (US-FDA, 2004). Claims supported by the European Food Safety Authority supported additional claims about the health benefits for maintaining normal eye and brain function, and could be the basis for marketing claims if products were made for export to European markets (EFSA (European Food Safety Administration), 2011). The size of such domestic markets is difficult to analyze, but gives credence to the market forecast offered by Monsanto for potential use of omega-3 uses for MON 87769 (Addendum 1 (Monsanto, 2010b)).

This product will have decreased oxidative stability relative to commodity soybean oil (Addendum 1 (Monsanto, 2010b)) and thus may not be useful for certain industrial lubricant uses (Monsanto, 2010b; USB, 2010b). Saturated fats in MON 87769 soybean are not lower than commodity soybean oil (Table 14) so that this parameter does not improve use as a biodiesel fuel over commodity soybean oil because these fatty acids may be one factor that improves cold weather performance (AGRA, 2009; Graef et al., 2009; Knothe, 2005; Monsanto, 2010b) performance. Cetane numbers, which are a measure of the ignition quality of an oil, will likely be reduced compared to commodity soybean oil, since increased unsaturation depresses this value (see Table 7, Moser, 2009), and SDA itself and modestly increased linolenic acid both increase unsaturated fatty acids. Lower cetane numbers would not offer improvements over commodity soybean oil.

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

These IP management costs may be offset by premium value received for the crop and the product, as well as increased yields for certain IP varieties. Pritchett reports that specialty soybean yields are generally higher than those reported for commodity soybeans, which he attributes to either the managerial talent of the specialty grower or higher land quality which is recognized and optimized by the grower (Pritchett et al., 2002). There is no information whether these market entry costs for cultivation and use of specialty soybean would be offset by increased yields and premium prices for the products of MON 87769 soybean. Irrespective of the value added application of oils derived from MON 87769 soybean, adherence to soybean IP practices will be essential to ensure that the crop value is preserved.

In the alternative, inadvertent use of MON 87769 soybean by a user desiring an alternative fatty acid composition may give rise to negative impacts to those consumers. For example, when polyunsaturated fatty acids are high, rapid oxidation can occur in fried foods and result in undesirable taste and odor (Addendum (Monsanto, 2010b)). Also, the taste commonly associated with fried food is due to the presence of linoleic acid (AGRA, 2009) and MON 87769 soybean will have decreased content. High-oleic acid soy oils are not considered ideal for fried food applications (AGRA, 2009) and high levels of linolenic acid contribute to oxidation during frying and over extended storage times (Rosseli, 1998). If MON 87769 soybean were inadvertently used in high proportions for fried food applications, the resulting food products would likely be unacceptable. As noted in the Addendum, however, at low levels of admixture of MON 87769 soybean with commodity soybean oil (up to 15%), no adverse effects can be detected on either oxidative stability or on flavor perception (Appendix C: Addendum 1, (Monsanto, 2010b))

The need to maintain identity and control product characteristics are similar concerns for industrial applications. Oils with high concentrations of linolenic acid are comparable to linseed oil and are very desirable in the coatings industry where they are used to enhance drying of paints, inks, and varnishes (Cahoon, 2003). SDA and the less saturated linolenic acid, may have decreased oxidative stability (Appendix 2) and thus be valuable in this type of application. Vegetable oil polyols formed via epoxides are used in production of polyurethanes, When vegetable oils contain high levels of specific unsaturated fatty acids, epoxidized soybean-produced oils can be produced that lead to higher quality chemicals with more homogeneous character (Cahoon, 2003). While the inadvertent substitution of one specialty oil for another specialty oil is highly unlikely, the results of such an accidental substitution in the industrial sector may nonetheless be substantial. If the IP practices do not maintain the identity of MON 87769 soybean and either conventional soy oil or other specialty oils, desired oil composition would be compromised and the product would not meet its specifications. Those entities crushing or using oil from MON 87769 soybean will be required under Monsanto’s stewardship plan to be continually monitoring fatty acid content of oil, both upon arrival and after processing. Those oil industry entities that do not purchase or expect MON 87769 soybean derived oil will also need to monitor fatty acid content of oil products, which for standard quality assurance programs would be done under any circumstance, but also because various specialty soybean oils besides MON 87769 are also present in the marketplace, which could also have impacts on fatty acid content.

Identity preserved product such as low-linolenic varieties provide the grower with a premium price as high as $1.25 per bushel (Conley et al., 2008) but more recently have declined to 50-60 cents per bushel (Wallaces Farmer, 2010). In 2005, when Monsanto introduced the low-linolenic soybean “Vistive” variety, food producers such as Kellogg noted that there was a high demand and significant shortage for soy oils with these traits (Woznicki, 2005). MON 87769 soybean market share will be contingent on a demonstrated price and high yield potential as well as consumer and producer preference to other modified fatty acid soybean varieties.

Net income differentials cannot be projected, since the net income of soybean producers growing conventional soybean is not easily predicted (see regional differences in years 2009-10) (USDA-ERS, 2010e). However, as Monsanto anticipates that MON 87769 soybean would be cultivated as a specialty crop under an IP system, resulting domestic socioeconomic impacts are expected to be similar to the No Action Alternative. Similar to other specialty crops currently being grown under IP systems, resulting economic benefits are contingent on adherence to IP practices at all stages of MON 87769 soybean cultivation and production.

4.7.2 Trade Economic Environment

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

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

Brazil, Indonesia, and Malaysia are being brought into production for soybean and palm oil (USDA-ERS, 2009). This will increase global competition for export market share.

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

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

<u>No Action Alternative: Trade Economic Environment</u>

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

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

<u>Preferred Alternative: Trade Economic Environment</u>

To support commercial introduction of MON 87769 soybean in the U.S., regulatory submissions will be made by the petitioner to countries that import significant quantities of soybean or its processed fractions from the U.S. and have established regulatory approval processes in place (Monsanto, 2010b). These will include submissions to a number of foreign government regulatory authorities, including: Ministry of Agriculture, People's Republic of China; Japan's Ministry of Agriculture, Forestry, and Fisheries (MAFF) and the Ministry of Health, Labor, and Welfare (MHLW); the Canadian Food Inspection Agency (CFIA) and Health Canada; the Intersectoral Commission for Biosafety of Genetically Modified Organisms (CIBIOGEM), Mexico; the European Food Safety Authority (EFSA); and the regulatory authorities in other soybean importing countries with functioning regulatory systems. As appropriate, notifications of importation will be made by the petitioner to importing countries that do not have a formal approval process.

MON 87769 soybean is intended to be cultivated as a specialty GE soybean variety and the SDA soybean oil will be produced and processed using a closed loop stewardship system to capture the food quality value of the oil (Monsanto, 2010b). The cultivation of MON 87769 soybean is not expected to result in an increase in the total acreage devoted to soybean cultivation, although the allocation of acreage to specialty soybean cultivation could increase contingent upon market demand. As with the No Action Alternative, U.S. soybeans will continue to play a role in the global soybean market.

To the extent that the modified fatty acid soybean oil derived from MON 87769 soybean achieves market acceptance, it is conceivable that this soybean-based oil could displace other fish oils and small scale production of exotic SDA vegetable oils in the international market. Products potentially displaced by MON 87769 soybean oil may include crops producing oils from such plants of the genera *Echium* and *Ribes* (black current). Although MON 87769 soybean oil may not be used in food products to the exclusion of existing products, at least some diminution of other oils from commodity soybean, canola, corn and so forth may be marginally displaced in the production of food products augmented with the new soybean oil.

Consistent with the potential increase in international demand for this specialty oil product, as well as price competitiveness, a determination of nonregulated status of MON 87769 soybean may have a positive benefit on U.S. exports as soy oil based on this product increases soybean oil sales. The international market share of MON 87769 soybean as specialty variety is contingent on global vegetable oil market requirements, food processor acceptance, consumer preference, demonstrated availability of the product, and price competitiveness (Monsanto, 2010b). However, with an inability to predict the size of these variable inputs, APHIS cannot reliably foresee the outcome for an increase in world market share of soybean resulting from planting of this variety.

Global sensitivities to GE products, including international restrictions on import of GE products and inability of the petitioner to gain local approval for cultivation or importation, will continue to impede trade with those countries. These challenges to international trade in GE products are already in place. Restrictions on international trade in GE products, including MON 87769 soybean, are unlikely to change with a determination of nonregulated status of MON 87769 soybean.

A determination of nonregulated status of MON 87769 soybean will not adversely impact the trade economic environment and could potentially enhance it through the subsequent demand for the SDA MON 87769 soybean line and its oil products. The MON 87769 soybean follows trends in the continuing development of specialty soybeans with modified fatty acid profiles. The trade economic impacts associated with a determination of nonregulated status of MON 87769 soybean are anticipated to be very similar to the No Action Alternative.

4.7.3 Social Environment

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

No Action Alternative: Social Environment

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

Preferred Alternative: Social Environment

MON 87769 soybean is not intended to confer any competitive advantage in terms of weed management or to extend the range of cultivation outside of existing cultivation areas. Monsanto expects that MON 87769 soybean will be cultivated as a specialty crop, with the SDA soybean oil produced and processed under existing identity protection systems to capture the food quality value of the oil (Monsanto, 2010b). Consistent with the expectations that this variety is to be cultivated as a specialty crop, a determination of nonregulated status of MON 87769 soybean is not expected to result in an expansion of the number of soybean acres, since oil from the variety will likely replace existing oils from soybean on a highly limited scale. Soybean acreage is expected to remain stable, and overall impacts relative to the total soybean market system are similar to the No Action Alternative.

To the extent that MON 87769 soybean is accepted by producers and consumers, MON 87769 soybean has the potential to displace other specialty soybean varieties, but given the expected market growth of the variety, is expected to have no significant impact. Only 0.5% of the existing acres of soybean in the affected area are likely to be planted to the MON 87769 soybean. Those growers currently cultivating specialty soybean varieties have already invested in equipment and practices to maintain the identity of the product from seed through harvest and processing and would not be impacted by this change. To the extent that a grower currently cultivating commodity soybean elects to cultivate MON 87769 soybean, that grower will need to invest in handling equipment and management practices to capture and preserve the food quality value of the oil. Growers adopting specialty varieties already make such investment decisions based upon perceived value and return on investment (Iowa State University, 2008).

The soybean market also includes seed production, equipment manufacturers, handlers, and producers. Monsanto's analysis of agronomic characteristics did not identify any differences between MON 87769 soybean and conventional varieties (Monsanto, 2010b). Monsanto expects that MON 87769 soybean would be cultivated, handled, and processed consistent with existing identity protection practices and systems (Monsanto, 2010b). Other than equipment required to maintain identity protection, no specialized equipment is required to cultivate, handle, or process MON 87769 soybean.

Food processors potentially impacted by MON 87769 soybean include those parts of the industry using soybean oil for frying, and cooking oil, and shortening products where shelf life and oxidative stability are important features. Monsanto intends to oversee the product using a closed loop stewardship system (Addendum 1) (Monsanto, 2010b). Because other modified oil products are already present in the commodity oil market and routinely handled by processors using standard industry processing methods and equipment, no new processes or equipment are required to introduce MON 87769 soybean. Thus, workers in these areas are not likely to be impacted by any major alterations of soybeans or of qualities of soybeans processed.

Monsanto has evaluated the market and trade applications of MON 87769 soybean, and has determined that this product will be used in a variety of uses, including margarine, shortenings, salad dressings, ready to eat foods, baked goods and a variety of other products (Addendum) (Monsanto, 2010b). In the event that MON 87769 soybean is introduced into a commodity oil unintentionally at the level of a misdirected truckload of soybean, or other unit delivery at a higher level of processing, the consequent mixture would be less than 15%, at which level, no impacts on food ingredient labels or nutrition facts panels or changes to oxidative stability or food sensory properties would result (Addendum) (Monsanto, 2010b).

Potential impacts to industrial users of soybean products are similar. Existing identity protection measures are already in place to allow industrial users to manage feedstocks and products for specific applications and needs (Smyth and Phillips, 2002a; Sonka et al., 2004). No new equipment or practices are required to incorporate MON 87769 soybean into this industrial market. However, for industrial users that require close tolerances in the ratios of fatty acid to ensure product quality, continuous monitoring of properties of input oils may be necessary. This scrutiny may already have been enhanced, given that the industry has increasingly begun to encounter and already needs to manage an increasing range of different soy-based feedstocks, ranging from ultra-low linolenic acid varieties, through and including feedstock oils for blending from other crops, such as high-oleic and high linolenic varieties that have various uses (Cargill, 2011; USB, 2010b). Thus, APHIS does not expect that changes to the social environment including workforce will be altered by entry of this variety into the soybean market.

Consistent with the above assessment of potential impacts to the growers, and workforce in the food processing and industrial use categories, the impacts of a determination of nonregulated status of MON 87769 soybean are expected to be the same as the No Action Alternative.

5 CUMULATIVE IMPACTS

A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. For example, the potential effects associated with a determination of nonregulated status of a GE crop in combination with the future production of crop seeds with multiple traits that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (i.e., "stacked" traits), including drought tolerance, herbicide tolerance, and pest resistance, would be considered a cumulative impact.

5.1 Assumptions Used for Cumulative Impacts Analysis

Specialty soybeans are cultivated to meet specific consumer needs. MON 87769 soybean is anticipated to be cultivated as another specialty soybean, offering growers and consumers an option for an omega-3 fatty acid easily converted by human metabolism to desirable fatty acids, EPA and DHA. Herbicide tolerant soybean is already extensively deployed in the seed market, as are a variety of specialty fatty acid ratios in other vegetable oil sources. No additional potential cumulative impacts to the commodity soybean market or the specialty soybean market can be reliably anticipated as a result of a determination of nonregulated status and cultivation of MON 87769 soybean.

MON 87769 soybean will be a readily produced source of omega-3 fatty acids, but not the only one, since there are other specialty vegetable oils that also provide SDA, such as the minor crops, borage, *Echium* spp. and blackcurrant. MON 87769 soybean successes in replacing these other high-oleic vegetable oils will be contingent upon producer and customer acceptance, availability of the product, and price. Monsanto estimates that the market for marine oils in the U.S. is 26,477 metric tons, and that this market and an annual increase in demand of 13.4% will provide the opportunity for use of this product.

Stacked varieties of soybean, those crop varieties that may contain more than one trait, are currently found in the marketplace and in agricultural production. In the event APHIS reaches a determination of nonregulated status, MON 87769 soybean may be combined with non-GE and GE soybean varieties by traditional breeding techniques. There is no assurance that MON 87769 soybean will be stacked with any particular GE soybean trait (one no longer subject to the requirement of Part 340 and the provisions of the Plant Protection Act), as company plans and market demands play a significant role in those business decisions. APHIS' regulations at 7 CFR Part 340 do not provide for Agency oversight of GE soybean varieties no longer subject to the requirement of Part 340 and the plant pest provisions of the Plant Protection Act, nor over stacked varieties combining these GE varieties, unless it can be positively shown that such stacked varieties were to pose a likely plant pest risk. Predicting all potential combinations of stacked varieties is hypothetical and purely speculative.

5.2 Cumulative Impacts: Acreage and Area of Soybean Production

Cumulative effects of a determination of nonregulated status of MON 87769 soybean are unlikely. While APHIS expects that this variety will be stacked with glyphosate tolerance or other herbicide tolerance, as is a large percentage (93%) of other soybean crops in the U.S., it will not lead to any significant changes in the specifics of soybean production. Neither the No Action Alternative nor a determination of nonregulated status of MON 87769 soybean are expected to directly cause an increase in agricultural acreage devoted to soybean production or those soybean acres devoted to GE soybean cultivation. It is anticipated that seed for this variety will not be marketed beyond five northern U.S. states (Monsanto, 2010b) and, in consideration of the low expected acreage (100,000 acres by 2016), will have no substantial impact on general soybean production. The availability of MON 87769 soybean is not expected to change the cultivation areas for soybean production in the U.S., and there are no anticipated changes to the availability of GE and non-GE soybean varieties on the market under either alternative.

5.3 Cumulative Impacts: Agronomic Practices

Monsanto has stated that MON 87769 soybean would be stacked with either glyphosate or other available nonregulated herbicide resistance traits (Monsanto, 2010c). Monsanto has also indicated that glyphosate will be the continuing cornerstone of any multiple herbicide stack, with additional resistance complementing the activity, or allowing additional flexibility in designing weed control (Monsanto, 2010a). The adoption of herbicide tolerance traits complements conservation tillage practices by allowing farmers to substitute herbicide application for some tillage operations as a weed management practice (NRC, 2010). 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-tolerant 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). It is anticipated that herbicide use will continue the trends noted by Beckie and Tardif (Beckie and Tardif, 2012) associated with the wide use of glyphosate-tolerant soybean along with crops stacked with multiple herbicide resistances as they are available or become so, and that alternative herbicides will more frequently be used sequentially, or in mixtures, or as required in crop rotations, to manage herbicide resistant weed populations.

Although weed control with excessive reliance on only glyphosate has possibly favored development of glyphosate resistance, such resistance was not an inevitable consequence of the use of glyphosate resistant crops, but mainly a consequence of failing to use total weed control management plans (Shaner et al., 2012) and indeed, use of any herbicide can lead to weed resistance (Heap, 2012). Growers have been provided with an array of tactics to deal with either existing resistant weeds, or to deter the development of these by seed providers (Monsanto, 2012) or by local university extension specialists. These recommendations for glyphosate resistant soybean varieties include crop rotations, use of preplant residual herbicides, and tank mixes with residual or post emergent herbicides. The National Research Council (NRC, 2010) summarized strategies that may be used by growers to avoid development of glyphosate-resistant weeds to include:

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

Currently, thirteen weeds have been identified as glyphosate-resistant in the US (Heap, 2012), with seven of these weeds identified as difficult to control weeds in soybean: common ragweed (*Ambrosia artemisiifolia*), common waterhemp (*Amaranthus rudis*), giant ragweed (*Ambrosia trifida*), horsetail (marestail) (*Conyza canadensis*), Italian ryegrass (*Lolium multiflorum*), Johnsongrass (*Sorghum halapense*), and Palmer amaranth (*Amaranthus palmeri*) (Benbrook, 2009). Because the U.S. 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, USDA has no regulatory authority over the subsequent use of herbicides on herbicide tolerant plants that may be stacked with the MON 87769 trait.

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

Volunteer soybean is normally not a concern. Soybean is not winter hardy, and existing mechanical and chemical methods are available to manage the occasional volunteer soybean. Herbicides are available to control volunteer soybeans in corn, and wheat (above). These herbicides are suitable for post-emergent control of volunteer soybean. The challenges which growers face in managing glyphosate-resistant weeds is also not expected to differ between MON 87769 soybean stacked with glyphosate resistant trait and other glyphosate-tolerant varieties, and similar herbicides would be used in either crop for such weeds.

A determination of nonregulated status of MON 87769 soybean will not result in changes in the current practices of crop rotation and pesticide use. Studies demonstrate MON 87769 soybean is essentially indistinguishable from other soybean varieties (either herbicide tolerant ones, when stacked with an herbicide tolerant trait, or non-GE soybean when not stacked with an herbicide tolerant trait) in terms of agronomic characteristics, and cultivation practices would closely follow the herbicide tolerant GE or non-GE variety (Monsanto, 2010b). It is anticipated that herbicide use will continue the trends associated with the wide adoption of glyphosate-tolerant soybean and the emergence of glyphosate-resistant weeds, but that growers are increasingly cognizant of the risks of failing to respond to possible development of glyphosate resistance (in a 2009 telephone survey 89% of growers were taking steps to minimize development of resistance (WSSA, 2010)). APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to effect changes in crop rotation, and pesticide use.

5.4 Cumulative Impacts: Soybean Seed Production

Based on current acreage trends, GE soybean varieties will likely continue to dominate the soybean market. Since 2007, the GE varieties of soybean have comprised 91 to 93% of the U.S. soybean acreage. Changes in the agronomic practices and locations for soybean seed production using MON 87769 soybean are not expected. The availability of MON 87769 soybean will not change cultivation areas for soybean seed production in the U.S.; no cumulative effects have been identified for this issue

5.5 Cumulative Impacts: Organic Soybean Production

A determination of nonregulated status of MON 87769 soybean is not expected to change the market demands for GE soybean or soybean produced using organic methods. A determination of nonregulated status of MON 87769 soybean will add another GE soybean variety to the conventional soybean market. Based upon recent trend information, adding GE varieties to the market is not related to the ability of organic production systems to maintain their market share.

5.6 Cumulative Impacts: Specialty Soybean Production

A determination of nonregulated status of MON 87769 soybean is not expected to change the market demands for GE soybean or non-GE soybean produced using specialty systems. MON 87769 soybean is expected to be cultivated as a specialty soybean consistent with identity preserved practices. From Monsanto's market analysis for needs of the soybean product, in five years the acreage produced will likely be only 1% of total specialty soybean acreage, assuming that specialty soybean stays at current estimates of 12% of commodity soybean production (Monsanto, 2010b). Based on demonstrated agronomic characteristics and cultivation practices, and because the market share of specialty soybean varieties is unlikely to substantially change following the introduction of MON 87769 soybean, APHIS has determined that there are no past, present, or reasonably foreseeable changes that would impact specialty soybean producers and consumers. No cumulative effects have been identified for this issue.

5.7 Cumulative Impacts: Water Resources

Monsanto proposes that MON 87769 soybean will be stacked with a glyphosate tolerant trait or potentially with other herbicide tolerant traits no longer subject to the regulatory requirements of Part 340 and the plant pest provisions of the Plant Protection Act or with both (Monsanto, 2010c). Current application rates of glyphosate for weed control with MON 87769 soybean are not expected to change.

Although glyphosate is very soluble in water, it is strongly adsorbed to soils; consequently, glyphosate is unlikely to leach into groundwater or surface water runoff following application (Giesy et al., 2000; US-EPA, 1993b). However, Coupe et al. (Coupe et al., 2011) has shown that in agricultural basins with high glyphosate use rates, high overland runoff rates, and low flow through soil, glyphosate can be readily detected in surface waters. Relying on toxicological data, bioaccumulation and biodegradation studies, and acute and chronic tests on fish and other aquatic organisms, EPA however, has determined that "the potential for environmental effects of glyphosate in surface water is minimal" (US-EPA, 1993b).

No cumulative effects on water use have been identified associated with a determination of nonregulated status of MON 87769 soybean. A determination of nonregulated status of MON 87769 soybean will not change the water use and irrigation practices used in commercial soybean production.

5.8 Cumulative Impacts: Soil Quality

APHIS has not identified any cumulative effects to soils. Comprehensive phenotypic, agronomic, and ecological assessments conducted by the petitioner for MON 87769 soybean did not find significant differences between MON 87769 soybean and control soybeans for these characteristics (Monsanto, 2010b). The few differences that were identified were typically small, site specific, and unlikely to be biologically meaningful. Event MON 87769 soybean required the same soil, fertilizer, water and pest management practices as non-GE soybean (Monsanto, 2010b). Consequently, the phenotypic, agronomic, and ecological data presented by Monsanto (Monsanto, 2010b) support the conclusion by APHIS that MON 87769 soybean will not significantly modify soil characteristics associated with conventional soybean production practices.

If MON 87769 soybean is stacked with herbicide tolerance traits, persistence of pesticides in soil may be modulated by cultivation (see review of runoff potential in conservation tillage versus no-till and runoff potential (Warnemuende et al., 2007)). The glyphosate tolerant trait would likely be stacked with this variety, and so glyphosate would be the predominant post-emergent herbicide applied to MON 87769 soybean, as it is with other glyphosate tolerant soybean. Glyphosate has been shown to rapidly dissipate from most agricultural ecosystems across a wide range of soil and climatic conditions, with a median soil half-life (the time it takes for half of the glyphosate to dissipate in the soil) of 13 days (Giesy et al., 2000). A survey reported by Borggard and Gimseng (Borggaard and Gimsing, 2008) noted soil half-lives ranging from 1.2 to 197 days, depending on a wide range of chemical and physical parameters of soil.

If MON 87769 were to be stacked with the glyphosate tolerant trait, this would present certain environmental benefits over other herbicides that may be used for control of weeds in non-GE soybean production (Cerdeira and Duke, 2006; Hin et al., 2001).

Pesticide products approved for application to emerged weeds normally are applied with surfactants. Surfactants increase the permeability of the weed foliage to increase the foliar uptake of glyphosate and thereby improve the efficacy of the herbicide (Stock and Holloway, 1993). Polyethoxylated alkyl amine (POEA) is the predominant surfactant used in formulated glyphosate products. Glyphosate and the POEA surfactant have similar soil dissipation rates and the same primary route of dissipation, i.e., microbial degradation (Giesy et al., 2000). The half-life of POEA in soil is estimated to range from 7 to 14 days (Giesy et al., 2000). On that basis, the POEA surfactant is expected to behave similarly to glyphosate in field soil, and an increase in residual soil concentrations (accumulation) of the POEA surfactant is not anticipated. Because MON 87769 soybean when stacked with glyphosate or other herbicide tolerance does not differ in its agronomic requirements from conventional soybean or other GE varieties expressing glyphosate tolerance, agronomic practices associated with soil and land use are not expected to change with the availability of this new plant product. Based on these findings, and because the amount of soybean grown in the U.S. is unlikely to change by the introduction of MON 87769 soybean, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to impact soil.

5.9 Cumulative Impacts: Air Quality

APHIS has not identified any cumulative effects for this issue. The use of MON 87769 soybean in commercial soybean production is not expected to cause any cumulative effect on air quality because APHIS does not anticipate any changes in soybean production practices or an expansion of soybean acreage as a result of a determination of nonregulated status of MON 87769 soybean. The consequences of the Preferred Action Alternative on commercial soybean production and acreage are the same as for the No Action Alternative.

5.10 Cumulative Impacts: Climate Change

APHIS has not identified any cumulative effects for this issue. The use of MON 87769 soybean in commercial soybean production is not expected to cause any cumulative effect on climate change because APHIS does not anticipate any changes in soybean production practices or an expansion of soybean acreage as a result of a determination of nonregulated status of MON 87769 soybean. The consequences of the Preferred Action Alternative on commercial soybean production and acreage are the same as for the No Action Alternative.

5.11 Cumulative Impacts Animal Communities

Soybean may be used by mammals and birds, and diverse numbers of insects may feed on the vegetative parts of the plant, or feed on other arthropods that feed on the soybean grain. Monsanto data for food and feed safety has established substantial evidence that the MON 87769 soybean is safe for long term consumption, since no acute impacts could be identified. Dietary exposure to the two new proteins expressed by MON 87769 is not a risk to human or animal health; the proteins are not toxic and fatty acids produced are common in the environment, produced by some other plants, fish and algae. There are no composition differences between this and conventional soybean, except for increased production of SDA, gamma linolenic acid and some expected decreases in other fatty acids. No differences in insect feeding damage to MON 87769 soybean and the comparator, conventional variety A3525 were observed over two years (Table I-5 and I-6) (Monsanto, 2010b). No significant cumulative impacts to animals or insects that feed on soybean expressing MON 87769 soybean would follow a decision to choose the Preferred Alternative.

5.12 Cumulative Impacts: Plant Communities

If MON 87769 soybean is stacked with the glyphosate tolerance trait growers would continue to use glyphosate predominately for post-emergent weed control. The Roundup Ready® soybean system has become the standard weed control program in the U.S. cultivation of soybean. Approximately 92% of the U.S. soybean acreage is planted in Roundup Ready® soybean varieties. Monsanto anticipates that MON 87769 soybean will not replace commodity type glyphosate-tolerant soybean varieties previously found to no longer be subject to the requirement of Part 340 and the plant pest provisions of the Plant Protection Act. Rather, MON 87769 soybean will remain a minor product with limited acreage. While any broad spectrum herbicide application has the potential to impact off-site plant communities, the impacts of planting MON 87769 soybean expressing glyphosate tolerance will not be novel or extensive. Accordingly, the cultivation of MON 87769 soybean is not expected to result in an increase in the application of glyphosate or changes in herbicide treatments when compared with existing glyphosate-tolerant soybean 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.

5.13 Cumulative Impacts: Gene Flow and Weediness

One introduced gene expected to be stacked in the MON 87769 soybean is the *cp4 epsps* gene, which confers tolerance to the herbicide glyphosate. This gene is commonly found in other Roundup Ready® crops (USDA-APHIS, 2010c). No data have been presented to suggest that the incorporation of the *cp4 epsps* gene allows soybean to survive and reproduce without human intervention (USDA-APHIS, 2010c).

The soybean industry has identity protection measures in place to restrict pollen movement and gene flow between soybean fields through the use of isolation distances, border and barrier rows, the staggering of planting dates and various seed handling, transportation, and ginning procedures (Bradford, 2006; NCAT, 2003; Sundstrom et al., 2002). As a specialty soybean variety, MON 87769 soybean would be cultivated within these identity protection practices. In addition, there is no evidence that horizontal gene transfer and expression of DNA occurs between soybean and soil bacteria or unrelated plant species under natural field conditions, and even if this did occur, proteins corresponding to the transgenes are not likely to be produced. Gene movement between sexually compatible soybean varieties is no greater for MON 87769 soybean than it is for other non-GE or GE cultivars. In its PPRA, APHIS assessed the weediness potential of MON 87769 soybean based on the introduced *Primula juliae* delta-6 desaturase (Pj.D6D) and the *Neurospora crassa* delta-15 desaturase (Nc.Fad3) genes controlling fatty acid composition (USDA-APHIS, 2010c). In each case, the changes introduced in the MON 87769 soybean were deemed to not present a weediness risk (USDA-APHIS, 2010c). Based on the scientific evidence, APHIS has not identified any cumulative effects on gene movement that would occur from a determination of nonregulated status of MON 87769 soybean. From data presented by Monsanto on those agronomic characteristics likely to be associated with a change in weediness of the crop, there were no differences that were found between the host soybean and the genetically engineered MON 87769 soybean (USDA-APHIS, 2010c); APHIS concluded that potential for weediness of MON 87769 was unlikely.

5.14 Cumulative Impacts: Microorganisms

Cultivation of MON 87769 soybean is highly unlikely to have direct toxic effects on microorganisms. The glyphosate tolerant trait would likely be stacked with this variety, and therefore glyphosate would likely be the predominant post-emergent herbicide applied to MON 87769 soybean, as it is with other glyphosate tolerant soybean. Microorganisms produce aromatic amino acids through the shikimate pathway, similar to that in plants (USDA-FS, 2003). Because glyphosate inhibits this pathway, it could be expected that glyphosate would be toxic to microorganisms. Glyphosate use has been identified as potentially causing increases in certain disease-causing microbes (Fernandez et al., 2009; Kremer and Means, 2009). Reported increases in infections in cereal crops from pathogenic soil fungi have in some cases been determined to be more closely related to reduced tillage and continuous cropping using herbicide-tolerant crops, whereas in others, application of glyphosate correlated with increased bacterial species (Fernandez et al., 2009). The U.S. Forest Service, while acknowledging that in some cases, increases in soil pathogens following glyphosate treatment can be detected, “there is no indication that the transient enhancement in populations of soil fungi or bacteria will result in any substantial or lasting damage to soil ecology” (USDA-FS, 2003).

Because any microorganism is already extensively exposed to glyphosate, it is unlikely that any new organisms would be impacted. Therefore, the likelihood of adverse cumulative effects on microorganisms following the introduction of MON 87769 soybean is minimal.

5.15 Cumulative Impacts: Biodiversity

Cultivation of MON 87769 soybean is highly unlikely to have direct toxic effects on non-target animals and microorganisms and is likely to be neutral to biodiversity compared with conventionally managed GE and non-GE soybean. Because any nontarget plants are already extensively exposed to glyphosate, it is unlikely that any new plants will be impacted. Therefore, the likelihood of adverse cumulative effects on non-target organisms and biodiversity following the introduction of MON 87769 soybean is minimal.

The use of genetically modified soybean such as MON 87769 soybean when stacked with glyphosate tolerance may improve biological diversity by providing growers the opportunity to use conservation practices. Incorporation of herbicide tolerance in the crop facilitates the grower adoption of conservation and no-till strategies, improved soil porosity, enhancing soil fauna and flora (CTIC, 2010a), increasing the flexibility of crop rotation, and facilitating strip cropping (Fernandez-Cornejo et al., 2002), each of which contributes to the health of the faunal and floral communities in and around soybean fields thereby promoting biodiversity (Palmer et al., 2010; Sharpe, 2010).

Based on available scientific data, the changes in fatty acid composition associated with MON 87769 soybean are not expected to directly or indirectly affect plants, animals or biodiversity. The genes responsible for the change in fatty acid composition are endogenous to the soybean and are thus already a part of the soybean cultivation environment. The U.S. EPA has reviewed the safety of the CP4 EPSPS protein and has established a tolerance exemption for the protein and the genetic material necessary for its production in or on all raw agricultural commodities ((US-EPA, 1996); 40 CFR§174.523). The lack of any documented reports of adverse effects since the introduction of other Roundup Ready® crops in 1996 suggests the safety of its use. The CP4 EPSPS protein expressed in MON 87769 soybean is the same as that previously reviewed by the U.S. EPA, accordingly, MON 87769 soybean is anticipated to be safe for animal consumption with regard to the *cp4 epsps* gene.

APHIS has determined that there are no impacts from past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to create cumulative impacts or reduce the long-term productivity or sustainability of any of the resources associated with the ecosystem in which MON 87769 soybean is planted (USDA-APHIS, 2010c).

5.16 Cumulative Impacts: Human Health

5.16.1 Cumulative Impacts: Worker Safety

MON 87769 soybean is not expected to increase the total acreage of soybean production or the use of GE soybean. Monsanto anticipates that MON 87769 soybean will be a minor crop, produced to fill a small market need. To a limited extent, if stacked with an herbicide tolerant trait, MON 87769 soybean would simply replace a small percentage of acres of the herbicide-tolerant soybean cultivars already on the market today. As APHIS analyzed in the Proposed Alternative, no hazards of exposure to the new fatty acids exist and therefore cumulative impacts are unlikely.

Monsanto is expected to stack MON 87769 soybean with the glyphosate tolerance trait (Monsanto, 2010c). The introduced protein for the tolerance is the CP4 EPSPS protein derived from *Agrobacterium* sp. The U.S. EPA has reviewed the safety of the CP4 EPSPS protein and has established a tolerance exemption for the protein and the genetic material necessary for its production in or on all raw agricultural commodities ((US-EPA, 1996); 40 CFR §174.523). This exemption was also based on a safety assessment for allergenicity that included rapid digestion in simulated gastric fluids, lack of homology to known toxins and allergens, and lack of toxicity in an acute oral mouse gavage study. The lack of any documented reports of adverse effects since the introduction of other Roundup Ready® crops in 1996 suggests the safety of its use. Worker safety issues related to the use of glyphosate and other U.S. EPA registered pesticides during conventional and GE soybean production should remain the same. If a grower replaces a non-herbicide-tolerant soybean variety with MON 87769 soybean it would be expected that there would be a corresponding increase in the post-emergent use of glyphosate. To the extent that such changes result in the replacement of more toxic herbicides with glyphosate, the change should positively benefit worker safety.

The CP4 EPSPS protein likely to be expressed in MON 87769 soybean is the same protein previously reviewed by the U.S. EPA. Accordingly, worker safety risk associated with cultivation of and exposure to MON 87769 soybean is the same as the No Action Alternative.

5.16.2 Cumulative Impacts: Public Health

APHIS determined no significant adverse impacts on human health from consumption of the oil derived from MON 87769 soybean, although certain potential beneficial impacts may be possible. However, because Monsanto has decided to stack tolerance to the herbicide glyphosate with MON 87769 soybean, APHIS considers briefly the possible impacts of the gene on human health. Similar products are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act and have been used for general cultivation beginning in the mid-1990s with the introduction of Roundup Ready® products providing tolerance to glyphosate with the introduction of the *cp4 epsps* gene. In each case, FDA and U.S. EPA reviews and approvals determined that the products met the agency's review criteria for approval. The cultivation of these existing crop products would not change under either alternative. Both characteristics have been successfully cultivated in multiple crops in the ensuing years with no evidence of human health impacts.

The CP4 EPSPS protein confers tolerance to glyphosate. This protein is structurally homologous and similar functionally to endogenous plant EPSPS enzymes and is identical to the CP4 EPSPS in other commercially available Roundup Ready® crops, including Roundup Ready® soybean (40-3-2 and MON 89788), Roundup Ready® canola, Roundup Ready® sugar beet, Roundup Ready® flax, and Roundup Ready® cotton (USDA-APHIS, 2010c). The first generation of Roundup Ready® soybean (40-3-2) no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act in 1995 (USDA-APHIS, 2010c). The *cp4 epsps* gene has been assessed extensively in the last 15 years. The safety of CP4 EPSPS protein present in biotechnology derived crops has been evaluated as part of comprehensive reviews of the safety of glyphosate exposure and ingestion (Harrison et al., 1996) (see also (Hammond et al., 1996; Padgette et al., 1996)).

The CP4 EPSPS enzyme is likely to be expressed in MON 87769 containing varieties. FDA had no further questions on Monsanto's conclusion that their glyphosate-tolerant soybean with this enzyme, event MON 89788, when present in feeds and foods derived from this variety is not materially different in safety, composition, or any other relevant parameter from soybeans now grown, marketed, and consumed (see BNF 0104, January 19, 2007, http://www.fda.gov/Food/Biotechnology/Submissions/ucm155610.htm).

The EPA has also reviewed the safety of the CP4 EPSPS protein and has established a tolerance exemption for the protein and the genetic material necessary for its production in or on all raw agricultural commodities ((US-EPA, 1996); 40 CFR §174.523). This exemption is based on a safety assessment that included rapid digestion in simulated gastric fluids, lack of homology to known toxins and allergens, and lack of toxicity in an acute oral mouse gavage study. The CP4 EPSPS protein expressed in MON 87769 soybean is the same as that previously reviewed by the EPA. Accordingly, MON 87769 soybean is anticipated to be safe for human and animal consumption with regard to the *cp4 epsps* gene.

There are no significant impacts on human health related to the No Action Alternative or a determination of nonregulated status of MON 87769 soybean. Moreover, no cumulative effects have been identified by APHIS.

5.17 Cumulative Impacts: Animal Feed

No impacts were determined from APHIS' analysis of possible impacts MON 87769 soybean on animal feed. However, Monsanto plans to market the MON 87769 soybean with the Roundup tolerance trait. The gene for the trait expresses the CP4 EPSPS protein, derived from *Agrobacterium* sp., to achieve glyphosate herbicide tolerance. The U.S. EPA has reviewed the safety of the CP4 EPSPS protein and has established a tolerance exemption for the protein and the genetic material necessary for its production in or on all raw agricultural commodities ((US-EPA, 1996); 40 CFR §174.523). This exemption is based on a safety assessment that included rapid digestion in simulated gastric fluids, lack of homology to known toxins and allergens, and lack of toxicity in an acute oral mouse gavage study. The lack of any documented reports of adverse effects since the introduction of other Roundup Ready® crops in 1996 suggests the safety of its use.

There are no significant impacts on animal health related to the No Action Alternative or a determination of nonregulated status of MON 87769 soybean and no cumulative effects have been identified.

5.18 Cumulative Impacts: Domestic Economic Environment

MON 87769 soybean is intended to be cultivated as a specialty soybean product and its oil fraction will be produced and used within a closed loop stewardship system (Monsanto, 2010b). The likelihood that MON 87769 soybean will be stacked with an herbicide tolerance trait could potentially lead some IP producers to replace existing specialty soybean varieties to plant MON 87769 soybean as a new specialty oilseed product.

Agronomic and phenotypic analyses conducted by Monsanto did not demonstrate any substantial differences between MON 87769 soybean and conventional varieties. No new agronomic characteristics providing benefits for cultivation beyond traditional soybean cultivation regions were determined and none of the modifications expressed by MON 87769 soybean are considered likely to result in new acreage devoted to soybean cultivation outside of those regions where soybean is currently cultivated (Monsanto, 2010). The percentage of the U.S. soybean acreage dedicated to specialty oil soybeans does have the potential to change, contingent upon market acceptance and consumer demand, and specific applications of the specialty products.

In the food supplements market, MON 87769 soybean has the potential to displace fish oils (containing stearidonic and higher level omega-3 fatty acids) and also some other non-soy oil crops that may produce SDA (Addendum 1, (Monsanto, 2010b)). The latter market derives from the likely small scale production of oils from *Echium plantagineum*, black currant (*Ribes*) and a few other plant sources of the fatty acid (Cyberlipid Center, 2011). In the foods production industry, the ability to provide SDA containing oils for large scale use in various manufactured foods, and baked products will likely expand business opportunities. These specifically will include supplementing existing oils used in functional foods and healthful products.

For the past decade, soybean oil has consistently been the least expensive domestic vegetable oil (Table 16) (USDA-ERS, 2011b) and the ability to produce a high value specialty fatty acid in soybean will keep production costs of the oil low. If MON 87769 soybean oil achieves market acceptance, the product has the potential to marginally displace other vegetable food oils, including other soybean, canola, or sunflower oils in certain specialized products, and then most likely as a supplement, and consequently may not completely replace other oils in existing formulations for those products. Given that a determination of nonregulated status of MON 87769 soybean is not expected to lead to an expansion of U.S. soybean acreage or substantial changes in oil products industry, APHIS determines no significant impacts from production of MON 87769 soybean and no cumulative impacts.

Table 16. U.S. vegetable oil prices (dollars/gallon).

Marketing Year	Soybean Oil	Cottonseed Oil	Sunflower oil	Canola Oil	Peanut Oil	Corn Oil
2000/01	1.09	1.23	1.22	1.35	2.69	1.04
2001/02	1.27	1.38	1.79	1.81	2.48	1.47
2002/03	1.70	2.91	2.55	2.29	3.60	2.17
2003/04	2.31	2.40	2.57	2.60	4.68	2.19
2004/05	1.77	2.16	3.37	2.37	4.13	2.15
2005/06	1.80	2.27	3.13	2.39	3.42	1.94
2006/07	2.39	1.98	4.47	3.12	4.08	2.45
2007/08	4.01	5.66	7.02	5.05	7.28	5.34
2008/09	2.48	2.09	3.87	3.04	6.04	2.52
2009/10	2.77	3.01	4.07	3.30	4.59	3.03
2010/11	4.27	4.46	5.92	4.77	6.31	4.65

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

5.19 Cumulative Impacts: Trade Economic Environment

Contingent upon producer and consumer acceptance, availability, and price, and considering that the market for MON 87769 soybean will be about 100,000 acres by 2016, this variety will occupy 0.5% of acreage planted to soybean in the affected area. Thus, there is insignificant potential to displace some of these comparable, non-soybean vegetable oils on the international market. Consistent with the analysis of international markets for GE soybean, a specialty oil for a small healthful products niche, and GE crops generally, APHIS has determined that there are no past, present, or reasonable foreseeable effects of the proposed action which would present a negative cumulative impact on the trade economic environment.

5.20 Cumulative Impacts: Social Environment

The planting and production of oils deriving from MON 87769 will not change the percentage of growers who plant specialty soybean products because the market for these products will likely remain small for the next five years (Monsanto, 2011). No changes can be foreseen in the crusher/refiner businesses, since again, only those businesses which already crush small scale specialty soybean will likely be signed up to accept the MON 87769 soybean. APHIS has determined that there are no past, present, or reasonably foreseeable actions that will aggregate with the effects of the proposed action to impact the social environment surrounding soybean farming.

6 THREATENED AND ENDANGERED SPECIES

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

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

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

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

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or critical habitat. To facilitate APHIS' ESA consultation process, APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS' regulatory authority and effects analysis for petitions for nonregulated status, and developed a process for conducting an effects determination consistent with the Plant Protection Act of 2000 (Title IV of Public Law 106-224). This process is described in a decision tree document, which is presented as appendix B. APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

APHIS' regulatory authority for GE organisms under the PPA is limited to those 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, APHIS concluded that MON 87769 soybean does not pose a plant pest risk (USDA-APHIS, 2010c). Because the agency has concluded that MON 87769 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of MON 87769 soybean is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the

Coordinated Framework. Nevertheless, APHIS has chosen to analyze the potential effects to threatened and endangered species and critical habitat under the ESA. As part the environmental review process, APHIS thoroughly reviews genetically engineered product information and data to inform the ESA effects analysis and, if necessary, the biological assessment related to the organism (generally a plant species, but may also be other genetically engineered organisms) for which regulatory jurisdiction applies under the plant pest provisions of the Plant Protection Act of 2000 and implementing regulations in 7 CFR part 340. For each transgene(s)/transgenic plant the following information, data, and questions are considered by APHIS:

- 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 impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant); and
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES.

In following this process, APHIS evaluated the potential effects that a determination of nonregulated status to MON 87769 soybean would have on Federally listed TES and species proposed for listing, as well as designated critical habitat and habitat proposed for designation (See Appendix B). Based upon the scope of the EA and production areas identified in the Affected Environment section of the EA, APHIS obtained a list of TES species (listed and proposed) from the USFWS Environmental Conservation Online System (ECOS) for each state where MON 87769 soybean is likely to be commercially produced (ECOS; as accessed 4/15/2011 at http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp).

As discussed above in the analysis of Gene Movement and Weediness and Plants, APHIS has determined that there is no risk to unrelated plant species from the cultivation of MON 87769 soybean. Monsanto submitted results of a comparison of agronomic and phenotypic differences between MON 87769 soybean and conventional soybean; there is no reason to believe that MON 87769 soybean is different from the commercial variety from which it was developed (USDA-APHIS, 2010c). Consistent with these studies, APHIS has concluded the determination of nonregulated status of MON 87769 soybean does not present a plant pest risk, does not present a risk of weediness, and does not present an increased risk of gene flow when compared to other currently cultivated varieties.

Accordingly, APHIS focuses our assessment of possible impacts on TES animal species, particularly those potentially at risk from the consumption of MON 87769 soybean. Few TES animal species are likely to frequent soybean fields because the habitat would not be suitable. Some animal species, particularly migratory birds, may visit soybean fields, but their presence would be a passing one as the habitat is either not suitable or does not contain constituent elements required by the species. It is reasonable to assume that populations of the species adjacent to soybean production fields could be impacted by aspects of cultivation of MON 87769 soybean or could feed on MON 87769 soybean. As described below, the EPA and the FDA have conducted independent evaluations of these potential risks directly relevant to APHIS' analysis.

Monsanto measured compositional aspects of MON 87769 soybean and compared these data with conventional soybean. The intended expression of SDA and also of gamma linolenic acid is new to commodity soybean. Although the animal feed consultation with FDA is pending, submitted data showed that these new components are both intermediates in mammalian systems during production of docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), and also are found in the environment in numerous other plant and animal sources. Linoleic acid (18:2) is decreased to about 41% of control percentage, and this altered soybean content is similar to that of canola oil. Statistically significant but small differences were observed in the comparisons of the A3525 conventional variety to MON 87769 soybean in the concentrations of several fatty acids (16:0 palmitic, 18:0 stearic, 18:1 oleic, 18:3 alpha linolenic acid, 20:0 arachidic, 22:0 behenic). APHIS evaluated these differences in composition, and has determined that those reported for MON 87769 either fall within the typical commercial range for percentage composition, or within the 99% tolerance interval for soybean composition (Monsanto, 2010b). For several amino acids % of total amino acid content, % dry weight of proximates (protein and carbohydrate) and two isoflavones were also different from controls (US-EPA, 1993b), but these also were within either the range of commercial values or the 99% tolerance level for commercial soybean (Monsanto, 2010b).

Because the composition of MON 87769 soybean is either similar to other commercial soybean plants in most constituents, or expresses fatty acids that are unlikely to impact human or animal health with consumption, it is unlikely that MON 87769 soybean poses a hazard to TES animal species. Because no hazards are identified, the risk of MON 87769 soybean affecting TES animal species is also unlikely, regardless of exposure.

Based on the above information, APHIS has determined that the Preferred Alternative, a determination of nonregulated status of MON 87769 soybean, would have no effect on Federally listed TES proposed for listing, or on designated critical habitat or habitat proposed for designation. Following the BRS Decision Tree Document that indicates when a consultation with FWS is triggered (See Appendix B), APHIS BRS has determined that a written concurrence or formal consultation with the USFWS is not required for this action.

6.1 Cumulative Impacts of Stacking MON 87769 Soybean with a Glyphosate Tolerant Trait on TES

Monsanto has stated that MON 87769 soybean will likely be conventionally bred with the *cp4 epsps* gene (glyphosate tolerance trait), and as a result, APHIS has decided to conduct a cumulative NEPA impact analysis of this potential future action on TES.

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

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

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

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

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

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

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

In conclusion, there are legal precautions in place (U.S. EPA label use restrictions) and "best practice" guidance to reduce the possibility of exposure and adverse impacts to TES from glyphosate application. U.S. EPA has considered potential impacts to TES as part of their registration and labeling process for glyphosate; and adherence to U.S. EPA label use restrictions by the pesticide applicator will ensure that the use of glyphosate will not adversely affect TES or critical habitat. Furthermore, pesticide applicators are legally required to follow U.S. EPA label use restrictions.

Finally, cultivation of MON 87769 soybean is not expected to result in an increase in the application of glyphosate or changes of any other herbicide treatments when compared with existing herbicide-tolerant and non-GE soybean varieties.   APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action on TES.

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

7.1 Executive Orders with Domestic Implications

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

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

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

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

Based on the information submitted by the applicant and assessed by APHIS, MON 87769 soybean is agronomically, phenotypically, and biochemically comparable to conventional soybean except for the intended unique fatty acid profile (i.e., the presence of SDA and GLA). The information provided in the petition indicates that the two desaturase proteins, PjD6D and NcFad3, expressed in MON 87769 soybean are not expected to be allergenic, toxic, or pathogenic in mammals (Monsanto, 2010b). Also, FDA indicated that they had no questions "regarding Monsanto's conclusion that SDA soybean oil is GRAS under the intended conditions of use" (US-FDA, 2009a). The use of SDA soybean oil in selected food categories could provide a wide range of dietary alternatives for increasing human intake of omega-3 fatty acid. The oil derived from MON 87769 soybean, is intended for use only in certain markets and will be identity preserved to maintain its value and assure its use in appropriate food applications. Additionally, the defatted soybean meal from MON 87769 soybean is compositionally similar to other defatted commodity soybean meal and will be used in a manner similar to the meal derived from these commodity soybean. This information establishes the safety of MON 87769 soybean and its products to humans, including minorities and low income populations who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken.

None of the impacts on agricultural practices expected to be associated with a determination of nonregulated status of MON 87769 soybean are expected to have a disproportionate adverse effect on minorities and low income populations. MON 87769 soybean is not genetically engineered to produce a toxin or pesticide, and is not genetically engineered to be tolerant to an herbicide. Due to the lack of pesticidal and herbicidal traits in MON 87460 Soybean, soybean hybrid varieties may be produced with MON 87769 soybean and other nonregulated soybean hybrids containing herbicide tolerant traits. Thus, pesticide application practices and usage associated with a determination of nonregulated status of MON 87769 soybean are not expected to change from the current trends for existing nonregulated GE soybean.

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

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

Non-GE soybean, as well as other modified fatty acid soybean varieties, are widely grown in the U.S. Based on the historical experience with these varieties and the data submitted by the applicant and reviewed by APHIS, MON 87769 soybean are sufficiently similar in fitness characteristics to other soybean varieties currently grown and are not expected to become weedy or invasive (USDA-APHIS, 2010c).

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

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

Monsanto has presented results of field trials conducted to evaluate field phenotypic, agronomic and environmental interactions. These data, presented in Appendix G of the petition (USDA-APHIS, 2010c), showed no differences in arthropod damage or arthropod pest and beneficial insect abundance between MON 87769 soybean and other varieties, supporting the conclusion that the modified oil trait is unlikely to impact food sources for migratory bird species. Migratory bird use of soybean in harvested fields is reduced in terms of species numbers as well as population densities compared to their use of corn and sunflower fields (Galle et al., 2009), so usefulness of soybean for these birds may be as only a secondary source of grain.

Migratory birds may forage on soybean seed before seed germination in a field that produced soybean the previous growing season, and following harvest, may also ingest additional seed. Data submitted by the applicant has shown no difference in compositional and nutritional quality of MON 87769 soybean compared to commercial soybean or non-GE-soybean, apart

from the modification of the fatty acid composition. Fatty acid content is unlikely to impact bird species, since the oils derived from MON 87769 are both typical of other seeds and have been approved for GRAS status. Based on APHIS' assessment of MON 87769 soybean, it is unlikely that a determination of nonregulated status of MON 87769 soybean will have a negative effect on migratory bird populations that occasionally forage in soybean fields.
International Implications

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

APHIS has given this EO careful consideration and does not expect a significant environmental impact outside the U.S. in the event of a determination of nonregulated status of MON 87769. 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 87769 subsequent to a determination of nonregulated status of the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC, 2010). The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC, 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (172 countries as of March 2010). In April 2004, a standard for PRA of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

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

LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (NBII, 2010). These data will be available to the Biosafety Clearinghouse.

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the Organization for Economic Cooperation and Development (OECD). NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures (RSPM) No. 14, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO, 2009).

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

7.2 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the changes in soybean production due to a determination of nonregulated status of MON 87769 soybean. Cultivation of MON 87769 soybean will not lead to the increased production of soybean in U.S. agriculture.

There is no expected change in water use due to the cultivation of MON 87769 soybean compared to current soybean seed and production regimes. There is no expected change in air quality associated with agronomic practices associated with the cultivation of MON 87769 soybean.

Based on this review, APHIS concludes that the cultivation of MON 87769 soybean would inherently comply with the Clean Water Act and the Clean Air Act.

7.3 Impacts on Unique Characteristics of Geographic Areas

A determination of non-regulated status of MON 87769 soybean is not expected to adversely impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

The common agricultural practices that would be carried out in the cultivation of MON 87769 soybean are not expected to deviate from current practices. The product will be deployed on agricultural land currently suitable for production of soybean, will replace existing varieties, and is not expected to increase the acreage of soybean production.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to a determination of non-regulated status of MON 87769 soybean. This action would not convert land use to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to MON 87769 soybean including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment.

7.4 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.

A determination of nonregulated status of MON 87769 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.

A determination of nonregulated status of MON 87769 soybean 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 non-regulated status of MON 87769.

A determination of nonregulated status of MON 87769 soybean 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 87769 soybean does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

8 REFERENCES

Adam KL. (2005) Seed Production and Variety Development for Organic Systems. National Center for Appropriate Technology. Retrieved November 3, 2010 from https://attra.ncat.org/attra-pub/summaries/summary.php?pub=70.

ADM. (2006) ADM to Process Monsanto's Vistive™ Low Linolenic Soybeans at Indiana Facility. Retrieved from http://www.adm.com/en-US/news/_layouts/PressReleaseDetail.aspx?ID=170

AGRA. (2009) A Study Assessing the Opportunities and Potential of Soybean Based Products and Technologies. Retrieved March 15, 2011 from http://www.auri.org/research/Informa%20Soybean%20Report%20Final.pdf.

Aitzetmüller K and Werner G. (1991) Stearidonic acid (18:4[omega]3) in Primula florindae. *Phytochemistry, 30*(12), 4011-4013.

Al-Kaisi M, Hanna M, and Tidman M. (2003) Crop rotation considerations for 2004 management season rotation. Retrieved November 29, 2010 from http://www.ipm.iastate.edu/ipm/icm/2003/12-15-2003/croprotation.html.

Alt JL, Fehr WR, Welke GA, and Sandhu D. (2005) Phenotypic and Molecular Analysis of Oleate Content in the Mutant Soybean Line M23 *Crop Science, 45*, 1997-2000.

Altieri MA. (1999) The ecological role of biodiversity in agroecosystems. *Agriculture, Ecosystems and Environment, 74*, 19-31.

American Heart Association. (2011) Fry Oils and Shortenings - Heavy-Duty (For Restaurants). Retrieved from http://www.heart.org/HEARTORG/GettingHealthy/FatsAndOils/FacetheFatsRestaurantResources/Fry-Oils-and-Shortenings---Heavy-Duty-For-Restaurants_UCM_304476_Article.jsp.

Anderson RL. (2008) Weed Seedling Emergence and Survival as Affected by Crop Canopy. *Weed Technology, 22*(4), 736-740.

Aneja VP, Schlesinger WH, and Erisman JW. (2009) Effects of agriculture upon the air quality and climate: Research, policy, and regulations. *Environmental Science & Technology, 43*(12), 4234–4240.

AOSCA. (2009) *Seed Certification Handbook*. Moline, IL: Association of Official Seed Certifying Agencies.

AOSCA. (2010) General IP Protocols Standards. The Association of Official Seed Certifying Agencies. Retrieved November 8, 2010 from http://www.identitypreserved.com/handbook/aosca-general.htm.

APAG. (2011) Fatty Acids & Glycerine: Major Production Routes Starting from Vegetable & Animal Oils and Fats. The European Oleochemicals and Allied Products Group. Retrieved March 13, 2011 from http://www.apag.org/oleo/fats.htm.

Aref S and Pike DR. (1998) Midwest farmers' perceptions of crop pest infestation. *Agronomy Journal, 90*(6), 819-825.

ASA. (2011) Soy Stats: A Reference Guide to Important Soybean Facts and Figures. Retrieved April 19, from American Soybean Association http://www.soystats.com/2011/.

Asgrow. (2011) Asgrow Seed Resource Guide-North (Soybean). from Asgrow Brand. Monsanto Co. https://www.asgrowanddekalb.com/products/Documents/2011_seed_resource_guide_north.pdf.

Baier AH. (2008) Organic Standards for Crop Production. National Center for Appropriate Technology. Retrieved December 7, 2010 from http://attra.ncat.org/attra-pub/PDF/nopstandard_crops.pdf.

Baker J, Southard R, and Mitchell J. (2005) Agricultural dust production in standard and conservation tillage systems in the San Joaquin Valley. *Journal of Environmental Quality*, *34*, 1260-1269.

Barrentine WL. (1989) Minimum effective rate of chlorimuron and imazaquin applied to common cocklebur (*Xanthium strumarium*). *Weed Technology*, *3*(1), 126-130.

Basore NS, Best LB, and Wooley JB, Jr. (1986) Bird Nesting in Iowa No-Tillage and Tilled Cropland. *The Journal of Wildlife Management*, *50*(1), 19-28.

Beckie HJ and Tardif FJ. (2012) Herbicide cross resistance in weeds. *Crop Protection*, *35*, 15-28.

Benbrook C. (2009) Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Thirteen Years. Critical Issue Report Number 3. The Organic Center. Retrieved from

Bengtsson J, Ahnstrom J, Weibull A-C, and Ecology JoA. (2005) The effects of organic agriculture on biodiversity and abundance: a meta-analysis. *42*, 261-269.

Bennett JM, Hicks DR, and Naeve SL (Eds.). (2011). *The Minnesota Soybean Field Book*: University of Minnesota.

Berg JM, Tymoczko JL, and Stryer L. (2002) *Biochemistry*. New York: W H Freeman.

Berglund D and Helms T. (2003) Soybean Production. NDSU Extension Service Circular A-250. Fargo, ND: North Dakota State University Extension Service Retrieved June 2003, from http://library.ndsu.edu/tools/dspace/load/?file=/repository/bitstream/handle/10365/5450/a250.pdf?sequence=1.

Berk A (Producer). (2008, May 27, 2011). Do deer love soybeans? *Sports and Fitness Articles*. Retrieved from http://www.articlesbase.com/sports-and-fitness-articles/do-deer-love-soybeans-700903.html

Bernal-Santos G, O'Donnell AM, Vicini JL, Hartnell GF, and Bauman DE. (2010) Hot topic: Enhancing omega-3 fatty acids in milk fat of dairy cows by using stearidonic acid-enriched soybean oil from genetically modified soybeans. *Journal of Dairy Science*, *93*(1), 32-37.

Besler M, Helm RM, and Ogawa T. (2000) Allergen Data Collection - Update: Soybean (Glycine max). Retrieved 2(Suppl.3), from http://www.food-allergens.de/symposium-2-2/soybean/soy-abstract.htm.

Betzelberger AM, Gillespie KM, McGrath JM, Koester RP, Nelson RL, and Ainsworth EA. (2010) Effects of chronic elevated ozone concentration on antioxidant capacity, photosynthesis and seed yield of 10 soybean cultivars. *Plant, Cell and Environment*, *33*(9), 1569-1581.

Beuerlein J (2005). 2005 Inoculation Study. Submitted by Registration Manager. Ohio State University (See Table http://agcrops.osu.edu/specialists/soybean/current-research-projects/2005SoyInoculationReport.pdf).

Bharadwaj AS, Hart SD, Brown BJ, Li Y, Watkins BA, and Brown PB. (2010) Dietary source of stearidonic acid promotes higher muscle DHA concentrations than linolenic acid in hybrid striped bass. *Lipids*, *45*, 21-27.

Bitzer RJ, Rice ME, Pilcher CD, Pilcher CL, and Lam W-KF. (2005) Biodiversity and Community Structure of Epedaphic and Euedaphic Springtails (Collembola) in Transgenic Rootworm Bt Corn. *Environmental Entomology 34*(5), 1346-1376.

Bohm GMB, Alves BJR, Urquiaga S, Boddey RM, Xavier GR, Hax F, and Rombaldi CV. (2009) Glyphosate- and imazethapyr-induced effects on yield, nodule mass and biological nitrogen fixation in field-grown glyphosate-resistant soybean. *Soil Biology and Biochemistry, 41*(2), 420-422.

Borggaard OK and Gimsing AL. (2008) Fate of glyphosate in soil and the possibility of leaching to ground and surface waters: A review. *Pest Management Science, 64*(4), 441-456.

Bottomley P. (1992) Ecology of *Bradyrhizobium* and *Rhizobium*. In, *Biological Nitrogen Fixation* (pp. 293 - 348). G Stacey, RH Burris and HJ Evans (Eds.). New York: Routledge, Chapman and Hall.

Bradford KJ. (2006) Methods to Maintain Genetic Purity of Seed Stocks. University of California, Division of Agriculture and Natural Resources. Retrieved November 8, 2010 from http://ucanr.org/freepubs/docs/8189.pdf.

Brookes G and Barfoot P. (2010) GM Crops: Global Socio-Economic and Environmental Impacts 1996-2008. United Kingdom: PG Economics Ltd. Retrieved from

Brooks DR, Clark SJ, Perry JN, Bohan DA, Champion GT, Firbank LG, Haughton AJ, Hawes C, Heard MS, and Woiwod IP. (2005) Invertebrate biodiversity in maize following withdrawal of triazine herbicides. *Proceedings of the Royal Society B: Biological Sciences, 272*(1571), 1497-1502.

Brown JR. (2003) Ancient horizontal gene transfer. *Nature Reviews: Genetics, 4*, 121-132.

Brumm TJ and Hurburgh Jr CR. (2006) Changes in long-term soybean compositional patterns. *JAOCS, Journal of the American Oil Chemists' Society, 83*(11), 981-983.

Buckelew LD, Pedigo LP, Mero HM, Owen MDK, and Tylka GL. (2000) Effects of weed management systems on canopy insects in herbicide-resistant soybeans. *Journal of Economic Entomology, 93*(5), 1437-1443.

Burdge GC and Calder PC. (2005) α-Linolenic acid metabolism in adult humans: the effects of gender and age on conversion to longer-chain polyunsaturated fatty acids. *European Journal of Lipid Science and Technology, 107*(6), 426-439.

Byrd JD, Blaine A, and Poston D. (2003) Soybean Postemergence Weed Control. Mississippi State University Extension Service. Retrieved from

Cahoon EB. (2003) Genetic enhancement of soybean oil for industrial uses: Prospects and challenges. *AgBioForum, 6*(1&2), 11-13.

Cardnoentrix. (2011) Economic Analysis: Economic Impact of Removing the Biodiesel Tax Credit for 2010 And Implementation of RFS2 Targets Through 2015. Retrieved from http://www.biodiesel.org/news/pressreleases/supporting_docs/20110615_Economic%20Impact.pdf.

Cargill. (2011) Oils for Healthy Solutions. High oleic / low linolenic. Cargill, Inc. Retrieved from http://www.cargill.com/food/na/en/products/oils-shortenings/oils-for-healthy-solutions/from-our-experts/high-oleic-low-linolenic/index.jsp.

Cargill. (2011) Oils for healthy solutions. Food ingredients. Blends. Retrieved from http://www.cargill.com/food/na/en/products/oils-shortenings/oils-for-healthy-solutions/solutions/blends/index.jsp.

Carlsen SCK, Spliid NH, and Svensmark B. (2006) Drift of 10 herbicides after tractor spray application. 2. Primary drift (droplet drift). *Chemosphere 64*(5), 787-794.

Carpenter JE, Felsot A, Goode T, Hammig M, Onstad D, and Sankula S. (2002) Comparative Environmental Impacts of Biotechnology-Derived and Traditional Soybean, Corn, and Cotton Crops. Retrieved November 30, 2010 from www.cast-science.org.

Carpenter SR, Caraco NF, Correll DL, Howarth RW, Sharpley AN, and Smith VH. (1998) Nonpoint pollutin of surface waters with phosphorus and nitrogen. *Ecological Applications, 8*(3), 559-568.

Causarano HJ, Franzluebbers AJ, Reeves DW, and Shaw JN. (2006) Soil organic carbon sequestration in cotton production systems of the Southeastern United States: A review. *Journal of Environmental Quality, 35*(4), 1374-1383.

Caviness CE. (1966) Estimates of natural cross-pollination in Jackson soybeans in Arkansas. *Crop Science, 6*, 211-212.

CBD. (2010) The Cartegena Protocol on Biosafety. Convention on Biological Diversity. Retrieved January 31, 2011 from http://www.cbd.int/biosafety/.

Cerdeira AL and Duke SO. (2006) The current status and environmental impacts of glyphosate-resistant crops: A review. *Journal of Environmental Quality, 35*(5), 1633-1658.

Chamberlain DE, Freeman SN, and Vickery JA. (2007) The effects of GMHT crops on bird abundance in arable fields in the UK. *Agriculture, Ecosystems & Environment, 118*(1-4), 350-356.

Chen M, Zhao JZ, Collins HL, Earle ED, Cao J, and Shelton AM. (2008) A Critical Assessment of the Effects of Bt Transgenic Plants on Parasitoids. *PLoS ONE, 3*(5), e2284.

Clarke C. (2007) Gene Flow between Genetically Modified and Non-GM Plants. Retrieved January 9, 2011 from http://cosmos.ucdavis.edu/archives/2007/cluster1/clarke_cornelia.pdf.

Cober ER, Tanner JW, and Voldeng HD. (1996) Genetic Control of Photoperiod Response in Early-Maturing, Near-Isogenic Soybean Lines. *Crop Sci., 36*(3), 601-605.

CODEX. (2010) CODEX Standard for Named Vegetable Oils. Retrieved November 29, 2010 from http://www.codexalimentarius.net/web/more_info.jsp?id_sta=336.

Cole CV, Duxbury J, J. F, Heinemeyer O, Minami K, Mosier A, Paustian K, Rosenberg N, Sampson N, Sauerbeck D, and Zhao Q. (1997) Global estimates of potential mitigation of greenhouse gas emissions by agriculture. *Nutrient Cycling in Agroecosystems, 49*, 221–228.

Conley SP, Boerboom C, and Gaska J. (2008) Double Crop Soybeans in WI: More Risk than Reward. University of Wisconsin Agronomy, Soybean Research, University of Wisconsin-Extension. Retrieved 2011 from http://soybean.uwex.edu/documents/Doublecrop.pdf.

Conley SP and Gaska J. (2011) Considerations for switching soybean maturity groups for delayed plantings. University of Wisconsin-Madison. Retrieved from http://soybean.uwex.edu/documents/MGSoybeanSwitch.pdf.

Council for Responsible Nutrition. (2005) Long Chain Omega-3 Fatty Acids in Human Health, Heart Health: The Role of Eicosapentaenoic, Docosahexaenoic, & Alpha-Linolenic Acids (EPA, DHA, and ALA). White Paper. Council for Responsible Nutrition Retrieved from http://www.crnusa.org/pdfs/CRNo3wg_whitepaper.pdf.

Coupe RH, Kalkhoff SJ, Capel PD, and Gregoire C. (2011) Fate and transport of glyphosate and aminomethylphosphonic acid in surface waters of agricultural basins. *Pest Manag Sci*.

CRC (2011). Physical Constants of Organic Compounds. Submitted by WM Haynes, Registration Manager. CRC Press/Taylor and Francis (See Table http://www.hbcpnetbase.com/).
CTIC. (2010a) Facilitating Conservation Farming Practices and Enhancing Environmental Sustainability with Agricultural Biotechnology. Conservation Technology Information Center. Retrieved from http://www.improveagriculture.com/uploads/files/BiotechFinal2.pdf.
CTIC. (2010b) National Crop Residue Management Survey. 2008. Retrieved from http://www.ctic.purdue.edu/media/pdf/National%20Summary%202008%20(Amendment).pdf.
Cui Z, James AT, Miyazaki S, Wilson RF, and Carter TE. (2004) Breeding Specialty Soybeans for Traditional and New Soyfoods (Chapter 14),. In, *In Soybeans as Functional Foods and Ingredients* (pp. 266-322). AOCS Publishing.
Cunnane SC, Plourde M, Pifferi F, Bégin M, Féart C, and Barberger-Gateau P. (2009) Fish, docosahexaenoic acid and Alzheimer's disease. *Progress in Lipid Research, 48*(5), 239-256.
Cyberlipid Center. (2011) Polyenoic Fatty Acids. Retrieved from http://www.cyberlipid.org/fa/acid0003.htm.
Dalley CD, Renner KA, and Kells JJ. (2001) Weed Competition in *Roundup Ready* Soybeans and Corn. Dept. of Crop and Soil Sciences, Michigan State University. Retrieved November 30, 2010 from http://www.ipm.msu.edu/cat06field/pdf/weedfactsheet.pdf.
Daniells S. (2011) All-conquering omega-3 market set for further growth. William Reed Business Media. Retrieved from http://www.nutraingredients.com/Consumer-Trends/All-conquering-omega-3-market-set-for-further-growth.
Dively GP and Rose R. (2003) *Effects of Bt Transgenic and Conventional Insecticide Control on the Non-Target Natural Enemy Communtiy in Sweet Corn.* Presented at 1st International Symposium on Biological Control of Arthropods. Honolulu, HI.
Domagalski JL, Ator S, Coupe R, McCarthy K, Lampe D, Sandstrom M, and Baker N. (2008) Comparative study of transport processes of nitrogen, phosphorus, and herbicides to streams in five agricultural basins, USA. *Journal of Environmental Quality, 37*(3), 1158-1169.
Doran J, Sarrantonio M, and Liebig M. (1996) Soil health and sustainability. *Advances in Agronomy, 56*, 1-54.
Du Pont. (2011) The science behind New Harvest. . E.I. du Pont de Nemours and Company Retrieved 25 August, 2011 from http://newharvest.com/New_Harvest/ub_US/about/science_behind_new_harvest.html.
Dubois V, Breton S, Linder M, Fanni J, and Parmentier M. (2007) Fatty acid profiles of 80 vegetable oils with regard to their nutritional potential. *European Journal of Lipid Science and Technology*, *109*(7), 710-732.
Duke SO and Powles SB. (2009) Glyphosate-resistant crops and weeds: Now and in the future. *AgBioForum*, *12*(3&4), 346-357.
EFSA (European Food Safety Administration). (2011) Scientific Opinion on the substantiation of health claims related to docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and brain, eye and nerve development (ID 501, 513, 540), maintenance of normal brain function... *EFSA Journal*, *9*(4), 2078-2108.

EIA. (2007) Biofuels in the U.S. Transportation Sector. US Energy Information Administration, US Department of Energy. Retrieved from http://www.eia.gov/oiaf/analysispaper/biomass.html.

Elbehri A. (2007) The Changing Face of the U.S. Grain System: Differentiation and Identity Preservation Trends. U.S. Department of Agriculture, Economic Research Service. Retrieved from

Eldridge AC, Black LT, and Wolf WJ. (1979) Carbohydrate Composition of Soybean Flours, Protein Concentrates, and Isolates. *Journal of Agricultural & Food Chemistry, 27*, 799-802.

Ellstrand NC. (2003) Current knowledge of gene flow in plants: Implications for transgene flow. *Philosophical Transactions of the Royal Society of London. Series B, Biological Sciences, 358*(1434), 1163-1170.

Ernst M and McNulty S. (2011 download) Green Edible Soybeans. Fresh Market. University of Kentucky Agricultural Economics Extension. Retrieved from http://www.uky.edu/Ag/NewCrops/soybeanmarketing.pdf.

FAO. (2010) Crop Production. Soybean. Food and Agriculture Organization of the United Nations. Retrieved from http://faostat.fao.org/site/567/DesktopDefault.aspx?PageID=567#ancor.

FAPRI. (2009) U.S. and World Agricultural Outlook. Ames, Iowa: Food and Agricultural Policy Research Institute. Retrieved from http://www.fapri.iastate.edu/outlook/2009/.

Farooq FT and Vessey JK. (2009) Genetic diversity of Bradyrhizobium japonicum within soybean growing regions of the north-eastern Great Plains of North America as determined by REP-PCR and ERIC-PCR profiling. *48*(1/3), 131-142.

Faust MA. (2002) New feeds from genetically modified plants: the US approach to safety for animals and the food chain. *74*(3), 239-254.

Fehr WR. (2007) Breeding for Modified Fatty Acid Composition in Soybean. *Crop Sci., 47*((S3)), S72-S87

Ferguson RB, Shapiro CA, Dobermann AR, and Wortmann CS. (2006) Fertilizer recommendations for soybean. University of Nebraska-Lincoln. Retrieved from http://elkhorn.unl.edu/epublic/live/g859/build/g859.pdf.

Fernandez-Cornejo J and Caswell M. (2006) The First Decade of Genetically Engineered Crops in the United States. U.S. Department of Agriculture-Economic Research Service. Retrieved July 21 from http://www.ers.usda.gov/publications/eib11/.

Fernandez-Cornejo J, Klotz-Ingram C, and Jans S. (2002) Farm level effects of adopting *Journal of Agriculture and Applied Economics, 34*(1), 149-163.

Fernandez MR, Zentner RP, Basnyat P, Gehl D, Selles F, and Huber D. (2009) Glyphosate associations with cereal diseases caused by *Fusarium* spp. in the Canadian Prairies. *European Journal of Agronomy, 31*(3), 133-143.

Flachowsky G, Chesson A, and Aulrich K. (2005) Animal nutrition with feeds from genetically modified plants. *Archives of Animal Nutrition, 59*(1), 1 - 40.

Franzen D and Nowatzki J. (2009) NDSU Offers Tillage and Residue Management Options. North Dakota State Extension. Retrieved from http://www.ag.ndsu.edu/news/newsreleases/2009/april-16-2009/ndsu-offers-tillage-and-residue-management-options/.

Freibauer A, Rounsevell M, Smith P, and Verhagen J. (2004) Carbon sequestration in the agricultural soils of Europe. *Geoderma, 122*(1), 1-23.

Gage DJ. (2004) Infection and invasion of roots by symbiotic, nitrogen-fixing rhizobia during nodulation of temperate legumes. *Microbiology and Molecular Biology Reviews, 68*, 280-300.

Galle AM, Linz GM, Homan HJ, and Bleier WJ. (2009) Avian use of harvested crop fields in North Dakota during Spring Migration. *Western North American Naturalist, 69*(4), 491-500.

Gamble LR, Johnson KM, Linder G, and Harrahy EA. (2002) *The migratory bird treaty act and concerns for nontarget birds relative to spring baiting with DRC-1339.* Presented at Management of North American Blackbirds, Proceedings of a special symposium of The Wildlife Society, 9th Annual Conference. Bismarck, North Dakota.

Garbeva P, van Veen JA, and van Elsas JD. (2004) Microbial diversity in soil: Selection of microbial populations by plant and soil type and implications for disease suppressiveness. *Annual Review of Phytopathology, 42*(1), 243-270.

Gardiner MM, Landis DA, Gratton C, DiFonzo CD, O'Neal M, Chacon JM, Wayo MT, Schmidt NP, Mueller EE, and Heimpel GE. (2009) Landscape diversity enhances biological control of an introduced crop pest in the north-central USA. *Ecological Applications, 19*(1), 143-154.

Garrison RL and Lewis JC. (1987) Effects of Browsing by White-Tailed Deer on Yields of Soybeans. *Wildlife Society Bulletin, 15*(4), 555-559.

GCIA. (1988) Soybean Seed Certification Standards. Georgia Crop Improvement Association, Inc. Retrieved 1988, from http://www.certifiedseed.org/.

Gelderman R. (2009) Estimating nutrient loss from crop residue fires. Brookings, SD: South Dakota State University. Retrieved June 2009, from http://pubstorage.sdstate.edu/AgBio_Publications/articles/ExEx8164.pdf.

Gianessi LP and Reigner NP. (2007) The Value of Herbicides in U.S. Crop Production. *Weed Technology, 21*(2), 559-566.

Gianessi LP, Silvers CS, Sankula S, and J.E. C. (2002) Plant biotechnology: Current and potential impact for improving pest management in U.S. agriculture, an analysis of 40 case studies. Washington, DC: National Center for Food and Agricultural Policy. Retrieved June, 2002 from http://croplife.intraspin.com/Biotech/plant-biotechnology-current-and-potential-impact-for-improving-pest-management-in-u-s-agriculture-an-analysis-of-40-case-studies/.

Giannakas K and Yiannaka A. (2010) The Market Potential of a New High-Oleic Soybean: An Ex Ante Analysis *AgBioForum, 7*(3).

Giesy JP, Dobson S, and Solomon KR. (2000) Ecotoxicological risk assessment for Roundup herbicide. *Reviews of Environmental Contamination and Toxicology, 167*, 35-120.

Giles D, Downey D, and Thompson J. (2006) In Field Assessments of Dust Generation of Harvesting Equipment. Workshop on Agricultural Air Quality. Retrieved from http://www.ncsu.edu/airworkshop/Emissions_Crop.pdf.

Givens WA, Shaw DR, Kruger GR, Johnson WG, Weller SC, Young BG, Wilson RG, Owen MDK, and Jordan D. (2009) Survey of Tillage Trends Following The Adoption of Glyphosate-Resistant Crops. *Weed Technology, 23*(1), 150-155.

Goldblum D. (2009) Sensitivity of corn and soybean yield in Illinois to air temperature and precipitation: the potential impact of future climate change. *Physical Geography, 30*(1), 27-42.

Goldsmith P, Masuda T, and Farrell R. (2008) Iowa 2006 Specialty Soybean and Corn Survey. Urbana, IL: National Soybean Research Laboratory,

University of Illinois. Retrieved from https://netfiles.uiuc.edu/pgoldsmi/www/research_presentations/2008-Iowa_Corn_Srvy.pdf.

Graef G, LaVallee BJ, Tenopir P, Tat M, Schweiger B, Kinney AJ, Van Gerpen JH, and Clemente TE. (2009) A high-oleic-acid and low-palmitic-acid soybean: Agronomic performance and evaluation as a feedstock for biodiesel. *Plant Biotechnology Journal, 7*(5), 411-421.

Gunsolus JL. (1990) Mechanical and cultural weed control in corn and soybeans. *American Journal of Alternative Agriculture, 5*(03), 114-119.

Hamer M, Owen G, and Kloek J. (2005) The role of functional foods in the psychobiology of health and disease. *Nutrition Research Reviews, 18*(01), 77-88.

Hammond BG, Lemena JK, Ahmeda G, Miller KD, Kirkpatrick J, and Fleeman T. (2008) Safety assessment of SDA soybean oil: Results of a 28-day gavage study and a 90-day/one generation reproduction feeding study in rats *Regulatory Toxicology and Pharmacology, 52*(3), 311-323.

Hammond BG, Vicini JL, Hartnell GF, Naylor MW, Knight CD, Robinson EH, Fuchs RL, and Padgette SR. (1996) The feeding value of soybeans fed to rats, chickens, catfish and dairy cattle is not altered by genetic incorporation of glyphosate tolerance. *The Journal of Nutrition, 126*(3), 717-727.

Hanna HM and Jarboe DH. (2005) *Clean-out of combines for identity preserved grain production.* Presented at Integrated Crop Management Conference.

Hansen Jesse LC and Obrycki JJ. (2000) Field deposition of Bt transgenic corn pollen: lethal effects on the monarch butterfly. *Oecologia, 125*, 241-248.

Harlan JR. (1975) Our vanishing genetic resources. *Science, 188*(4188), 618-621.

Harrison LA, Bailey MR, Naylor MW, Ream JE, Hammond BG, Nida DL, Burnette BL, Nickson TE, Mitsky TA, Taylor ML, Fuchs RL, and Padgette SR. (1996) The expressed protein in glyphosate-tolerant soybean, 5-enolypyruvylshikimate-3-phosphate synthase from *Agrobacterium* sp. strain CP4, is rapidly digested in vitro and is not toxic to acutely gavaged mice. *The Journal of Nutrition, 126*(3), 728-740.

Hartman HT and Kester DE. (1975) *Plant Propagation: Principles and Practices*. Englewood Cliffs, NJ: Prentice-Hall, Inc.

Hartnell GF. (2010) *Do Genetically Engineered Crops Make Economic Sense?* Presented at Southwest Nutrition and Management Conference. Tempe, AZ.

Hatfield JL, Boote KJ, Kimball BA, Ziska LH, Izaurralde RC, Ort D, Thomson AM, and Wolfe D. (2011a) Climate Impacts on Agriculture: Implications for Crop Production. *Agron. J., 103*, 351-370.

Hatfield JL, Boote KJ, Kimball BA, Ziska LH, Izaurralde RC, Ort D, Thomson AM, and Wolfe D. (2011b) Climate impacts on agriculture: Implications for crop production. *Agronomy Journal, 103*(2), 351-370.

Haughton AJ, Champion GT, Hawes C, Heard MS, Brooks DR, Bohan DA, Clark SJ, Dewar AM, Firbank LG, Osborne JL, Perry JN, Rothery P, Roy DB, Scott RJ, Woiwod IP, Birchall C, Skellern MP, Walker JH, Baker P, Browne EL, Dewar AJG, Garner BH, Haylock LA, Horne SL, Mason NS, Sands RJN, and Walker MJ. (2003) Invertebrate responses to the management of genetically modified herbicide-tolerant and conventional

spring crops. II. Within-field epigeal and aerial arthropods. *Philosophical Transactions of the Royal Society B: Biological Sciences, 358*(1439), 1863-1877.
Hawes C, Haughton AJ, Osborne JL, Roy DB, Clark SJ, Perry JN, Rothery P, Bohan DA, Brooks DR, Champion GT, Dewar AM, Heard MS, Woiwod IP, Daniels RE, Young MW, Parish AM, Scott RJ, Firbank LG, and Squire GR. (2003) Responses of plants and invertebrate trophic groups to contrasting herbicide regimes in the Farm Scale Evaluations of genetically modified herbicide-tolerant crops. *Philosophical transactions of the Royal Society of London. Series B, Biological sciences, 358*(1439), 1899-1913.
Heap I. (2012) International Survey of Herbicide Resistant Weeds. Weed Science. Retrieved April 2012, from http://www.weedscience.org/In.asp.
Heard MS, Hawes C, Champion GT, Clark SJ, Firbank LG, Haughton AJ, Parish AM, Perry JN, Rothery P, Scott RJ, Skellern MP, Squire GR, and Hill MO. (2003) Weeds in fields with contrasting conventional and genetically modified herbicide-tolerant crops. I. Effects on abundance and diversity. *Philosophical Transactions of the Royal Society B: Biological Sciences, 358*(1439), 1819-1832.
Heatherly L, Dorrance A, Hoeft R, Onstad D, Orf J, Porter P, Spurlock S, and Young B. (2009) Sustainability of U.S. Soybean Production: Conventional, Transgenic, and Organic Production Systems. Ames, Iowa, USA: Council for Agricultural Science and Technology. Retrieved from
Heatherly LG and Hodges H, F. (Eds.). (1999). *Soybean production in the midsouth*. Boca Raton, FL: CRC Press.
Hefle SL and Taylor SL. (1999) Allergenicity of Edible Oils. *Food Technology, 53*(2), 62-70.
Helsel ZR and Minor HC. (1993) Soybean Production in Missouri. University of Missouri Extension. Retrieved November 29, 2010 from http://extension.missouri.edu/publications/DisplayPrinterFriendlyPub.aspx?P=G4410.
Herro A. (2008) Adjustments to agriculture may help mitigate global warming. Retrieved May-June from http://findarticles.com/p/articles/mi_hb6376/is_3_21/ai_n29427848/.
Higdon J and Drake V. (2009) Soy Isoflavones. Linus Pauling Institute: Oregon State University. Retrieved December 7, 2010 from http://lpi.oregonstate.edu/infocenter/phytochemicals/soyiso/.
Higley L and Boethel D. (1994) *Handbook of Soybean Insect Pests*. The Entomological Society of America.
Hin CJA, Schenkelaars P, and Pak GA. (2001) Agronomic and environmental impacts of the commercial cultivation of glyphosate tolerant soybean in the USA. CLM: Centrum voor Landbouw en Milieu (Centre for Agriculture and Environment). Utrecht. Retrieved from http://foodsafety.k-state.edu/articles/145/enviro_impact_soy_hrbcd.pdf.
Hodges T and French V. (1985) Soyphen: Soybean growth stages modeled from temperature, daylength, and water availability. *Agronomy Journal, 77*(3), 500-505.
Hoeft RG, Nafziger ED, Johnson RR, and Aldrich SR. (2000) *Modern Corn and Soybean Production*. Champaign, IL: MCSP Publications.
Holm LG, Plucknett DL, Pancho JV, and Herberger JP. (1977) *The world's worst weeds. Distribution and biology*. Honolulu, Hawaii: University Press of Hawaii.
Holmén B, Miller D, Hiscox A, Yang W, Wang J, Sammis T, and Bottoms R. (2006) *Aerosol Emissions from Field Planting Operations*
Hoover's. (2011) South Dakota Soybean Processors LLC. Hoover's (A D&B Co.). Retrieved from

http://www.hoovers.com/company/South_Dakota_Soybean_Processors_LLC/rrkfhhi-1.html.
Horowitz J, Ebel R, and Ueda K. (2010) “No-Till” Farming Is a Growing Practice United States Department of Agriculture Economic Research Service. Retrieved from http://www.ers.usda.gov/Publications/EIB70/EIB70.pdf.
Hou G, Ablett G, Pauls K, and Rajcan I. (2006) Environmental effects on fatty acid levels in soybean seed oil. *Journal of the American Oil Chemists' Society, 83*(9), 759-763.
Hymowitz T and Singh RJ. (1987) Taxonomy and speciation. In, *Soybeans: Improvement, Production, and Uses; 2nd edition* (pp. 23-48). JR Wilcox (Ed.), Madison, Wisconsin: American Society of Agronomy.
Imura O, Shi K, Iimura K, and Takamizo T. (2010) Assessing the effects of cultivating genetically modified glyphosate-tolerant varieties of soybeans (Glycine max (L.) Merr.) on populations of field arthropods. *Environmental Biosafety Research, 9*(2), 101-112.
Institute of Shortening and Edible Oils. (2006) Food Fats and Oils. Institute of Shortening and Edible Oils. Retrieved from http://www.iseo.org/FoodFatsOils2006.pdf.
Iowa Soybean Association. (2010) Soybean Meal Composition Retrieved from http://www.soymeal.org/sbmcomposition.html.
Iowa State University. (2008) Six New Soybean Varieties Highlight Progress in Developing Healthier Oils at ISU. Retrieved March 14, 2011 from http://www.notrans.iastate.edu/.
IPCC (2007). Subsection 14.4.4: Agriculture, Forestry and Fisheries. Submitted by Registration Manager. Cambridge University Press (See Table http://www.ipcc.ch/publications_and_data/ar4/wg2/en/ch14s14-4-4.html).
IPMCenters. (2011) Crop Profile for Soybean in Minnesota. General Production Information. Prepared 2003. National Information System of the Regional Integrated Pest Management Centers. Retrieved from http://www.ipmcenters.org/cropprofiles/docs/MNSoybeans.pdf.
IPPC. (2010) Official Web Site for the International Plant Protection Convention: International Phytosanitary Portal,. International Plant Protection Convention. Retrieved November 30, 2010 from https://www.ippc.int/IPP/En/default.jsp.
Jacobsen C, Let MB, Nielsen NS, and Meyer AS. (2008) Antioxidant strategies for preventing oxidative flavour deterioration of foods enriched with n-3 polyunsaturated lipids: a comparative evaluation. *Trends in Food Science and Technology, 19*(2), 76-93.
James MJ, Ursin VM, and Cleland LG. (2003) Metabolism of stearidonic acid in human subjects: comparison with the metabolism of other n-3 fatty acids. *The American Journal of Clinical Nutrition, 77*(5), 1140-1145.
Kandel H. (2008) North Dakota Soybean Performance Testing 2008. N.D. Agricultural Experiment Station, NDSU Extension Service. Retrieved from http://hdl.handle.net/10365/4680.
Kaneko T, Nakamura Y, Sato S, Asamizu E, Kato T, Sasamoto S, Watanabe A, Idesawa K, Ishikawa A, Kawashima K, Kimura T, Kishida Y, Kiyokawa C, Kohara M, Matsumoto M, Matsuno A, Mochizuki Y, Nakayama S, Nakazaki N, Shimpo S, Sugimoto M, Takeuchi C, Yamada M, and Tabata S. (2000) Complete genome structure of the nitrogen-fixing symbiotic bacterium *Mesorhizobium loti* (supplement). *DNA Research, 7*, 381-406.
Kaneko T, Nakamura Y, Sato S, Minamisawa K, Uchiumi T, Sasamoto S, Watanabe A, Idesawa K, Iriguchi M, Kawashima K, Kohara M, Matsumoto M, Shimpo S, Tsuruoka H, Wada

T, Yamada M, and Tabata S. (2002) Complete genomic sequence of nitrogen-fixing symbiotic bacterium *Bradyrhizobium japonicum* USDA110. *DNA Research, 9*, 189-197.

Keese P. (2008) Risks from GMOs due to horizontal gene transfer. *Environmental Biosafety Research, 7*(3), 123-149.

Kennedy ET, Luo H, and Ausman LM. (2012) Cost Implications of Alternative Sources of (n-3) Fatty Acid Consumption in the United States. *Journal of Nutrition, 142*(3), 605S-609S.

Knothe G. (2005) Dependence of biodiesel fuel properties on the structure of fatty acid alkyl esters. *Fuel Processing Technology, 86*(10), 1059-1070.

Kodama H. (1994) Genetic enhancement of cold tolerance by expression of a gene for chloroplast [omega]-3 fatty acid desaturase in transgenic tobacco. *Plant Physiology, 105*, 601-605.

Kodama H, Horiguchi G, Nishiuchi T, Nishimura M, and Iba K. (1995) Fatty acid desaturation during chilling acclimation is one of the factors involved in conferring low-temperature tolerance to young tobacco leaves. *Plant Physiology, 107*, 1177-1185.

Koonin EV, Makarova KS, and Aravind L. (2001) Horizontal gene transfer in prokaryotes: Quantification and classification. *Annual Review of Microbiology, 55*, 709-742.

Kowalchuk GA, Bruinsma M, and van Veen JA. (2003) Assessing responses of soil microorganisms to GM plants. *Trends in ecology & evolution (Personal edition), 18*(8), 403-410.

Kremer RJ and Means NE. (2009) Glyphosate and glyphosate-resistant crop interactions with rhizosphere microorganisms. *European Journal of Agronomy, 31*(3), 153-161.

Krupa S, Booker F, Bowersox V, and Grantz D. (2006) *Uncertainties in the Current Knowledge of Atmospheric Trace Gases Associated with Cropping Systems in the US*

Kucharik CJ, Serbin, S.P. . (2008) Impacts of recent climate change on Wisconsin corn and soybean yield trends. . *Environ. Res. Lett. , 3 034003*, 10pp.

Kuepper G. (2003) Organic Soybean Production. National Center for Appropriate Technology. Retrieved December 7, 2010 from http://attra.ncat.org/attra-pub/PDF/organicsoy.pdf.

Kuiken KA and Lyman CM. (1949) Essential amino acid composition of soy bean meals prepared from twenty strains of soy beans. *Journal of Biological Chemistry, 177*(1), 29-36.

Lal R. (2011) Sequestering carbon in soils of agro-ecosystems. *Food Policy () 36*(Supplement 1), S33-S39.

Lal R and Bruce JP. (1999) The potential of world cropland soils to sequester C and mitigate the greenhouse effect. *Environmental Science & Policy, 2*(2), 177-185.

Lee C and Herbek J. (2004) Specialty soybean production and management in Kentucky. University of Kentucky Cooperative Extension, University of Kentucky. Retrieved from http://www.ca.uky.edu/agc/pubs/agr/agr182/agr182.pdf.

Leep R, Undersander D, Min D, Harrigan T, and Grigar J (2003). Steps to Successful No-till Establishment of Forages. Submitted by Registration Manager. Michigan State University Extension (See Table http://www.fieldcrop.msu.edu/documents/E2880.pdf).

Lemke SL, Vicini JL, Su H, Goldstein DA, Nemeth MA, Krul ES, and Harris WS. (2010) Dietary intake of stearidonic acid-enriched soybean oil increases the omega-3 index: Randomized, double-blind clinical study of efficacy and safety. *American Journal of Clinical Nutrition 92*(4), 766-775

Li X, Wang S, Duan L, Hao J, Li C, Chen Y, and Yang L. (2007) Particulate and Trace Gas Emissions from Open Burning of Wheat Straw and Corn Stover in China. *Environmental Science & Technology, 41*(17), 6052-6058.

Liu K. (1997) *Soybeans : chemistry, technology, and utilization*. New York: Chapman & Hall.

Loux M, Johnson B, and Nice G. (2009) Herbicide Program for non-GMO Soybeans. Purdue University

Ohio State University Extension Weed Science. Retrieved from http://www.btny.purdue.edu/weedscience/2009/nonGMO09.pdf.

Loux MM, Dobbels AF, Stachler JM, Johnson WG, Nice G, and Bauman TT. (2008) "Weed Control Principles". Ohio State University Extension. Retrieved from http://ohioline.osu.edu/b789/index.html.

Lovett S, Price P, and Lovett J (2003). Managing Riparian Lands in the Cotton Industry. Submitted by Registration Manager. Cotton Research and Development Corporation (See Table http://live.greeningaustralia.org.au/nativevegetation/pages/pdf/Authors%20L/18_Lovett_Price.pdf).

Lubowski RN, Vesterby M, Bucholtz S, Baez A, and Roberts MJ. (2006) Major Uses of Land in the United States, 2002. USDA-ERS. Retrieved from http://www.ers.usda.gov/publications/EIB14/eib14a.pdf.

Lundgren JG, Hesler LS, Tilmon K, Dashiell K, and Scott R. (2009) Direct effects of soybean varietal selection and Aphis glycines-resistant soybeans on natural enemies. *Arthropod-Plant Interactions, 3*(1), 9-16.

MacGowan BJ, Humberg LA, Beasley JC, DeVault TL, Retamosa MI, and Rhodes J, O.E. . (2006) Corn and Soybean Crop Depredation by Wildlife. FNR-265-W. Purdue Extension, Department of Forestry and Natural Resources, Purdue University. Retrieved from http://www.ces.purdue.edu/extmedia/FNR/FNR-265-W.pdf.

Mallory-Smith C and Zapiola M. (2008) Gene flow from glyphosate-resistant crops. *Pest Management Science, 64*(4), 428-440.

Manach C, Scalbert A, Morand C, Rémésy C, and Jiménez L. (2004) Polyphenols: food sources and bioavailability. *The American Journal of Clinical Nutrition, 79*(5), 727-747.

Marshall EJP, Brown VK, Boatman ND, Lutman PJW, Squire GR, and Ward LK. (2003) The role of weeds in supporting biological diversity within crop fields*. *Weed Research, 43*(2), 77-89.

Martek. (2010) Why life's DHA™ Martek Biosciences Corp. Retrieved 25 August, 2011 from http://www.martek.com/Products-and-Services/Child-and-Adult-Nutrition/General-Information/Why-lifesDHA-.aspx.

Marvier M, McCreedy M, Regetz J, and Kareival P. (2007) A meta-analysis of effects of *Bt* cotton and maize on nontarget invertebrates. *Science 316*, 1475-1477.

McDaniel P. (2011) The Twelve Soil Orders. Soil Taxonomy. University of Idaho. College of Agriculture and Life Sciences. Retrieved from http://soils.cals.uidaho.edu/soilorders/orders.htm.

MCIA. (2009) Seed Certification Handbook. St. Paul, MN: Minnesota Crop Improvement Association. Retrieved from http://www.mncia.org/program_seedcert.html.

MCIA. (2010) Seed Certification Handbook. Columbia, MO: Missouri Crop Improvement Association. Retrieved from

McKnight TL. (2004) *Regional Geography of the United States and Canada*. Prentice Hall.

MDA. (2009) 2007 Pesticide Usage on Four Major Crops in Minnesota. St. Paul, MN: Minnesota Department of Agriculture,

USDA NASS - MN and ND Field Offices. Retrieved from http://www.mda.state.mn.us/news/publications/chemfert/2007pesticideuse.pdf.

Micha R and Mozaffarian D. (2008) Trans Fatty Acids: Effects on Cardiometabolic Health and Implications for Policy. *Prostaglandins Leukot Essent Fatty Acids, 79*(3-5), 147-152.

Micha R and Mozaffarian D. (2010) Saturated Fat and Cardiometabolic Risk Factors, Coronary Heart Disease, Stroke, and Diabetes: a Fresh Look at the Evidence. *Lipids*, *45*, 893-905.

Monsanto. (2008) Monsanto to offer more Vistive low-lin soybean varieties for 2008 Retrieved 7-28-11, 2011 from https://www.vistive.com/News/Pages/Monsanto-to-offer-more-Vistive-low-lin-soybean-varieties-for-2008.aspx.

Monsanto. (2009). *GRAS Notice for Stearidonic (SDA) Omega-3 Soybean Oil*

Monsanto 09-SY-195F. Retrieved from http://www.accessdata.fda.gov/scripts/fcn/gras_notices/grn000283.pdf

Monsanto. (2010a) Monsanto Completes Key Regulatory Submission for Soybeans With Dicamba Herbicide Tolerance Trait. . Retrieved from http://monsanto.mediaroom.com/index.php?s=43&item=863.

Monsanto. (2010b). *Petition for the Determination of Nonregulated Status for Improved Fatty Acid Profile MON 87705*. Petition. Monsanto Company. Retrieved from http://www.aphis.usda.gov/brs/aphisdocs/09_20101p.pdf

Monsanto (2010c). Phone Record. C.Roseland Conversation with Cherian George, Monsanto Co. Submitted by Registration Manager. (See Table

Monsanto. (2010b) Petition for the Determination of Non-Regulated Status for MON 87769. Submitted by C George and GJ Rogan, Regulatory Affairs Manager. Monsanto Company, St. Louis MO (See Table: http://www.aphis.usda.gov/biotechnology/not_reg.html).

Monsanto. (2011) Roundup Ready® Soybeans. Monsanto Co. Retrieved from https://www.genuity.com/stewardship/Documents/TUG.pdf.

Monsanto. (2012) US Technology Use Guide. Monsanto, Inc. Retrieved from http://www.monsanto.com/SiteCollectionDocuments/Technology-Use-Guide.pdf.

Mori S, M. K, and Ido T. (2010) GISELA - GIS-based evaluation of land use and agriculture market analysis under global warming. *Applied Energy, 87*, 236-242.

Mozzaffarian D, Katan MB, Ascherio A, Stampfer MJ, and Willett WC. (2006) Trans fatty acids and cardiovascular disease. *The New England Journal of Medicine, 354*(15), 1601-1613.

MSA. (2009) Market Trends for IP Crops. Midwest Shippers' Association. Retrieved November 29, 2010 from http://www.mnshippers.com/html/news.cfm?ID=44.

MSU-Extension. (2010) 2010 Michigan Soybean Performance Report. Michigan State University Extension Retrieved from http://www.css.msu.edu/varietytrials/soybean/2010%20pdf/2010%20Performance%20Report-final.pdf.

MSU. (2011) 2011 Weed Control Guide. Soybean, Table 2a Chemical Weed Control in Soybean. Retrieved from http://www.msuweeds.com/assets/2011WeedGuide/2011WeedGuideSoy.pdf.

Muth MK, Mancini D, and Viator C. (2003) The role of identity-preservation systems in food-manufacturer responses to bioengineered foods. *Journal of Food Distribution Research, 34*(1), 43-49.

NAPPO. (2009) North American Plant Protection Organization approved standards North American Plant Protection Organization. Retrieved April 18, 2011 from http://www.nappo.org/Standards/Std-e.html.

Naranjo SE. (2009) Impacts of Bt crops on non-target invertebrates and insecticide use patterns. *CAB Review: Perspectives in Agriculture, Veterinary Science, Nutrition and Natural Resources, 4*(11), 1-23.

NBII. (2010) United States Regulatory Agencies Unified Biotechnology Website Retrieved 2011 from http://usbiotechreg.nbii.gov/.

NCAT. (2003) NCAT's Organic Crops Workbook: A Guide to Sustainable and Allowed Practices. National Center for Appropriate Technology. Retrieved November 8, 2010 from http://attra.ncat.org/attra-pub/PDF/cropsworkbook.pdf.

NCCIA. (2011) Soybeans: Specific Certification Standards. North Carolina Crop Improvement Association. Retrieved April, 2011 from http://www.nccrop.com/files/Soybean%20Certification%20Standards.pdf.

NDSU Weed Science. (unknown) Soybean, Dry Bean, Edible Pulses. North Dakota State University, Weed Science Department. Retrieved from http://www.ag.ndsu.edu/weeds/weed-control-guides/nd-weed-control-guide-1/wcg-files/5-Soy.pdf.

Nice G and Johnson B. (2005) Indiana’s Top Ten Most Problematic Weeds. Retrieved November 30, 2010 from http://www.btny.purdue.edu/weedscience/2005/topten05.pdf.

NOAA. (2011 download) Climatology by State; 1971-2000. In). NOaA Administration (Ed.).

NOPA. (2011) Oilseed Processing Plants. National Oilseed Processors Association. Retrieved from http://www.nopa.org/content/oilseed/NOPA%20Plants%20-%20Location%20by%20State%20_%20August%202011.pdf.

NRC. (2004) Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects. Washington DC: National Resource Council. Retrieved from

NRC. (2010) *The Impact of Genetically Engineered Crops on Farm Sustainability in the United States*. Washington, DC: National Academies Press.

NSA. (2006) Ten Years of NuSun. Retrieved March 17, 2011 from https://www.sunflowernsa.com/magazine/details.asp?ID=408&Cat=20.

NYC-DOH (Producer). (2009, June 6, 2011). Fry Oils and Shortenings. Light/Medium Duty. Retrieved from http://www.nyc.gov/html/doh/html/transfat/english/oillist.pdf

O'Brien RD. (2004) *Fats and Oils - Formulating and Processing for Applications*. Boca Raton, FL: CRC Press.

O'Brien RD. (2009a) Baking Shortenings. In, *Fats and Oils: Formulating and Processing for Applications*). O'Brien (Ed.), Boca Raton: CRC Press.

O'Brien RD. (2009b) Liquid Oils In, *Fats and Oils: Formulating and Processing for Applications*). RD O'Brien (Ed.), Boca Raton: CRC Press.

OECD. (2000) Series on Harmonization of Regulatory Oversight in Biotechnology No. 15:. Paris, France: Environment Directorate, Organization for Economic Co-operation and Development. Retrieved from

OECD. (2001) Series on the Safety of Novel Foods and Feeds No. 12:. Paris, France: Organization for Economic Co-operation and Development. Retrieved from

Oliva ML, Shannon JG, Sleper DA, Ellersieck MR, Cardinal AJ, Paris RL, and Lee JD. (2006) Stability of Fatty Acid Profile in Soybean Genotypes with Modified Seed Oil Composition. *Crop Sci., 46*(5), 2069-2075.

Orthoefer FT. (2005) Performance of trans-free vegetable oils in shortenings and deep-fat frying. *Lipid Technology, 17*(5).

Otten JJ, Pitzi Hellwig J, and Meyers LD. (2006) Dietary Reference Intakes: The Essential Guide to Nutrient Requirements. Riverdale, MD: United States Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html.

Padgette SR, Re DB, Barry GF, Eichholtz D, Delannay X, Fuchs RL, Kishore G, and Fraley RT. (1996) New weed control opportunities: Development of soybeans with a Roundup Ready gene. In, *Herbicide Resistant Crops: Agricultural, Environmental, Economic, Regulatory, and Technical Aspects* (pp. 53–84). SO Duke (Ed.), New York: Lweis Publishers.

Palmer WE, Bromley PT, and Anderson JR. (2010) Pesticides and Wildlife - Soybeans. Retrieved November 29, 2010 from http://ipm.ncsu.edu/wildlife/soybeans_wildlife.html.

Pedersen P. (2007) Seed Inoculation. Iowa State University Extension. Retrieved February 4, 2011 from http://extension.agron.iastate.edu/soybean/production_seedinoc.html.

Pedersen P. (2010) Soybean Growth and Development. Department of Agronomy, Iowa State University. Retrieved November 29, 2010 from http://extension.agron.iastate.edu/soybean/documents/SoybeanGrowthandDevelopment_000.pdf.

Pedersen P and Lauer JG. (2004) Soybean growth and development in various management systems and planting dates. *Crop Science, 44*, 508-515.

Pilcher CD, Rice ME, and Obrycki JJ. (2005) Impact of transgenic Bacillus thuringiensis corn and crop phenology on five nontarget arthropods. *Environmental Entomology, 34*, 1302-1316.

Pioneer. (2011) Field Facts: Soybean Variety Maturity Ratings. Pioneer Hi-Bred Co. Retrieved from https://www.pioneer.com/home/site/ca/template.CONTENT/guid.01FD7761-12B6-F2DC-5E45-015867C14C14/.

Pioneer Hi-Bred. (2011) Plenish High Oleic Soybeans. Retrieved May 20, 2011, 2011 from http://www.pioneer.com/home/site/about/products/product-traits-technology/plenish.

Ponsard S, Gutierrez AP, and Mills NJ. (2002) Effect of Bt-toxin (Cry1Ac) in transgenic cotton on the adult longevity of four heteropteran predators. *Environmental Entomology, 31*, 1197-1205.

Potter B and Ostlie K. (2003) Crop Profile for Soybean in Minnesota. Minnesota Project, NCPM Center, National Information System of the Regional Integrated Pest Management Centers. Retrieved from http://www.ipmcenters.org/cropprofiles/docs/MNSoybeans.pdf.

Primomo VS, Falk DE, Ablett GR, Tanner JW, and Rajcan I. (2002) Genotype × Environment Interactions, Stability, and Agronomic Performance of Soybean with Altered Fatty Acid Profiles. *Crop Sci., 42*(1), 37-44.

Pritchett JJ, Fulton J, Beyers R, Pederson L, and Lawson L. (2002) Specialty Corn and Soybeans: Production and Marketing in Indiana. Purdue University Cooperative Extension Service. Retrieved from

Purves W, Sadava D, Orians G, and Heller H. (2004) *Life: The science of biology*. Gordonsville, VA: Sinauer Associates and W. H. Freeman & Company.

Qualisoy. (2011) The traits. Low Linolenic. Qualisoy. Retrieved from http://qualisoy.com/agriculture/section/the_traits.
Quist D. (2010) Vertical (Trans)gene Flow: Implications for Crop Diversity and Wild Relatives. In, *Biotechnology & Biosafety Series 11*). Penang, Malaysia: Third World Network.
Rackis JJ. (1974) Biological and physiological factors in soybean. Retrieved 51:161A-174A from http://ddr.nal.usda.gov/bitstream/10113/31316/1/CAIN749011713.pdf.
Randall GW and Mulla DJ. (2001) Nitrate Nitrogen in Surface Waters as Influenced by Climatic Conditions and Agricultural Practices. *J. Environ. Qual., 30*(2), 337-344.
Raper Jr. CD and Kramer PJ. (1987) Stress physiology. In, *Soybean: Improvement, Production, and Uses* (pp. 589–641). JR Wilcox (Ed.), Madison, WI: Agron. Monogr. 16.
Ravier I, Haouisee E, Clement M, Seux R, and Briand O. (2005) Field experiments for the evaluation of pesticide spray-drift on arable crops. *Pest Management Science, 61*, 728-736.
Ray JD, Kilen TC, Abel CA, and Paris RL. (2003) Soybean natural cross-pollination rates under field conditions. *Environmental Biosafety Research, 2*(2), 133-138.
Rehm G. (2009). Burning would be a good option. Retrieved from http://minnesotafarmguide.com/app/blog/?p=311
Rehm G, Schmitt MA, Lamb J, and Eliason R. (2001) Fertilizing Soybeans in Minnesota. Retrieved from http://www.extension.umn.edu/distribution/cropsystems/DC3813.html.
Romeis J, Meissle M, and Bigler F. (2006) Transgenic crops expressing Bacillus thuringiensis toxins and biological control. *Nat Biotech, 24*(1), 63-71.
Ronald P and Fouche B. (2006) Genetic Engineering and Organic Production Systems. University of California, Division of Agriculture and Natural Resources. Retrieved Publication 8188, from http://ucanr.org/freepubs/docs/8188.pdf.
Rosenzweig C, Tubiello FN, Goldberg R, Mills E, and Bloomfield J. (2002) Increased crop damage in the US from excess precipitation under climate change. *Global Environmental Change, 12*, 197-202.
Rosseli JB. (1998) Industrial Frying Process. *Grasas y Aceites, 49*(3-4), 282-295.
Rostagno M. (2009) Soybeans Isoflavones. SciTopics. Retrieved December 7, 2010 from http://www.scitopics.com/Soybeans_Isoflavones.html.
Roy DB, Bohan DA, Haughton AJ, Hill MO, Osborne JL, Clark SJ, Perry JN, Rothery P, Scott RJ, Brooks DR, Champion GT, Hawes C, Heard MS, and Firbank LG. (2003) Invertebrates and vegetation of field margins adjacent to crops subject to contrasting herbicide regimes in the Farm Scale Evaluations of genetically modified herbicide-tolerant crops. *Philos Trans R Soc Lond B Biol Sci, 358*(1439), 1879-1898.
Rymer C, Hartnell GF, and Givens DI. (2011) The effect of feeding modified soyabean oil enriched with C18 : 4n-3 to broilers on the deposition of n-3 fatty acids in chicken meat. *British Journal of Nutrition, 105*, 866-878.
SANA. (2011download) Sales and Trends. Sales Data. Soyfoods Association of North America Retrieved from http://www.soyfoods.org/soy-information/sales-and-trends.
Sandretto C and Payne J (2008). Soil Management and Conservation. Submitted by K Wiebe and N Gollehon, Registration Manager. U.S. Department of Agriculture - Economic Research Service (See Table http://www.ers.usda.gov/publications/arei/eib16/eib16_4-2.pdf).
Sanvido O, Stark M, Romeis J, and Bigler F. (2006) Ecological Impacts of Genetically Modified Crops: Experiences from Ten Years of Experimental Field Research and Commercial

Cultivation. Zürich, Switzerland: Agroscope Reckenholz-Tänikon Research Station ART. Retrieved from
Sawyer JE. (2000) Dry fall leads to field fires. Iowa State University Extention. Retrieved IC-484(23), from http://www.ipm.iastate.edu/ipm/icm/2000/10-23-2000/dryfallfires.html.
Schlenker W and Roberts MJ. (2009) Nonlinear temperature effects indicate severe damages to U.S. crop yields under climate change. *Proceedings of the National Academy of Sciences, 106*(37), 15594-15598.
Scott WO and Aldrich SR. (1970) *Modern Soybean Production*. Cincinnati, OH: The Farm Quarterly.
Seed Certification Department. (2001) South Carolina Seed Certification Standards. Department of Fertilizer & Seed Certification Services of Clemson University. Retrieved from http://www.clemson.edu/public/regulatory/plant_industry/fertilizer_seed/images/SCertStandards.pdf.
Setiyono TD, Weiss A, Specht J, Bastidas AM, Cassman KG, and Dobermann A. (2007) Understanding and modeling the effect of temperature and daylength on soybean phenology under high-yield conditions. *Field Crops Research, 100*(2-3), 257-271.
Shaner DL, Lindenmeyer RB, and Ostlie MH. (2012) What have the mechanisms of resistance to glyphosate taught us? *Pest Management Science, 68*(1), 3-9.
Sharpe T. (2010) Cropland Management (*Chapter 4*). In, *Tarheel Wildlife: A Guide for Managing Wildlife on Private Lands in North Carolina* (pp. 26-29). MD Jones and JS Braden (Eds.). Raleigh: North Carolina Wildlife Resources Commission.
Singh E, Tiwari S, and Agrawal M. (2010) Variability in antioxidant and metabolite levels, growth and yield of two soybean varieties: An assessment of anticipated yield losses under projected elevation of ozone. *Agriculture, Ecosystems & Environment, 135*(3), 168-177.
Smith RG, Gross KL, and Robertson GP. (2008) Effects of crop diversity on agroecosystem function: Crop yield response. *Ecosystems, 11*, 355-366.
Smyth S and Phillips P. (2002a) Product differentiation alternatives: Identity preservation, segregation, and traceability. *AgBioForum, 5*(2), 30-42.
Smyth S and Phillips PWB. (2002b) Product Differentiation Alternatives: Identity Preservation, Segregation, and Traceability. *AgBioForum, 5*(2), 30-42.
Soil Survey Staff. (1999) Soil Taxonomy: A Basic System of Soil Classification for Making and Interpreting Soil Surveys. Riverdale, MD: United States Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html.
Soil Survey Staff. (2010) Keys to Soil Taxonomy. Riverdale, MD: United States Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html.
Sonka ST, Bender KL, and Fisher DK. (2004) Economics and Marketing (Chapter 19). In, *Soybeans: Improvement, Production, and Uses* (pp. 919-947). Madison, WI: American Society of Agronomy, Crop Science Society of America, Soil Science Society of America.
Soyatech. (2008) Soya and Oilseed Bluebook. Retrieved August 15, 2008 from http://72.32.142.180/oilseed_statistics.htm.

Soyatech. (2010) World Major Oilseeds: Area, Yield & Production by Main Producers 2003 - 2009. Retrieved November 29, 2010 from http://www.soyatech.com/bluebook_ref/statistics/html/T101.htm.

Soyconnection. (2011) Food and Fuel: Meeting the Challenges of Feeding the World and Creating Renewable Fuels. Retrieved March 14, 2011 from http://www.soyconnection.com/soybean_oil/pdf/foodvsfuel_soy_biofuels.pdf.

SoyStats. (2010a) Soybeans' Many Uses: Edible & Industrial. American Soybean Association. Retrieved November 30, 2010 from http://www.soystats.com/2010/page_06.htm.

SoyStats. (2010b) Top Ten U.S. Export Customers $ Million 2009. American Soybean Association. Retrieved November 30, 2010 from http://soystats.com/2010/page_27.htm.

SoyStats. (2010c) U.S. Soybean Meal Production 1984-2009. Retrieved March 23, 2011 from http://www.soystats.com/2010/page_19.htm.

SoyStats. (2010d) U.S. Soybean Oil Consumption 2009. Retrieved March 20, 2011 from http://www.soystats.com/2010/page_22.htm.

SoyStats. (2010e) U.S. Soybean Use by Livestock 2009. American Soybean Association. Retrieved March 23, 2011 from http://www.soystats.com/2010/page_19.htm.

SoyStats. (2010f) World Protein Meal Consumption 2009. American Soybean Association. Retrieved November 30, 2010 from http://www.soystats.com/2010/page_34.htm.

SoyStats. (2010g) World Soybean Exports 2009. American Soybean Association. Retrieved November 30, 2010 from http://soystats.com/2010/page_32.htm.

SoyStats. (2010h) World Soybean Production 2009. American Soybean Association. Retrieved November 30, 2010 from http://soystats.com/2010/page_30.htm.

Soystats. (2011a) Domestic Utilization. Meal Use by Livestock American Soybean Association Retrieved from http://www.soystats.com/2011/Default-frames.htm.

SoyStats. (2011b) A reference guide to important soybean facts and figures. Soy Stats. American Soybean Association. Retrieved from http://www.soystats.com/2011/Default-frames.htm.

Sprague C. (2006) Growing non-GMO soybeans: What do you need to know? Michigan State Crop and Soils Department. Retrieved 2011 from http://ipmnews.msu.edu/fieldcrop/fieldcrop/tabid/56/articleType/ArticleView/articleId/1884/categoryId/2/Growing-nonGMO-soybeans-What-do-you-need-to-know.aspx.

Squire GR, Brooks DR, Bohan DA, Champion GT, Daniels RE, Haughton AJ, Hawes C, Heard MS, Hill MO, May MJ, Osborne JL, Perry JN, Roy DB, Woiwod IP, and Firbank LG. (2003) On the rationale and interpretation of the Farm Scale Evaluations of genetically modified herbicide-tolerant crops. *Philosophical Transactions of the Royal Society of London. Series B: Biological Sciences, 358*(1439), 1779-1799.

Stanton JS, Steele GV, and Vogel JR. (2007) Occurrence of Agricultural Chemicals in Shallow Ground Water and the Unsaturated Zone, Northeast Nebraska Glacial Till, 2002-04. U.S. Department of the Interior. USGS Retrieved from http://pubs.usgs.gov/sir/2007/5228/pdf/sir2007-5228.pdf.

Starling S. (2011) Krill set for continued omega-3 stardom. William Reed Business Media. Retrieved from http://www.nutraingredients.com/content/view/print/394677.

Staton M and Warncke D. (2009) Fertilizing soybeans in Michigan. Michigan State University Integrated Pest Management Program Retrieved April 30, 2009 from http://ipmnews.msu.edu/fieldcrop/fieldcrop/tabid/56/articleType/ArticleView/articleId/179/categoryId/2/Fertilizing-soybeans-in-Michigan.aspx.

Stewart CN. (2008) Gene Flow and the Risk of Transgene Spread. University of Tennessee, Plant Molecular Genetics

Retrieved November 30, 2010 from http://agribiotech.info/details/Stewart-GeneFlow%20Mar%208%20-%2003.pdf

Stock D and Holloway PJ. (1993) Possible Mechanisms for Surfactant-Induced Foliar Uptake of Agrochemicals. *Pesticide Science, 38*, 165-177.

Sundstrom FJ, Williams J, Van Deynze A, and Bradford KJ. (2002) Identity Preservation of Agricultural Commodities. University of California, Division of Agriculture and Natural Resources. Retrieved Publication 8077, from http://anrcatalog.ucdavis.edu/pdf/8077.pdf.

TCM. (2008) Nightshade: Threat to Harvest and Export. Annex Publishing & Printing Inc. Retrieved November 29, 2010 from http://www.topcropmanager.com/content/view/2507/.

Torres JB and Ruberson JR. (2005) Canopy- and Ground-Dwelling Predatory Arthropods in Commercial Bt and non-Bt Cotton Fields: Patterns and Mechanisms. *Environmental Entomology, 34*(5), 1242-1256.

Twyman RM. (2003) Weeds: Herbicide Resistance. In, *In Encyclopedia of Applied Plant Sciences* (pp. 1516-1521). London, UK: Elsevier Science.

Tyson KS, Bozell J, Wallace R, Peterson E, and Moens L. (2004).Biomass Oil Analysis: Research Needs and Reco mmendations. Golden, CO. Last accessed from http://www.nrel.gov/docs/fy04osti/34796.pdf

UK. (2010) Specialty Soybeans. University of Kentucky Cooperative Extension Service, College of Agriculture. Retrieved from

UM. (2011) Some soybean insecticides labeled for control of soybean aphid. from University of Minnesota http://www.soybeans.umn.edu/crop/insects/aphid/aphid_insecticides.htm.

University of Connecticut. (2011) Dietary Recommendations for Omega-3 Fatty Acids. International Omega-3 Learning and Education Consortium for Health and Medicine. Retrieved from http://www.omega3learning.uconn.edu/info/what-are-omega-3-fatty-acids/dietary-recommendations-for-omega-3-fatty-acids/.

University of Illinois. (2006) No-till is now the "Conventional" Tillage System for Illinois Farmers Retrieved November 30, 2010 from http://web.extension.illinois.edu/state/newsdetail.cfm?NewsID=4991.

US-EPA. (1993a) R.E.D. Facts: Glyphosate. Washington, DC: U.S. Environmental Protection Agency, Prevention, Pesticides and Toxic Substances. Retrieved from

US-EPA. (1993b) Reregistration Eligibility Decision (RED): Glyphosate. Washington, DC: U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances. Retrieved from

US-EPA. (1996) 40 CFR Part 180 Plant Pesticide Inert Ingredient CP4 Enolpyruvylshikimate-3-D and the Genetic Material Necessary for Its Production in All Plants. *Federal Register, 61*(150), 40338-40340.

US-EPA (2004). Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency. Submitted by Registration Manager. U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs (See Table

US-EPA. (2005) Protecting Water Quality for Agricultural Runoff. (EPA 841-F-05-001).

US-EPA. (2007) Agricultural Sector Impacts. Chapter 8. Riverdale, MD: United States Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology

Regulatory Services. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html.
US-EPA. (2008) Risks of Glyphosate Use to Federally Threatened California Red-legged Frog (*Rana aurora draytonii*). Washington, DC: U.S. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division. Retrieved from
US-EPA. (2009) Soil Preparation. Environmental Protection Agency. Retrieved March 2011, from http://www.epa.gov/agriculture/ag101/cropsoil.html.
US-EPA (2010a). Agriculture (Chapter 6). Submitted by Registration Manager. United States Environmental Protection Agency (See Table http://www.epa.gov/climatechange/emissions/downloads10/508_Complete_GHG_1990_2008.pdf).
US-EPA. (2010b) Basic Information - Air Emission Sources. Retrieved March 2011, from http://www.epa.gov/air/emissions/basic.htm.
US-EPA. (2010c) National Ambient Air Quality Standards (NAAQS). Retrieved March 2011, from http://www.epa.gov/air/criteria.html.
US-EPA. (2011a) Agricultural Burning. Retrieved October 12, 2011 from http://www.epa.gov/agriculture/tburn.html.
US-EPA. (2011b) Particulate Matter (PM-2.5) 2006 Standard Nonattainment Area/State/County Report Retrieved 2011 from http://www.epa.gov/airquality/greenbk/rnca.html#5081.
US-FDA. (1996) Biotechnology Consultation Note to the File BNF No. 000039. Retrieved February 4, 2011 from http://www.fda.gov/food/biotechnology/submissions/ucm161157.htm.
US-FDA. (1998) Use of Antibiotic Resistance Marker Genes in Transgenic Plants (*Draft Guidance*). Retrieved November 30, 2010 from http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096135.htm.
US-FDA. (2004).Letter Responding to Health Claim Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003Q-0401). U.S. Food and Drug Administration, Last accessed from http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072932.htm
US-FDA. (2009a).Agency Response Letter GRAS Notice No. GRN 000283. U.S. Food and Drug Administration, Washington, D.C. Last accessed from http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm185688.htm
US-FDA. (2009b).GRAS Notice for Stearidonic (SDA) Omega-3 Soybean Oil. Center for Food Safety and Applied Nutrition (CFSAN)

U.S. Food and Drug Administration, Washington, D.C. Last accessed from http://www.accessdata.fda.gov/scripts/fcn/gras_notices/grn000283.pdf
US-FDA. (2011) Generally Recognized as Safe (GRAS). Retrieved September 30, 2011 from http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/default.htm.
US-FWS. (2011) Species Reports - Listings and Occurrences for Each State. Retrieved May 25, 2011 from http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp.

US-NARA. (2010a) Executive Orders Disposition Tables Index. United States National Archives and Records Administration. Retrieved January 31, 2011 from http://www.archives.gov/federal-register/executive-orders/disposition.html.
US-NARA. (2010b) Executive Orders disposition tables index. United States National Archives and Records Administration. Retrieved March 11, 2010 from http://www.archives.gov/federal-register/executive-orders/disposition.html.
US Census Bureau. (2007) Soybean processing. Census Bureau. Retrieved from http://www.census.gov/econ/industry/hierarchy/i311222.htm.
US Census Bureau (2008). Fats and Oils: Oilseed Crushings - Summary 2007 and 2006. Submitted by Registration Manager. (See Table http://academicarchive.snhu.edu/bitstream/handle/10474/958/m311j0713.pdf?sequence=1).
US Census Bureau. (2009a) 2007 Economic Census, Sector 31: Manufacturing: Industry Series: Products Statistics for the United States: 2007 , Fats and Oils: Oilseed Crushings. Retrieved 7/21/11, from http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-_skip=100&-ds_name=EC0731I2&-_lang=en.
US Census Bureau. (2009b) 2007 Economic Census. American Factfinder. Sector 31: Manufacturing: Industry Series. Retrieved from
USB. (2010a) Animal Agriculture Economic Analysis: 1999-2009. United Soybean Board. Retrieved from http://unitedsoybean.org/images/uploads/multimedia/National_Animal_Agriculture_Economic_Analysis_2010.pdf.
USB. (2010b) A Survey of Recent Chemical Price Trends: The Potential Impact of Rising Petrochemical Prices on Soy Use for Industrial Applications. OMNI TECH, Prepared for the *United Soybean Board*. Retrieved from
USB. (2011a) Food and Fuel: Meeting the challenge of feeding the world and creating renewable fuels. United Soybean Board

Retrieved from http://www.soyconnection.com/soybean_oil/pdf/foodvsfuel_soy_biofuels.pdf.
USB (2011b). Online Market View Database. Domestic Data 2008/2009. Submitted by US Board, Registration Manager. (See Table http://usb.adayana.com:8080/usb/reports/domestic_data.jsp).
USB. (2011c) Soyfoods Guide 2011. United Soybean Board. Retrieved from http://www.soyconnection.com/soyfoods/pdf/soyfoods_guide.pdf.
USDA-AMS. (2010) National Organic Program. Agricultural Marketing Service, United States Department of Agriculture. Retrieved November 23, 2010 from http://www.ams.usda.gov/AMSv1.0/nop
USDA-APHIS. (1997) DuPont Petition 97-008-01p for determination of nonregulated status for transgenic High Oleic Acid soybean sublines G94-1, G94-19, and G-168. 97. Retrieved June, 2010 from http://www.aphis.usda.gov/brs/aphisdocs2/97_00801p_com.pdf.
USDA-APHIS. (2010a) Monsanto Company and KWS SAAT AG Supplemental Request for Partial Deregulation of Sugar Beet Genetically Engineered to be Tolerant to the Herbicide Glyphosate (*Draft EA*). Riverdale, MD: US Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services. Retrieved from

USDA-APHIS. (2010b) Pioneer Hi-Bred International High Oleic Soybean DP-305432-1, Final Environmental Assessment. Riverdale, MD: US Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services. Retrieved from

USDA-APHIS. (2010c) Plant Pest Risk Assessment for MON 87769 Soybean. Riverdale, MD: APHIS - Animal and Plant Health Inspection Service. Retrieved from http://www.aphis.usda.gov/biotechnology/not_reg.html.

USDA-APHIS. (2010d) Syngenta Biotechnology, Inc. Petition (07-108-01p) for Determination of Nonregulated Status for Lepidopteran-Resistant Event COT67B Cotton "Draft Environmental Assessment". Riverdale, MD: U.S. Department of Agriculture, Animal and Plant Health Inspection Service. Retrieved from

USDA-ARS. (2008a) National Program 304: Crop Protection & Quarantine Action Plan. Retrieved February 3, 2011 from http://www.ars.usda.gov/research/programs/programs.htm?np_code=304&docid=355&page=14.

USDA-ARS. (2008b) USDA National Nutrient Database for Standard Reference, Release 21. Retrieved November 29, 2010 from http://www.ars.usda.gov/main/site_main.htm?modecode=12-35-45-00.

USDA-ERS. (2006a) Soybean Backgrounder. U.S. Department of Agriculture, Economic Research Service. Retrieved from

USDA-ERS (2006b). Soybean Production Costs and Returns Per Planted Acre, by Region, Excluding Government Payments. Submitted by Registration Manager. Developed from the *2006 Agricultural Resource Management Survey* of Soybean Producers (See Table

USDA-ERS. (2008) Soybeans and Oil Crops: Market Outlook. Economic Research Service. Retrieved January 21, 2011 from http://www.ers.usda.gov/briefing/soybeansoilcrops/2008baseline.htm.

USDA-ERS. (2009) Cotton: Background. Retrieved November 2, 2010 from http://www.ers.usda.gov/Briefing/Cotton/background.htm.

USDA-ERS. (2010a) Adoption of Genetically Engineered Crops in the U.S. Retrieved November 29, 2010 from http://www.ers.usda.gov/data/biotechcrops/.

USDA-ERS. (2010b) Adoption of Genetically Engineered Crops in the U.S. - Soybeans Varieties. Retrieved November 29, 2010 from http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable3.htm.

USDA-ERS. (2010c) Agricultural Chemicals and Production Technology: Soil Management. Retrieved November 29, 2010 from http://www.ers.usda.gov/briefing/agchemicals/soilmangement.htm.

USDA-ERS (2010d). Data Sets. Organic Production. State Level Tables. Submitted by TCO Beans., Registration Manager. USDA Economic Research Service (See Table http://www.ers.usda.gov/Data/Organic/).

USDA-ERS. (2010e) Soybean and Oil Crops: Background. Retrieved December 7, 2010 from http://www.ers.usda.gov/Briefing/SoybeansOilcrops/background.htm.

USDA-ERS. (2010f) Table 3--Certified Organic and Total U.S. Acreage, Selected Crops and Livestock, 1995-2008. Economic Research Service. Retrieved November 5, 2010 from http://www.ers.usda.gov/Data/Organic/.

USDA-ERS. (2011a) Adoption of Genetically Engineered Crops in the U.S. Genetically Engineered Soybean Varieties. Retrieved from http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable3.htm

USDA-ERS. (2011b) Oil Crops Outlook. Retrieved March 13, 2011 from http://usda.mannlib.cornell.edu/usda/current/OCS/OCS-03-11-2011.pdf.

USDA-FAS. (2008) Table 31: Vegetable Oil Prices US Dollars per Metric Ton. USDA-Foreign Agricultural Service. Retrieved from http://usda.mannlib.cornell.edu/usda/fas/oilseed-trade/2000s/2008/oilseed-trade-03-01-2008.pdf.

USDA-FAS. (2011) Oilseeds: World Markets and Trade. USDA Foreign Agricultural Service. Approved by the World Agricultural Outlook Board/USDA. Retrieved from http://www.fas.usda.gov/psdonline/circulars/oilseeds.pdf.

USDA-FS. (2003).Glyphosate – Human Health and Ecological Risk Assessment Final Report. Syracuse Environmental Research Associates, Inc., Fayetteville, NY. Last accessed from

USDA-NASS. (1997) Usual Planting and Harvesting Dates for U.S. Field Crops - December 1997. USDA - National Agricultural Statistics Service. Retrieved from http://www.nass.usda.gov/Publications/Usual_Planting_and_Harvesting_Dates/uph97.pdf.

USDA-NASS. (2006) Agricultural Chemical Usage 2005 Field Crops Summary. U.S. Department of Agriculture, National Agricultural Statistics Service. Retrieved November 30, 2010 from http://usda.mannlib.cornell.edu/usda/nass/AgriChemUsFC//2000s/2006/AgriChemUsFC-05-17-2006.pdf.

USDA-NASS. (2007a) 2007 Census of Agriculture: Grain and Oilseed Farming. National Agricultural Statistics Service. Retrieved from

USDA-NASS. (2007b) Agricultural Chemical Usage 2006 Field Crops Summary. Retrieved from http://usda.mannlib.cornell.edu/usda/nass/AgriChemUsFC//2000s/2007/AgriChemUsFC-05-16-2007_revision.pdf.

USDA-NASS. (2007c).Table 33. Specified Crops by Acres Harvested: 2007 and 2002. Last accessed from http://www.agcensus.usda.gov/Publications/2007/Full_Report/Census_by_State/index.asp

USDA-NASS. (2009).2007 Census of Agriculture U.S. Department of Agriculture - National Agricultural Statistics Service, Washington, DC. Last accessed from http://www.agcensus.usda.gov/Publications/2007/Full_Report/index.asp

USDA-NASS. (2010a) Crop Production. Soybean. National Agricultural Statistics Service. Retrieved 2011 from http://usda.mannlib.cornell.edu/usda/nass/CropProd//2010s/2010/CropProd-10-08-2010.pdf.

USDA-NASS. (2010b).Table 29. Selected Crops Harvested by Chemigation and Water Source: 2008 and 2003. 2007 Census of Agriculture. Farm and Ranch Irrigation Survey. . Washington, DC. Last accessed from http://www.agcensus.usda.gov/Publications/2007/Online_Highlights/Farm_and_Ranch_Irrigation_Survey/fris08_1_29.pdf

USDA-NASS. (2010) Table 27. Crops Harvested from Irrigated Farms: 2008 and 2003. Soybeans for Beans. . Retrieved from http://www.agcensus.usda.gov/Publications/2007/Online_Highlights/Farm_and_Ranch_Irrigation_Survey/fris08_1_27.pdf.

USDA-NASS. (2010e) Crop Production. National Agricultural Statistics Service. Retrieved November 5, 2010 from http://usda.mannlib.cornell.edu/usda/nass/CropProd//2010s/2010/CropProd-10-08-2010.pdf.

USDA-NASS. (2011a).Acreage. Washington, DC. Last accessed 9-29-2011, from http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-30-2011.pdf

USDA-NASS. (2011b).USDA Long-Term Agricultural Projection Tables. Table 24: U.S. soybeans and soybean products long-term projections Washington, DC. Last accessed 9-30-2011, from http://usda.mannlib.cornell.edu/MannUsda/viewStaticPage.do?url=http://usda.mannlib.cornell.edu/usda/ers/94005/./2011/index.html

USDA-NASS_Wisconsin-Field-Office. (2009 download) 2006 Soybean Production Practices. USDA NASS, Wisconsin. Retrieved from http://www.nass.usda.gov/Statistics_by_State/Wisconsin/Publications/Miscellaneous/chemuse_soybeans_06.pdf.

USDA-NRCS. (2006a) Conservation Resource Brief: Air Quality, Number 0605. National Resources Conservation Service. Retrieved November 9, 2010 from http://www.nrcs.usda.gov/feature/outlook/Air%20Quality.pdf.

USDA-NRCS. (2006b) Conservation Resource Brief: Soil Erosion, Number 0602. National Resources Conservation Service. Retrieved November 9, 2010 from http://www.nrcs.usda.gov/feature/outlook/Soil%20Erosion.pdf.

USDA-NRCS. (2006c) Conservation Resource Brief: Soil Quality, Number 0601. National Resources Conservation Service. Retrieved November 9, 2010 from http://www.nrcs.usda.gov/feature/outlook/Soil%20Quality.pdf.

USDA-OCE (2012). USDA Agricultural Projections to 2021. Submitted by Registration Manager. USDA, Office of the Chief Economist, World Agricultural Outlook Board (See Table http://usda.mannlib.cornell.edu/usda/ers/94005/2011/OCE111.pdf).

USSEC. (2006) Biotechnology, IP Soybeans, Soyfoods, and Industrial Uses (Chapter 6). U.S. Soybean Export Council. Retrieved March 9, 2011 from http://ussec.org/ussoy/buyersguide/Chap6.pdf.

UW-Extension. (2004) Including a small grain in the corn-soybean rotation: Production economics of small grains.

UW-Extension. (2008) Wisconsin Soybean Variety Test Results. University of Wisconsin – Madison. Departments of Agronomy and Plant Pathology. Retrieved from http://soybean.uwex.edu/soytrials/printable/documents/2008WISoybeanReport.pdf.

Vogel JR, Majewski MS, and Capel PD. (2008) Pesticides in rain in four agricultural watersheds in the United States. *J Env Qual, 37*(3), 1101-1115.

Wallaces Farmer. (2010) 2011 Vistive Low-Linolenic Soybean Program Announced. Retrieved 7-16-2011, from http://wallacesfarmer.com/story.aspx/2011-vistive-lowlinolenic-soybean-program-announced-44648.

Warnemuende EA, Pattersona JP, Smitha DR, and Huanga C-H. (2007) Effects of tilling no-till soil on losses of atrazine and glyphosate to runoff water under variable intensity simulated rainfall *Soil and Tillage Research*

95(1-2), 19-26.

Warner RE, Havera SP, and David LM. (1985) Effects of Autumn Tillage Systems on Corn and Soybean Harvest Residues in Illinois. *The Journal of Wildlife Management, 49*(1), 185-190.

Wijendran V and Hayes KC. (2004) Dietary n-6 and n-3 Fatty Acid Balance and Cardiovascular Health. *Annual Review of Nutrition, 24*(1), 597-615.

Wilcox JR and Cavins JF. (1992) Normal and Low Linolenic Acid Soybean Strains: Response to Planting Date. *Crop Sci., 32*(5), 1248-1251.

Wilkes RS. (2008) Low linolenic soybeans and beyond. *Lipid Technology, 20*(12), 277-279.

Wilson EO. (1988) *Biodiversity*. Washington, DC: National Academy Press.

Wolfenbarger L, Naranjo SE, Lundgren JG, Bitzer RJ, and Watrud LS. (2008) Bt Crop Effects on Functional Guilds of Non-Target Arthropods: A Meta-Analysis. *PLoS ONE 3*(5), 1-11.

Wood D, Setubal J, Kaul R, Monks D, Kitajima J, Okura V, Zhou Y, Chen L, Wood G, Almeida N, Woo L, Chen Y, Paulsen I, Eisen J, Karp P, Bovee S, Chapman P, Clendenning J, Deatherage G, Gillet W, Grant C, Kutyavin T, Levy R, Li M, McClelland E, Palmieri A, Raymond C, Rouse G, Saenphimmachak C, Wu Z, Romero P, Gordon D, Zhang S, Yoo H, Tao Y, Biddle P, Jung M, Krespan W, Perry M, Gordon-Kamm B, Liao L, Kim S, Hendrick C, Zhao Z, Dolan M, Chumley F, Tingey S, Tomb J, Gordon M, Olson M, and Nester E. (2001) The genome of the natural genetic engineer *Agrobacterium tumefaciens* C58. *Science, 294*(5550), 2317-2323.

Woodruff J, Whitaker J, Prostko E, Roberts P, Kemerait R, Smith N, Smith A, Sumner P, Harrison K, and Harris G. (2010) Soybean Weed Control. University of Georgia College of Agriculture and Environmental Sciences. Retrieved from http://www.caes.uga.edu/commodities/fieldcrops/soybeans/documents/Compiled2010SoybeanProductionGuide.pdf.

Woznicki K. (2005) Kellogg Replaces Trans Fat with Genetically Modified Soybean Oil. Retrieved January 22, 2011 from http://www.medpagetoday.com/tbprint.cfm?tbid=2317.

WSSA. (2010) WSSA supports NRC findings on weed control. Weed Science Society of America. Retrieved June 16 2010, from http://www.wssa.net/.

Yoshimura Y, Matsuo K, and Yasuda K. (2006) Gene flow from GM glyphosate-tolerant to conventional soybeans under field conditions in Japan. *Environmental Biosafety Research, 5*(3), 169-173.

Zapiola ML, Campbell CK, Butler MD, and Mallory-Smith CA. (2008) Escape and establishment of transgenic glyphosate-resistant creeping bentgrass Agrostis stolonifera in Oregon, USA: a 4-year study. *Journal of Applied Ecology, 45*(2), 486-494.

Zhang LX, Kyei-Boahen S, Zhang J, Zhang MH, Freeland TB, Watson CE, Jr. , and Liu XM. (2007) Modifications of optimum adaptation zones for soybean maturity groups in the USA. Plant Management Network. Retrieved Online, from http://www.plantmanagementnetwork.org/pub/cm/research/2007/zone/.

Zhou YY, Luo SH, Yi TS, Li CH, Luo Q, Hua J, Liu Y, and Li SH. (2011) Secondary Metabolites from Glycine soja and Their Growth Inhibitory Effect against Spodoptera litura. *J Agric Food Chem, 59*(11), 6004-6010.

Zollinger R. (2010) ND Weed Control Guide. North Dakota State University. Retrieved November 30, 2010 from http://www.ag.ndsu.edu/weeds/weed-control-guides/nd-weed-control-guide-1.

9 APPENDIX A: FDA SUSBSTANCES GENERALLY RECOGNIZED AS SAFE (GRAS) – AGENCY RESPONSE LETTER GRAS NOTICE NO. GRN 000283

Agency Response Letter GRAS Notice No. GRN 000283

CFSAN/Office of Food Additive Safety

September 4, 2009

Raymond C. Dobert, Ph.D.
Monsanto Company
800 North Lindbergh Blvd
St. Louis, MO 63167

Re: GRAS Notice No. GRN 000283

Dear Dr. Dobert:

The Food and Drug Administration (FDA) is responding to the notice, dated February 25, 2009, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on February 26, 2009, filed it on March 3, 2009, and designated it as GRAS Notice No. GRN 000283.

The subject of the notice is stearidonic acid (SDA) soybean oil. The notice informs FDA of the view of Monsanto Company (Monsanto) that SDA soybean oil is GRAS, through scientific procedures, for use as an ingredient in baked goods and baking mixes, breakfast cereals and grains, cheeses, dairy product analogs, fats and oils, fish products, frozen dairy desserts and mixes, grain products and pastas, gravies and sauces, meat products, milk products, nuts and nut products, poultry products, processed fruit juices, processed vegetable products, puddings and fillings, snack foods, soft candy, and soups and soup mixes, at levels that will provide 375 milligrams (mg) of SDA per serving.[1]

21 CFR 101.4 states that all ingredients must be declared by their common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for nonstandardized foods. Our use of "SDA soybean oil" in this letter should not be considered an endorsement or recommendation of that term as an appropriate common or usual name for the purpose of declaring the substance in the ingredient statement of foods that contain that ingredient. Issues associated with labeling and the appropriate common or usual name of a food are the responsibility of the Office of Nutrition, Labeling, and Dietary Supplements (ONLDS) in the Center for Food Safety and Applied Nutrition.

As part of its notice, Monsanto includes the report of a panel of individuals (Monsanto's GRAS panel) who evaluated the data and information that are the basis for Monsanto's GRAS determination. Monsanto considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. Monsanto's GRAS panel evaluated estimates of dietary exposure, method of production, and product specifications. as well as published studies. Based on this review, Monsanto's GRAS panel concluded that SDA soybean oil that meets its established food grade specifications is GRAS under the conditions of its intended use.

Monsanto describes the identity of SDA soybean oil. The oil is obtained from a bioengineered soybean. Monsanto states that SDA soybean oil is compositionally different from conventional soybean oil. SDA soybean oil contains 15 to 30 percent SDA and 5 to 8 percent *gamma*-linolenic acid (GLA), neither of which is present in conventional soybean oil. SDA soybean oil also contains slightly higher levels of *alpha*-linolenic acid (ALA) and palmitic acid than conventional soybean oil. SDA soybean oil contains lower levels of oleic acid and linoleic acid (LA) than those present in conventional soybean oil. Monsanto notes that the variability in the oil's fatty acid composition, notably the SDA concentration, is due to natural variation in growing conditions for the soybean.

Monsanto discusses the biosynthetic pathway of SDA in the bioengineered soybean. SDA biosynthesis involves the introduction of two desaturase genes that encode for the proteins *Primula juliae delta* 6-desaturase and *Neurospora crassa delta* 15-desaturase. Conventional soybeans lack *delta* 6-desaturase; *delta* 6-desaturase is required for the production of SDA in soybeans. Addition of the *delta* 15-desaturase with temporal expression similar to the *delta* 6-desaturase increases the flux of ALA to SDA. The *delta* 15-desaturase also lowers LA levels, thus lowering the substrate pool for GLA production. Monsanto notes that the introduced desaturases are the only non-soybean genes expressed in the bioengineered soybean.[2]

SDA soybean oil is processed using conventional industry standard processing methods. The soybean meat is first mechanically separated from the hulls. The resulting soybean meat is then flaked and solvent extracted with iso-hexane/hexane to yield crude soybean oil and soybean meal. The crude oil is degummed and bleached, and further purified through filtration and steam distillation. Anti-oxidants, primarily TBHQ, are added at the end of processing to inhibit oxidation of the oil. All processing aids used in the manufacture of SDA soybean oil are used in compliance with appropriate federal regulations.

Monsanto states that stability of SDA soybean oil was determined with respect to peroxide value and fatty acid content. SDA soybean oil maintains a peroxide value similar to that of conventional soybean oil under similar storage conditions. Monsanto notes that SDA oil is stable when stored under nitrogen, as is typical for soybean oil, for as long as nine months.

Monsanto provides specifications for SDA soybean oil with comparison to the specifications set forth in the Food Chemicals Codex (FCC), 6th Edition, for conventional soybean oil. Specifications include fatty acid composition, stability, limits for free fatty acids (< 0.1 percent), lead (< 0.1 milligrams/kilogram), peroxide value (< 10 milliequivalents/kilogram), unsaponifiable matter (< 1.5 percent), and water (< 0.1 percent).

Monsanto estimates the *per capita* consumption of SDA soybean oil from all intended food uses using the intended use levels in conjunction with food consumption data included in the

National Health and Nutrition Examination Surveys (1999-2002). The current intake of fat, *trans*-fat, and fatty acids in the diet as well as intake following the addition of 20 or 30 percent SDA soybean oil to the intended food uses was calculated. SDA soybean oil was either added to foods or used as a replacement for unhydrogenated oil (including soybean oil, 'not further specified' oil, corn oil, cottonseed oil, peanut oil, sunflower oil, coconut oil, olive oil, canola oil, or palm oil). Monsanto notes that in order to achieve 375 milligrams SDA per serving of food, target foods need to have 1.8 g of 20 percent SDA soybean oil or 1.3 grams of 30 percent SDA soybean oil per serving of food.

Monsanto estimates, on a *per capita* basis, mean and 90th percentile intakes of 20 percent SDA soybean oil to be 10.1 and 19.6 grams per day (g/day), respectively (0.18 and 0.38 grams per kilogram body weight per day (g/kg bw/day), respectively). Monsanto also estimates *per capita* mean and 90th percentile intakes of 30 percent SDA soybean oil to be 7.6 and 14.8 g/day, respectively (0.10 and 0.30 g/kg bw/day, respectively). Monsanto estimates the *per capita* mean and 90th percentile intakes of SDA to be 2.1 g/day and 4.1 g/day, respectively. Estimated intakes of SDA were similar for 20 or 30 percent SDA soybean oil due to the constant use level of SDA per serving.

Monsanto discusses the known biochemical pathways through which SDA soybean oil is metabolized after absorption into the body. The fatty acids (FA) of SDA soybean oil may undergo *beta*-oxidation to produce acetyl-CoA, or they may be elongated to form long chain fatty acids such as eicosapentaenoic acid (EPA). Monsanto describes published studies that discuss the FA elongation conversion rate in humans as being as high as 3:1 SDA to EPA; this equates to 0.73 g/day at the mean, and 1.4 g/day at the 90th percentile for the intended food uses.

Monsanto discusses published animal studies for SDA soybean oil, in which rats received up to 4 g/kg bw/day; no toxicologically significant effects were observed. Monsanto also cites other published animal studies where rats, guinea pigs, and dogs consumed SDA oil derived from sources other than soybean at up to 2.1 g/kg bw/day with no toxicologically significant effects observed. In addition, no reproductive or developmental effects were seen in a published study in which rats received up to 4 g/kg bw/day. Furthermore, Monsanto describes a published study in humans where SDA soybean oil, consumed at 3.66 g/d for 16 weeks, did not affect physiological or blood chemistry endpoints. Other published studies in which humans consumed SDA oil derived from non-soybean sources, showed no adverse effects at levels up to 1.875 g/day.

Standards of Identity

In the notice, Monsanto states its intention to use SDA soybean oil in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA), a food is misbranded if its labeling is false or misleading in any particular. Section 403(r) of the FFDCA lays out the statutory framework for the use of labeling claims that characterize the level of a nutrient in a food or that characterize the relationship of a nutrient to a disease or health-related condition. In describing the intended use of SDA soybean oil and in describing the information that Monsanto relies on to conclude that SDA soybean oil is GRAS under the conditions of its intended use, Monsanto raises a potential issue under these labeling provisions of the FFDCA. If products that contain SDA soybean oil bear any claims on the label or in labeling, such claims are the purview of ONLDS. The Office of Food Additive Safety neither consulted with ONLDS on this labeling issue nor evaluated the information in your notice to determine whether it would support any claims made about SDA soybean oil on the label or in labeling.

Allergen Labeling

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) amends the FFDCA to require that the label of a food that is or contains an ingredient that bears or contains a "major food allergen" declare the presence of the allergen (section 403(w)). FALCPA defines a "major food allergen" as one of eight foods or food groups (i.e., milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) or a food ingredient that contains protein derived from one of those foods. Issues associated with labeling food are the responsibility of ONLDS.

Use in Meat, Poultry, and Egg Products

During its evaluation of GRN 000283, FDA consulted with the Risk and Innovations Management Division of the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, FSIS is responsible for determining the efficacy and suitability of food ingredients in meat, poultry, and egg products as well as prescribing safe conditions of use. Suitability relates to the effectiveness of the ingredient in performing the intended purpose of use and the assurance that the conditions of use will not result in an adulterated product, or one that misleads consumers.

FSIS requested that FDA advise Monsanto to seek regulatory guidance from FSIS about the use of SDA soybean oil in meat and poultry products. Monsanto should direct such an inquiry to Dr. John M. Hicks, Jr., Risk and Innovations Management Division, Office of Policy and Program Development, Food Safety and Inspection Service, United States Department of Agriculture, George Washington Carver Center (GWCC), 5601 Sunnyside Ave., Mailstop 5271, Beltsville, MD 20705-5271. The telephone number for that office is (391) 504-0884 and the telefax number is (301) 504-0876.

Section 301(ll) of the FFDCA

The Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amends the FFDCA to, among other things, add section 301(ll). Section 301(ll) of the FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FFDCA, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In its review of Monsanto's notice that SDA soybean oil is GRAS for use in certain foods, FDA did not consider whether section 301(ll) or any of its exemptions apply to foods containing SDA soybean oil. Accordingly, this response should not be construed to be a statement that foods that contain SDA soybean oil, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information provided by Monsanto, the agency has no questions at this time regarding Monsanto's conclusion that SDA soybean oil is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of SDA soybean oil. As always, it is the continuing responsibility of Monsanto to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter responding to GRN 000283, as well as a copy of the information in this notice that conforms to the information in the GRAS exemption claim (proposed 21 CFR 170.36(c)(1)), is available for public review and copying via the FDA home page at http://www.fda.gov. To view or obtain an electronic copy of the text of the letter, follow the hyperlinks from the "Food" topic to the "Food Ingredients and Packaging" section to the "Generally Recognized as Safe (GRAS)" page where the GRAS Inventory is listed.

Sincerely,

Mitchell A. Cheeseman, Ph.D.
Acting Director
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition

cc: John M. Hicks, Jr. DVM, MPH
Risk and Innovations Management Division
Office of Policy and Program Development
Food Safety and Inspection Service
United States Department of Agriculture
George Washington Carver Center (GWCC)
5601 Sunnyside Ave., Mailstop 5271
Beltsville, MD 20705-5271

[1]Reference amounts customarily consumed (21 CFR 101.12)

[2]Monsanto states that *Neurospora crassa* is considered a non-pathogenic organism and is found in foods worldwide. Monsanto also notes that *Primula juliae* is a member of the *Primula* (Primrose) genus that includes plants that are commonly used as sources of GLA for human uses.

10 APPENDIX B: APHIS THREATENED AND ENDANGERED SPECIES DECISION TREE FOR FWS CONSULTATIONS

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

This decision tree document is based on the phenotypes (traits) that have been field tested under APHIS oversight (for a list of approved field tests, visit Information Systems for Biotechnology.) APHIS will re-evaluate and update this decision document as it receives new applications for field testing of new traits that are genetically engineered into plants.

BACKGROUND

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

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

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

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

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

1) Is the transgenic plant sexually compatible with a TE plant[2] without human intervention?

2) Are naturally occurring plant toxins (toxicants) or allelochemicals increased over the normal concentration range in parental plant species?

3) Does the transgene product or its metabolites have any significant similarities to known toxins[3])?

4) Will the new phenotype(s) imparted to the transgenic plant allow the plant to be grown or employed in new habitats (e.g., outside agro-ecosystem)[4]?

5) Does the pest resistance[5] gene act by one of the mechanisms listed below? If the answer is **YES** then a consultation with U.S. Fish and Wildlife Service is **NOT** necessary.

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

      As a structural barrier to either the attachment of the pest to the host, to penetration of the host by the pest, to the spread of the pest in the host plant (e.g., the production of lignin, callose, thickened cuticles);

      In the plant by inactivating or resisting toxins or other disease causing substances produced by the pest;

      By creating a deficiency in the host of a component required for growth of the pest (such as with fungi and bacteria);

---

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

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

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

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

By initiating, enhancing, or potentiating the endogenous host hypersensitive disease resistance response found in the plant;

In an indirect manner that does not result in killing or interfering with normal growth, development, or behavior of the pest;

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

For the biotechnologist:

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

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

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

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

11 APPENDIX C: PETITION FOR THE DETERMINATION OF NONREGULATED STATUS FOR MON 87769 – ADDENDUM: POTENTIAL MARKET IMPACT OF MON 87769

Petition for the Determination of Nonregulated Status for MON 87769

ADDENDUM

Potential Market Impact of MON 87769

Submitted July 1st, 2011

OECD Unique Identifier: MON-87769-7

Monsanto Petition Number: 09-183-01p

Introduction

Monsanto has developed biotechnology-derived soybean MON 87769 (SDA soybean) that contains stearidonic acid (SDA), a sustainable alternate source of an omega-3 fatty acid to help meet the need for increased dietary intake of long chain omega-3 fatty acids. In mammals, SDA is a metabolic intermediate in the production of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) from alpha linolenic acid (ALA), a common dietary constituent. Refined oil produced from MON 87769 contains approximately 20 to 30% SDA (wt% of total fatty acids) and can be included in a range of food products for health benefits. The oil from MON 87769 (SDA soybean oil) is Generally Recognized As Safe (GRAS) in the United States and can be used for the production of products such as margarine, shortenings, salad dressings, ready-to-eat foods, and other food categories specified in the GRAS notification[6].

MON 87769 is a specialty trait soybean, not developed for the commodity soybean market, and it is anticipated that MON 87769 will be a low acreage product planned initially for production in North America. In bringing this product to market, Monsanto will adhere to the Biotechnology Industry Organization's (BIO's) Product Launch Stewardship policy[7], including its Annex 2: "Specialty Use Traits in Commodity Crops."

Market and Trade Assessment:

Monsanto has evaluated the potential impacts from the introduction of MON 87769 into the marketplace. This assessment which is hereafter referred to as 'market and trade assessment' has taken into consideration the potential impacts which could be anticipated within the value chain due to the introduction of SDA soybean. The defatted soybean meal from MON 87769 is compositionally similar to other commodity defatted soybean meal and will be used in a manner similar to commodity soybean meal. The oil derived from MON 87769, however, has a unique fatty acid profile and will be identity preserved to maintain its value and assure its use in appropriate food applications. Compared to commodity soybean oil, SDA soybean oil contains two additional fatty acids, SDA and GLA. SDA soybean oil is intended for use only in certain markets. The presence of this oil in markets where it is not intended could result in potential market and trade impacts.

At the time SDA soybean oil is first introduced to the market, we do not expect that MON 87769 will have approvals in all key soybean export markets with functioning regulatory systems. Until such approvals are received, MON 87769 will be grown and handled in a closed loop stewardship system (CLSS).

---

[6] http://www.accessdata.fda.gov/scripts/fcn/gras_notices/grn000283.pdf

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

Monsanto will utilize and implement the CLSS throughout the initial product introduction phase, at least until approvals are received from key soybean export countries with functioning regulatory systems. After such approvals are received, Monsanto will, based on the experiences and learning gained during the initial product introduction phase under the CLSS, refine and update the stewardship system for long-term implementation. This long-term system will include measures to preserve the identity of this high value product and mitigation measures to minimize any impact resulting from the inadvertent comingling of SDA soybeans or oil with commodity or other specialty soybean products.

This document describes the intended uses for SDA soybean oil, current processes for handling vegetable oils, and potential impacts to commodity soybean oil as well as other vegetable oils from the commercial introduction of SDA soybean oil. This document also describes the CLSS which Monsanto will implement during the initial phase of the product introduction.

2. Intended Uses SDA Soybean

MON 87769 is a sustainable source of omega-3 fatty acid for food use. SDA has fewer double bonds than other omega-3 fatty acids such as EPA (20:5) and DHA (22:6). Therefore, SDA soybean oil is more stable to oxidation (i.e., less prone to fishy or rancid odors and taste) compared to other oils containing EPA or DHA, thereby expanding the potential formulation options for food companies and consumers. SDA soybean oil is generally recognized as safe in the United States[8].

SDA is a metabolic precursor to the long chain omega-3 fatty acids, EPA and DHA, in humans and animals and is found in products such as fish and fish/algal oils. Although the benefits of omega-3 fatty acid consumption are widely recognized, typical Western diets contain very little fatty fish, while at the same time current foods and supplements provide limited alternatives to satisfy consumer demand for long chain omega-3 fatty acids. An alternative approach to increase omega-3 fatty acid intake is to provide a wider range of foods that are enriched in omega-3 fatty acids so that people can choose foods that suit their usual dietary habits. Human and animal studies have shown that 1 g dietary SDA is approximately equivalent to 200 - 300 mg dietary EPA in terms of increasing tissue concentrations of EPA. Thus, MON 87769 can serve as an alternate source of an omega-3 fatty acid to help meet the need for increased dietary intake of long chain omega-3 fatty acids in food. SDA soybean oil can be used for the production of margarine, shortenings, salad dressings, ready-to-eat foods, and other food categories described in the GRAS notification[9]. The use of SDA soybean oil in selected food categories could provide a wide range of dietary alternatives for increasing omega-3 fatty acid intake.

---

[8] http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm185688.htm

[9] http://www.accessdata.fda.gov/scripts/fcn/gras_notices/grn000283.pdf

Given the targeted commercial application of SDA soybean as an alternate source of omega-3 fatty acids in food it is anticipated that MON 87769 will be a low acreage product planned initially for production in North America. The oil derived from MON 87769, however, has a unique fatty acid profile and will be identity preserved to maintain its value and assure its use in appropriate food applications. The co-product, soybean meal, derived from MON 87769 has been shown to be compositionally comparable to other commodity soybean meal and will be used in a manner similar to commodity soybean meal.

As a food ingredient, SDA soybean oil uses would be limited to those applications that demonstrate (1) functional suitability for incorporation into food products, (2) acceptable sensory properties (no off-flavors or bad taste) to the food, and (3) appropriate stability profile and shelf life of food products containing SDA soybean oil during food production and storage. As expected, SDA soybean oil from MON 87769 contains high levels of SDA (approximately 20-30 wt% of total fatty acids). Vegetable oils containing high levels of polyunsaturated fatty acids (PUFUs) like SDA are known to undergo rapid oxidation during frying applications and will impart undesirable taste and odor to the fried foods. Therefore, SDA soybean oil will not be suitable for all food applications and may not be suitable as a substitute for saturated fats in food recipes. However, SDA soybean oil can partially replace commodity soybean oil or other oils in many food categories. As is the case with fish oils, containing omega-3 fatty acids, hydrogenation of SDA-containing oil would be without purpose, as hydrogenation would eliminate the benefits of long chain polyunsaturated fatty acids (LCPUFAs). Thus, hydrogenation is not applicable to SDA soybean oil from MON 87769. The current anticipated food applications for SDA soybean oil are in baked goods and baking mixes, breakfast cereals and grains, cheeses, dairy product analogs, fats and oils, fish products, frozen dairy desserts and mixes, grain products and pastas, gravies and sauces, milk products, nuts and nut products, poultry products, processed fruit juices, processed vegetable products, puddings and fillings, snack foods, soft candy, and soups and soup mixes[10].

3. Market Potential of SDA Soybean

Consumer demand for long chain omega-3 fatty acids through food and supplements is expected to continue to grow. As of 2008, the United States omega-3 ingredient market for marine oils was estimated at 26,447 metric tons (MT) per year, with 13.8% of that volume being consumed in functional foods. Furthermore, the projected average annual growth rate for this industry between 2008 and 2013 is 13.4% (Strategic Analysis of the North American Marine and Algae Oil Omega-3 Ingredients Market, Frost & Sullivan, March 2010[11]). The value added product derived from MON 87769 is SDA soybean oil. SDA soybean oil provides increased alternatives

[10] FDA Food classifications 21 CFR §170.3(n).

[11] http://www.frost.com/prod/servlet/report-brochure.pag?id=N73E-01-00-00-00

for food companies to formulate omega-3 fatty acids into a wider range of foods. Because SDA soybean oil can be used in wider food categories, Monsanto estimates, for the purposes of this analysis that the industry growth of omega-3 oils in functional foods could increase by 26.6%. For the purposes of this analysis, Monsanto assumed that SDA soybean oil could capture 100% of that incremental growth, which, given market dynamics, may over estimate the demand for this oil. SDA soybean oil will typically contain 20% SDA, the expected relative conversion of SDA to EPA in humans is estimated at about 5:1 and marine oils in average may contain about 30% long chain omega-3 fatty acids (James et al., 2003 and Lemke et al., 2010). As a result, it is expected that about 7.5 times the volume of SDA soybean oil might be needed to satisfy the EPA equivalent amount currently provided by other marine oils. Under such a scenario, and assuming this growth is sustained at that constant level through 2016 the incremental amount of SDA soybean oil needed to satisfy that 26.6% industry growth would be approximately 20,000 MT. Furthermore, assuming an average oil yield of 0.2 MT/acre for soybean, this would equate to around 100,000 acres per year of SDA soybean needed to be grown to satisfy the U.S. demand for SDA soybean oil derived from MON 87769. It is foreseeable that global market demands for omega-3 containing foods may augment the U.S. soybean acres grown with MON 87769 for the purposes of SDA soybean and/or SDA soybean oil exports. The United States is the largest producer of soybeans and regularly exports soybean and soybean products to global markets. In 2010 approximately 75 million acres of soybean crop was grown in the U.S. producing approximately 87 million MT of soybeans.

4. Stewardship of SDA Soybean

Monsanto is committed to product stewardship[12] and adhere to the BIO Product Launch Stewardship Policy[13]. In compliance with BIO's Product Launch Stewardship Policy, Monsanto considered Annex 2 “Special Use Traits in Commodity Crops” to develop launch plans for SDA soybean including: (1) identifying relevant stakeholders for the trait and crop and engaging them in dialogue and outreach regarding use of SDA soybean, (2) conducting a market and trade assessment to evaluate the potential impact from the introduction of MON 87769 to the market place, and (3) implementing a closed loop stewardship system to direct MON 87769 and derived products to their proper channels and developing a risk mitigation plan.

4.1. Stakeholder Dialogue and Outreach

Monsanto is committed to dialogue with key industry stakeholder groups and has held several meetings with the National Oil Processors Association (NOPA) as well as other key industry associations such as the North American Export Grain Association (NAEGA), National Grain

[12] http://www.monsanto.com/ourcommitments/pages/product-stewardship.aspx

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

and Feed Association (NGFA), National Agri-Marketing Association (NAMA), American Bakers Association (ABA), and Grocery Manufacturers Association (GMA). Soybean grower organizations consulted include: American Soybean Association (ASA), United States Soybean Board (USB), and many state soybean associations. Additionally, Monsanto has kept QUALISOY, a collaborative program sponsored by USB that serves as an independent third party resource for information on trait-enhanced soybean oils, informed of the plans for this product, along with dietary and nutrition thought leaders. Monsanto continues to have conversations with, and considers the input of several soybean and food industry key stakeholders regarding the oil composition, stewardship plan and performance of MON 87769 oil.

Monsanto has been marketing specialty Vistive low linolenic soybeans to growers since 2005. As grower and market demand for this specialty soybean product has grown, we have continued to work with processors to assure adequate testing methods and quality processes are applied to assure that the commodity soybean supply stream is not impacted. At a minimum, the same outreach, education, and quality principles will be applied as we further develop SDA soybean stewardship and commercialization plan. These quality systems are described in the following sections.

4.2 Market and Trade Assessment

Approximately 85 million MT of soybeans are produced in the U.S. annually and the U.S. is a leading exporter of soybean, soybean meal and soybean oil to global markets. Approximately 12% of soybean grown is specialty soybean produced for a specific market or use[14]. These soybean varieties are specified by buyers and end-users of soybean for production, and premiums are paid for delivering a product that meets purity and quality standards of that soybean variety. The specialty, value-added, product may be the whole soybean or, in the case of MON 87769, a processed fraction such as the oil. Product differentiation and market segmentation in the specialty soybean industry includes mechanisms to keep track of the soybean (traceability), methods for identity preservation (IP), including closed-loop stewardship systems, and quality assurance processes (e.g., ISO9001-2000 certification), as well as contracts between growers and buyers that specify delivery agreements within product specifications.

Monsanto has conducted a market and trade assessment to anticipate and consider the potential impacts within the value chain from the introduction of SDA soybean, and to commodity soybean oil as well as other vegetable oil in the market place. Soybean is a globally traded commodity with the U.S. being the top global producer[15]. Biotechnology-derived crops are

---

[14] http://usb.adayana.com:8080/usb/jsp/login.jsp. Percent U.S. Soybean acreage estimate based on U.S. Domestic Consumption by Segment – 2008/09. D. Ludwig, personal communication, 2009.

[15] http://www.soyatech.com/oilseed_statistics.htm

subject to regulation in many countries. In order to support free trade in soybean, Monsanto is pursuing regulatory approval for MON 87769 and any stacked products intended for commercialization in all key soybean export countries with a functioning regulatory system. International regulatory authorities are evaluating the food and feed safety of MON 87769 as well as the processed fractions derived from MON 87769. It is expected that uses of SDA soybean oil would be similar on a global basis. Defatted soybean meal from MON 87769 is similar to commodity soybean meal and therefore it can be comingled with commodity soybean meal upon gaining regulatory approval from all key soybean export countries that have functioning regulatory systems.

The stewardship system will be designed to prevent the comingling of SDA soybean or oil with commodity products. The market and trade assessment supports the conclusion that in the unlikely event that comingling of SDA soybean or oil in the commodity stream did occur, the impact would be minimal. Sections 4.2.1, 4.2.2 and 4.2.3 below discuss in detail the potential impacts of inadvertent comingling of SDA soybean, oil, and meal with commodity soybean, oil, and meal in the market place and show that any such comingling would have only minimal impact to current soybean and vegetable oil markets. As discussed earlier, the SDA soybean and oil are for a specialty market and are not meant to be part of the commodity chain. The comingling scenarios and impacts are presented as worst case situations. Oilseed processors and users of vegetable oils are accustomed to the presence of numerous vegetable oils that are currently available for various food applications. The comingling levels where an impact would occur could only happen if there were a major deviation in the system which is highly unlikely as routine analytical methods are in place. Additionally, there is economic motivation, legal contracts, standard operating procedures (seed quality to end user), and demonstrated competency handling other vegetable oils of similar fatty acid profiles.

4.2.1 Potential Impact to Commodity Soybean in the Market Place

The impact from comingling was assessed based on the following , scenario: An inadvertent unloading of a truck containing 100% SDA soybean into the commodity stream at an elevator or processor where the event goes unnoticed. This scenario was chosen because it represents a “worst case” situation. This is unlikely to occur because a farmer producing SDA soybeans is financially motivated to identity preserve the SDA soybean from commodity soybean during harvest to realize the premium paid upon delivery. Further, comingling can be identified via routine fatty acid analysis or QC checks before the oil is shipped from the processing facility. All soybean oil is analyzed by gas chromatography (GC) to determine the fatty acid profile prior to shipping. This information is placed on the “Certificate of Analysis” (CofA) accompanying the shipment. Any commingling of commodity oil with SDA soybean oil should be identified prior to loading for export shipment, which minimizes commingled oil arriving at an exporting country.

For the purposes of this analysis, the following assumptions were made: the load limit on roads in most soybean producing states is 80,000 lbs gross weight. The empty weight of most semi trucks is at or below 35,000 lbs, leaving a load capacity of 45,000 lbs (the difference). At 60 lbs per bushel, a standard semi truck will haul less than 800 bushels of soybeans. Thus, this commingling scenario assumes 800 bushels of SDA soybean commingled with commodity soybean.

Upon processing of the comingled soybeans, 800 bushels of SDA soybeans would yield approximately 8000 lbs of refined SDA soybean oil. The capacity of the smallest soybean oil holding tank at U.S. processing plants is approximately 200,000 lbs. Thus the accidental comingling of the truck load of SDA soybean will result in a 25X dilution of SDA soybean oil in a 200,000 lb tank of commodity soybean oil. In this situation, 8000 lbs of 20% SDA soybean oil will be diluted to 200,000 lb resulting in a final SDA concentration of 0.8% SDA in commodity soybean oil. The presence of 0.8% SDA in commodity soybean oil will have no impact to human health because the oil has been through the food safety assessment[16]. Impacts to food labeling and oil performance are discussed in Section 4.2 of this document.

Another scenario would involve delivery of 800 bushels of SDA soybean to a grain elevator. In this case**,** the SDA soybean would be diluted with commodity soybean in a grain storage bin that typically holds 100,000 to 500,000 bushels of soybean, resulting in 125X to 625X dilution of SDA soybean in commodity soybean. The commodity soybean oil produced from this comingling scenario will only have SDA ranging from 0.03% to 0.16% of total fatty acids.

Soybeans are exported as whole beans or as processed fractions. Soybean oil is commonly exported via cargo ships in containers with a capacity of approximately 40,000 lbs. These oil filled containers are transferred from the cargo ships to trucks at the importing ports. If a container of SDA soybean oil unintentionally ends up in a port where it is not suppose to be, it can be identified and diverted back to the country of origin or to another importing country. Due to the CofA and the high value of the product, the chance of SDA in soybean oil entering into the export market unintentionally is very small.

Commodity soybean shipped for export are typically loaded into unit trains (360,000 bushels) or barges (50,000 bushels/barge) that eventually are loaded into 2 million bushel ocean going vessels. Before a ship loaded with commodity soybean reaches a destination country, the inadvertent delivery of a truck containing 800 bushels would be mixed and diluted within 2 million bushels. The amount of SDA soybean in the vessel would be less than 0.04% of the total amount, or 2500X dilution. The soybean oil produced from this commingled soybean will have

[16] http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm185688.htm

SDA at level below 0.008% of total fatty acids, which is the more than six time below the CODEX limit of quantitation for fatty acids in vegetable oil (0.05%).

4.2.2 Potential Impact to Commodity Soybean Meal in the Market Place

Monsanto provided information to USDA in the petition demonstrating that the composition of the meal from MON 87769 is equivalent to meal derived from conventional soybean and safe and wholesome for food or feed applications as commodity soybean meal. Defatted SDA soybean meal contains approximately 1% residual oil. According to the National Oil Processors Association defatted soybean meal should contain a minimum of 0.5% oil to meet quality standards and guidelines for soybean meal from domestic and international shipping (NOPA, 2006). With the exception of the presence of minor amounts of the PjΔ6D and NcΔ15D proteins and *de minimis* amounts of residual oil, the soybean meal and other non-oil processed fractions used for animal feed and human food applications are unchanged from commodity processed soybean fractions. Upon receiving regulatory approval for MON 87769 in all major soybean export countries, SDA soybean meal can be comingled with commodity soybean meal in the market place. Therefore no trade impact is anticipated from the commingling of SDA soybean meal with commodity soybean meal.

4.2.3 Potential Impact to Commodity Soybean Oil in the Market Place

Monsanto has assessed the impact due to the presence of SDA soybean oil on commodity and other vegetable oils.

Areas of potential impact identified include the following: (1) food ingredient labeling, (2) nutritional facts panel labeling (3) functionality of the oil, and (4) sensory evaluation. This assessment has been shared with key stakeholders such as NOPA, NAEGA, ASA, QUALISOY, USB and GMA.

Food Ingredient Labeling:

The impact due to the presence of SDA soybean oil in commodity soybean oil from the perspective of soybean oil ingredient labeling was considered. SDA soybean oil contains two additional fatty acids (SDA and GLA) that are not present in commodity soybean oil. Therefore, we evaluated the potential impact to food ingredient labeling if SDA soybean oil was inadvertently present in the soybean oil that is added to food.

The U.S. Food and Drug Administration requires that all ingredients present in a food to be declared with a few exceptions. Although the regulations do not explicitly define “ingredient” they do discuss a class of “incidental additives” that are not considered ingredients and yet can be present in a food. An “incidental additive” is exempt if, according to the regulations, it is present at “insignificant levels” and has no “technical or functional effect” in a food[17]. Residual product from a previous soybean oil processing run may occasionally be mixed into a different product in a new run. Such residual product would fit the concept of “incidental additive”[18] and need not be included on the label. Thus, the unintended presence of insignificant amounts of SDA soybean oil in soybean oil is tolerated under the food label laws and should not impact the ingredient labeling of soybean oil or foods containing such oil.

Nutrition Facts Panel Labeling:

The FDA requires that information on fats to be declared on the nutrition facts panel of foods. They are (1) total fat, (2) trans fat, and (3) saturated fat. It is voluntary for a food company to list the amounts of monounsaturated fat and polyunsaturated fat on the nutrition facts panel. The nutrition facts panel of SDA soybean oil will be similar to commodity soybean oil because the total fat, saturated fat and trans fat content of SDA soybean oil is similar to commodity soybean oil. Many vegetable oil providers voluntarily list also monounsaturated and polyunsaturated fatty acids present in the oil. Since in SDA soybean oil one polyunsaturated fatty acid (LA) is replaced with two other (SDA and GLA) polyunsaturated fatty acids; the impact of comingling on nutrition facts panel labeling from listing mono and polyunsaturated fatty acid is negligible. Even though bottled SDA soybean oil is not an intended use at this time, a worst case assessment using 100% commodity soybean oil was considered to assess the potential impact of SDA soybean oil comingling with commodity soybean oil on nutritional facts panel labeling of bottled soybean oil. Table 1 shows the amount of SDA soybean oil that would be needed to be comingled with commodity bottled soybean oil in order to significantly impact the nutrition facts panel for major fatty acids on bottled soybean oil. Based on this analysis even 25% of SDA soybean oil comingled with commodity soybean oil will not significantly impact the nutritional facts panel label for soybean oil. This example illustrates that any incidental presence of SDA soybean oil in commodity soybean oil will not have any impact on the nutritional labeling of soybean oil or SDA soybean oil containing food products. Figure 1 shows the typical nutrition facts panel for commodity soybean oil (100 % soybean oil) and a theoretical nutrition facts panel for SDA soybean oil.

---

[17] 21 CFR § 101.100

[18]21 CFR § 101.100(3)i

Table 1. Impact of Comingling SDA Soybean Oil with Commodity Soybean Oil on Nutritional Facts Panel Labeling for Bottled Soybean Oil

Major Fatty Acids	SBO[1]	SDA SBO	1% SDA SBO in SBO	5% SDA SBO in SBO	10% SDA SBO in SBO	25% SDA SBO in SBO
Saturated Fat (g)	2.11	2.27	2.11	2.12	2.13	2.15
Polyunsaturated Fat (g)	8.35	9.05	8.36	8.38	8.42	8.52
Monounsaturated Fat (g)	3.19	2.15	3.18	3.14	2.98	2.93

[1]SBO=Soybean Oil

Note: The impact of mixing SDA soybean oil (SDA SBO) on nutritional facts labeling for bottled soybean oil (SBO) is depicted in the table above. The impact to nutritional facts panel labeling was assessed at various percentages of SDA soybean oil mixed with commodity soybean oil.

14 g serving size and FCC rounding rules applied. GLA and SDA included in polyunsaturated fatty acid calculation. Mono and polyunsaturated fatty acid labeling is voluntary. No change in trans fat.

Figure 1. Nutrition Facts Panel for Commodity Soybean Oil and Theoretical Nutrition Facts Panel for SDA Soybean Oil

100% Soybean Oil

Nutrition Facts

Serving Size (14g)
Servings Per Container

Amount Per Serving	
Calories 120	Calories from Fat 120
	% Daily Value*
Total Fat 14g	**22**%
Saturated Fat 2g	**10**%
Trans Fat 0g	
Polyunsaturated Fat 8g	
Monounsaturated Fat 3.5g	
Cholesterol 0mg	**0**%
Sodium --mg	**--**%
Total Carbohydrate 0g	**0**%
Dietary Fiber 0g	**0**%
Sugars 0g	
Protein 0g	
Vitamin A --%	• Vitamin C --%
Calcium --%	• Iron --%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Saturated Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

100% SDA Soybean Oil

Nutrition Facts

Serving Size (14g)
Servings Per Container

Amount Per Serving	
Calories 120	Calories from Fat 120
	% Daily Value*
Total Fat 14g	**22**%
Saturated Fat 2.5g	**13**%
Trans Fat 0g	
Polyunsaturated Fat 9g	
Monounsaturated Fat 2.5g	
Cholesterol 0mg	**0**%
Sodium --mg	**--**%
Total Carbohydrate 0g	**0**%
Dietary Fiber 0g	**0**%
Sugars 0g	
Protein 0g	
Vitamin A --%	• Vitamin C --%
Calcium --%	• Iron --%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Saturated Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

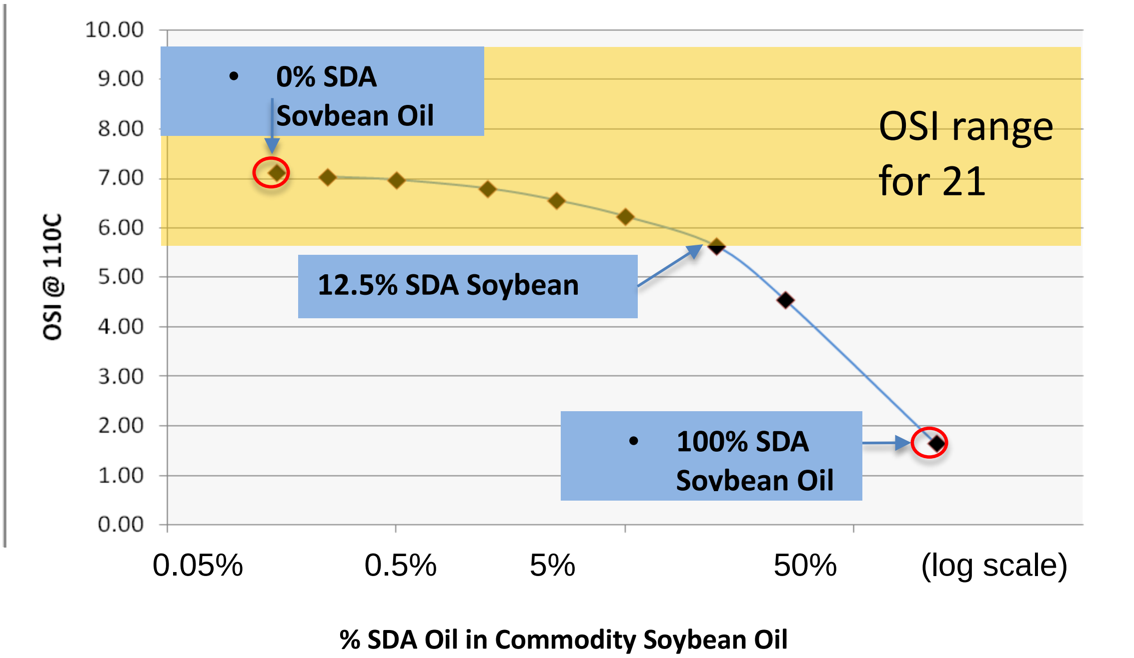
Note: Nutrition facts panel generated using Genesis SQL R&D software (© 2011 ESHA Research), the same as used typically by food companies. Commodity soybean oil exists in the database. SDA soybean oil's typical fatty acid composition was utilized to develop a theoretical nutrition facts panel.

Oil Functionality:

<u>Oxidative Stability</u> Monsanto conducted an assessment of the impact of the oxidative stability of commodity soybean oil comingled with SDA soybean oil. Figure 2 demonstrates that comingling of SDA soybean oil with commodity soybean oil decreases the Oxidative Stability Index (OSI) of commodity soybean oil. The OSI stability index is an indicator of soybean oil stability. All oils and fats have a resistance to oxidation, which depends on the degree of saturation, antioxidant and pro-oxidant concentration, and prior abuse. Oxidation is slow until this resistance is overcome, at which point oxidation accelerates and becomes more rapid. The length of time prior to the acceleration of oxidation is referred to as the 'induction period,' and the point of maximum rate change is referred to as the OSI, and is reported in hours. The oxidative stability of soybean oil is significantly influenced by the proportion of monounsaturates to polyunsaturates.

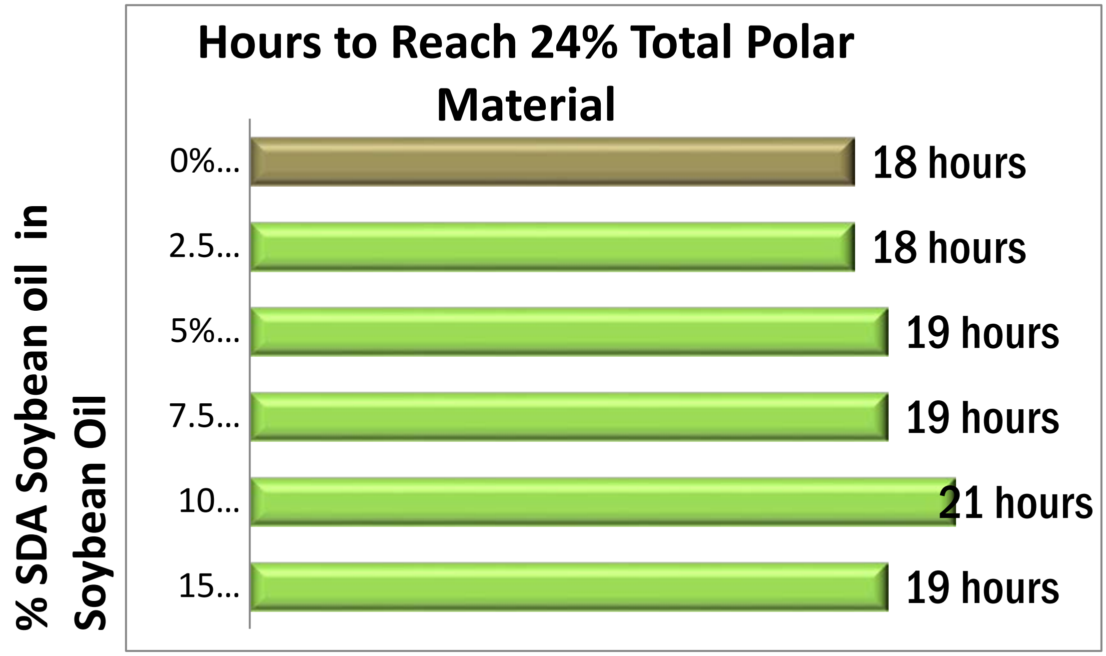
To assess the impact of comingling on the OSI, the OSI of 21 commercially available soybean oil as well as blends of commodity soybean oil with SDA soybean oil were evaluated. Commodity/SDA soybean oil blends were prepared in duplicate (wt./wt.) using SDA soybean oil in retail salad oil (soybean oil) obtained from a local St. Louis market. Neither oils contained added antioxidants. SDA soybean oil used for preparing the blends contained 22.9% of SDA (%wt of total fatty acid). Oil Stability Index measurements were obtained on an Omnion OSI instrument at 110^{o}C using AOCS Official Method Cd 12b-92. OSI was run in duplicate for each blend sample, and means were averaged to obtain the data points shown. Target blend accuracy in the commodity/SDA soybean oil blends was confirmed by fatty acid composition determined using capillary gas chromatographic (GC) analysis (data not shown). The "Commercial soy" range shown in Figure 2 represents 21 unstabilized salad oils that were obtained at retail markets in St. Louis over a 3 year period and analyzed for OSI within 2 weeks of purchase. Oils were selected with 'best by...' dates of 6 to 24 months from date of purchase. The OSI values of these oils ranged from 5.63 to 9.68 with a median value of 6.66. SDA soybean oil is estimated to have decreased oxidative stability compared to conventional soybean oil (Figure 2). Based on this study it is reasonable to conclude that minor levels of SDA will not impact the OSI index of commodity soybean oil. At comingling levels of 12.5% of SDA soybean oil in commodity soybean oil, the OSI index falls below the range observed for commercial soybean oils.

Figure 2. Oxidative Stability Index (OSI) of SDA Soybean Oil Blended with Commodity Soybean Oil



Heat Treatment Vegetable oils containing high levels of PUFA are known to undergo rapid oxidation during frying applications and are known to impart undesirable taste and odor to the fried foods. SDA soybean oil contains relatively high levels of PUFAs compared to other vegetable oils, and therefore, is not intended for frying applications. However, as part of the evaluation of the potential impact of SDA soybean oil on the functional properties of commodity soybean oil, the influence of SDA soybean oil on the ability of fry oil to withstand heat treatment was determined. From a practical standpoint, commercial fryers use the level of polar materials formed during frying as a measure of oxidation and to determine the fry life of oil. Total polar material values are often used to determine when the oil has deteriorated to a point where the oil can no longer be used (Ortheofer and List, 2007). When the polar material reaches the threshold level of 24%, the oil is typically discarded and fresh oil is used. Polar compounds are byproducts that are generated as the oil degrades in quality. A common means of measuring total polar material in oils is by the use of the Ebro Food Oil Meter (Ebro International, Lino Lakes, MN). As oil degrades during frying, there is an increase in the polar materials that affect the dielectric constant of the oil. Measurements are taken of the fry oil throughout the length of the fry study to determine when the oil has reached 24% total polar material (TPM), which typically indicates the need to discard the oil. Figure 3 shows the time in hours that it took for each SDA soybean oil/commodity soybean oil blend to reach 24% TPM during frying. The results indicate within the range of blends tested the level of SDA soybean oil had minimal impact on the formation of total polar materials in the oil.

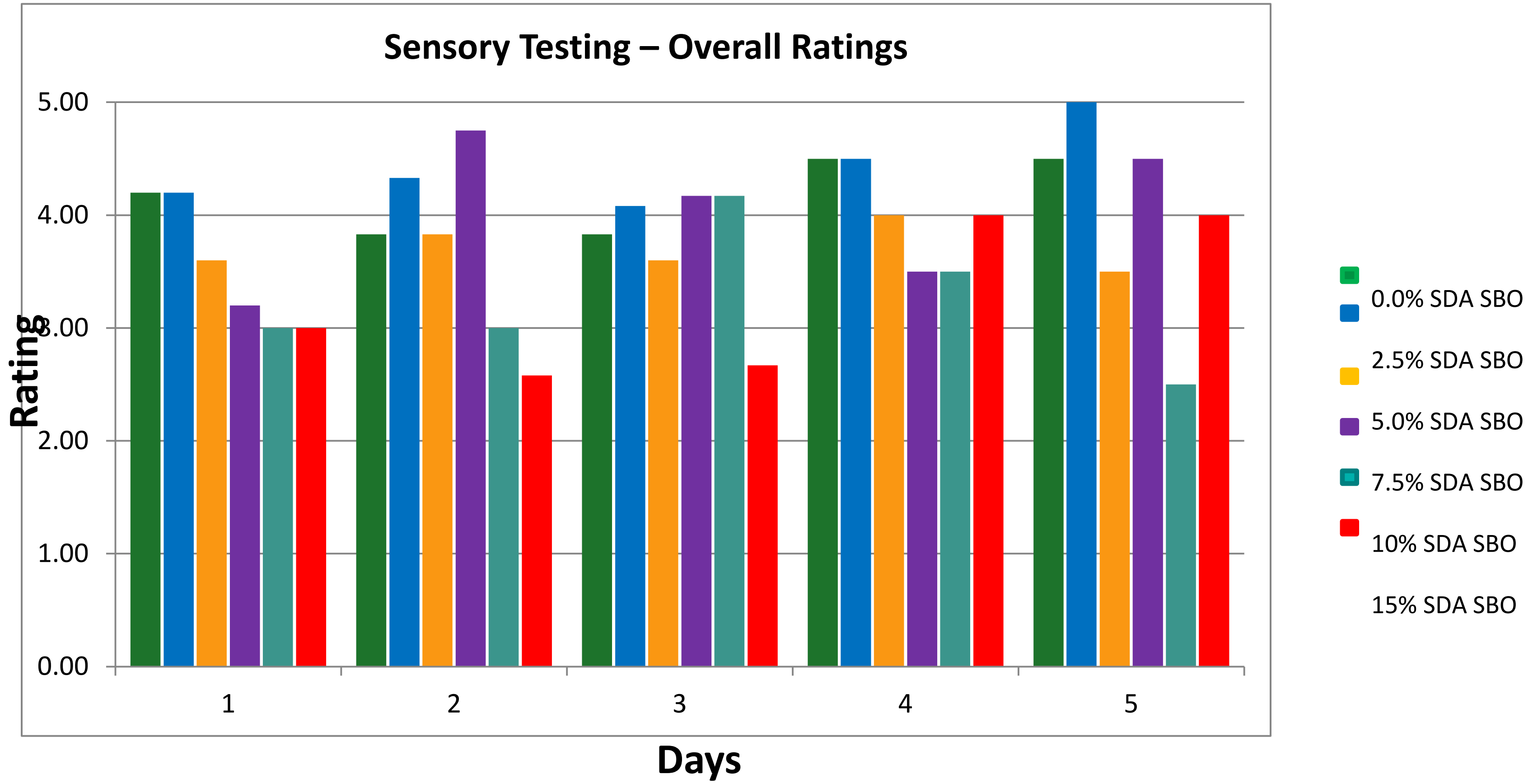
Figure 3. Hours to Reach 24% Total Polar Material During Frying Application of Soybean Oil Containing Varying Amounts of SDA SoybeanOil



Food Sensory Assessment:

A sensory assessment of SDA soybean oil was performed to evaluate consumer acceptability of SDA soybean oil. Sensory assessment has concluded that the sensory attributes of SDA soybean oil is comparable to commodity soybean oil. Even though SDA soybean oil is not intended for frying application, sensory results for SDA soybean oil in the most challenging environment of high temperature food frying applications was evaluated as a worst case scenario. To determine the impact SDA soybean oil on the quality of foods prepared from blends of SDA soybean oil and commodity soybean oil, french fries were prepared. The five oil blends (ranging from 2.5 to 15% SDA soybean oil) and commodity soybean oil were heated continuously for over 40 hours. During this time, batches of french fries were cooked in each of the oil samples and one batch each day of frying was evaluated for the difference in sensory properties from a control (100% commodity oil) using the Sensory Quality System method (King et al., 2002). Each panelist was provided a control fry and test fry and asked to rate the overall quality score (overall difference) along with the differences in individual French fry attributes. A rating of 5 indicates no difference, 4 slight difference, 3 difference, 2 significant difference and 1 extremely different. Figure 4 shows the results from this study. The outcome from the sensory evaluation showed that up to 15% of SDA soybean oil can be comingled with commodity soybean oil without impacting the flavor perception of fried food (Figure 4).

Figure 4. Sensory Results from Frying Applications of Soybean oil Containing Varying Amounts of SDA Soybean Oil.



Ratings: 5 = No Difference; 0 = Completely different

The market and trade assessment has concluded that in the unlikely event comingling did occur, the impact to labeling and functionality of commodity soybean oil would be minimal. Monsanto will have an appropriate stewardship plan in place to direct MON 87769 and oil to its intended markets, both in its initial commercial phase when produced and used under CLSS as well as longer-term.

4.3 Risk Mitigation Plan

4.3.1 Stewardship Plan for MON 87769 - Closed Loop Stewardship System

To mitigate potential impacts to commodity soybean, a Closed Loop Stewardship System (CLSS) has been developed to support the commercialization of SDA soybean prior to obtaining approvals in key soybean export markets with functioning regulatory systems. The CLSS defines procedures and processes relevant to the production, handling, and processing of all stewarded materials generated within the closed loop. Stewarded materials include viable soybean seed and grain, meal, hulls, oil, and downstream co-products derived from the crude oil that are in direct control of Monsanto, its licensees or partners, and their customers. Monsanto will continue to utilize the CLSS through the initial product introduction phase until necessary global approvals are received from key soybean export countries with functioning regulatory systems. After the approvals are received, Monsanto will refine and update the stewardship system for long-term implementation based on the experience developed during the introduction phase and in consultation with key stakeholders.

Under the CLSS, Monsanto will develop and implement best practices and systems consistent with the Excellence Through Stewardship[19] initiative. Monsanto will carefully evaluate capabilities of partners and downstream entities to contain downstream products to their intended market(s) and include terms and conditions in agreements with those partners or entities. These agreements will require that appropriate quality management systems (QMS), including both quality assurance (QA) and quality control (QC), are in place to manage and verify containment of all stewarded materials in countries of production and use.

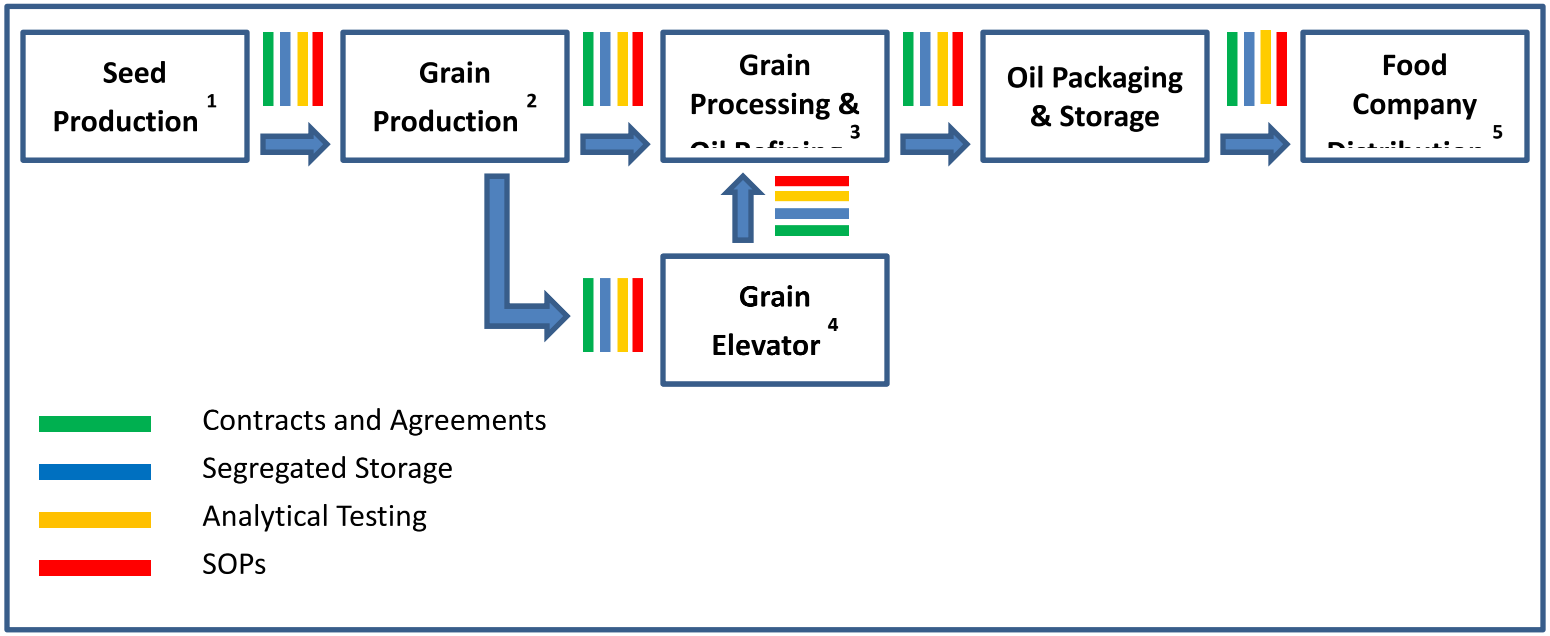
Monsanto will only work with downstream partners that have proven traceability, identity preservation, and CLSS production capabilities. Monsanto, its licensees, partners and processors will implement an annual auditing process for material under their control. Commercial production of soybean seed for planting and harvested soybean and the subsequent processing or manufacturing of stewarded end use products requires strict adherence to established processes under the CLSS to ensure each material is handled and used appropriately. If any part of the process is contracted out to a third party, Monsanto will require a Stewardship Management Plan

[19] Excellence Through Stewardship (ETS) is an initiative to promote the global adoption of stewardship programs and quality management systems for the full life cycle of biotechnology-derived plant products.

that meets CLSS standards. Monsanto reserves the right to audit these plans directly or through a third party.

Activities under the CLSS are organized into five relevant sections identifying critical control points: (1) Production of SDA Soybean Seed for Planting, (2) Production of SDA Soybean for Processing, (3) SDA Soybean Processing and Oil Refining, (4) SDA Soybean Oil Packaging and Storage, and (5) SDA Soybean Oil Distribution to Food Company Supply Chain. The information presented in each section describes the purpose, scope, and procedures necessary to conduct and verify the proper handling and use of all relevant materials under the CLSS.

Figure 5. Parts of the Closed Loop Stewardship System and Critical Control Points



[1] Monsanto contracts approximately 1 M acres of soybean seed production each year produced under ISO 9000 Standards

[2] Contract production with processor – on farm storage and segregation – analysis of grain upon delivery to processor or grain elevator

[3] Grower delivers to a processor, on-site segregated storage, analytical testing conducted

[4] Grower delivers to elevator, analytical testing methods on-site, elevator holds soybeans until called by processor

[5] Food Co handles multiple vegetable oil ingredients, segregated storage, formulation supported by analytical methods, SOP's in place to assure product quality

The requirements and processes for activities at each of these control points under a CLSS are consistent with Monsanto stewardship guidelines. These guidelines include processes to prevent commingling with commodity soybean seed, soybean, and oil (e.g. isolation, equipment cleaning and segregated storage). All Monsanto and non-Monsanto personnel involved with producing material under the CLSS are required to follow these guidelines and requirements.

Detection Methods Monsanto has developed event-specific detection methods to detect the MON 87769 event in articles of commerce including soybean seed, harvested soybean, soybean meal and oil. More importantly, Monsanto has developed analytical methods to assess the fatty acid profile for SDA soybean oil as well as detect the presence of SDA in vegetable oil. Monsanto will provide these methods to the industry upon request. Oil processors and downstream distributors are accustomed to using oil analysis methods during their normal course of business. Fatty acid profile analyses of soybean oil are considered routine within the industry.

Production of SDA Soybean Seed for Planting:

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

The first step in production of SDA soybean is the production, processing and delivery of high quality parent seed to the grower. Monsanto's seed manufacturing organization uses specific SOPs and documentation forms to ensure compliance with Monsanto stewardship and compliance standards. The entire seed production process at the majority of the seed companies and tollers operates using International Organization for Standardization[20] (ISO) certification standards and include internal and external audits (ISO, 2009). By following ISO quality standards it is possible to validate that the processes are followed which have been designed to generate the desirable characteristics of seeds and services such as quality, safety, reliability, and efficiency. The ISO standards represent an international consensus on good management practices with the aim of ensuring that the organization can consistently deliver excellent product or services. The standards not only must meet the customer's requirements and applicable seed regulatory requirements, but also must aim to enhance customer satisfaction and achieve continual improvement of its performance in pursuit of these objectives (ISO, 2009).

---

[20]http://www.iso.org/iso/ims_2009.htm

Commercially certified soybean seed must meet state and federal seed standards and labeling requirements. The Association of Official Seed Certifying Agencies (AOSCA) standards for certified soybean seed are as follows: 98% pure seed (minimum), 2% inert matter (maximum). The inert matter can contain up to 0.05% weed seed (maximum, not to exceed 10 per lb.), 0.60% total of other crop seeds (maximum), 0.5% other varieties (maximum, includes off-colored beans and off-type seeds), 0.10% other crop seeds (maximum, not to exceed three per lb.), and have 80% germination and hard seed (minimum) (AOSCA, 2009). Seed that meets or exceeds these standards are provided in appropriately labeled seed bags to growers. Monsanto's seed manufacturing practices for MON 87769 will be designed to contain MON 87769 within the boundaries of the production system thereby assuring that levels of the trait and the subsequent SDA and GLA fatty acids do not cause impacts to conventional soybeans or other commodity soybean varieties produced at seed manufacturing sites.

Production of SDA Soybean for Processing:

SDA soybean will be produced under contracts similar to those currently issued by processors or elevators for commercial specialty soybean such as food grade, organic, Vistive low linolenic or other specialty soybeans.

The income opportunity is achieved by the farmer only when the soybean is delivered to the processor within specifications. Therefore, the motivation is a financial incentive for the farmer to avoid comingling with commodity soybean, keeping SDA soybean identity preserved within system of seed – farmer – processor. Many farmers may willingly choose to plant all their acreage to specialty soybeans because it eliminates any risk of comingling that may occur during the harvest. If a farmer chooses to produce the specialty soybean for the processor, the farmer will arrange to store the soybean on farm or at their local elevator, if the elevator is participating in the specialty program with the processor.

The steps involved in securing soybean production are:

1. Monsanto, its licensees, partners or processors will be responsible to issue production contracts. These contracts will be either to an elevator or directly to the farmer. If issued to an elevator, the elevator will in turn issue contracts with farmer customers in the amount of acreage established in its processor contract. The contract will include number of acres and the timeline for the delivery of harvested soybeans.
2. Monsanto, its licensees or partners will distribute SDA soybean seed to the farmer after verifying that the farmer has a valid contract that has been issued for SDA soybean production and stewardship in their operation. This will include an amount of seed needed to plant the number of acres established on the production contract by the processor or elevator.
3. Monsanto, its licensees or partners will work with all parties involved to confirm and reconcile acres contracted with seed sales. Processors can plan processing schedules

according to demand of the oil and supply of SDA soybean anticipated from contracted farmers.

4. After harvest, the farmer will deliver the harvested SDA soybean to the location specified in his contract, either a participating elevator or processor. If delivered to the elevator, the elevator will keep the SDA soybean segregated from commodity soybean and pay the farmer any premiums as applicable, provided it passes the analytical testing. The elevator will deliver the SDA soybean to the processor as delivery windows and crush schedules have been established. Upon delivery of SDA soybean by the farmer, samples will be analyzed from every truckload. This is to confirm the soybean contains the SDA trait as required by the production contract. Upon confirmation that the SDA soybean meets specification, the processor or elevator will approve the premium payment to the farmer. SDA soybean that does not meet specifications at the elevator or processor will be segregated, processed and the oil will be directed to appropriate uses such as for the production of biofuel.

Soybean Grain Elevator Grain elevators play an important role in specialty programs with their long term storage of the soybeans. Because processing facilities crush soybeans throughout the year, soybeans used to supply these crush plants need to be stored year round. Farmers typically prefer to empty their storage prior to planting of the new crop and prior to temperature warm up in the spring. The warm spring and summer weather presents challenges as condensation can build up in the bins creating moisture-related issues that make soybean-eating insects more active. To avoid this, commercial elevators have expert grain managers on staff to monitor soybean quality and keep soybean in good condition in all weather situations throughout the year. Commercial grain elevators are also better equipped to ship soybeans to processors during times of severe weather even when farmers cannot get to their bins.

Processors will therefore enter into supply contracts with commercial grain elevators and work with farmers to establish inventories and to assure proper routing of SDA soybean through the supply chain. The elevator pays the farmer the specialty soybean premium upon successful analytical testing performed at the elevator location. Testing equipment will be provided as needed by Monsanto to participating elevators.

In order for the elevator to be reimbursed for the premiums paid out to farmers that have delivered SDA soybeans to them, the elevator must in turn preserve the identity of the soybean as it is delivered to the processor. Every load delivered to the processor by the elevator will be analyzed to make this determination. Processors will approve the premium payment to the elevator after analysis of the soybean to confirm the SDA trait. SDA soybean that does not meet specifications at the elevator or processor will be segregated, processed and the oil will be directed to appropriate uses such as for the production of biofuel.

SDA Soybean Processing and Oil Refining:

All SDA soybean processors must be approved in advance by Monsanto. In order for the processor to be approved by Monsanto to process SDA soybean, certain requirements must be met. They must posses the ability to store, segregate and identity preserve SDA soybeans. They must demonstrate the ability to clean the equipment associated with the receiving and subsequent handling of SDA soybeans. The processor's facility must have procedures in place and the ability to assure that SDA soybean processing, extracting, and oil refining equipments can be flushed to commercially acceptable standards after processing SDA soybeans. Monsanto and the processor will enter into an agreement to establish the terms and conditions of SDA soybean processing services. These agreements will also include terms for distribution of SDA soybean co-products resulting from processing as stewarded products within the United States prior to receiving necessary regulatory approvals in soybean export markets. The resulting oil from processing SDA soybean is generally recognized as safe in the United States.

Upon the transition from commodity soybeans to the SDA soybeans, a sample of crude oil is required to confirm the presence of the appropriate fatty acid composition (FAC) unique to SDA soybean oil. Crude oil will be collected and handled in a way that ensures that any SDA soybean oil as well as SDA soybean oil comingled with commodity soybean oil are handled in an appropriate manner and segregated from other oils. This will include all comingled oil before and after the collection of SDA soybean oil. Testing methods will be used to aid in identifying the appropriate time to start and stop collecting crude SDA soybean oil. Storage tanks approved for SDA soybean oil will be assigned for the storage of crude and refined SDA soybean oil. Upon the completion of SDA soybean processing, a commodity soybean flush will be initiated. After all SDA soybean and commodity soybean used to flush the channels have been processed, crude oil exiting the extractor will be sampled and analyzed to confirm the equipment has been flushed to an acceptable level, yielding commercially acceptable commodity soybean oil. Off-spec, commingled or flush SDA soybean oil will be segregated from commodity soybean oil and directed to appropriate use such as for the production of biofuel.

SDA Soybean Oil Packaging and Storage:

Soybean oil produced under the CLSS will be distributed as a stewarded product within the United States until receiving approvals in all key soybean export markets. An agreement will be executed between Monsanto, its licensees, partners, the processor and/or the packager to establish the terms and conditions for packaging stewarded SDA soybean oil at a contract packaging facility. A separate agreement will be executed with a long-term storage facility, if used, to establish the terms and conditions for SDA soybean oil receipt, storage, and distribution.

Bulk liquid semi-trailers (tankers) will be used to transport packaged and/or bulk SDA soybean oil. Refined, bleached, and deodorized (RBD) SDA soybean oil packaging will be conducted in an area that is clean, secure, and segregated to eliminate potential comingling with commodity soybean and/or other vegetable oils. The containers will be properly labeled using predetermined methods that will include chain of custody documentation. Periodic visual inspections will occur in and around the packaging area for the collection and disposal of any spilled oil or damaged containers. All semi-trailers used in the transportation of bulk SDA soybean oil will be verified to be clean at the processing plant or other Monsanto approved facility prior to being released. After packaging is complete, the facility will be flushed with adequate amounts of commodity soybean oil to remove SDA soybean oil and return the oil stream to commodity soybean oil specifications. Flush oil containing SDA soybean oil will be segregated and directed to appropriate use such as for the production of biofuel.

SDA Soybean Oil Distribution to Food Company Supply Chain:

Monsanto, its licensees and/or partners will execute agreements with food companies to establish the terms and conditions for the use of stewarded SDA soybean oil. During the development of these contracts, it will be necessary to verify that the food companies have the capabilities in place to control and limit distribution of stewarded products and track all products that use specific batches of the SDA soybean oil as ingredient. These contracts will include stewardship obligations and will require compliance including auditing. Third party consultants will be used if necessary under the CLSS. These third party consultants will have expertise in supply and demand chain procedures, to enable verification of a food company's capabilities.

SDA soybean oil will be used by the food industry and will be supplied to specific customers by Monsanto, its licensees or partners and suppliers after verifying that it meets specific customer requirements including quality factors. From the time the oil is packaged until it is utilized at the specific customer's facility there will be proper identification of the oil through labeling and manufacturing codes allowing for sufficient product traceability. Individual facilities will utilize proprietary inventory and ordering systems that are in place to insure that the appropriate oil is ordered, delivered and utilized.

Food companies will use SDA soybean oil as a food ingredient consistent with the GRAS notification[21]. Each individual food company has in place systems for ingredient (oil) ordering, receipt, storage, access and lot identification at specific manufacturing locations, as well as finished product (the food which incorporates SDA soybean oil) batch identification, manufacturing facility, storage, shipment to distribution centers, customer order picking, customer order shipment and receipt. Appropriate procedures are currently in place to ensure traceability from receipt of the ingredient through distribution to a specific retailer's facility. Food manufacturing facilities also comply with federal and state requirements for good

---

[21] http://www.accessdata.fda.gov/scripts/fcn/gras_notices/grn000283.pdf

manufacturing practices and product traceability. Supply chain consultants can be employed to confirm appropriate systems have been established that meet ingredient and product traceability requirements.

Incident Response

All activities conducted by Monsanto and non-Monsanto personnel under the scope of the CLSS must be consistent with Monsanto's corporate expectations for regulatory and stewardship compliance prior to obtaining all relevant global regulatory approvals. Monsanto has an incident response policy in place. If an unforeseen process failure or a breach of containment of stewarded material occurs, the CLSS incident response would be managed according to Monsanto's Global Product Stewardship and Quality process and procedures document. The Incident Response Process engages a multi-disciplinary team for immediate response investigation, assessment and mitigation of any potential adverse impacts that could result from the process failure. The incident investigation and analysis process will determine the reason for the occurrence and develop recommendations for corrective action including process improvement to prevent similar occurrences in the future.

Development of Long Term Stewardship Processes

The CLSS described above to support the commercialization of SDA soybean oil prior to obtaining all relevant regulatory approvals will be utilized through the initial product introduction phase until all relevant global approvals in key soybean export countries with functioning regulatory systems are received. Monsanto will refine and update the stewardship system for long-term implementation based upon the experience and learning developed during the CLSS production phase and through continued dialogue with stakeholders. This dialog will aid in the assessment and development processes while enabling transparent communication regarding policy implementation. The long-term stewardship plan for MON 87769 derived through these actions will be designed to ensure that the SDA soybean oil is directed to its intended specialty market.

Summary

SDA soybean offers U.S. soybean growers the opportunity to supply a value added and sustainable omega-3 alternative that will provide food industry with choices to satisfy a growing omega-3 market. The closed loop stewardship system for the production and handling of MON 87769 and derived products is designed to ensure that SDA soybean and oil will be isolated from commodity soybean and oil as well as other vegetable oils in the market place and are directed to their intended specialty uses. The market and trade assessment has concluded that in the unlikely event comingling did occur, the impact to labeling and functionality would be minimal. Because SDA soybean is generally recognized as safe in the United States[22] and the defatted meal from SDA soybean is similar to commodity soybean meal, there would be no negative impact to human heath from the use of any of the other processed fractions produced from soybean due to comingling of SDA soybean with commodity soybean. Given the abundance of vegetable oils on the market and demonstrated ability of the system to adapt to consumer preferences incorporating new oils into existing food manufacturing processes, the introduction of SDA soybean is expected to be easily managed by existing industry mechanisms and identity preservation systems. Monsanto continues to engage stakeholders and educate them on the benefits of SDA soybeans and proper stewardship practices.

[22] http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm185688.htm

References

James, M.J., V.M. Ursin, and L.G. Cleland. 2003. Metabolism of stearidonic acid in human subjects: comparison with the metabolism of other n-3 fatty acids. American Journal of Clinical Nutrition 77:1140-1145.

Lemke, S.L., Vicini, J.L., Su, H., Goldstein, D.A., Nemeth, M.A., Krul, E.A., and Harris, W.S. 2010. Dietary intake of stearidonic acid–enriched soybean oil increases the omega-3 index: randomized, double-blind clinical study of efficacy and safety. Am J Clin Nutr 92:766–75.

NOPA. 2006. Trading Rules for the Purchase and Sale of Soybean Meal. National Oilseed Processors Association, Washington, D.C.

Orthoefer, F. T. and List, G. R. 2007. Evaluation of Used Frying Oil in Deep Frying: Chemistry, Nutrition and Practical Applications, 2nd Edition. Erickson, M.D. Editor. p 329-342.

King, S. et al. 2002. The sensory quality system: a global quality control solution. Food Quality and Preference (13) 385-395.

12 LIST OF PREPARERS

David Reinhold, Assistant Director, APHIS-BRS-Environmental Risk Assessment Program

Craig Roseland, Ph.D., APHIS-BRS-Senior Environmental Protection Specialist

Diane Sinkowski, APHIS-BRS-Environmental Protection Specialist

Khamkeo Vongpaseuth, Ph.D. APHIS-BRS-Environmental Protection Specialist