Bayer Petition 09-328-01 for Determination of Non-regulated Status of Double Herbicide-tolerant Soybean (*Glycine Max*) Event FG72

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Draft Environmental Assessment

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ACRONYMS AND ABBREVIATIONS

4-HPPD	4-hydroxyphenylpyruvate dioxygenase
AIA	advanced informed agreement
AMS	Agricultural Marketing Service
AOSCA	American Organization of 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
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (United States)
CH_4	methane
CO_2	carbon dioxide
CWA	Clean Water Act
DNA	deoxyribonucleic acid
DKN	diketonitrile
EA	environmental assessment
EFED	Environmental Fate and Effects Division
EIQ	Environmental Impact Quotient
EIS	environmental impact statement
EO	Executive Order
EPA	U.S. Environmental Protection Agency
EPSPS	5-enolpyruvylshikimate-3-phosphate synthase
ESA	Endangered Species Act of 1973
ESPP	Endangered Species Protection Program
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FSANZ	Food Standards Australia New Zealand
FR	Federal Register
FQPA	Food Quality Protection Act
GE	genetically engineered

GHG	greenhouse gas
HED	Health Effects Division
IFT	isoxaflutole
IP	Identity Preservation
IPCC	Intergovernmental Panel on Climate Change
ISPM	International Standard for Phytosanitary Measure
IPPC	International Plant Protection Convention
LD50	lethal dose that kills 50% of the animals being tested
LMO	Living modified organism
MoA	Mode of Action
N_2O	nitrous oxide
NABI	North American Biotechnology Initiative
NAPPO	North American Plant Protection Organization
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NOEL	no observable effect level
NOP	National Organic Program
NPS	non-point source
NRC	National Research Council
OECD	Organization for Economic Cooperation and Development
PIP	Plant incorporated protectants
PPRA	Plant Pest Risk Assessment
PPA	Plant Protection Act
PRA	Pest Risk Assessment
RSPM	Regional Standards for Phytosanitary Measures
RUP	Restricted Use Pesticide
TES	threatened and endangered species
TSCA	Toxic Substances Control Act
U.S.	United States
USFWS	United States Fish and Wildlife Services
USDA	U.S. Department of Agriculture
USDA-ERS	U.S. Department of Agriculture-Economic Research Service

USDA-FAS	U.S. Department of Agriculture-Foreign Agricultural Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service
USDA-NOP	U.S. Department of Agriculture-National Organic Program
USC	United States Code
WPS	Worker Protection Standard for Agricultural Pesticides

1 PURPOSE AND NEED

1.1 Coordinated Framework Review and Regulatory Review

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

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

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

<u>USDA-APHIS</u>

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

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 GE organisms. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) that the GE 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.

Environmental Protection Agency

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*), EPA regulates the use of pesticides, including plant-incorporated protectants, requiring registration of a pesticide for a specific use prior to distribution or sale of the pesticide for a proposed use pattern. EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; and storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, EPA must determine through testing that the pesticide will not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions. EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide's label or labeling. The overall intent of the label is to provide clear directions for effective product performance while minimizing risks to human health and the environment.

EPA also sets tolerances 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). EPA is required, before establishing pesticide tolerance, to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the Food Quality Protection Act of 1996 (FQPA). FDA enforces the pesticide tolerances set by EPA.

Food and Drug Administration

FDA regulates GE organisms under the authority of the FFDCA (21 U.S.C. 301 *et seq.*). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, 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. This voluntary consultation process provides a way for developers to receive assistance from FDA in complying with their obligations under Federal food safety laws prior to marketing.

1.2 Petition for Determination of Nonregulated Status: Double Herbicide-tolerant Soybean Event FG72

Bayer CropScience of Research Triangle Park, NC submitted petition 09-328-01 to APHIS in June 2011 seeking a determination of nonregulated status for soybean event FG72 that can tolerate exposure to the herbicides glyphosate and isoxaflutole (IFT). FG72 soybean is currently regulated under 7 CFR part 340. Interstate movements and field trials of FG72 soybean have been conducted under permits issued or notifications acknowledged by APHIS since 2001. These field trials were conducted in diverse growing regions within the U.S., including Indiana, Iowa, Nebraska, Florida, Arizona, Illinois, Michigan, Missouri, and Minnesota. Data resulting from these field trials are described in the FG72 petition (Bayer, 2011c) and analyzed for plant pest risk in the USDA-APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2012b).

The petition stated that APHIS should not regulate FG72 soybean because it does not present a plant pest risk. In the event of a determination of nonregulated status, the nonregulated status would include FG72 soybean, any progeny derived from crosses between FG72 and conventional soybean, including crosses of FG72 with other biotechnology-derived soybean that are no longer subject to subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

1.3 Purpose of Product

Weed management is one of the largest concerns in soybean production. The development of glyphosate-resistant weeds has generally compounded this concern. Several management options are available to manage current glyphosate-resistant weed populations and limit the potential development of glyphosate resistance in other weed species (Table 1). Reflecting the first of these potential management options, the development of FG72 soybean facilitates the use of an additional herbicide with a different mode of action (MoA) to control soybean weed populations, including those weed populations that are resistant to glyphosate.

Under typical field conditions, application of glyphosate or IFT would disrupt soybean aromatic amino acid and carotenoid biosynthesis, respectively (RSC, 2011; USDA-APHIS, 2008). FG72 soybean is engineered to tolerate exposure to the herbicides glyphosate and IFT. This double herbicide-tolerant phenotype is enabled by stable introduction of the 2mEPSPS and HPPD W336 proteins that correspondingly confer glyphosate and IFT tolerance. 2mEPSPS is derived from *Zea mays* and HPPD W336 is derived from the A32 strain of *Pseudomonas fluorescens*. Both introduced proteins impart herbicide tolerance in a mechanistically similar manner, where 2mEPSPS and HPPD W336 are less susceptible to competitive inhibition by glyphosate and IFT, respectively, than native soybean EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) or 4-HPPD (4-hydroxyphenylpyruvate dioxygenase) proteins.

Table 1. Assessment of resistance risk by agricultural management options.

Management Option	Risk of Resistance		
	Low	Moderate	High
Herbicide mix or rotation in cropping system	> 2 MoA*	2 MoA*	1 MoA*
Weed control in cropping system	Cultural**, mechanical, and chemical	Cultural** and chemical	Chemical only
Use of same MoA* per season	Once	More than once	Many times
Cropping system	Full rotation	Limited rotation	No rotation
Resistance status to MoA*	Unknown	Limited	Common
Weed infestation	Low	Moderate	High
Control in the last three years	Good	Declining	Poor

*Mode of Action. **Cultural control includes stubble burning, competitive crops, stale seedbeds, etc. See HRAC guidelines for more details. Source: HRAC (2012).

1.4 Purpose and Need for APHIS Action

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 FG72 soybean. APHIS has prepared this Environmental Assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality's (CEQ) 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 FG72 soybean.

1.5 Public Involvement

APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. APHIS does this through a notice published in the *Federal Register*. 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 soybean using various production methods and the environmental and food/feed safety of GE plants were addressed to analyze the potential environmental impacts of FG72 soybean.

[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).

This EA, the petition submitted by Bayer CropScience, 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 FG72 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.

1.6 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 range of soybean production
- Agronomic practices
- Organic soybean production

Environmental Considerations:

- Soil Quality
- Water resources
- Air quality
- Climate change
- Animal communities
- Plant communities
- Gene flow and weediness
- Microorganisms
- Biodiversity

Human Health Considerations:

- Public health and worker safety

Livestock Health Considerations:

- Animal feed/livestock health

Socioeconomic Considerations:

- Domestic economic environment
- Trade economic environment

2 AFFECTED ENVIRONMENT

2.1 Agricultural Production of Soybean

2.1.1 Acreage and Range of Soybean Production

Soybean production in the U.S. extends over a wide range of geographies and regions, and is generally grown from North Dakota eastward. In 2010, 76.6 million acres of soybeans were cultivated in at least 31 states (USDA-NASS, 2011c). Also in the 2010 growing season, more than one million acres of soybeans were harvested in the following 18 states (from highest to lowest acreage): Iowa, Illinois, Minnesota, Indiana, Nebraska, Missouri, Ohio, Kansas, South Dakota, North Dakota, Arkansas, Michigan, Mississippi, Wisconsin, North Carolina, Tennessee, Kentucky, and Louisiana (Figure 1 and Table C1, Appendix C). Due to increased domestic and international demand for soybeans and its products, the U.S. soybean harvest is projected to slightly increase to approximately 79.5 million acres by 2020 (USDA-ERS, 2011c).

In general, soybean is profitably grown on high quality agricultural land, not lands of lower productivity (EIA, 2007; USDA-NASS, 2011b). Much of the high quality land in the U.S. is already committed to agricultural production (EPA, 2007) and in 2002, the USDA Economic Research Service (USDA-ERS) estimated that only 2.1 percent of cropland was idle (Lubowski et al., 2002). At the same time, total U.S. agricultural acreage decreased (EIA, 2007). To satisfy greater soybean demand, additional soybean acreage was generally planted at the expense of alternative crops, such as cotton or hay, with minor contributions from land exiting Conservation Reserve Program (CRP) agreements (O'Brian, 2010; USDA-ERS, 2011e). Consequently, it is unlikely that previously uncultivated land will be managed for future soybean production, but rather that growth of soybean production will compete with other agricultural plantings (EIA, 2007; USDA-ERS, 2011d).

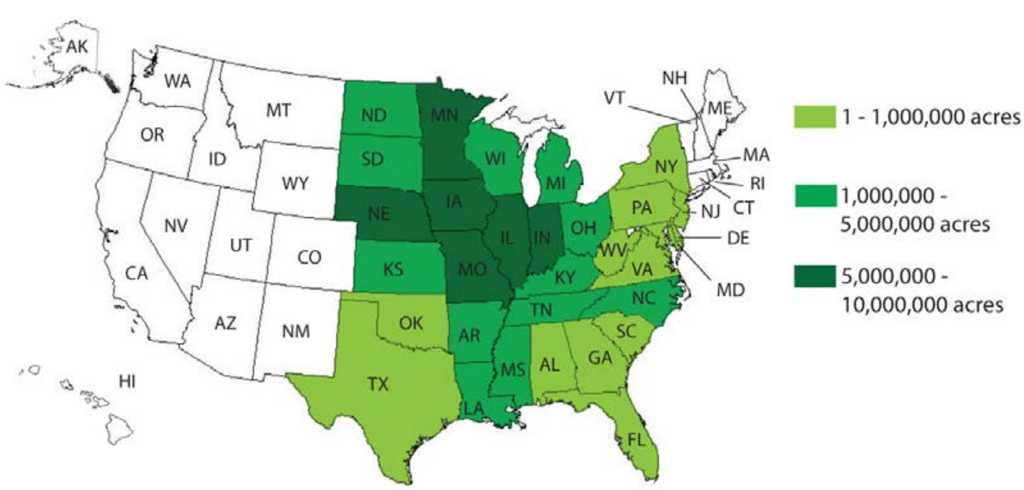

Figure 1. U.S. soybean production, 2010. Source: USDA-NASS (2011c).

2.1.2 Agronomic Practices

In this EA, conventional farming is defined as any farming system where synthetic pesticides or fertilizers may be used. Conventional farming covers a broad scope of farming practices, ranging from farmers who occasionally use synthetic pesticides and fertilizers to those farmers whose harvest depends on regular inputs of synthetic pesticides and fertilizers. Conventional farming also includes the use of GE varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

Soybean varieties are developed and adapted to certain geographical zones (i.e., maturity groups) (Helsel and Minor, 1993; NSRL, 2011). Additionally, GE herbicide-tolerant soybean varieties represents the most common soybean variety cultivated in the U.S., accounting for 94 percent of soybean varieties planted in 2011 (USDA-ERS, 2011a). The broad adoption of GE herbicide-tolerant soybean production systems is attributed to the simplification of herbicide application practices and positive contributions to productivity and yield (Carpenter and Gianessi, 1999; Fernandez-Cornejo and McBride, 2000). Among the GE herbicide-tolerant soybean varieties commercially available, glyphosate-tolerant varieties represent the vast majority that is planted in U.S. production fields. Since its introduction in 1996, domestic adoption of glyphosate-tolerant soybean varieties expanded to the majority of the market (NRC, 2010). While agronomic practices may be dependent on the soybean maturity group and variety cultivated, common management strategies are shared across regions. These include management strategies related to tillage, pest management, fertilization, and crop rotation.

Tillage

The broad adoption of glyphosate-tolerant soybean varieties and glyphosate has influenced several aspects of soybean management. In particular, tillage trends have been affected. Prior to planting, the soil must be stripped of weeds that would otherwise compete with soybean for space, water, and light. Tillage represents a mechanical means of weed control and is generally characterized by the amount of remaining in-field residue and may be classified as conservation (≥ 30 percent), reduced (15-30 percent), or intensive (0-15 percent) (CTIC, 2008). Conservation tillage practices by U.S. soybean growers increased following the commercialization of glyphosate-tolerant soybean in 1996, totaling 42 percent of soybean acreage in 2008 (CTIC, 2008; NRC, 2010). Conservation tillage adoption is generally associated with broad-spectrum herbicide use, due to the capacity of broad-spectrum herbicides to burn down a variety of weed populations prior to planting a crop. Though the causality between herbicide-tolerant soybean adoption and conservation tillage may be debated (Fernandez-Cornejo et al., 2003; Mensah, 2007), most empirical evidence suggests a direct relationship between grower adoption of herbicide-tolerant crops and conservation tillage (NRC, 2010).

Fertilization and Crop Rotation

Soybeans may remove up to 70 pounds of nitrogen from the soil when a 50-bushel yield of soybean is attained (Hoeft et al., 2000). USDA-ERS estimates that less than 40 percent of soybean acres in the U.S. receive nitrogen fertilizer (USDA-ERS, 2010d). The nitrogen requirement of soybean is often provided through fertilization of the previous rotation crop or through a symbiotic relationship with nodulating bacteria in root tissue (Ferguson et al., 2012).

Given the important role of these bacteria for meeting nitrogen needs of soybean, commercial sources of nodulating bacteria inoculants can be applied to soybean seeds just before planting (Beuerlein, 2005).

The benefits of crop rotation in soybean include improved yield and profitability of one or both crops, decreased need for additional nitrogen on the crop following soybean, increased residue cover, mitigation of pest cycles, reduced soil erosion and improved soil quality, or reduced runoff of agricultural inputs (Al-Kaisi et al., 2003). According to USDA-ERS, 95 percent of the soybean-planted acreage has been in some form of a crop rotation system since 1991 (USDA-ERS, 2011b). In a survey of major corn/soybean production states, corn and soybean were alternated on 72 to 80 percent of acreage, other rotations were grown on 16 to 20 percent of acreage, and soybean was grown continuously on 5 to 12 percent of acreage between 1996-2002 (Sandretto and Payne, 2006). In another analysis, the majority of the U.S. soybean acreage (68.6 percent) is rotated to corn (Monsanto, 2010) at page 157, et seq.). Approximately 14.5 percent of the soybean acreage is rotated back to soybean the following year. Other rotational crops that may be planted following soybean include wheat, cotton, rice, sorghum, barley, oats, and dry beans.

Pesticide Use

Pest management is an integral part of soybean production. However, U.S. soybean growers generally face reduced pest pressure from insects, due in large part to the capacity of soybeans to experience limited insect herbivory without a reciprocal loss in grain yield (Penn State Extension, 2011). This recalcitrance to insect damage is evident in the low use of insecticides on cultivated soybean acreage; in 2006, insecticides were applied on 16 percent of soybean acres, with no single insecticide exceeding 6 percent of chemically-treated acreage (USDA-NASS, 2007).

Weeds are the most problematic pests of soybean production fields, resulting in a 12 to 80 percent loss in grain yield (Barrentine, 1989). Individual weed species, including glyphosate-resistant species, are discussed in Section 2.3.2. Soybean growers may use a variety of methods to control soybean weeds. At present, application of glyphosate represents the most common weed management system in U.S. soybean fields (Figure 2). In 2006, 98 percent of soybean acreage was subject to herbicide application; glyphosate was the most-widely applied herbicide on these chemically-treated acres at 92 percent (USDA-NASS, 2007). While total herbicide use trends are subject to debate, it is clear that an herbicide-substitution effect occurred in U.S. soybean production (Benbrook, 2009; Fernandez-Cornejo et al., 2003; Fernandez-Cornejo et al., 2009). Since 1996, glyphosate use has increased at the expense of alternative herbicides, with respect to total pounds of active ingredient per acre (lbs. ai/acre) applied (Fernandez-Cornejo et al., 2009; NRC, 2010). This statement, however, should not be misinterpreted to mean that the diversity of herbicides available to U.S. soybean growers has decreased; rather, the diversity of herbicides used in U.S. soybean production fields has gradually increased while applied quantities of those same herbicides (except glyphosate) have generally decreased (Figure 3). However, it is prudent to note that total herbicide use may not be an effective metric to measure environmental impact, as this does not effectively permit the environmental comparison of different herbicides across time or across management strategies (Fernandez-Cornejo et al., 2009).

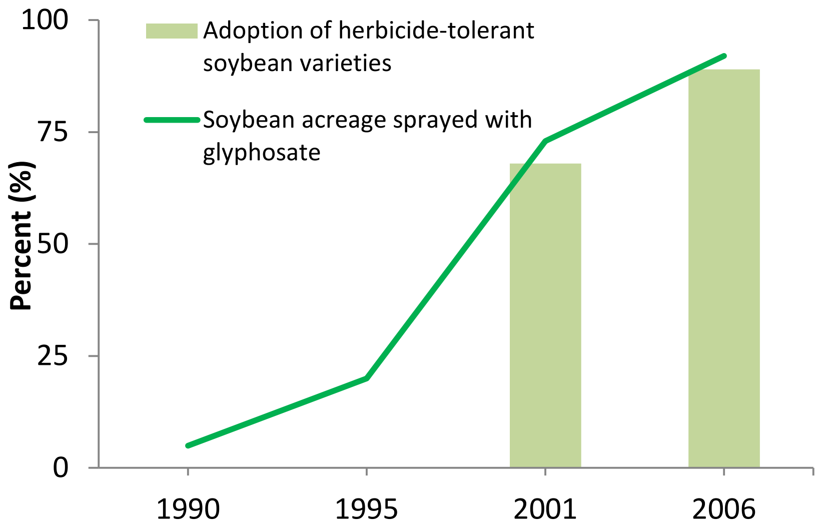

Figure 2. Adoption of GE herbicide-tolerant soybean and glyphosate use on U.S. soybean fields, 1990 – 2006. GE glyphosate-tolerant soybean was commercialized in 1996. Sources: USDA-ERS (2011a) and USDA-NASS (1991, 1996, 2002, 2007).

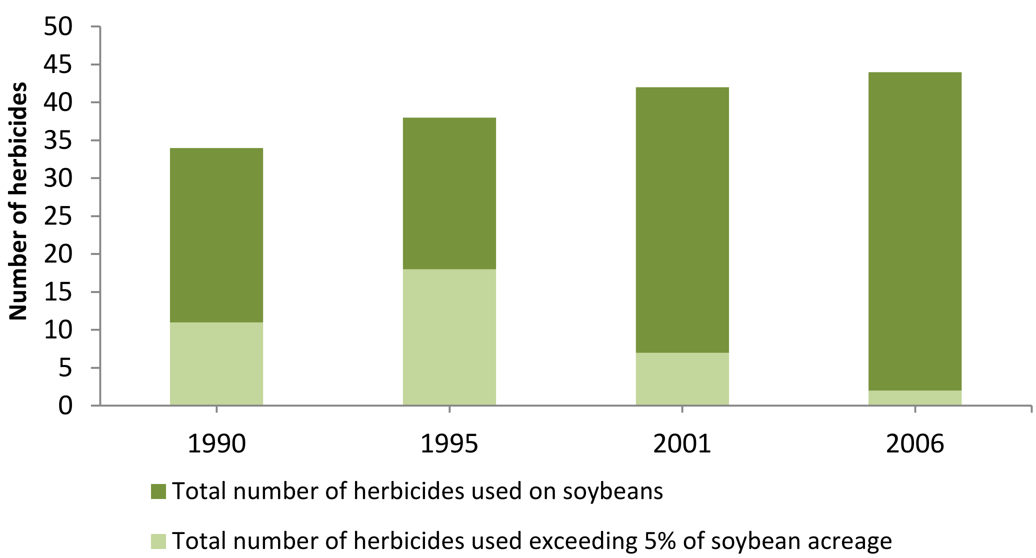

Figure 3. Extent of glyphosate use and diversity of herbicides applied in U.S. soybean production, 1990 – 2006. Sources: USDA-NASS (1991, 1996, 2002, 2007).

2.1.3 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, 2010a). 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 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, 2010a).

Common practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields (NCAT, 2003). Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2010a). 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 Fouce, 2006; USDA-AMS, 2010a).

In 2008, the U.S. produced 125,621 acres of NOP certified soybean (Figure 4).

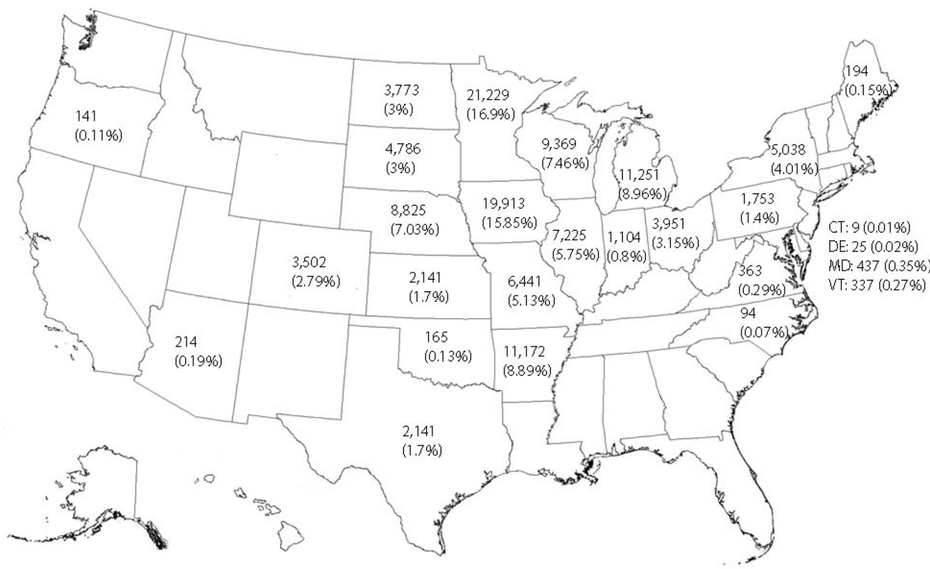

Figure 4. U.S. certified organic soybean, 2008. Source: USDA-ERS (2010c).

2.2 Physical Environment

2.2.1 Soil Quality

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)) (EPA, 2010d; Lal and Bruce, 1999a). 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.

2.2.2 Water Resources

Soybean cultivation may directly affect water resources through the use of local water sources or indirectly through associated management practices, including tillage and the use of agricultural inputs. The typical amount of water required for a high-yielding soybean crop is approximately 20 inches during the growing season (Hoeft et al., 2000). While normal climatic conditions may provide sufficient water to produce a soybean crop, precipitation may vary across states and irrigation may be needed to supplement precipitation amounts. Irrigation may also vary from year to year. In general, however, the majority of soybean acreage in the U.S. is grown with very little supplemental irrigation (Table C2, Appendix C) (The Keystone Center, 2009). In most states, irrigation water comes predominantly from groundwater sources, with comparatively little derived from surface water sources (USDA-NASS, 2010).

Agricultural non-point source (NPS) pollution is the primary source of discharge pollutants to groundwater (aquifers), flowing water (permanent or intermittent streams), or semi-static water (ponds, lakes, and reservoirs) (Ramanarayanan et al., 2005). NPS pollutants generally include agricultural inputs, such as fertilizers or pesticides. Although meteorological (e.g., precipitation, temperature), morphological (e.g., land use, soil type), and environmental fate drivers affect water quality, anthropogenic practices (product use and management) are the most relevant, as this driver is generally under direct grower control on a soybean farm (Ramanarayanan et al., 2005). In particular, tillage practices often have a strong, indirect effect on water quality through the improvement of soil quality and water retention characteristics. 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 (EPA, 2005).

2.2.3 Air Quality

Agriculture, including land-use changes for farming, is estimated to be responsible for eight percent of all human-induced GHG emissions in the U.S. (Massey and Ulmer, 2010). Many agricultural activities affect air quality, including smoke from agricultural burning, machinery, and N_2O emissions from the use of nitrogen fertilizer (Aneja et al., 2009; EPA, 2010b; Hoeft et al., 2000). Emissions released from agricultural equipment (e.g., irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (EPA, 2010b). Tillage contributes to the release of greenhouse gases (GHG) because of the loss of CO_2 to the atmosphere and the exposure and oxidation of soil organic matter (Baker et al., 2005b). Pesticides may volatilize after application to soil or plant surfaces and move following wind erosion (Vogel et al., 2008).

2.2.4 Climate Change

Climate change represents a statistical change in global climate conditions, including shifts in the frequency of extreme weather (Cook et al., 2008; Karl et al., 2008). Agriculture is recognized as a direct (e.g., exhaust from equipment) and indirect (e.g., agricultural-related soil disturbance) source of GHG emissions. Greenhouse gases, including CO_2, methane (CH_4), and N_2O, function as retainers of solar radiation (Aneja et al., 2009). The U.S. agricultural sector is identified as the second largest contributor to GHG emissions (EPA, 2010a).

Agriculture may also affect dynamic soil processes through tillage and other land management practices (Smith and Conen, 2004). In general, conservation tillage strategies are associated with more stable and increased carbon sequestration due to a net reduction in carbon dioxide emissions (Lal and Bruce, 1999b; West and Marland, 2002). Recent literature, however, suggests that the relationship between conservation tillage and increased carbon sequestration require more study, as soil depth level and seasonal sampling bias may inadvertently affect measurements (Baker et al., 2007; Potter et al., 1998). Additionally, the relationship between different GHG emissions, such as carbon dioxide and nitrous oxide may influence paradigms related to tillage strategies and global climate change (Gregorich et al., 2005). For example, increased nitrous oxide emissions as a result of conservation tillage strategies may offset any gains achieved through increased carbon sequestration. Like the relationship between conservation tillage strategies and carbon sequestration, a broad generalization regarding the impact of tillage strategy and nitrous oxide emissions is difficult, as numerous factors influence soil nitrification cycles, including geographic location, soil structure, moisture, and farm-level management practices (Grandy et al., 2006; Gregorich et al., 2006; Rochette et al., 2008).

Global climate change may also affect agricultural crop production (CCSP, 2008). 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 (Rosenzweig et al., 2001; Schmidhuber and Tubiello, 2007). The impacts of GE crop varieties on climate change are unclear, though it is likely dependent on cropping systems, production practices, geographic distribution of activities, and individual grower decisions. APHIS will continue to monitor developments that may lead to possible changes in the typical production system likely to result from GE products brought to APHIS for a determination of nonregulated status. The potential impact of climate change on agricultural output, however, has been examined in more detail. A recent Intergovernmental Panel on Climate Change (IPCC) forecast (2007) for aggregate North American impacts on agriculture from climate change actually projects yield increases of 5 to 20 percent for this century. The IPCC report notes that certain regions of the U.S. will be more heavily impacted because water resources may be substantially reduced. While agricultural impacts on existing crops may be substantial, North American production is expected to adapt with improved cultivars and responsive farm management (IPPC, 2007).

2.3 Biological Resources

2.3.1 Animal Communities

Wildlife may be found within or near soybean fields. Deer and groundhogs feed on soybean and cause soybean damage, while feeding damage from Eastern cottontail, raccoon, squirrels, and other rodents is of less importance (MacGowan et al., 2006). Additionally, migratory birds may feed on spilled soybean following harvest (Galle et al., 2009; Gamble et al., 2002).

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. A variety of insect pests may be found in U.S. soybean fields, including those that feed on reproductive tissue, foliage, and roots/nodules (Table C3, Appendix C). Insect pests are managed during the growth and development of soybean to enhance soybean yield (Aref and Pike; Higley and Boethel, 1994), with 16 percent of soybean acreage treated with insecticides (USDA-NASS, 2007).

2.3.2 Plant Communities

The vegetative landscape surrounding a soybean field varies with region; soybean fields may be surrounded by additional soybean varieties, other crops, or woodland/pasture/ grassland areas. Weeds are perceived to be the most substantial pest problem in soybean production, negatively affecting yield through competition for light, nutrients, and moisture (Aref and Pike, 1998). When weeds are left to compete with soybean for the entire growing season, yield losses can exceed 75 percent (Dalley et al., 2001). Eighty-six common weeds of soybean across three growing regions have been identified (Tables B4 - B6, Appendix B).

Weed populations can change in response to agricultural management decisions, including decisions related to herbicide application. Weeds can develop resistance to herbicides for the following reasons: frequent exposure to a single herbicide, the spread of naturally-resistant weeds seeds, and the out-crossing of herbicide-tolerant genes from plants (GE or naturally-resistant plants) to weedy relatives. The development of herbicide resistance in weeds is not unique to any one country (Figure C1, Appendix C), particular herbicide (Figure C2, Appendix C), or crop variety. In the U.S., 76 weed species have developed resistance to at least 17 herbicide MoAs (Heap, 2011a). Currently, nine glyphosate-resistant weeds have been identified in U.S. soybean fields (Figure 5), inhabiting approximately two million acres of farmland in the U.S. (Hubbard, 2008).

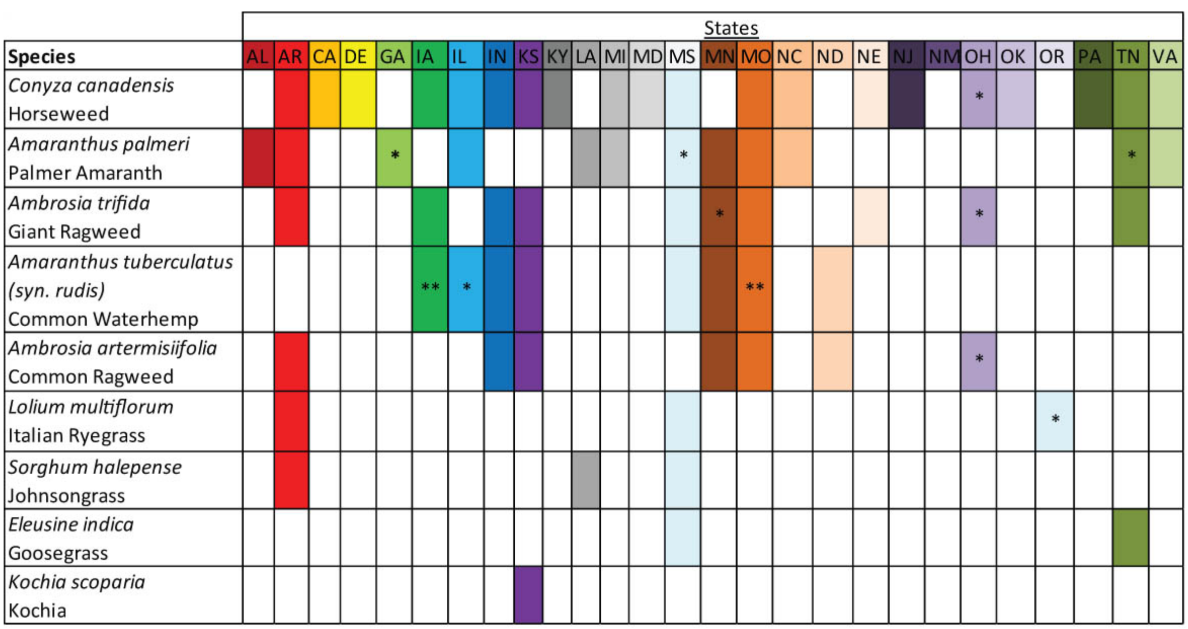

Figure 5. Glyphosate-resistant weeds in the U.S. soybean fields. Note that presence of a population is unrelated to prevalence. * indicates at least one population in that states possesses resistance to glyphosate and another herbicide. **indicates at least one population in that state possesses resistance to glyphosate and two other herbicides. Source: Heap (2011a).

2.3.3 Gene Flow and Weediness

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

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

Soybean is not native to the U.S. and there are no feral or weedy relatives. Consequently, soybean in the U.S. can cross only with other soybean varieties. Additionally, potential of soybean weediness is low, due to domestication syndrome traits that generally lower overall fitness outside an agricultural environment (Stewart et al., 2003). Mature soybean seeds have no innate dormancy, are sensitive to cold, and are not expected to survive in freezing winter conditions (Raper and Kramer, 1987).

2.3.4 Microorganisms

Microorganisms in the field may mediate both negative and positive outcomes. Various bacterial and fungal species have been identified as the causal agents of various diseases afflicting soybean plants (Ruhl, 2012). Additionally, soil microorganisms may play a key role in dynamic biochemical soil processes (Garbeva et al., 2004). They may 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, plant type, and agricultural management practices (Garbeva et al., 2004). Microbial diversity in the rhizosphere may be extensive and differ from the microbial community in the bulk soil (Garbeva et al., 2004).

2.3.5 Biodiversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson, 1988). Biodiversity provides valuable genetic resources for crop improvement and also provides other functions beyond food, fiber, fuel, and income (Harlan, 1975). These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 1999). The loss of biodiversity 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 (Southwood and Way, 1970).

Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas. Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest result limit the diversity of plants and animals (Lovett et al., 2003).

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.

2.4 Human Health

Public health concerns surrounding GE soybean primarily involve the human consumption of GE soybean products. Additionally, soybean growers and farm workers may also be exposed to GE soybean and its respective cultivation practices.

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.

Worker hazards in farming are common to all types of agricultural production, and include hazards of equipment and plant materials. Pesticide application represents the primary exposure route to pesticides for farm workers (USDA-NASS, 2007). However, common farm practices, training, and specialized equipment can mitigate exposure to pesticides by farm workers (Baker et al., 2005a). For example, choosing from less toxic groups of insecticides to control soybean insects is a good common agricultural practice.

Agricultural pesticide exposure levels are regulated by 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.

2.5 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 were produced, 27 million tons of which were marketed for animal feed, with the largest volumes consumed by poultry (48 percent), swine (26 percent), and beef (12 percent) (Soy Stats, 2010).

Similar to the regulatory control for direct consumption of soybean under the FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from GE soybean must comply with all applicable legal and regulatory requirements, which are designed to protect human health. To help ensure compliance, a voluntary consultation process with FDA may be implemented before release of GE plants in animal feed into the market.

2.6 Socioeconomic

2.6.1 Domestic Economic Environment

The domestic soybean industry is primarily composed of commodity production businesses and the users of soybean products (Figure 6). A more detailed description of the domestic soybean industry is presented in Appendix C.

In 2010, 76 million acres of soybeans were cultivated in the U.S., yielding 3.3 billion bushels at a value of 38.9 billion U.S. dollars (USDA-NASS, 2011c). Total 2010 U.S. inventory (2009 remaining stocks plus 2010 production) totaled 3.5 billion bushels, with 43 percent of U.S. soybean destined for the export market (USDA-ERS, 2010b). The remaining 57 percent of U.S. soybean inventory was primarily utilized to produce soybean meal for feed, with lesser amounts processed for soybean oil for industrial or consumption purposes; seed and residuals; or ending stock for storage (Figure 7). The majority of soybean in the U.S. is used to produce animal feed or secondary industrial products, with only a small proportion of the soybean crop being consumed directly by humans (GINA, 2011).

Soy meal typically contains about 50 percent protein by dry weight, and is the most important product of soybean production. Of the domestically crushed soybean, 53 percent of soybean by weight produces meal and 19 percent produces oil (USB, 2011). 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). 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 (Cahoon, 2003; Cargill, 2011; Soy Connection, 2011).

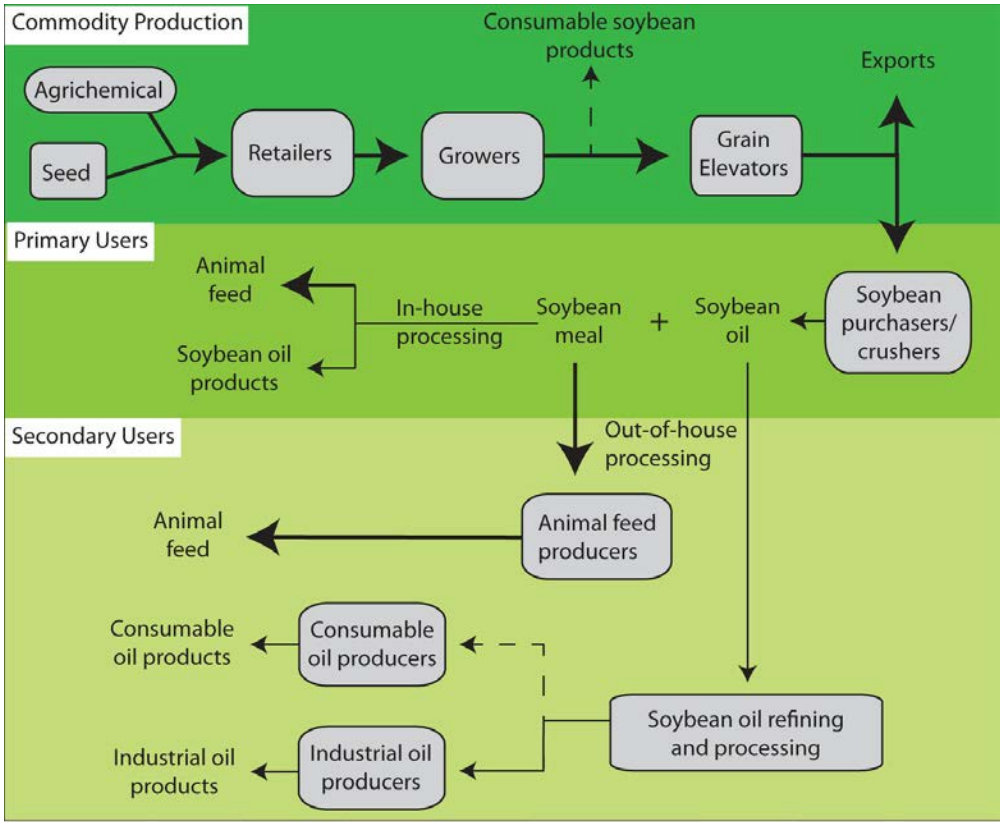

Figure 6. General flow of U.S. soybean commodities. Size of directional arrows is approximately proportional to use. For example, bold arrows represent the primary path of soybean commodities, whereas dashed arrows represent paths of soybean use that are relatively minor. Businesses are boxed in gray, while commodities are unboxed.

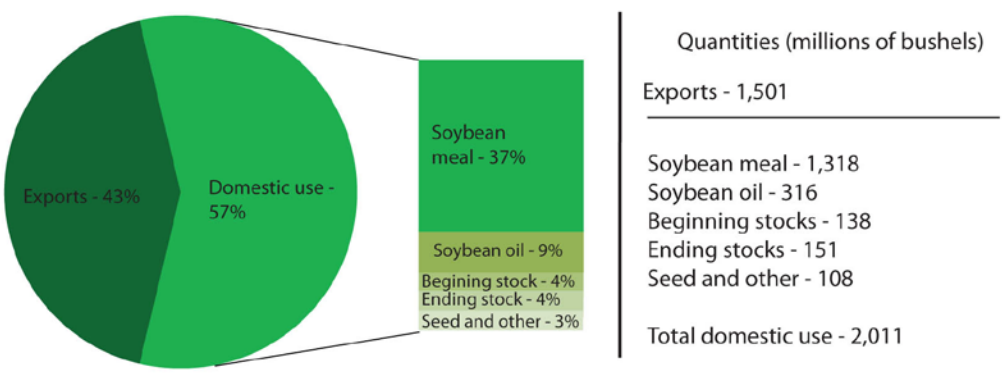

Figure 7. U.S. inventory and use of harvested soybeans, 2010. Source: USDA-ERS (2010b).

2.6.2 Trade Economic Environment

The U.S. produces approximately 35 percent of the global soybean supply (Soy Stats, 2011c). In 2010, the U.S. exported 1.6 billion bushels of soybean, which accounted for 44 percent of the world's soybean exports (Soy Stats, 2011b). In total, the U.S. exported $18.6 billion worth of soybean and soybean products globally in 2010 (Soy Stats, 2011a). China is the largest export market for U.S. soybean with purchases totaling $10.8 billion. Mexico is the second largest export market with sales of $1.5 billion in the same year (Table 2). Other important markets include Japan and the EU.

Table 2. U.S. export markets for soybean and soybean products. Values of exports are listed in millions of dollars.

Top Ten U.S. Export Customers 2010					
Soybean Exports		Soybean Meal Exports		Soybean Oil Exports	
China+Hong Kong	10,823	Canada	354	China+Hong Kong	420
Mexico	1,495	Mexico	344	Mexico	200
Japan	1,127	Philippines	256	Morocco	198
Indonesia	806	Venezuela	217	India	133
Taiwan	653	Morocco	164	Peru	76
Germany	502	Dominican Republic	145	Algeria	71
Egypt	411	Japan	126	Domican Republic	56
Spain	349	Vietnam	116	Canada	47
South Korea	312	Guatemala	106	Venezuela	43
Turkey	250	Poland	100	Nicaragua	36
Other	1,858	Other	1,174	Other	290
Total	18,586	Total	3,103	Total	1,569

Source: Soy Stats (2011a).

3 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of FG72 soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that FG72 is unlikely to pose a plant pest risk. APHIS has concluded through a PPRA that FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012b). Therefore, APHIS must determine that FG72 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: Continuation as a Regulated Article and (2) Preferred Alternative: Determination that FG72 Soybean is No Longer a Regulated Article. 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. FG72 soybean and progeny derived from FG72 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 FG72 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 FG72 soybean.

This alternative is not the Preferred Alternative because APHIS has concluded through a PPRA that FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012b). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition seeking nonregulated status.

3.2 Preferred Alternative: Determination that FG72 Soybean is No Longer a Regulated Article

Under this alternative, FG72 soybean and progeny would no longer be regulated articles under the regulations at 7 CFR part 340. FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012b). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of FG72 soybean and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a petition seeking 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 FG72 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of FG72 soybean is a response that is consistent with the plant pest provisions of the Plant Protection Act, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Under this alternative, growers may have future access to FG72 soybean and progeny derived from this event if the developer decides to commercialize FG72 soybean.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for FG72 soybean. The agency evaluated these alternatives with respect to 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 FG72 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 FG72 Soybean from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of FG72 soybean, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012b).

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, 2012b) and the scientific data evaluated therein, APHIS concluded that FG72 soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of FG72 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 FG72 soybean is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3.3.3 Isolation Distance between FG72 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 FG72 from non-GE soybean production. However, because APHIS has concluded that FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012b), 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 FG72 soybean based on the location of production of non-GE soybean in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' PPRA for FG72 soybean, there are no geographic differences associated with any identifiable plant pest risks for FG72 soybean (USDA-APHIS, 2012b). This alternative was rejected and not analyzed in detail because APHIS has concluded that FG72 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 FG72 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 FG72 soybean is available from the Association of Official Seed Certifying Agencies (AOSCA, 2010).

3.3.4 Requirement of Testing for FG72 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 FG72 soybean does not pose a plant pest risk (USDA-APHIS, 2012b), 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 FG72 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 3 presents a summary of the potential impacts associated with selection of either of the alternatives evaluated in this EA. The impact assessment is presented in Section 4 of this EA.

Table 3. Summary of issues of potential impacts and consequences of alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	**No**	**Yes**
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2012b)
Management Practices		
Acreage and range of soybean production	No	No
Agronomic practices	No	No
Pesticide use	No	No
Organic soybean production	No	No
Environment		
Soil quality	No	No
Water resources	No	No
Air quality	No	No
Climate change	No	No
Animal communities	No	No
Plant communities	No	No
Gene flow/weediness	No	No

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Soil microorganisms	No	No
Biodiversity	No	No
Human and Animal Health		
Human/worker health	No	No
Livestock health/animal feed	No	No
Socioeconomic		
Domestic economic environment	No	No
Trade economic environment	No	No
Other Regulatory Approvals		
U.S.	Non-completed FDA consultation	Non-completed FDA consultation
Compliance with Other Laws		
CWA, CAA, Eos	Fully compliant	Fully compliant

4 ENVIRONMENTAL CONSEQUENCES

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA. Potential environmental impacts from the No Action Alternative and the Preferred Alternative for FG72 soybean are described in detail throughout this section. Certain aspects of this product and its cultivation would be no different between the alternatives: those instances are described below.

A cumulative effects analysis is also included for each resource area in Section 5. 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 FG72 soybean with other events 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.

4.1 Scope of Analysis

Under the No Action Alternative, FG72 soybean will remain subject to the regulatory requirements of 7 CFR part 340 (Section 3.1); additionally, under the Preferred Alternative, FG72 soybean will no longer be subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (Section 3.2).

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for FG72 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.

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 FG72 soybean to occur anywhere in the U.S., APHIS will primarily focus the environmental analysis to those areas that currently support soybean production. To determine areas of soybean production, APHIS used data from USDA-NASS and USDA-ERS.

4.2 Agricultural Production of Soybean

4.2.1 Acreage and Range of Soybean Production

No Action Alternative: Acreage and Range of Soybean Production

Continued domestic and international demand for soybean products, coupled with relatively high soybean commodity prices, is likely to continue increasing (USDA-ERS, 2010b, 2011c) under the No Action Alternative. In response, total U.S. soybean acreage is anticipated to incrementally increase from 76.6 million acres in 2010 to 79.5 million acres in 2020, based on soybean production trends and projections (USDA-ERS, 2011c). In order to accommodate this increase of U.S. soybean acreage in spite of a net decrease in available U.S. agricultural land (EIA, 2007), growers are likely to plant additional soybean acreage at the expense of other crops, such as cotton or hay (O'Brian, 2010; USDA-ERS, 2011e). The use of existing agricultural land in lieu of previously uncultivated land for additional soybean acreage is a necessary land-use decision, as soybean is profitably grown on high quality arable land, not land of lower productivity (EIA, 2007; USDA-NASS, 2011c).

Preferred Alternative: Acreage and Range of Soybean Production

A determination of a nonregulated status of FG72 soybean is unlikely to substantially expand soybean acreage beyond the projected increases (USDA-ERS, 2011c) described in the No Action Alternative for two major reasons. First, FG72 soybean is unlikely to disrupt the causal relationship between market forces and U.S. soybean acreage, which is ultimately affected by growing domestic and international demand for soybean commodity products, such as animal feed or industrial oils/plastics (USDA-ERS, 2010b, 2011c). Secondly, FG72 soybean is unlikely to expand soybean acreage beyond projected values (USDA-ERS, 2011c) because it requires similar management conditions as conventional soybean, does not present any absolute yield gains over conventional soybean varieties under typical management conditions, and exhibits no phenotype that would be indicative of an improved capacity to grow outside an agricultural environment (Bayer, 2011c; USDA-APHIS, 2012b). Similar to currently available soybean varieties, FG72 soybean will likely require cultivation on high quality arable land to produce a grower profit, precluding the use of lower quality, uncultivated land to supply additional soybean acreage. FG72 soybean is unlikely to be cultivated on land not previously used for agriculture, thus maintaining observed farm-level land-use decisions to shift agricultural land away from other crops, such as cotton or hay, toward soybean production to satisfy market demand (USDA-ERS, 2010e, 2011c).

4.2.2 Agronomic Practices

No Action Alternative: Tillage

The current trend of increasing conservation tillage adoption is unlikely to change under the No Action Alternative, due to the extensive market penetration of glyphosate-tolerant soybean varieties (Dill, 2005; Owen, 2010) and its relationship with conservation tillage practices (Bonny, 2011; Givens et al., 2009; USDA-ERS, 2010a). Conservation tillage adoption rates by U.S. soybean growers are likely to be sustained by the continued use of glyphosate as a broad-spectrum herbicide (Carpenter and Gianessi, 1999) that enable conservation tillage strategies to be undertaken as an economical alternative to conventional tillage (Givens et al., 2009; USDA-ERS, 2010a).

In the presence of glyphosate-resistant weeds, some U.S. soybean growers may reincorporate the use of conventional tillage practices to manage those problematic weed populations (NRC, 2010). However, in spite of increasing concern with glyphosate-resistant weed populations, the majority of U.S. growers are likely to continue using glyphosate at increased rates/frequencies rather than reincorporate conventional tillage into their weed management strategies. This response is due to several reasons, though the most relevant include the substantial costs of conventional tillage (USDA-NRCS, 2011), grower familiarity with glyphosate (Johnson et al., 2009; NRC, 2010; Owen et al., 2011), and the overall value placed on simplicity and convenience that is provided by glyphosate-tolerant systems (Owen, 2010). These reasons, coupled with the extent of glyphosate-resistant weeds in U.S. soybean fields (at least 3 percent of U.S. soybean acreage) (Owen, 2010), suggest that the continued use of conservation tillage is likely to continue as practiced under the No Action Alternative.

Preferred Alternative: Tillage

Effective broad-spectrum herbicide use is generally associated with the adoption of conservation tillage in U.S. soybean production practices (NRC, 2010). Similar to the No Action Alternative, FG72 soybean permits the continued use of an existing broad-spectrum herbicide (glyphosate) that contributed to the general use of conservation tillage in U.S. production fields; additionally, FG72 soybean will permit the use of another broad-spectrum herbicide, IFT. The presence of the glyphosate-tolerant phenotype in FG72 soybean will permit the continued use of glyphosate as it is used presently in conventional U.S. soybean production, maintaining current trends of conservation tillage (Bonny, 2011; Owen, 2010; Owen et al., 2011). Concurrently, FG72 soybean will also permit the use of IFT, another effective broad-spectrum herbicide that will permit the continued use of conservation tillage in U.S. soybean production fields (Bayer, 2011a, 2011b). Thus, there is no reason to suspect that a determination of nonregulated status of FG72 soybean would alter the shift toward conservation tillage in soybean, as FG72 soybean will represent another herbicide-tolerant soybean variety that may facilitate the use of conservation tillage (AOSCA, 2011).

No Action Alternative: Fertilization and Crop Rotation

Compared to other crop plants, soybean cultivation requires less nitrogen fertilization. USDA-ERS estimates that less than 40 percent of soybean acres in the U.S. receive nitrogen fertilizer (USDA-ERS, 2010d); this trend of percent soybean acreage treated with nitrogen fertilizer, along with application rates of nitrogen fertilizer, have remained relatively constant since 1992. Under the No Action Alternative, current trends related to fertilizer use in U.S. soybean production are not anticipated to substantially change.

According to USDA-ERS, 95 percent of the soybean-planted acreage has been in some form of a crop rotation system since 1991 (USDA-ERS, 2011b). 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 percent of acreage, other rotations were grown on 16 to

20 percent of acreage, and soybean was grown continuously on 5 to 12 percent of acreage during the years 1996 – 2002 (Sandretto and Payne, 2006). Under the No Action Alternative, current trends related to soybean rotation are unlikely to substantially change.

Preferred Alternative: Fertilization and Crop Rotation

Similar to the No Action Alternative, a determination of nonregulated status of FG72 soybean is unlikely to substantially change fertilization patterns in U.S. soybean production. Standard agricultural practices are required for the cultivation of FG72 soybean, demonstrating that it requires typical quantities of nitrogen in the soil (Bayer, 2011c). In general, GE herbicide tolerant soybean varieties have not required more supplemental nitrogen fertilization compared to other soybean varieties, despite the increase in GE soybean variety adoption (Figure 8).

Additionally, similar to the No Action Alternative, a determination of nonregulated status of FG72 soybean is unlikely to substantially change current patterns of soybean crop rotation because it exhibits similar agronomic performance relative to its nontransgenic parent variety, Jack (Bayer, 2011c). In particular, no differences in phytopathology were generally observed between FG72 and its nontransgenic parent variety (Jack) in experimental plots (USDA-APHIS, 2012b). These similar measures of disease susceptibility suggest that FG72 soybean would benefit from currently-practiced soybean rotation strategies. Furthermore, cultivation of FG72 soybean and potential corresponding IFT use may not restrict common corn/soybean rotation, as the rotation interval for corn following IFT use is 0 months (Bayer, 2011b). Due to this general benefit from crop rotational strategy on disease mitigation and an unlikely disruption with common soybean rotational crops, a determination of nonregulated status of FG72 soybean is likely to continue current patterns of rotation in U.S. soybean production.

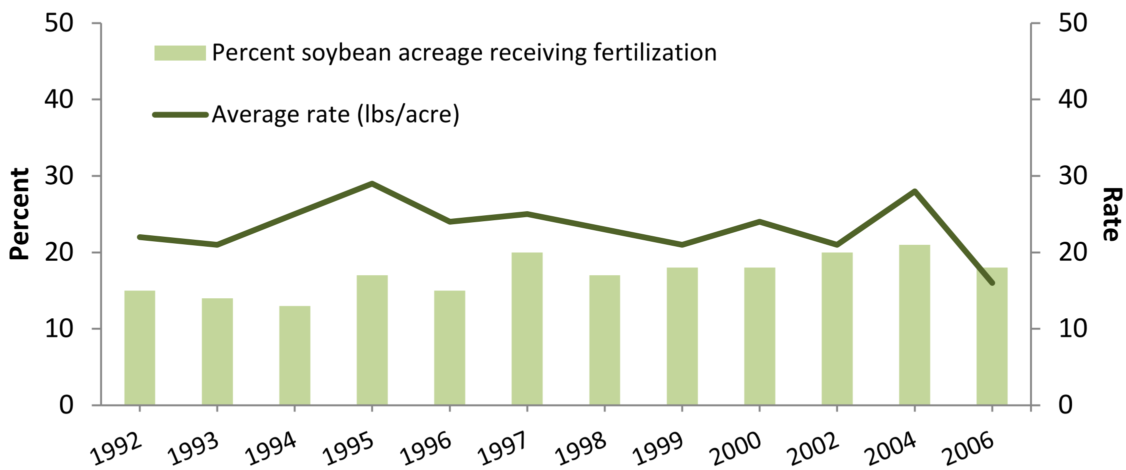

Figure 8. Percent and application rate of nitrogen fertilization in U.S. soybean production, 1992 – 2006. Source: USDA-ERS (2011f, 2011g).

No Action Alternative: Pesticide Use

Under the No Action Alternative, pesticide use in U.S. soybean fields will likely continue as it is currently practiced. Insecticide application in soybean, though variable between states, will likely continue to be restricted to a small percentage of soybean acres (USDA-NASS, 2002, 2007), due in large part to the capacity of soybean to experience limited insect herbivory without a reciprocal loss in grain yield (Penn State Extension, 2011).

With regard to weed management practices, U.S. soybean growers will continue to have access to herbicide-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. U.S. soybean growers will likely continue utilizing herbicides, primarily in the form of glyphosate, as the basis of a weed management system due to the extensive adoption of glyphosate-tolerant soybean varieties (Carpenter and Gianessi, 1999; Fernandez-Cornejo and McBride, 2000) and grower preference for the familiarity and convenience of glyphosate-tolerant soybean systems (USDA-ERS, 2011a). Since the introduction of glyphosate-tolerant soybean varieties, glyphosate application has increased at the expense of alternative herbicides, with respect to total pounds of active ingredient applied (Fernandez-Cornejo et al., 2009). This statement, however, should not be misinterpreted to mean that the diversity of herbicides available to U.S. soybean growers has decreased; rather, the diversity of herbicides used in U.S. soybean production fields has gradually increased while applied quantities of those same herbicides (except glyphosate) have generally decreased (NRC, 2010; USDA-NASS, 1996, 2002, 2007).

The increasing frequency of glyphosate-resistant weeds in some soybean production fields may decrease the technical efficacy of glyphosate in controlling weeds. In spite of this, some U.S. soybean growers are hesitant to stop using glyphosate due to familiarity and comfort with the glyphosate-tolerant soybean system. For example, a survey of 400 corn, cotton, and soybean growers found that a majority would not restrict their use of glyphosate-tolerant crops [or glyphosate] when facing increased weed pressure from glyphosate-resistant weed populations (Scott and VanGessel, 2007). Similarly, Delaware soybean growers continued planting and cultivating glyphosate-tolerant soybean varieties in the presence of glyphosate-resistant horseweed (Scott and VanGessel, 2007).

U.S. soybean growers, however, are beginning to understand that a diversification of selection pressure in their weed management strategies may be necessary to manage and slow glyphosate-resistant weed development (Johnson et al., 2009; NRC, 2010; Owen et al., 2011). One general farm-level response to glyphosate-resistant weeds has been to increase the rate/frequency of glyphosate application and incorporate the use of different herbicidal chemistries (NRC, 2010). A possible consequence of this action may be an absolute increase in total herbicide use (lbs. ai/acre) in U.S. soybean production (NRC, 2010; Owen, 2010). It is prudent to mention, however, that total herbicide use may not be an effective metric to measure environmental impact, as this does not effectively permit the environmental comparison of different herbicides across time or across management strategies (Fernandez-Cornejo et al., 2009).

Preferred Alternative: Pesticide Use

General trends related to soybean pest management are unlikely to change under the Preferred Alternative. Insecticide application practices are likely to be similar between FG72 soybean and conventional soybean, as FG72 soybean is not more susceptible to insect herbivory than conventional soybean varieties (USDA-APHIS, 2012b).

Herbicide use trends in U.S. soybean production are not anticipated to be substantially affected following a determination of nonregulated status of FG72 soybean. FG72 soybean is tolerant to both glyphosate and IFT. Accordingly, FG72 soybean may be integrated into current soybean pest management practices using glyphosate, thereby mitigating any impact on glyphosate-use trends. Additionally, while not previously used in soybean production, IFT represents another herbicide available to U.S. soybean growers. Despite a trend of glyphosate substitution in U.S. soybean production (NRC, 2010), diversity of used herbicides has increased since 1995 (USDA-NASS, 1996, 2002, 2007). The potential use of IFT on FG72 soybean does not represent a shift from this herbicide diversity trend.

The use of IFT in U.S. soybean production may increase under the Preferred Alternative. This is an expected outcome, as IFT was not previously utilized in U.S. soybean production (EPA, 2011d). The extent of IFT use in U.S. soybean production, however, may not substantially increase total pesticide application (lbs. a.i./acre) for several reasons. First, IFT is classified as a restricted use pesticide (EPA, 2011b). IFT may only be applied by a certified applicator or under the direct supervision of a certified applicator in specific agroenvironments and a certain number of states, thus potentially precluding its common and widespread use (EPA, 2012b). Second, as a pre-emergent/early post-emergent herbicide, IFT application is restricted to a short application timeframe in the beginning of a soybean growing season. This limited application window, coupled with restrictions on annual use (no more than one application per growing season, Appendix A) and reduced application rates relative to other common soybean herbicides (Table 4), suggests that IFT may not substantially increase total pesticide use beyond the current projections stated in the No Action Alternative.

Lastly, current use of IFT in field corn suggests that use in soybean may not be substantial. IFT has not been widely used in field corn since commercial introduction in 1999 (Table 5). In 2010, IFT use in field corn totaled 399,000 lbs.; this value was much less than total glyphosate use (57,536,000 lbs.) and represented only 0.11 percent of total herbicide use in corn that same year (USDA-NASS, 2011a). Contributing to this relatively low application in corn is the application rate of IFT; in contrast to other corn herbicides, such as atrazine (0.9 – 1.8 kg/ha) and metochlor (0.7 – 1.4 kg/ha), IFT is typically applied at the rate of 0.05 – 0.11 kg/ha (Ramanarayanan et al., 2005).

As described in the No Action Alternative, total herbicide use may increase in U.S. soybean production due to farm-level response to glyphosate-resistant weeds (NRC, 2010). A determination of nonregulated status of FG72 soybean would likely contribute to this trend, as it would facilitate the use of an herbicide not previously used in U.S. soybean production. However, the contribution of IFT to soybean total herbicide use (lbs. a.i./acre) is likely to be small, due to its use restrictions and reduced application rates (single and annual rate) relative to other common soybean herbicides.

Table 4. Maximum soybean herbicide application rates (single and annual application).

Herbicide Active Ingredient	Rate/Application (lbs./acre)	Rate/Crop Year (lbs./acre)
2,4-D, 2-EHE	0.493	0.503
2,4-D, BEE	0.426	0.459
2,4-D, dimeth. salt	0.462	0.475
Acifluorfen, sodium	0.287	0.296
Alachlor	1.931	1.931
Bentazon	0.687	0.687
Carfentrazone-ethyl	0.038	0.046
Chlorimuron-ethyl	0.017	0.017
Clethodim	0.096	0.102
Cloransulam-methyl	0.019	0.019
Dicamba, digly salt	0.25	0.25
Fenoxaprop	0.031	0.031
Fluazifop-P-butyl	0.099	0.099
Flufenacet	0.265	0.265
Flumetsulam	0.048	0.048
Flumiclorac-pentyl	0.02	0.028
Flumioxazin	0.066	0.066
Fomesafen	0.19	0.233
Glyphosate	0.63	1.044
Glyphosate amm. salt	0.489	0.745
Glyphosate iso. salt	0.802	1.33
Imazamox	0.03	0.03
Imazaquin	0.061	0.062
Imazethapyr	0.053	0.053
Imazethapyr, ammon	0.048	0.048
Isoxaflutole (IFT)	0.07	0.07
Lactofen	0.11	0.11
Metribuzin	0.255	0.26
Paraquat	0.492	0.511
Pendimethalin	0.92	0.926
Quizalofop-P-ethyl	0.038	0.041
S-Metolachlor	1.023	1.023
Sethoxydim	0.153	0.153
Sulfentrazone	0.087	0.091
Sulfosate	0.967	1.701
Thifensulfuron	0.004	0.004
Tribenuron-methyl	0.008	0.008
Trifluralin	0.818	0.818

Source: USDA-NASS (2002, 2007).

Table 5. Use of glyphosate and isoxaflutole (IFT) in U.S. corn production, 2000 – 2010.

Year	Glyphosate application in corn - Measured in total lbs.	Average glyphosate application in corn - Measured in total lbs./acre	Isoxaflutole application in corn - Measured in total lbs.	Average isoxaflutole application in corn - Measured in total lbs./acre
2010	57,536,000	0.82	399,000	0.07
2005	22,967,000	0.73	233,000	0.05
2003	11,913,000	0.69	321,000	0.06
2002	3,307,000	0.64	331,000	0.07
2001	6,868,000	0.66	439,000	0.07
2000	4,438,000	0.59	171,000	0.07

Source: USDA-NASS (2011a).

4.2.3 Organic Soybean Production

No Action Alternative: Organic Soybean Production

Current availability, market demand, and acreage of organic soybean are anticipated to remain unchanged under the No Action Alternative. Similar to market trends for other U.S. organic products, demand of organic soybean is likely to increase (USDA-ERS, 2007). Despite this increasing demand, however, the share of U.S. organic soybean production remains relatively small and steady. While this flat production of U.S. organic soybean correlates with an increase in GE soybean adoption, there is little or no evidence to suggest a cause-and-effect relationship. An alternative explanation is that U.S. organic soybean acreage remains limited because of unrelated reasons, such as: 1) the three-year period transition period between conventional and organic farming; 2) a lack of contractors for organic agronomic practices, including pest and nutrient management; 3) intensive labor requirements; 4) fear of criticism from neighbors; 5) An absence of government infrastructure and policy support; and 6) unknown risks (Clarkson, 2007; USDA-ERS, 2007).

From 2005 - 2008, total organic soybean acreage ranged between 122,000 and 126,000 acres (USDA-ERS, 2010c). This represented less than 0.2 percent of the total U.S. soybean acreage for this period and is not anticipated to substantially change in spite of rising domestic demand, due in part to increasing competition and imports from international organic soybean producers (USDA-ERS, 2007). Therefore, domestic demand for organic soybean and organic soybean products appear to be sustained by increasing imports from international organic soybean producers (The Organic & Non-GMO Report, 2007; USDA-ERS, 2007).

Preferred Alternative: Organic Soybean Production

It is not likely that organic farmers will be substantially affected by a determination of nonregulated status of FG72 soybean. Soybean is primarily a self-pollinated plant (OECD, 2010), and there is no reason to suspect that the biology of FG72 soybean will increase its potential to outcross with soybean varieties utilized in organic soybean production (USDA-

APHIS, 2012b). Field study of FG72 soybean reproductive biology revealed no substantial differences in factors influencing reproductive potential, including pollen viability, date of emergence, date of 50 percent flowering, and date of maturity (Bayer, 2011c).

It is important to note that the current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an product labeled organic (USDA-ERS, 2010c). 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 (Ronald and Fouche, 2006; USDA-AMS, 2010b). However, certain markets or contracts may have defined thresholds (Non-GMO-Project, 2010).

A determination of nonregulated status of FG72 soybean is unlikely to substantially affect U.S. organic soybean market conditions. In contrast to other U.S. organic crops, U.S. organic soybean production has not kept pace with demand (USDA-ERS, 2010c). Domestic production of organic soybean has not kept pace with demand due to the reasons outlined in the previous No Action Alternative section. The increased demand for organic soybean in the U.S. has generally been met by increasing imports from international organic soybean producers (The Organic & Non-GMO Report, 2007; USDA-ERS, 2007).

4.3 Physical Environment

4.3.1 Soil Quality

<u>No Action Alternative: Soil Quality</u>

Soil quality in the agroenvironment is influenced by a variety of agronomic practices, including the crop cultivated and its associated management practices. In particular, tillage is strongly correlated with soil quality (NRC, 2010). As discussed in Section 4.2.2, conservation tillage in U.S. soybean is generally associated with 30 percent or greater remaining plant residue and reduced soil erosion and compaction. The use of conservation tillage in U.S. soybean production has increased and is not expected to change under the No Action Alternative, an effect attributed to the glyphosate-tolerant soybean system. Consequently, because of the strong relationship between conservation tillage and soil quality (Holland, 2004), soil quality in soybean fields is not anticipated to substantially change under the No Action Alternative.

Soil quality may also be affected by the addition of pesticides. Under the No Action Alternative, insecticide use will remain as it is currently practiced and limited to a small percentage of total U.S. soybean acreage (USDA-NASS, 2007). Additionally, glyphosate is anticipated to remain the most widely-applied herbicide in U.S. soybean production, continuing the current trend.

<u>Preferred Alternative: Soil Quality</u>

Soil quality in U.S. soybean production fields is unlikely to be substantially affected under the Preferred Alternative. The increasing adoption of conservation tillage has been partially enabled by the capacity to apply a broad-spectrum herbicide [glyphosate] over a tolerant variety [glyphosate-tolerant soybean]. FG72 soybean is tolerant to glyphosate and IFT, both broad-spectrum herbicides. Thus, conservation tillage trends, and its direct effects on soil quality, are unlikely to deviate as currently practiced.

A consequence of conservation tillage is the incorporation of plant material from the preceding crop into the soil (CTIC, 2008). Consequently, any changes in remaining plant tissue from previous growth may affect soil quality. However, FG72 soybean plant material is unlikely to substantially affect soil quality, as compositional analysis of FG72 soybean tissue demonstrates that it is not substantially different from its non-GE parent variety, Jack (Bayer, 2011c; USDA-APHIS, 2012b).

Under the Preferred Alternative, glyphosate and IFT may be applied to the soil during FG72 cultivation. Glyphosate use has been reviewed in previous APHIS documents and is not anticipated to negatively affect soil quality, when it is used in accordance with the EPA restricted use label (USDA-APHIS, 2012a). IFT, at present, has been primarily applied on field corn. As described in Appendix A, IFT yields a DKN and benzoic acid derivative through biotic or abiotic processes. IFT itself is not likely to substantially affect soil quality, as degradation of IFT is generally rapid, resulting in a half-life of only 0.5 – 13.9 days across a variety of soil types (Beltrán et al., 2002; EPA, 2011b; Papiernik et al., 2007). Furthermore, the estimated half-life of DKN is 61 days, facilitated by aerobic soil metabolism (EPA, 1998). DKN is the bioactive principle of IFT, and thus, may be responsible for non-target plant injury that may result from growth on the treated soil. However, EPA label use restrictions on IFT formulations places minimum limits on when another crop may be planted following IFT application. These intervals, ranging from 4-18 months, exceed the half-life of DKN and are designed to mitigate any incidental plant injury from the soil (Bayer, 2011b). As a consequence of its registration of IFT, EPA has effectively determined that there is no unreasonable environmental risk if the end user adheres to the label use restrictions when applying IFT herbicide formulations.

4.3.2 Water Resources

<u>No Action Alternative: Water Resources</u>

Under the No Action Alternative, water resources associated with soybean production is not likely to be substantially affected. Herbicide-tolerant soybeans, cultivated on 93 percent of soybean acreage, have resulted in the adoption of increased conservation practices (NRC, 2010; USDA-ERS, 2011a). These conservation practices, including reduced tillage and precision agriculture, play a major role in water conservation and maintaining water quality by minimizing soil erosion (USDA-NRCS, 2006). As discussed previously, conservation tillage trends are not expected to change in U.S. soybean production from what is currently practiced; accordingly, the impacts of conservation tillage on water resources are also expected to not change.

<u>Preferred Alternative: Water Resources</u>

Cultivation of FG72 soybean is likely to permit the continued use of conservation tillage as it is currently practiced, and its effects on water resources through the mitigation of water loss and runoff attributes, is not expected to be substantially different from the No Action Alternative. The agronomic performance of FG72 soybean is similar to that of its non-transgenic parent variety, Jack. This implies that FG72 soybean does not require more moisture. Therefore, its irrigation requirements will not differ substantially from that of soybean varieties that are commercially available (Bayer, 2011c; USDA-APHIS, 2012b).

Under the Preferred Alternative, glyphosate and IFT may be applied on FG72 soybean. Glyphosate is applied to most U.S. soybean acreage (Dill, 2005); it will likely be applied to FG72 soybean following a determination of nonregulated status. Glyphosate use has been reviewed in previous APHIS documents and is not anticipated to negatively affect water resources when it is used in accordance with the EPA restricted use label (USDA-APHIS, 2012a). With regard to IFT application, degradation occurs rapidly in both soil and aqueous environments (Beltrán et al., 2002; Rice et al., 2004; Taylor-Lovell et al., 2002). Thus, IFT is not expected to persist in groundwater (aquifers) or surface water (DATCP, 2002; EPA, 2001a), with detection only occurring shortly after field application (Scribner et al., 2006).

DKN, the bioactive principle of IFT, is relatively stable and more mobile in the aqueous phase than parent IFT (EPA, 2011d). Laboratory and tile-drain studies demonstrated the relative stability of DKN in aqueous environments and suggested that it may persist in surface water (DATCP, 2002; EPA, 2011d). Detection of DKN in surface water resources surrounding midwestern corn fields further demonstrated the persistence and mobility of DKN under field conditions (EPA, 2001a, 2002; Rector et al., 2003; Scribner et al., 2006).

Presence of a metabolite in a water resource does not, in itself, represent a negative impact. More relevant is the plausibility and magnitude of an impact. Phytotoxicity risks to non-target terrestrial plants due to the presence of DKN in field runoff and surrounding surface water precipitated the characterization of IFT as a restricted use pesticide by the EPA (EPA, 2011b). Risk to aquatic plants, birds, mammals, invertebrates, and fish from IFT and DKN were determined to be below the EPA level of concern, suggesting that the toxicity of IFT and DKN is relatively low (EPA, 2011b) (Appendix A). Relative to other herbicides applied to U.S. soybean fields, IFT and its degradates fall within the range of environmental impact quotient (EIQ) for several parameters related to water resources, such as leaching potential, and effects on fish, birds, beneficial organisms, and ecology (Table 6). Indeed, when compared to other herbicides applied on soybean, IFT appears to possess an average leaching potential (Table 6). As a consequence of its registration of IFT, EPA has effectively determined that there is no unreasonable environmental risk if the end user adheres to the label use restrictions when applying IFT herbicide formulations. EPA label directions include application restrictions plus requirement for a certified applicator to minimize effects on nearby environments. IFT is currently undergoing a registration review by EPA (EPA, 2011b). If EPA determines that additional restrictions beyond current restrictions (Appendix A) on IFT use are required to mitigate environmental risk to non-target plant communities, then it is expected that EPA would amend IFT use labels accordingly.

Table 6. Environmental Impact Quotient (EIQ) of soybean herbicides with respect to several factors related to water resources. Highlighted rows indicate an herbicide that was applied on a percentage of soybean acres greater than 5 percent in 2006. Isoxaflutole is generally not applied on soybean.

Active ingredient	EIQ Review date	Leaching	Fish	Birds	Beneficials	Ecology
2,4-D, 2-EHE	April-04	1	5	6	15	35
2,4-D, dimethyl salt	April-04	5.00	1.00	6.00	15.00	31.00
Chlorimuron-ethyl	April-04	5.00	3.00	6.00	24.60	42.60
Clethodim	Dec-00	5.00	1.00	6.00	15.00	31.00
Cloransulam-methyl	Jan-03	3.00	3.00	6.00	15.00	33.00
Fluazifop-P-butyl	Mar-09	1.00	15.00	4.65	21.00	72.15
Flumiclorac-pentyl	Mar-09	5.00	3.00	9.00	25.20	46.20
Flumioxazin	Dec-05	2.10	10.20	6.00	24.60	49.80
Fomesafen	Mar-09	5.00	1.00	7.65	17.64	32.59
Glyphosate amm. Salt	April-08	1	5	6	15	35
Imazaquin	Mar-09	5.00	1.00	3.00	25.00	32.00
Imazethapyr	Mar-09	5.00	1.00	7.65	17.54	32.49
Metribuzin	Apr-03	5.00	1.00	27.00	32.10	69.10
Paraquat	Mar-09	1.00	5.00	10.65	13.97	35.92
Pendimethalin	Mar-08	1.00	25.00	9.00	30.00	73.00
S-Metoachlor	Jan-03	3.00	9.00	12.00	15.00	45.00
Sulfentrazone	Jan-04	5.00	1.00	9.00	8.20	21.20
Sulfosate	Mar-01	3.00	3.00	9.00	45.00	66.00
Tribenuron-methyl	Apr-04	3.10	3.40	6.00	15.00	33.40
Trifluralin	Apr-08	1.00	25.00	9.00	5.00	42.00
Isoxaflutole	Jan-04	3.00	9.00	6.00	15.00	39.00

Sources: NY State IPM Program (2012b) and USDA-NASS (2007).

4.3.3 Air Quality

No Action Alternative: Air Quality

All agricultural practices have the potential to cause negative impacts to air quality. Agricultural emission sources include smoke from machinery, pesticide drift from spraying, GHG emissions, and particulate matter (EPA, 2010d; USDA-NRCS, 2006). Under the No Action Alternative, current impacts to air quality associated with soybean acreage and cultivation practices would not be affected. Agronomic practices associated with conventional soybean production that 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

As previously discussed in Section 4.2, the majority of agronomic practices (with the exception of IFT use) commonly utilized in conventional soybean production are not likely to be substantially different between FG72 and conventional soybean. Accordingly, a determination of a nonregulated status of FG72 soybean is unlikely to change the use of agricultural practices with the potential to affect air quality from what is currently practiced. In particular, the adoption of conservation tillage is generally increasing in conventional soybean production, partially enabled by the use of effective, non-selective herbicides such as glyphosate. Under the Preferred Alternative, FG72 soybean would also permit the use of two non-selective herbicides (glyphosate and IFT) that may facilitate conservation tillage. Thus, the effects of tillage on air quality conservation tillage trends would be maintained and not deviate substantially as it is currently practiced in typical soybean production practices.

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.

FG72 soybean use would be limited to areas APHIS has approved it for regulated releases under the No Action Alternative. Agronomic management practices and phenotypic characteristics regarding FG72 soybean are similar to those of conventional soybean, so impact from soybean varieties would be minimal. Measurable effects from these confined field releases would also be minor because of the small scale of management and acreage relative to current soybean production in the U.S.

Preferred Alternative: Climate Change

As described in Section 4.2.1, the range and area of U.S. soybean production is not likely to expand under the Preferred Alternative. As described in the Bayer petition (Bayer, 2011c) and USDA-APHIS PPRA (USDA-APHIS, 2012b), FG72 soybean requires management strategies similar to that for conventional soybean production, thus precluding changes in agricultural activities that may affect climate change, such as machine usage and tillage. Collectively, because the range, area, and agronomic practices of soybean are unlikely to change following a determination of nonregulated status of FG72 soybean, the agricultural impacts of soybean cultivation are also unlikely to change under the Preferred Alternative.

While agricultural activities may affect climate change, the converse is also true; climate change may affect agriculture. For example, climate change may result in shifts of herbivorous insects to higher latitudes. There is evidence that insect diversity and vegetative consumption intensity increase with increasing temperature at the same latitude in the fossil record (Bale et al., 2002). How climate change will affect individual species of pest insects will depend on their physiology, feeding behavior, and overwintering strategies (Bale et al., 2002). In cases where climate change favors the expansion of the range of soybean pests, additional soybean acres may be treated with insecticides. FG72 soybean is not any more susceptible to insect herbivory than conventional soybean varieties (USDA-APHIS, 2012b), so change in insect pressure resulting from climate change is likely to impact FG72 soybean just as it would conventional soybean.

4.4 Biological Resources

4.4.1 Animal Communities

No Action Alternative: Animal Communities

Soybean production fields may be host to many animal and insect 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.

Under the No Action Alternative, conventional soybean production would continue while FG72 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

As described in Chapter 4.2, land use and agricultural production of FG72 soybean under the Preferred Alternative is likely to continue as currently practiced. Consequently, any impact to animal communities as a result of soybean production practices under the Preferred Alternative is likely to be similar to the No Action Alternative.

Consumption of FG72 soybean is unlikely to substantially affect non-target organisms, such as animals, birds, or insects. 2mEPSPS has been previously analyzed and approved by several international regulatory agencies, demonstrating that it is not likely to have any significant impact on animal health (CFIA, 1998; FSANZ, 2001; SCF, 2002; USDA-APHIS, 1997). Though HPPD W336 has not previously been evaluated, there is no reason to suspect it would present a risk to non-target organisms. HPPD proteins are ubiquitous in the environment and are not novel. Bioinformatic analysis of HPPD W336 showed no significant lengthwise alignment with known toxins or allergens (Bayer, 2011c). Additionally, compositional analysis of FG72 soybean proximate and fiber components, amino acid and fatty acid content, and antinutrients and isoflavone concentrations revealed no substantial differences between it and conventional soybean varieties (Bayer, 2011c).

Non-target organisms may be exposed to glyphosate and IFT under the Preferred Alternative. The majority of U.S. soybean acreage is already subject to glyphosate application (USDA-NASS, 2007); consequently, exposure to glyphosate through the cultivation of FG72 soybean is not likely to increase non-target organism exposure to glyphosate. Based on information provided in existing APHIS EAs (USDA-APHIS, 2012a), exposure to glyphosate by non-target organisms is expected to be similar to the No Action Alternative. The potential impact of IFT on non-target organisms has been evaluated by the EPA (EPA, 2011b, 2011d). In summary, following three separate ecological risk assessments, EPA concluded that the level of concern for acute and chronic risks for birds, mammals, and fish was not exceeded as a result of IFT application (Tables A3-A4, Appendix A). On an acute contact an oral basis, IFT was determined to be practically non-toxic to honey bees (*Apis mellifera*) (Table 7) (EPA, 2011d). Mysid shrimp (*Mysidopsis bahia*), an estuarine invertebrate species, was found to be highly sensitive to IFT (LC_{50} = 0.018) (Table 8) (DATCP, 2002); however, given the rapid decay of parent IFT to DKN and the decreased sensitivity of *M. bahia* to DKN (LC_{50} = 3.6) (EPA, 2011d), this may be less of an issue in field conditions. As a result of these conclusions, it is unlikely that IFT would pose a risk to animal communities under the Preferred Alternative.

Table 7. Summary of the most sensitive endpoints from submitted terrestrial toxicity studies for isoxaflutole (IFT).

Taxa represented	Species (common name)	Toxicity value	Comments
Birds, terrestrial-phase amphibians and reptiles	Bobwhite quail (*Colinus virginianus*)	LD_{50} > 2150 mg/kg-bw	No observed mortalities at highest treatment level.
		LD_{50} > 4255 mg/kg-food	
	Mallard duck (*Anas platyrhynchos*)	LD_{50} > 2150 mg/kg-bw	
		LD_{50} > 4255 mg/kg-food	
Terrestrial mammals	Laboratory rat (*Rattus norvegicus*)	LD_{50} > 5000 mg/kg-bw	Acute inhalation LC50 > 5.23 mg/L.
		NOAEC = 17.4 mg a.i./kg-food	Values based on exposure to males; LOAEC = 414 mg/kg-food based on decreased body weight in parents and offspring.
Terrestrial invertebrates	Honey bee (*Apis mellifera*)	LD_{50} > 5000 mg/kg-bw	No observed mortalities at highest treatment level. Oral LD_{50} > 168.7 ug/bee.

Source: EPA (2011d).

Table 8. Summary of the most sensitive endpoints for submitted aquatic toxicity studies for isoxaflutole (IFT).

Taxa represented	Species (common name)	Toxicity value (mg a.i./L)	Comments
Freshwater fish and aquatic-phase amphibians	Rainbow trout (*Oncorhynchus mykiss*)	96-hr LC_{50} > 1.7	No observed mortalities at highest treatment level. 1.7 ppm represents maximum water solubility obtainable under test conditions.
		NOAEC = 0.096	No toxicity data are available for this taxa. NOAEC derived using ACR for mysid shrimp (17.8) and acute toxicity value for rainbow trout.

Taxa represented	Species (common name)	Toxicity value (mg a.i./L)	Comments
Freshwater invertebrates	Water flea (*Daphnia magna*)	48-hr LC_{50} > 1.5	No observed immobility at highest treatment level. 1.5 ppm represents maximum water solubility obtainable under test conditions.
		NOAEC = 0.087	No toxicity data are available for this taxa. NOAEC derived using ACR for mysid shrimp (17.8) and acute toxicity value for water flea.
Estuarine/ Marine fish	Sheepshead minnow (*Cyprinodon variegates*)	96-hr LC_{50} > 6.4	No observed immobility at highest treatment level. 6.4 ppm represents maximum water solubility obtainable under test conditions.
		NOAEC = 0.36	No toxicity data are available for this taxa. NOAEC derived using ACR for mysid shrimp (17.8) and acute toxicity value for sheepshead minnow.
Estuarine/ Marine invertebrates	Mysid shrimp (*Mysidopsis bahia*)	96-hr LC_{50} > 0.0178	Slope = 2.9.
		NOAEC = 0.001	LOAEC = 0.0019 based on effects to survival.

Source: EPA (2011d).

4.4.2 Plant Communities

No Action Alternative: Plant Communities

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 percent (Barrentine, 1989).

Weed 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 and other registered herbicides. The majority of U.S. soybean acres will continue to be subject to herbicide application. No changes to cultivation practices are expected under the No Action Alternative.

Preferred Alternative: Plant Communities

Under the Preferred Alternative, FG72 soybean is not expected to affect plant communities due to toxicity or allergenicity of the transgene proteins. Both introduced proteins, 2mEPSPS and HPPD W336, are not derived from organisms that are known for pathogenic or toxic effects on plants; these traits themselves are effectively benign in the environment (Bayer, 2011c). There are no compatible wild relatives of soybean in the U.S. (OECD, 2010), so there will be no impact on the wild genetic resources of soybean following a determination a nonregulated status of FG72 soybean. Furthermore, FG72 soybean does not display or possess any weedy characteristics, and thus, is not expected to behave as a weed (USDA-APHIS, 2012b).

FG72 soybean will permit the continued use of glyphosate on soybean, as described in Section 4.2.2. Thus, any impact of glyphosate use on the plant community will be the same as the No Action Alternative. Based on information provided in existing APHIS EAs (USDA-APHIS, 2012a), the impacts on the plant community in soybean from glyphosate is expected to be similar to the No Action Alternative.

As described in Section 4.2.2, FG72 soybean may also facilitate the increased use of IFT in U.S. soybean production. IFT, through its degradation to DKN, functions as a nonselective herbicide. Therefore, both non-target plant and weed species may experience high levels of toxicity following exposure to IFT. Possible routes of exposure include direct exposure in the agricultural field and runoff. Soybean weed species are the most likely to be exposed to IFT through direct application. As a nonselective herbicide, IFT can be expected to control a wide variety soybean weed species (Table 9). Direct exposure of weeds to IFT under the Preferred Alternative is not anticipated to be substantially different than direct exposure of weeds to alternative herbicides under the No Action Alternative, as IFT represents yet another herbicide in a growing diversity of herbicides utilized in soybean production (Section 4.2.2).

Table 9. Control of common broadleaf and grassy weeds by isoxaflutole (IFT) (Balance® Pro). C = controlled; S = suppression; and N = not controlled or suppressed.

Broadleaf Weeds			**Grassy Weeds**
Palmer amaranth - C	Hairy nightshade - C		Barnyardgrass - C
Buffalobur - C	Field pennycress - C		Large crabgrass - C
Burcucumber - S	Broadleaf plantain - C		Smooth crabgras - C
Carpetweed - N	Prostrate pigweed - C		Wooly cupgrass - C
Chamomile spp. - C	Redroot pigweed - C		Bristly foxtail - C
Common chickweed - C	Smooth pigweed - C		Giant foxtail - C
Cocklebur - N	Common purslane - C		Green foxtail - C
Dandelion- C	Wild radish - C		Robust purple foxtail - C
Galinsoga - C	Common ragweed - C		Robust white foxtail - C
Henbit - S	Giant ragweed - S		Yellow foxtail - C
Jimsonweed - C	Russian thistle - C		Goosegrass - C
Kochia - C	Shepherds purse - C		Johnsongrass, seedling - C
Lambsquater - C	Pennsylvania smartweed - C		Fall panicum - C
Venice mallow - C	Toothed spurge - C		Texas panicum - C
Marestail - C	Wild sunflower - N		Wild proso millet - C
Annual morning glory - C	Velvetleaf - C		Field sandbur - S

Broadleaf Weeds			Grassy Weeds
Wild mustard - C	Common waterhemp - C		Shattercane - S
Black nightshade - C	Tall waterhemp - C		Broadleaf signalgrass - C
Eastern black nightshade - C			Witchgrass - N

Adapted from DATCP (2002).

As described in Section 4.3.2, runoff may pose an environmental risk to non-target plants (EPA, 2011d). However, as a consequence of its registration, EPA has determined that there is no unreasonable environmental risk if the end user adheres to the label use restrictions when applying IFT herbicide formulations. EPA label directions include application restrictions plus requirement for a certified applicator to minimize effects on nearby environments(Bayer, 2011a, 2011b). Violators of the regulations are liable for all negative consequences of their actions. This serves as an added incentive to farmers who use restricted use pesticides, so they are more likely to carefully follow its label restrictions. Given that the leaching potential of IFT is not substantially higher than many currently-registered soybean herbicides (Table 6), it is unlikely that IFT poses any more of a risk to non-target plants than the herbicides that would otherwise be utilized under the No Action Alternative. IFT is currently undergoing a registration review by EPA (EPA, 2011b). If EPA determines that additional restrictions beyond current restrictions (Appendix A) on IFT use are required to mitigate environmental risk to non-target plant communities, then it is expected that EPA would amend IFT use labels accordingly.

Weed populations can change in response to multiple agricultural management decisions, including those related to herbicide application. At present, nine glyphosate-resistant weeds have been identified in soybean fields (Figure 5), inhabiting approximately two million acres of farmland in the U.S. (Hubbard, 2008). As described in Section 4.2.2, FG72 soybean may facilitate the use of IFT in U.S. soybean production. Following a determination of nonregulated status of FG72 soybean, IFT application may be utilized to control glyphosate-resistant weeds in U.S. soybean fields. Possessing an alternative MoA, IFT is expected to control glyphosate-resistant weeds. Of the nine glyphosate-resistant weeds found in U.S. soybean fields, horseweed, Palmer amaranth, common waterhemp, common ragweed, johnsongrass, goosegrass, and kochia are controlled by IFT (Table 10). Control of the remaining glyphosate-resistant weeds potentially found in soybean fields, such as giant ragweed or Italian ryegrass, may be controlled by alternative herbicide use alone or in conjunction with IFT.

Table 10. Control of glyphosate-resistant broadleaf and grassy weeds found in soybean by isoxaflutole (IFT) (Balance® Pro). C = controlled; S = suppression; and N/T = not determined.

Broadleaf Weeds		Grassy Weeds
Horseweed (Marestail) (*Conyza candensis*) - C		Goosegrass (*Eleusine indica*) - C
Kochia (*Kochia scoparia*) - C		Italian Ryegrass (*Lolium spp. multiflorum*) - N/A
Palmer Amaranth (*Amaranthus palmeri*) - C		Johnsongrass (*Sorghum halepense*) - C

Broadleaf Weeds		Grassy Weeds
Ragweed, Common (*Ambrosia artemisiifolia*) - C		
Ragweed, Giant (*Ambrosia trifida*) - S		
Waterhemp, Common (*Amaranthus tuberculatus*) - C		

Adapted from DATCP (2002).

Since 2009, four populations of common waterhemp in Illinois, Iowa, and Nebraska corn fields were reported to be resistant to 4-HPPD inhibitors (Heap, 2011b). While three of these biotypes were resistant to the triketone family of 4-HPPD inhibitors, cross-family resistance to IFT may be possible. One example of this was found in 2011 in a common waterhemp biotype from Iowa that displayed cross-family resistance to triketone-based 4-HPPD inhibitors as well as IFT (Heap, 2011b). The conditions leading to the advent of at least one of these reported cases is not likely to be common in FG72 soybean fields. In the Illinois biotype found in 2009, an absence of crop and herbicide rotation in the corn seed production field contributed to the development of 4-HPPD resistance (Hausman et al., 2011). Unlike seed corn production fields, however, the majority of soybean production fields are rotated with another crop (USDA-ERS, 2011b). FG72 soybean fields are not anticipated to be any different. Under the Preferred Alternative, FG72 soybean will permit the pre-emergent use of both glyphosate and IFT; pre-emergent use of an herbicide was sufficient to control this population of 4-HPPD resistant waterhemp (Syngenta, 2010).

4.4.3 Gene Flow and Weediness

No Action Alternative: Gene Flow and Weediness

Soybean is a self-pollinated species, propagated by seed (OECD, 2010). Pollination typically takes place on the day the flower opens. The soybean stigma is receptive to pollen approximately 24 hours before anthesis 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 a very low frequency (0 to 6.3 percent) (Caviness; Ray et al., 2003; USDA-APHIS, 2011; Yoshimura et al., 2006).

Under the No Action Alternative, conventional soybean varieties, including GE soybean varieties no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act, will continue to be grown commercially while FG72 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

There are no compatible relatives of soybean in the U.S. Thus, gene flow is only possible between domesticated soybean plants (OECD, 2010). Soybean is predominantly a self-pollinated species (OECD, 2000), yet a small amount of outcrossing does occur. However, current cultivation practices to prevent out-crossing have been deemed sufficient to prevent unwanted gene flow. For soybean, the Association of Official Seed Certifying Agencies (AOSCA) mandates a zero isolation distance: "Fields of soybeans shall be separated from any other variety or uncertified seed of the same variety by a distance adequate to prevent mechanical mixture."

FG72 soybean, compared to its non-transgenic parent variety (Jack), did not exhibit any changes in reproductive characteristics that would increase likelihood of gene flow, such as fecundity, seed dispersal, increased persistence, or pollen viability/germination (Bayer, 2011c; USDA-APHIS, 2012b). Thus, under the Preferred Alternative, the likelihood of gene flow from FG72 soybean to other soybean varieties is not substantially different than between current soybean varieties.

FG72 soybean is not likely to be weedy. Soybean is not identified as a weed in the U.S. Phenotypic and agronomic characteristics of FG72 soybean were evaluated in a comparative manner to assess plant pest potential (OECD, 1993). These assessments included 17 plant growth and development characteristics: early stand count, plant vigor, days to flowering, flower color, leaf shape, health rating at stage V4-5, health rating at stage R1, health rating of mature plants, pubescence color, pod color, hilum color, canopy, days to maturity, yield in bu/ac, lodging, final stand count and pod shatter (Bayer, 2011c). Results of these evaluations indicate that there is no fundamental difference between FG72 soybean and conventional soybean for traits associated with weediness. Collectively, these findings support the conclusion that FG72 soybean is no more likely to be a weed compared to conventional soybean (USDA-APHIS, 2012b).

4.4.4 Microorganisms

No Action Alternative: Microorganisms

In particular, the soil microbial community is an integral ecosystem component that may provide and sustain 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 in agriculture, such as the crop cultivated or the tillage method utilized (Steenwerth et al., 2002).

Under the No Action Alternative, soybean cultivation practices would continue as currently practiced. Microbes in the field would continue to be exposed to common agronomic practices, glyphosate, and other pesticides applied to soybean.

Preferred Alternative: Microorganisms

Field observations were conducted to assess potential agronomic differences between FG72 soybean and conventional soybean in 2003 and 2008 and at a total of 15 planting sites (Bayer, 2011c). The disease analysis included observation of a wide range of bacterial and fungal pathogens, including downy mildew (*Peronospora manshurica*); bacterial blight (*Pseudomonas syringae* pv. *Glycinea*); Cercospora leaf blight (*Cercospora kikuchii*); brown spot (*Septoria glycines*); frogeye leafspot (*Cercospora sojina*); powdery mildew (*Microsphaera diffusa*); and sudden death syndrome (*Fusarium virguliforme*). No differences in disease susceptibility were observed between FG72 and conventional soybean, suggesting that the two introduced traits did not alter soybean interactions with microorganisms in the field (USDA-APHIS, 2012b).

The soil microbial community is affected by standard agronomic practices, such as tillage patterns, agricultural inputs, and rotations strategies of the crop cultivated (Steenwerth et al., 2002). FG72 soybean requires similar cultivation practices as commercialized soybean varieties, suggesting that a determination of nonregulated status is unlikely to substantially change current soybean production practices. In particular, tillage patterns have been identified as an important determinant of soil microbial community and structure (Eileen J, 2001; Lupwayi et al., 1998). Consequently, under the Preferred Alternative, FG72 soybean is unlikely to substantially affect microbial community and structure because it represents another herbicide-tolerant soybean variety that may enable conservation tillage strategies widely practiced in U.S. soybean production (NRC, 2010). Further support is evident from the decomposition of FG72 soybean plant material in the field following the implementation of conservation tillage (CTIC, 2008). It is unlikely to substantially affect the soil microbial community because FG72 soybean does not substantially differ from conventional soybean in compositional factors, including proximate and fiber components, amino and fatty acids, and relevant soybean anti-nutrients and isoflavones (USDA-APHIS, 2012b).

4.4.5 Biodiversity

No Action Alternative: Biodiversity

Biological diversity, or the variation in species or life forms in an area, is highly managed in agricultural systems. Farmers typically plant crops that are genetically adapted to grow well in a specific area of cultivation and have been bred for a specific market. In conventional agriculture, farmers want to encourage high yields from their corn crop, and will intensively manage plant and animal communities through chemical and cultural controls to protect the crop from damage. Therefore, the biological diversity in agricultural systems (the agro-ecosystem) is highly managed and may be lower than in the surrounding habitats.

Under the No Action Alternative, FG72 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 conventional soybean varieties, including 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. Agronomic practices associated with conventional soybean production such as tillage, cultivation, irrigation, pesticide application, fertilizer applications and agriculture equipment would continue unchanged. Animal and plant species that typically inhabit soybean production fields will continue to be affected by currently utilized management plans and systems, which include the use of mechanical, cultural, and chemical control methods.

Preferred Alternative: Biodiversity

Although soybean production fields are cultivated as plant monocultures to optimize yield, the adjacent landscape may harbor a wide variety of plants and animals. Broad spectrum herbicide application has the potential to impact off-site plant communities. Under the Preferred Alternative, cultivation, management, and land-use decisions related to FG72 soybean is not likely to be substantially different from conventional soybean varieties. Therefore, the four primary determinants of biodiversity in an agroecosystem (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) are likely to remain unchanged under the Preferred Alternative.

4.5 Human Health

No Action Alternative: Human Health

Under the No Action Alternative, human exposure to existing traditional and GE soybean varieties and their products would not change. Furthermore, soybean growers and farm workers will continue to be exposed to existing traditional and GE soybean varieties and their respective cultivation practices. In particular, soybean growers and farmworkers may be exposed to a variety of EPA-registered pesticides related to soybean pest management in both GE and non-GE soybean production systems. 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. No changes to current worker safety are anticipated under the No Action Alternative.

Preferred Alternative: Human Health

Bayer CropScience initiated the consultation process with FDA for the commercial distribution of FG72 soybean and submitted a safety and nutritional assessment of food and feed derived from FG72 soybean to the FDA on December 3, 2009. FDA is currently evaluating the submission, and as of March 16, 2012, has not completed the consultation.

Public health concerns surrounding GE soybean primarily involve the human consumption of GE soybean products. FG72 soybean contains two introduced proteins, 2mEPSPS and HPPD W336. 2mEPSPS has been previously analyzed and approved by several international regulatory agencies, thus demonstrating that it is not likely to have any significant impact on human health (CFIA, 1998; FSANZ, 2001; SCF, 2002; USDA-APHIS, 1997). HPPD W336 is currently being analyzed by several regulatory agencies (CFIA, 2011; EFSA, 2011a; FSANZ, 2011b). However, there is no evidence to suggest that HPPD W336 would be detrimental to general human health. Bioinformatic analysis of HPPD W336 showed no significant lengthwise alignment with known toxins or allergens (Bayer, 2011c). HPPD W336 is derived from *P. fluorescens*, a ubiquitous, soil-borne bacterium with a history of safe use (Maurhofer et al., 1994; Sanger, 2012). While *P.*

fluorescens may occur as an opportunistic pathogen in humans, this is generally limited to immune-compromised patients (McKellar, 1982; Wong et al., 2011).

A comparison of FG72 soybean with conventional soybean varieties reveals compositional equivalence. Analysis of FG72 soybean proximate and fiber components (moisture, protein, fat, ash, carbohydrates, ADF, and NDF), amino acids, fatty acid content (C16:0; C18:0; C20:0; C22:0; C24:0; C18:1; C20:1; C18:2; and C18:3), antinutrients (phytic acid, raffinose, stachyose, letchtin, and trypsin inhibitor), and isoflavones (daidzin, genistin, glycitin, daidzein, genistein, and glycitein) demonstrated that FG72 soybean is not compositionally different from currently available soybean varieties (Bayer, 2011c; USDA-APHIS, 2012b). The characterization of soybean seed allergens also indicates that there are no substantial increases between FG72 and conventional soybean (Rouquié et al., 2010).

The general public may come into contact with glyphosate and IFT used in the cultivation of GH72 soybean. Based on information provided in existing APHIS EAs (USDA-APHIS, 2012a), the potential human health risks associated with glyphosate use is expected to be similar to the No Action Alternative. Members of the general public are unlikely to come into direct exposure with IFT as a result of application. As a restricted-use pesticide, IFT is not registered for residential use and may only be applied by certified applicators or under the direct supervision of a certified applicator, thus mitigating potential exposure to IFT prior to harvest (EPA, 2011b, 2012b). Furthermore, EPA has included use restrictions on the IFT label to mitigate potential exposure to IFT (Appendix A). EPA recently established combined tolerances for IFT and DKN on soybean and aspirated soybean grain fractions following a human health risk assessment (Appendix A) (EPA, 2011c). As a result of this human health risk assessment, EPA concluded that there are no residue chemistry, toxicological, or occupational/residential exposure issues that would preclude the establishment of an unconditional registration or permanent tolerances for IFT and DKN on soybean and aspirated soybean grain fractions (EPA, 2011c). Establishment of a tolerance for IFT on soybean concludes that there is a reasonable certainty that no harm to human health will result from aggregate exposure to IFT or its residues, including all dietary exposures and all other exposures for which there is reliable information (76 FR 235, 2011). When used according with EPA label restrictions, the established tolerances of IFT on soybean and aspirated soybean grain fractions are unlikely to adversely affect human health.

4.6 Animal Feed

No Action Alternative: Animal Feed

The majority of the soybean cultivated in the U.S. is grown for animal feed and is usually fed as soybean meal. Under the No Action Alternative, soybean-based animal feed will still be available from currently cultivated conventional varieties, including 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. This includes herbicide-tolerant GE soybean varieties. No change in the availability of these crops as animal feed is expected under the No Action Alternative.

Preferred Alternative: Animal Feed

Under FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from FG72 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. Bayer CropScience initiated the consultation process with FDA for the commercial distribution of FG72 soybean and submitted a safety and nutritional assessment of food and feed derived from FG72 soybean to the FDA on December 3, 2009. FDA is currently evaluating the submission, and as of March 16, 2012, has not completed the consultation.

A determination of nonregulated status of FG72 soybean is unlikely to adversely affect the nutrition of animal feed, and thus, animal health. The two introduced proteins in FG72 soybean, 2mEPSPS and HPPD W336, are unlikely to substantially affect the nutritional quality of soybean meal derived from FG72 soybean. 2mEPSPS has been previously analyzed and approved by several international regulatory agencies, demonstrating that it is not likely to have any significant impact on animal health (CFIA, 1998; FSANZ, 2001; SCF, 2002; USDA-APHIS, 1997). Though HPPD W336 has not previously been evaluated in animal feed, there is no reason to suspect it would present a substantial risk to animal health. HPPD proteins are ubiquitous in the environment. Additionally, bioinformatic analysis of HPPD W336 showed no significant lengthwise alignment with known toxins or allergens (Bayer, 2011c).

With regard to FG72 soybean itself, compositional analysis revealed no substantial differences between it and conventional soybean in factors important for animal feed, such as proximate and fiber components, amino acid and fatty acid content, and antinutrients and isoflavone concentrations (Bayer, 2011c). Consequently, the quality of animal feed derived from FG72 soybean is unlikely to be substantially different than animal feed produced from current soybean varieties.

4.7 Socioeconomic Impacts

4.7.1 Domestic Economic Environment

No Action Alternative: Domestic Economic Enivonrment

In 2010, 76 million acres of soybeans were cultivated in the U.S., yielding 3.3 billion bushels at a value of 38.9 billion U.S. dollars (USDA-NASS, 2011c). The majority of soybeans produced in the U.S. is utilized domestically for animal feed, with less amounts and byproducts used for oil or fresh consumption (GINA, 2011; USDA-ERS, 2010b).

Under the No Action Alternative, FG72 soybean and its progeny would remain 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 FG72 soybean and its progeny, but would continue to have access to conventional soybean varieties, including 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. Domestic growers will continue to utilize conventional soybean varieties based upon availability and market demand.

Preferred Alternative: Domestic Economic Environment

Soybean composition greatly affects its viability as a component of animal feed. Soybean meal generally contains 50 percent protein by dry weight and is an important component of soybean production. An additional 19 percent (by weight) of domestically chorused soybeans are used to produce oil (USB, 2011). The fatty acid content of soybean grain is important for the domestic soybean oil industry, as the soybean oil profile affects melting point, oxidative stability, and chemical functionality, ultimately determining the market value/marketability of the product (APAG, 2011).

A determination of nonregulated status of FG72 soybean is expected to have similar impacts on the domestic economic environment as the No Action Alternative. Paired comparison of FG72 soybean with its nontransgenic, parent variety demonstrated no significant differences in fatty acid or crude protein content (Figure 9). Thus, market sector use of FG72 soybean under the Preferred Alternative is unlikely to be substantially different from market use of Jack, as the primary factors of oil and protein content are not substantially different between the two soybean varieties.

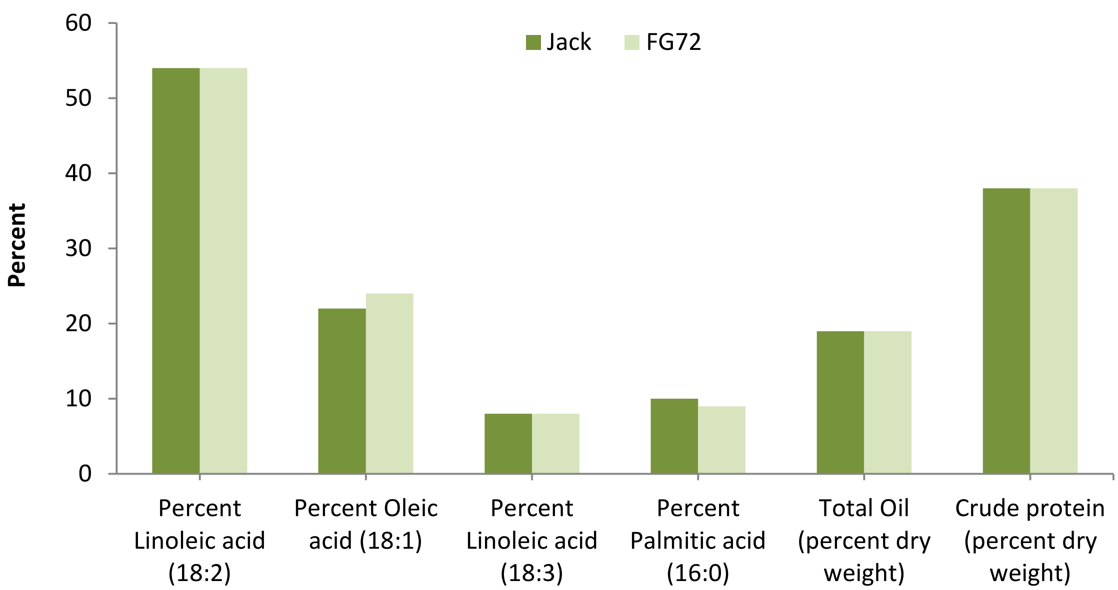

Figure 9. Comparison of typical soybean fatty acids and crude protein between FG72 soybean and Jack. Source: Bayer (2011c).

4.7.2 Trade Economic Environment

No Action Alternative: Trade Economic Environment

The U.S. produces approximately 35 percent of the global soybean supply (Soy Stats, 2011c). In 2010, the U.S. exported 1.6 billion bushels of soybean, which accounted for 44 percent of the world's soybean exports (Soy Stats, 2011b). The global demand for soybeans is expected to increase by a full third over 2010 consumption in the next ten years. China is expected to account for 80 percent of the increased demand (FAPRI, 2009; Hartnell, 2010). China and India are predicted to import 46 percent 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).

Under the No Action Alternative, there is unlikely to be any change to the current soybean market. Most (93 percent) of the soybean varieties currently cultivated in the U.S. are GE varieties and it is predicted that this will not change substantially (USDA-ERS, 2011a). U.S. soybeans will continue to play a role in global soybean production, and the U.S. will continue to be a supplier in the international market.

Preferred Alternative: Trade Economic Environment

FG72 soybean is not likely to adversely impact the U.S. trade economic environment and may have a positive impact through increased yields in soybean areas affected by glyphosate-resistant weeds. To support commercial introduction of FG72 soybean in the U.S., Bayer CropScience intends to submit dossiers to request import approval of FG72 soybean to the proper regulatory authorities of several countries that already have regulatory processes for GE soybean in place. These include, but is not limited to: Canada, Mexico, Japan, the EU, South Korea, and China (Bayer, 2011c; Coates, 2012). In general, a global launch (i.e., commercialization) may not be undertaken until the proper regulatory approvals have been obtained (Coates, 2012). Approval in these export countries is intended to mitigate global sensitivities to GE productions and work in accordance with international regulations. The trade economic impacts associated with a determination of nonregulated status of FG72 soybean are anticipated to be very similar to 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, this may include 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. A cumulative impact may also include the use of a pesticide with a similar mode of action to that of the intended pesticide described in the petition for nonregulated status.

5.1 Assumptions Used for Cumulative Impacts Analysis

Stacked soybean varieties may contain more than one GE trait as the result of crossing two GE soybean plants. Under the Preferred Alternative, FG72 soybean may be crossed with non-GE or 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 (USDA-APHIS, 2012a). 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, or 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. With regard to FG72 soybean, there is no indication in the Bayer CropScience FG72 soybean petition or international import approval application packages that FG72 soybean will be stacked with any specific GE or non-GE soybean trait (Bayer, 2011c; EFSA, 2011b; FSANZ, 2011a). Even with regard to possible stacking with Bayer CropScience's glufosinate-tolerant soybean (98-238-01p and 96-068-01p), there exists uncertainty in the development of that particular product, as glufosinate is described as a potential herbicide to control volunteer FG72 soybean in the Bayer CropScience petition (Bayer, 2011c). There is no assurance that FG72 soybean will be stacked with any particular GE or non-GE soybean trait, as company plans and market demands play a major role in those business decisions. Therefore, predicting all potential combinations of stacked varieties from current GE and non-GE soybean varieties is hypothetical and speculative.

With regard to foreseeable herbicide use in U.S. soybean production, it is reasonable to assume that FG72 soybean will also confer tolerance to other herbicides that, like IFT, function as HPPD inhibitors. In particular, mesotrione represents an herbicide that may be applied on FG72 soybean (Bay News, 2011). Mesotrione, developed by Syngenta, is commonly marketed under the Callisto® trade name. In 2009, the EPA established a tolerance for residues for mesotrione on soybean seed (74 FR 67119). EPA also amended the original Callisto® registration label to allow for a mesotrione-tolerant soybean at pre-emergent application rate of 0.188 lbs. a.i./acre (EPA, 2009b; Syngenta, 2011).

5.2 Cumulative Impacts: Acreage and Range of Soybean Production

Cumulative effects resulting from a determination of nonregulated status of FG72 soybean on acreage and range of soybean production are unlikely. GE soybean varieties already constitute a large proportion of U.S. soybean production (93 percent) (USDA-ERS, 2011a); cultivation of FG72 soybean with current GE soybean varieties is unlikely to substantially change this pattern of adoption, as it represents a replacement and not supplemental soybean variety for U.S. soybean growers.

Acreage of soybean production is primarily dependent on market demand; cultivation and associated production practices of FG72 soybean are unlikely to disrupt this causal relationship, as U.S. soybean production is strongly affected by market demand, not by any one soybean variety (USDA-ERS, 2010b, 2011c). Furthermore, the range of soybean cultivation is unlikely to be impacted by a determination of nonregulated status of FG72 soybean. FG72 soybean generally does not present an absolute yield gain under standard management conditions and does not display a phenotype that would be indicative of an improved capacity to grow outside an agricultural environment (USDA-APHIS, 2012b). Similar to currently-available soybean varieties, FG72 soybean is likely to require cultivation on high quality arable land to be profitable. Consequently, FG72 soybean is unlikely to encourage cultivation on marginal land, thus maintaining currently-observed farm-level land-use decisions to shift agricultural land away from other crops, such as cotton or hay, toward soybean production to satisfy market demand (USDA-ERS, 2010e, 2011c).

5.3 Cumulative Impacts: Agronomic Practices

Agronomic practices related to soybean production are often dependent on the particular soybean variety cultivated. FG72 soybean possesses similar agronomic requirements and pest sensitivities as conventional soybean, and thus, is not anticipated to have any cumulative effect on current and general soybean agronomic practices, such as fertilization, rotational, and pesticide application practices (USDA-APHIS, 2012b).

Farmers that grow FG72 soybean may apply glyphosate, IFT, and/or mesotrione. Glyphosate is already applied on the majority of U.S. soybean acreage (NRC, 2010). Therefore, cultivation of FG72 soybean is unlikely to change current glyphosate use patterns, so no cumulative effects on agronomic practices are likely. A determination of nonregulated status of FG72 soybean may permit the use of 4-HPPD inhibiting herbicides beyond IFT. Mesotrione, like IFT, is a broad-spectrum herbicide that may be used to control a variety of broad-leaf weed species (Syngenta, 2011). Additionally, mesotrione, like IFT, may be applied pre-emergence to FG72 soybean (74 FR 67119; Bay News, 2011). Application of IFT and/or mesotrione over FG72 soybean is unlikely to result in any cumulative effect on current conservation tillage practices because both herbicides can be applied during a similar application window and provide control over a similar range of weed species (Bayer, 2011b; Syngenta, 2011). Furthermore, application of mesotrione, like IFT, does not result in common corn rotational restrictions (Bayer, 2011b; Syngenta, 2011).

Application of mesotrione over FG72 soybean may result in a net herbicide use increase in U.S. soybean production, as mesotrione was only recently registered for use in soybean (74 FR 67119). This net increase, however, may not be substantially higher than anticipated increases in soybean herbicide use described in Sections 2.1.2 and 4.2.2. Using corn production as an example of mesotrione use trends, mesotrione use was substantially less than that of glyphosate between 2001 – 2010, and represented only three percent of total glyphosate application in 2010 (Table 11) (USDA-NASS, 2011a). Application in soybean may not be as high as corn due to restrictions in application time. In corn, mesotrione may be applied pre- or post-emergence; in soybean, however, mesotrione is only labeled for pre-emergent use (Syngenta, 2011).

Additionally, the maximum application rate of mesotrione in soybean is less than that of corn (6.0 fl. oz., versus 7.7 fl. oz. respectively). Consequently, mesotrione use in soybean may be less than that of corn, due to a more restricted application window and annual use rate. Taken in total, application of IFT or mesotrione in FG72 soybean is unlikely to result in a cumulative effect on herbicide use, as restrictions in use, reduced application rate, and residual control post application of both herbicides may limit use of both herbicides relative to glyphosate in soybean production systems.

Table 11. Use of glyphosate and mesotrione in U.S. corn production, 2001 – 2010.

Year	Glyphosate application in corn - Measured in total lbs.	Average glyphosate application in corn - Measured in total lbs./acre	Mesotrione application in corn - Measured in total lbs.	Average mesotrione application in corn - Measured in total lbs./acre
2010	57,536,000	0.82	1,693,000	0.121
2005	22,967,000	0.73	1,853,000	0.119
2003	11,913,000	0.69	976,000	0.1
2002	3,307,000	0.64	367,000	0.09
2001	6,868,000	0.66	7,000	0.09

Source: USDA-NASS (2011a).

5.4 Cumulative Impacts: Organic Soybean Production

A determination of nonregulated status of FG72 soybean is unlikely to have a cumulative effect on organic soybean production. FG72 soybean, like other soybean varieties, is primarily a self-pollinated crop (USDA-APHIS, 2012b). There is no reason to suspect that the biology of FG72 soybean will increase its potential to outcross with soybean varieties utilized in organic soybean production because field studies revealed no substantial differences in factors influencing reproductive potential, including pollen viability, date of emergence, date of 50 percent flowering, and date of maturity (USDA-APHIS, 2012b).

Despite increasing demand for organic soybean products and commodities, U.S. production of organic soybean is unlikely to keep pace (USDA-ERS, 2010c). It is unlikely that FG72 soybean will substantially affect this trend. Reasons for the inability of domestic organic soybean production to meet demand include: 1) the three-year period transition period between conventional and organic farming; 2) a lack of contractors for organic agronomic practices, including pest and nutrient management; 3) intensive labor requirements; 4) fear of criticism from neighbors; 5) an absence of government infrastructure and policy support; and 6) unknown risks (Clarkson, 2007; USDA-ERS, 2007). The increased demand for organic soybean in the U.S. has generally been met by increasing imports from international organic soybean producers (The Organic & Non-GMO Report, 2007; USDA-ERS, 2007).

5.5 Cumulative Impacts: Soil Quality

A determination of nonregulated status of FG72 soybean is unlikely to result in a cumulative impact on soil quality. Comprehensive phenotypic, agronomic, and ecological assessments conducted by the petitioner for FG72 soybean did not find substantial differences between FG72 soybean and control soybeans for these characteristics (Bayer, 2011c). The few differences that were identified were typically small, site specific, and unlikely to be biologically meaningful. Event FG72 soybean required similar agronomic practices as non-GE soybean (Bayer, 2011c). Consequently, the phenotypic, agronomic, and ecological data presented in the Bayer petition support the conclusion by APHIS that FG72 soybean will not substantially modify soil characteristics associated with typical soybean production practices. In particular, FG72 soybean will permit the continued trend of conservation tillage, an agricultural practice with strong direct and positive effects on soil quality (Holland, 2004; NRC, 2010).

Farmers that grow FG72 soybean may apply glyphosate, IFT, and/or mesotrione. Glyphosate is already applied on the majority of U.S. soybean acreage (NRC, 2010). Therefore, cultivation of FG72 soybean is unlikely to change current glyphosate use patterns, so no cumulative effects on soil quality are likely. Mesotrione may be applied pre-emergence to FG72 soybean production fields. Like IFT, mesotrione is a 4-HPPD inhibitor. Mesotrione does not persistent in soil, as indicated by photolysis, aerobic and anaerobic soil metabolism, and field dissipation studies (EPA, 2001b). Any impact directly from soil quality as a result of mesotrione application is most likely to affect rotational crops that may be planted sometime after mesotrione application. For this purpose, rotational restrictions are described on the EPA use label, indicating which crops are safe to plant (Syngenta, 2011). The presence of these rotational restrictions is not inherently any different than rotational restrictions with currently used soybean herbicides.

5.6 Cumulative Impacts: Water Resources

A determination of nonregulated status is unlikely to result in a cumulative impact on water resources related to soybean production. This conclusion is based on the fact that cultivation of FG72 soybean is likely to permit the continued use of conservation tillage, and thus, maintain its indirect and positive effects on water quality and runoff. The agronomic performance of FG72 soybean is similar to conventional soybean, suggesting that FG72 soybean does not require more irrigation than currently-available soybean varieties (Bayer, 2011c; USDA-APHIS, 2012b).

Farmers that grow FG72 soybean may apply glyphosate, IFT, and/or mesotrione. Glyphosate is already applied on the majority of U.S. soybean acreage. Therefore, cultivation of FG72 soybean is unlikely to change current glyphosate use patterns, so no cumulative effects on water quality are likely. IFT and mesotrione are not anticipated to result in any cumulative effect on water quality, because they do not persist in soil or aqueous environments (EPA, 2008, 2011d). Furthermore, while both IFT and mesotrione may be mobile in water, the leaching potential of each compound is not substantially greater than current herbicides commonly utilized in soybean production, suggesting that they pose no greater leaching risk to water resources (NY State IPM Program, 2012a, 2012b).

5.7 Cumulative Impacts: Air Quality

APHIS has not identified any cumulative effects for this issue resulting from a determination of nonregulated status of FG72 soybean. APHIS does not anticipate any substantial changes in soybean production practices or an expansion of soybean acreage as a result of a determination of nonregulated status of FG72 soybean. Agricultural practices will continue to have the potential to cause negative impacts to air quality. Agricultural emission sources will continue to include smoke from agricultural burning, tillage, traffic and harvest emissions, and nitrous oxide emissions from the use of nitrogen fertilizer. These agricultural emissions sources are anticipated to be similar between conventional soybean varieties and cultivation of FG72 soybean.

5.8 Cumulative Impacts: Climate Change

APHIS has not identified any cumulative effects on climate change following a determination of nonregulated status of FG72 soybean. APHIS does not anticipate any substantial changes in soybean production practices or an expansion of soybean acreage as a result of a determination of nonregulated status of FG72 soybean. The consequences of the Preferred Action Alternative on commercial soybean production and acreage are the same as for the No Action Alternative.

It is possible that climate change may affect soybean cultivation areas in the U.S. For example, as projected by the U.S. Global Change Research Program (2009), the northern regions of the Great Plains may become wetter while the southern regions may become drier. However, these shifts are unlikely to uniquely affect FG72 soybean, as there is no reasonable expectation that this soybean variety would require less moisture or possess a cultivation range that is different than conventional soybean.

5.9 Cumulative Impacts: Animal Communities

Under field conditions, soybean or soybean grain may be used by mammals, birds, or arthropods. Bayer CropScience data demonstrates that the composition of FG72 soybean does not substantially differ from conventional soybean varieties (USDA-APHIS, 2012b). Both APHIS and Food Standards Australia New Zealand (FSANZ) have concluded that FG72 soybean is compositionally similar to conventional soybean (FSANZ, 2011a; USDA-APHIS, 2012b). This indicates that FG72 soybean is unlikely to result in a cumulative effect on animal communities through consumption.

Pesticides are applied on a majority of U.S. soybean acres, with herbicides representing the majority of pesticide applications (NRC, 2010; USDA-NASS, 2007). Nontarget insects are unlikely to be substantially affected by insecticide application practices in FG72 soybean compared to conventional soybean, as insecticide application patterns are similar between FG72 and conventional soybean (USDA-APHIS, 2012b).

Farmers that grow FG72 soybean may apply glyphosate, IFT, and/or mesotrione. Glyphosate is already applied on the majority of U.S. soybean acreage (NRC, 2010). Therefore, cultivation of FG72 soybean is unlikely to change current glyphosate use patterns, so no cumulative effects on animals are likely. The potential pre-emergent application of mesotrione to FG72 soybean is not anticipated to cause a cumulative effect on animal communities because mesotrione is practically non-toxic to birds, small mammals, fish, daphnids and relatively non-toxic to honey bees (EPA, 2001b). This is effectively similar to the environmental fate of IFT, which poses little risk to birds, mammals, fish, and the honey bee (EPA, 2011b, 2011d).

5.10 Cumulative Impacts: Plant Communities

A determination of nonregulated status of FG72 soybean is unlikely to have any cumulative effect on plant communities beyond what is already occurring in soybean production. The introduced proteins in FG72 soybean, 2mEPSPS and HPPD W336, are derived from organisms that are non-pathogenic and/or non-toxic to plants; these proteins are effectively benign in the environment (Bayer, 2011c). There are no wild relatives of soybean in the U.S. This eliminates any gene transfer between FG72 and non-domesticated plants (OECD, 2010). Furthermore, FG72 soybean does not display weedy characteristics and is not expected to be a weed (USDA-APHIS, 2012b).

Cultivation of FG72 soybean will permit the use of glyphosate, IFT, and/or mesotrione to control weed populations. Glyphosate is already widely applied in U.S. soybean production fields (Bonny, 2011; NRC, 2010; USDA-NASS, 2007). Since FG72 soybean is tolerant to glyphosate, it is unlikely to disrupt current glyphosate use patterns and its effect on plant communities.

IFT and mesotrione are broad-spectrum herbicides that have not previously been utilized in soybean production. Both IFT and mesotrione share control characteristics of common weed species (Figure 10). Mesotrione demonstrates a smaller range in controllable weed species than IFT, primarily due to less effective grass weed control (Syngenta, 2011). However, mesotrione, like IFT, represents another herbicide in a growing diversity of herbicides utilized in soybean production and is not likely to result in a cumulative impact on weed species relative to other herbicides currently utilized in U.S. soybean production.

Runoff of IFT or mesotrione may pose an environmental risk to non-target plants (EPA, 2001b, 2011d). However, runoff is a risk associated with any broad-spectrum herbicide and is not unique to IFT or mesotrione. As a consequence of its registration, EPA has determined that there is no unreasonable environmental risk if end users adhere to the EPA label directions when applying IFT or mesotrione herbicide formulations on soybeans. Violators of the regulations are liable for all negative consequences of their actions. This imposes an added incentive on farmers use IFT and/or mesotrione to follow EPA label use restrictions.

Weed populations can change in response to farm-level agronomic practices, including weed management decisions. Cultivation of FG72 soybean may provide some utility in the control of glyphosate-resistant weeds because IFT and mesotrione represent broad-spectrum herbicides with an alternative MoA. With respect to glyphosate-resistant weeds that may be found in U.S. soybean fields, mesotrione provides a more limited spectrum of control, primarily due to its ineffectiveness against grassy weeds (Table 12). By possessing an alternative MoA, mesotrione can be expected to control kochia, Palmer amaranth, common and giant ragweed, and common waterhemp (Syngenta, 2011).

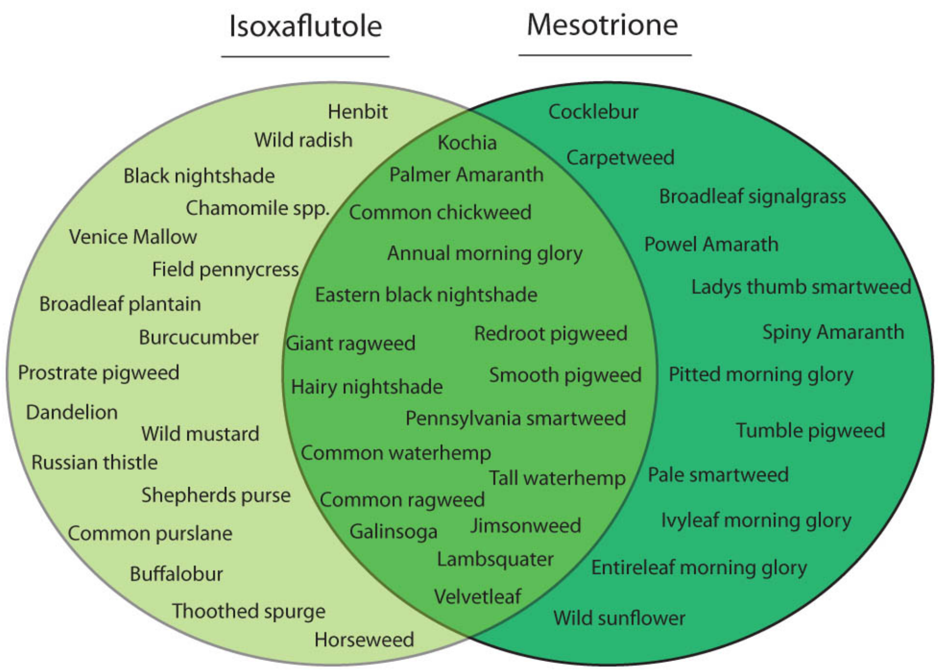

Figure 10. Weed control provided by herbicides isoxaflutole (IFT) and mesotrione. In contrast to isoxaflutole, mesotrione does not generally provide control of weedy grasses Sources: Bayer (2011b) and Syngenta (2011).

Table 12. Glyphosate-resistant weed (in soybean fields) control profiles for isoxaflutole (IFT) and mesotrione.

Broadleaf Weeds*	Isoxaflutole control/suppression	Mesotrione control/suppression
Horseweed (Marestail) (*Conyza candensis*)	Yes	No
Kochia (*Kochia scoparia*)	Yes	Yes
Palmer Amaranth (*Amaranthus palmeri*)	Yes	Yes
Common ragweed *(Ambrosia artemisiifolia*)	Yes	Yes
Giant ragweed (*Ambrosia trifida*)	Yes	Yes
Common waterhemp (*Amaranthus tuberculatus*)	Yes	Yes
Goosegrass (*Eleusine indica*)	Yes	No
Italian ryegrass (*Lolium spp. multiflorum*)	Yes	No
Johnsongrass (*Sorghum halepense*)	Yes	No

*Only certain weed populations demonstrate glyphosate resistance.
Sources: Bayer (2011b) and Syngenta (2011).

Since 2009, four populations of common waterhemp in Illinois, Iowa, and Nebraska were reported to be resistant to 4-HPPD inhibitors (Heap, 2011b). Despite the four reported cases, only one waterhemp population (Mclean County, IL) was studied in detail (Hausman et al., 2011; Syngenta, 2010). In the Mclean County population (which also possessed non-target site atrazine resistance), development of 4-HPPD resistance was generally linked to seed corn production and its respective management strategies that precluded the application of pre-emergent and broad-spectrum herbicides. As a result, 4-HPPD inhibitors were used without MoA rotation over the course of seven growing seasons (2003 – 2009) (Hausman et al., 2011). Further examination of this waterhemp population revealed that control could be achieved through several common agricultural strategies, including the pre-emergent application of 4-HPPD inhibitors and post-emergent foliar application of broad-spectrum herbicides, such as glyphosate and glufosinate (Syngenta, 2010).

While the Mclean County population of waterhemp demonstrated that the development of resistance to 4-HPPD inhibitors is possible, it also underscored the value of herbicide chemistry rotation (alternative MoA) across growing seasons and the utility of pre-emergent herbicide application in weed control. Effective management, however, does not ensure that herbicide use is intrinsically sustainable. Herbicide use (and indirectly, the use of herbicide-tolerant crops) is sustainable only as a component of a broader integrated weed management system (Mortensen et al., 2012) and that the preemptive incorporation of integrated weed management measures may prevent or mitigate the development of a resistant weed population (Bayer, 2011c). Agricultural weed development is not necessarily limited to herbicide use, but may also develop in response to cultural methods not reliant on herbicide use (Vaughan et al., 2008). Thus, integrated weed management does not exclude any one management technique. It incorporates a number of practices, including the use of cover and rotational crops, tillage, and herbicide applications to reduce selection pressure and weed populations in an agroenvironment (Mortensen et al., 2012). As part of its integrated weed management plan for FG72 soybean, Bayer has proposed the following in its stewardship of FG72 soybean:

- Correctly identify weeds and look for trouble areas within field to identify resistance indicators;
- Rotate crops;
- Start the growing season with clean fields;
- Rotate herbicide MoA by using multiple MoAs during the growing season and apply no more than two applications of a single herbicide MoA to the same field in a two-year period. One method to accomplish this is to rotate herbicide-tolerant trait systems;
- Apply recommended rates of herbicides to actively growing weeds at the correct time with the right application techniques;
- Control any weeds that may have escaped the herbicide application; and
- Thoroughly clean field equipment between fields (Bayer, 2011c).

Cultivation of FG72 soybean may potentially allow a more comprehensive approach to weed management. Crop and herbicide rotation are two factors that may mitigate the development of herbicide resistance in weeds. As stated previously in this EA, there is reason to believe that FG72 soybean would benefit from crop rotation (similar to commercial soybean varieties), and that FG72 soybean would permit the use of two herbicides with different MoAs, followed by use of an alternative MoA in the next growing season (e.g., glufosinate). Utilized within an integrated weed management system and within the context of best management practices, a determination of nonregulated status of FG72 soybean may positively contribute to the control of glyphosate-resistant weed populations while also reducing the development of other herbicide resistance.

5.11 Cumulative Impacts: Gene Flow and Weediness

As described in the USDA-APHIS PPRA for FG72 soybean, no substantial differences are observed in pollen viability, pollen morphology, or seed dormancy (Bayer, 2011c). Consequently, the barriers that exist between different soybean varieties and sexually-compatible soybean varieties would likely continue to act as limitations on gene flow without any cumulative effect on gene flow. The soybean industry has identity protection (IP) measures in place to restrict pollen movement and gene flow between soybean fields through the use of isolation distances, border and barrier rows, the staggering of planting dates and various seed handling, transportation, and cleaning procedures (Bradford, 2006; NCAT, 2003; Sundstrom et al., 2002). Furthermore, FG72 soybean represents a domesticated soybean variety that would not be anticipated to survive outside the agricultural environment, indicating that cultivation of FG72 soybean may not result in a cumulative effect on plant weediness.

5.12 Cumulative Impacts: Microorganisms

Cultivation of FG72 soybean is unlikely to have a cumulative effect on soil microorganisms relative to the cultivation of conventional soybean varieties, including 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. Microbial activity in agricultural soil is often strongly dependent on cultivation conditions, with the primary effectors representing crop type, seasonality, prevalent soil properties, and tillage strategy (Hart et al., 2009; Holland, 2004). When generally compared to existing soybean production practices, cultivation of FG72 will utilize similar management conditions, such as the continuation of conservation tillage, seasonal rotation of soybean with additional crops, and broad use of herbicides. In particular, the majority of U.S. soybean acres are sprayed with glyphosate and other herbicides. FG72 soybean will permit the continuation of this existing trend, as it will permit the application of glyphosate and IFT. Because any microorganism is already extensively exposed to herbicides in current U.S. soybean production fields, it is unlikely that any new microorganism would be affected through production practices associated with FG72 soybean or its progeny. For example, a determination of nonregulated status of FG72 soybean may result in the pre-emergent application of mesotrione. Toxicity of mesotrione at recommended field application rates, however, is generally not toxic to microorganisms or any more toxic than commonly applied agricultural herbicides (Bonnet et al., 2008; Crouzet et al., 2009).

5.13 Cumulative Impacts: Biodiversity

Cultivation of FG72 soybean is unlikely to have toxic effects on non-target animals and microorganisms. Additionally, cultivation of FG72 soybean is likely to be neutral with regard to biodiversity compared with typical GE and non-GE soybean production systems, due to similar management conditions for both production systems. Application of herbicides in U.S. soybean production will continue to be dictated by both individual farm need and EPA label use restrictions. As a consequence of its herbicide registration program, EPA has effectively determined that there is no unreasonable environmental risk if the end user adheres to the directions and restrictions on the EPA registration label when applying herbicide formulations. When required, application by a certified applicator further minimizes effects on biodiversity. Since violators of requirements are liable and can be held legally accountable for all negative consequences of their actions, this responsibility serves as an additional safeguard against any adverse cumulative effects on non-target organisms and biodiversity from the use of EPA restricted use pesticides.

The use of GE soybean varieties containing herbicide-tolerant traits may improve biological diversity by providing growers the opportunity to use conservation tillage practices (Bonny, 2011; NRC, 2010). 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, 2010), increasing the flexibility of crop rotation, and facilitating strip cropping (Fernandez-Cornejo et al., 2002). Each of these contributes to the health of the faunal and floral communities in and around soybean fields thereby promoting biodiversity (Palmer et al., 2010).

5.14 Cumulative Impacts: Human Health

A determination of nonregulated status of FG72 soybean is not anticipated to result in any cumulative effect on human health. FG72 soybean is compositionally equivalent to conventional soybean (USDA-APHIS, 2012b). Therefore, consumption of FG72 soybean is expected to be as safe as consumption of conventional soybean. FSANZ has already determined that FG72 soybean is as whole and nutritious as conventional soybean (FSANZ, 2011a, 2011b).

Farmers that grow FG72 soybean may apply glyphosate, IFT, and/or mesotrione. Glyphosate is already applied on the majority of U.S. soybean acreage (NRC, 2010). Therefore, cultivation of FG72 soybean is unlikely to change current glyphosate use patterns, so no cumulative effects on human health are likely. Human exposure to IFT or mesotrione, either indirectly through residue on soybean grain or directly through soybean production in the field, is not expected to result in a cumulative impact on human health. Pesticide tolerances have been established for both IFT and mesotrione on soybean, so no unnecessary risk to human health from residues resulting from application at approved labeled use rates are anticipated (74 FR 67119; 76 FR 235). Human health risk assessments for IFT and mesotrione have generally indicated that both herbicides pose no unnecessary risk to human health (EPA, 2009b, 2011c). Additionally, registration and application of these pesticides will also continue to be regulated by EPA, ensuring that there is no unnecessary risk for both the general public and agricultural workers.

5.15 Cumulative Impacts: Animal Feed

FG72 soybean is not anticipated to result in any cumulative effect on animal feed. The introduced proteins in FG72 soybean are not toxic or allergic. Since the composition of FG72 is similar to conventional soybean varieties, this also serves as a good indicator that negative effects on feed quality containing FG72 soybean grain are unlikely (Bayer, 2011c). FSANZ has already determined that FG72 soybean is as whole and nutritious as conventional soybean (FSANZ, 2011a, 2011b).

Farmers that grow FG72 soybean may apply glyphosate, IFT, and/or mesotrione. Glyphosate is already applied on the majority of U.S. soybean acreage (NRC, 2010). Therefore, cultivation of FG72 soybean is unlikely to change current glyphosate use patterns, so no cumulative effects on animal feeds are likely. Animals may be exposed to IFT or mesotrione through residue on soybean grain that is added to animal feed. This exposure route is not expected to result in a cumulative impact on animal health. Pesticide tolerances have been established for both IFT and mesotrione on soybean, so residues resulting from application at recommended rates are not anticipated to pose any unnecessary risks (74 FR 67119; 76 FR 235).

5.16 Cumulative Impacts: Domestic Economic Environment

Domestically-produced soybean and soybean products are produced for a number of markets. Market use of soybean is often dependent on the soybean variety, and thus composition, produced. There are compositional differences among some soybean varieties grown for animal feed and those for human consumption. These include those soybean varieties that are intentionally produced to yield a modified fatty acid profile. They may include soybeans that have been produced through standard breeding or GE methods. With regard to these modified oil soybean varieties, the soybean industry already utilizes identity protection measures to restrict pollen movement and gene flow between soybean fields through the use of mitigations such as isolation distances, border and barrier rows, the staggering of planting dates and various seed handling, transportation, and cleaning procedures (Bradford, 2006; NCAT, 2003; Sundstrom et al., 2002). FG72 soybean is compositionally similar to its non-GE comparator, Jack (Bayer, 2011c). Thus, market use of FG72 soybean should be similar to that of Jack. With regard to ensuring the quality of soybean animal feed, because of the general absence of plant reproductive attributes that could affect gene flow, it is unlikely that FG72 soybean would present any additional issue beyond those already discussed for conventional soybean varieties.

5.17 Cumulative Impacts: Trade Economic Environment

Although the primary U.S. soybean export destinations do not present major barriers to trade in GE products, Bayer CropScience would need to obtain FG72 soybean approval in destination countries before commercialization in the U.S. to avoid adversely affecting current trade flows. Requests for approvals have been submitted to several markets, including, but is not limited to, Canada, Mexico, Japan, the EU, South Korea, and China. Bayer CropScience has previously stated its intention to seek approval for FG72 soybean in primary U.S. export destinations with functioning regulatory systems before commercialization in the U.S. (Coates, 2012). Thus, a cumulative effect on the trade economic environment is not anticipated following a determination of nonregulated status of FG72 soybean, because it is unlikely to be commercialized until it is approved for export to major U.S. soybean importing countries.

6 THREATENED AND ENDANGERED SPECIES

Congress passed the Endangered Species Act (ESA) of 1973, as amended, to prevent extinctions facing many species of fish, wildlife and plants. The purpose of the ESA is to conserve endangered and threatened species and the ecosystems on which they depend as key components of America's heritage. To implement the ESA, the 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's 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 (PPA) of 2000 (Title IV of Public Law 106-224). APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

APHIS' regulatory authority over GE organisms under the PPA is limited to those GE organisms for which it has reason to believe might be a plant pest or those for which APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk (7 CFR § 340.1). APHIS does not have authority to regulate the use of any herbicide, including glyphosate or isoxaflutole (IFT). After completing a PPRA, if APHIS determines that FG72 soybean does not pose a plant pest risk, then FG72 soybean would no longer be subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR Part 340, and therefore, APHIS must reach a determination that the article is no longer regulated. As part of its EA analysis, APHIS is analyzing the potential effects of FG72 soybean on the environment including any potential effects to threatened and endangered species and critical habitat. As part of this process, APHIS thoroughly reviews the GE product information and data related to the organism (generally a plant species, but may also be other genetically engineered organisms). For each transgene/transgenic plant, APHIS considers the following information, data, and questions:

- A review of the biology and taxonomy of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental 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 species (TES) of plants or a host of any TES; and
- Any other information that may inform the potential for an organism to pose a plant pest risk.

In following this review process, APHIS, as described below, has evaluated the potential effects that a determination of nonregulated status of FG72 soybean may have, if any, on Federally-listed TES and species proposed for listing, as well as designated critical habitat and habitat proposed for designation. Based upon the scope of the EA and production areas identified in the Affected Environment section of the EA, APHIS obtained and reviewed the USFWS list of TES species (listed and proposed) for each state where soybean is commercially produced from the USFWS Environmental Conservation Online System (USFWS, 2012). Prior to this review, APHIS considered the potential for FG72 soybean to extend the range of soybean production and also the potential to extend agricultural production into new natural areas. Bayer CropScience's studies demonstrate that agronomic characteristics and cultivation practices required for FG72 soybean are essentially indistinguishable from practices used to grow other soybean varieties, including other herbicide-tolerant varieties (Bayer, 2011c; USDA-APHIS, 2012b). Although FG72 soybean may be expected to replace other varieties of soybean currently cultivated, APHIS does not expect the cultivation of FG72 soybean to result in new soybean acres to be planted in areas that are not already devoted soybean production. Accordingly, the issues discussed herein focus on the potential environmental consequences of the determination of nonregulated status of FG72 soybean on TES species in the areas where soybean are currently grown.

APHIS focused its TES review on the implications of exposure to the 2mEPSPS and HPPD W336 proteins in FG72 soybean, the interaction between TES and FG72 soybean, including the potential for sexual compatibility and the ability to serve as a host for a TES; and potential impacts of the use of glyphosate and IFT herbicides to non-target organisms and the natural environment.

6.1 Potential Effects of FG72 Soybean on TES

Threatened and Endangered Plant Species

The agronomic data provided by Bayer CropScience were used in the APHIS analysis of the weediness potential for FG72 soybean and further evaluated for the potential to impact TES. Agronomic studies conducted by Bayer CropScience tested the hypothesis that the weediness potential of FG72 soybean is unchanged with respect to conventional soybean (Bayer, 2011c; USDA-APHIS, 2012b). No differences were detected between FG72 soybean and conventional soybean in growth, reproduction, or interactions with pests and diseases, other than the intended effect of herbicide tolerance (USDA-APHIS, 2012b). Potential of soybean weediness is low, due to domestication syndrome traits that generally lower overall fitness outside an agricultural environment (Stewart et al., 2003). Mature soybean seeds have no innate dormancy, are sensitive to cold, and are not expected to survive in freezing winter conditions (Raper and Kramer, 1987). Soybeans have been cultivated around the globe without any report that it is a serious weed or that it forms persistent feral populations (USDA-APHIS, 2012b). Soybean cannot survive in the majority of the country without human intervention, and it is easily controlled if volunteers appear in subsequent crops. APHIS has concluded the determination of nonregulated status of FG72 soybean does not present a plant pest risk, does not present a risk of weediness, and does not present an increased risk of gene flow when compared to other currently cultivated soybean varieties. Based on the agronomic field data and literature survey on soybean weediness potential, FG72 soybean is unlikely to affect TES as a troublesome or invasive weed (USDA-APHIS, 2012b).

APHIS evaluated the potential of FG72 soybean to cross with a listed species. As discussed above and in the analysis of Gene Movement and Weediness, APHIS has determined that there is no risk to unrelated plant species from the cultivation of FG72 soybean. Soybean is highly self-pollinating and can only cross with other members of *Glycine* subgenus *Soja*. Wild soybean species are endemic in China, Korea, Japan, Taiwan and the former USSR; in the U.S. there are no *Glycine* species found outside of cultivation and the potential for outcrossing is minimal (OECD, 2010). After reviewing the list of threatened and endangered plant species in the U.S. states where soybean is grown, APHIS determined that FG72 soybean would not be sexually compatible with any listed threatened or endangered plant species proposed for listing, as none of these listed plants are in the same genus nor are known to cross pollinate with species of the genus *Glycine*.

Based on the agronomic field data, literature survey on soybean weediness potential, and that there are no TES sexually compatible with soybean, APHIS has concluded that FG72 soybean will have no effect on threatened or endangered plant species.

Threatened and Endangered Animal Species

Threatened and endangered animal species that may be exposed to the gene products in FG72 soybean would be those TES that inhabit soybean fields and feed on FG72 soybean. To identify potential effects on threatened and endangered animal species, APHIS evaluated the risks to threatened and endangered animals from consuming FG72 soybean. Soybean commonly is used as a feed for many livestock. Additionally, wildlife may use soybean fields as a food source, consuming the plant, grain, or insects that live on the plants. However, TES generally are found outside of agricultural fields. Few if any TES are likely to use soybean fields because they do not provide suitable habitat. Only whooping crane (*Grus americana*), sandhill crane (*Grus canadensis pulla*), piping plover (*Charadrius melodus*), and interior least tern (*Sterna antillarum*) (USFWS, 2011a). These bird species may visit soybean fields during migratory periods, but would not be present during normal farming operations (Krapu et al., 2004; USFWS, 2011a). In a study of soybean consumption by wildlife in Nebraska, results indicated that soybeans do not provide the high energy food source needed by cranes and waterfowl (Krapu et al., 2004). The Delmarva fox squirrel (*Sciurus niger cinereus*), which inhabits mature forests of mixed hardwoods and pines, may be found adjacent to agricultural areas of the Delmarva Peninsula (USFWS, 2011b). This species feeds primarily on acorns, nuts, and pine seeds and is not likely to utilize soybeans to any extent. The Louisiana black bear (*Ursus americanus luteolus*), occurring in Louisiana, Mississippi, and Texas (Johnsen et al., 2005), may occasionally forage on soybean; however, other crops such as corn, sugarcane, and winter wheat are preferred by this species (MSU Extension Service, Undated).

FG72 soybean is genetically engineered to show 2mEPSPS and HPPD W336 protein accumulation, and thus, herbicide tolerance to glyphosate and IFT. 2mEPSPS has been previously analyzed and approved by several international regulatory agencies, thus demonstrating that it is not likely to have any significant impact on animal health (CFIA, 1998; FSANZ, 2001; SCF, 2002; USDA-APHIS, 1997). The food and feed safety of 2mEPSPS has been assessed in these products and shown to present no food or feed safety risk. Though HPPD W336 has not previously been evaluated, there is no reason to suspect it would present a risk to non-target organisms. HPPD proteins are ubiquitous in the environment and are not novel. Bioinformatic analysis of HPPD W336 showed no significant lengthwise alignment with known toxins or allergens (Bayer, 2011c).

FG72 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. Bayer CropScience initiated the consultation process with FDA for the commercial distribution of FG72 soybean and submitted a safety and nutritional assessment of food and feed derived from FG72 soybean to the FDA on December 3, 2009. FDA is currently evaluating the submission, and as of March 16, 2012, has not completed the consultation.

Bayer CropScience has presented data on the food and feed safety of FG72 soybean, evaluating the agronomic and morphological characteristics of FG72 soybean, including compositional and nutritional characteristics, safety evaluations, and toxicity tests, as compared to a conventional soybean variety (Bayer, 2011c). Compositional elements, including proximate and fiber components, amino acid and fatty acid content, and antinutrients and isoflavone concentrations, revealed no substantial differences between FG72 soybean and conventional soybean varieties (Bayer, 2011c). As discussed in Section 4.4 and 4.6, the data collected indicate there is no difference in the composition and nutritional quality of FG72 soybean compared with conventional soybean varieties, apart from the presence of the 2mEPSPS and HPPD W336 proteins. Food Standards Australia New Zealand (FSANZ) also determined that FG72 soybean are compositionally similar to conventional soybean, thus suggesting that FG72 soybean is unlikely result in an effect on threatened and endangered animal species (FSANZ, 2011a, 2011b). The results presented by Bayer CropScience show that the incorporation of the *2mepsps* and *hppd w336* genes and the accompanying activity of the 2mEPSPS and HPPD W336 proteins in FG72 soybean does not result in any biologically-meaningful differences between FG72 soybean and non-GE hybrids.

Because there is no toxicity or allergenicity potential with FG72 soybean, there would be no direct or indirect toxicity or allergenicity impacts on wildlife species that feed on soybean or the associated biological food chain of organisms. Therefore, based on these analyses, APHIS concludes that consumption of FG72 soybean plant parts (seeds, leaves, stems, pollen, or roots) would have no effect on any listed threatened or endangered animal species or animal species proposed for listing.

After reviewing the possible effects of allowing the environmental release of FG72 soybean, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. APHIS also considered the potential effect of a determination of nonregulated status of FG72 soybean on designated critical habitat or habitat proposed for designation, and could identify no differences from effects that would occur from the production of other soybean varieties. Soybean is not considered a particularly competitive plant species and has been selected for domestication and cultivation under conditions not normally found in natural settings (OECD, 2001, 2010). Soybean is not sexually compatible with, or serves as a host species for, any listed species or species proposed for listing. Consumption of FG72 soybean by any listed species or species proposed for listing will not result in a toxic or allergic reaction. Based on these factors, APHIS has concluded that a determination of nonregulated status of FG72 soybean, and the corresponding environmental release of this soybean variety will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the USFWS or NMFS are not required.

6.2 Potential Effects of the use of Glyphosate and Isoxaflutole

APHIS met with USFWS officials on June 15, 2011, to discuss whether APHIS has any obligations under the ESA regarding analyzing the impacts of herbicide use associated with all GE crops on TES. As a result of these joint discussions, USFWS and APHIS have agreed that it is not necessary for APHIS to perform an ESA effects analysis on herbicide use associated with GE crops currently planted because EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under FIFRA. APHIS has no statutory authority to authorize or regulate the use of glyphosate and IFT, or any other herbicide, by soybean growers. Under APHIS' current Part 340 regulations, APHIS only has the authority to regulate FG72 soybean or any GE organism as long as APHIS believes it may pose a plant pest risk. For GE organisms, APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of herbicides or other pesticides on those organisms. Nevertheless, APHIS is aware that there may be potential environmental impacts resulting from the use of glyphosate and IFT on FG72 soybean, including potential impacts on TES and critical habitat, based on assessments performed by the EPA and as available in the peer reviewed scientific literature. APHIS is providing the available information of potential environmental impacts resulting from glyphosate and IFT use on FG72 soybean below.

Endangered Species Protection Program

In 1988, Congress enacted Public Law 100-478 (October 7, 1988) to in part address the relationship between ESA and EPA's pesticide labeling program (Section 1010), which required EPA to conduct a study, and report to Congress, on ways to implement EPA's endangered species pesticide labeling program in a manner that both complies with ESA and allows people to continue production of agricultural food and fiber. This law provided a clear sense that Congress wanted EPA to fulfill its obligation to conserve listed species, while at the same time consider the needs of agriculture and other pesticide users (211 FR 66392).

In 1988, EPA established the Endangered Species Protection Program (ESPP) to meet its obligations under the ESA. EPA's ESPP site[2] describes the EPA assessment process for endangered species. Some of the elements of that process, as reported on the website, are summarized below. The goal of EPA's ESPP is to carry out its FIFRA responsibilities in compliance with the ESA, without placing unnecessary burden on agriculture and other pesticide users consistent with Congress' intent.

EPA is responsible for reviewing pesticide information and data to determine whether a pesticide product may be registered for a particular use, including those uses associated with the approval of biotechnology products. As part of that determination, the Agency assesses whether listed endangered or threatened species or their designated critical habitat may be affected by use of the pesticide product. All pesticide products that EPA determines "may affect" a listed species or its designated critical habitat may be subject to the ESPP. If limitations on pesticide use are necessary to protect listed species in areas where a pesticide may be used, the information is related through Endangered Species Protection Bulletins. Bulletins identify the species of concern and the pesticide active ingredient that may affect the listed species. They also provide a description of the measures necessary to protect the species and contain a county-level map showing the geographic area(s) associated with the protection measures, depending on the susceptibility of the species. Bulletins are enforceable as part of the product label (EPA, 2011a).

EPA TES Evaluation Process

EPA evaluates listed species and their critical habitat concerns within the context of pesticide registration and registration review so that when a decision is made, it fully addresses issues relative to listed species protection. If a risk assessment determines that use limitations are necessary to ensure that legal use of a pesticide will not harm listed species or their critical habitat, EPA may either change the terms of the pesticide registration or establish geographically specific pesticide use limitations (EPA, 2011a). The use of any pesticide in a manner that may kill or otherwise harm an endangered species or adversely modify their habitat is a violation of federal law. Pesticides must be used in accordance with the restrictions specified on their product labels.

EPA's review of the pesticide and its registration decision is independent of APHIS' review and regulatory decisions under 7 CFR 340. EPA does not require data or analyses conducted by APHIS to complete its reviews. EPA evaluates extensive toxicity, ecological effects data, and

[2] http://www.epa.gov/espp/

environmental fate, transport and behavior data, most of which is required under FIFRA data requirements, to assess and determine how a pesticide will move through and break down in the environment. Risks to various taxa, e.g., birds, fish, invertebrates, plants and mammals are routinely assessed and used in EPA's determinations of whether a pesticide may be licensed for use in the U.S.

EPA's core pesticide risk assessment and regulatory processes ensure that protections are in place for all populations of non-target species, not just threatened and endangered species. EPA has developed a comprehensive risk assessment process modeled after, and consistent with, EPA's numerous guidelines for environmental assessments (EPA, 2004). The result of an assessment, which may go through several refinements, is to determine whether the potential effects of a pesticide's registration to a listed species will result in either a "no effect" or "may affect" determination. EPA consults on determinations that "may affect" a listed species or adversely modify its critical habitat (EPA, 2012a). As a result of either an assessment or consultation, EPA may require changes to the use conditions specified on the label of the product. When such changes are necessary only in specific geographic areas rather than nationwide to ensure protection of the listed species, EPA implements these changes through geographically-specific Endangered Species Protection Bulletins, otherwise, these changes are applied to the label for all uses of the pesticide.

Ecological Risks of Glyphosate and Isoxaflutole

Glyphosate and IFT are registered by the EPA for use in a variety of crops, including soybean (EPA, 2009c, 2011b). Pursuant to FIFRA Section 3(g), EPA is currently conducting registration reviews for both glyphosate and IFT to ensure continuing fulfillment of FIFRA registration standards. EPA implements its reregistration eligibility decisions via product reregistration by confirming that required risk reduction measures are reflected on pesticide product labels. The EPA registration reviews for glyphosate and IFT are scheduled to be completed in 2014 and 2017, respectively (EPA, 2009c, 2011b).

Glyphosate is a non-selective, phosphonomethyl amino acid herbicide that is widely used to control weeds in agricultural and non-agricultural sites, including forestry, greenhouse, and residential land. Glyphosate was first registered in 1974, and is currently registered for a variety of aquatic and terrestrial uses on fruits, vegetables, and field crops (EPA, 2009a). The effects for glyphosate are summarized in the RED fact sheet and the preliminary problem formulation for the herbicide (EPA, 1993, 2009c).

IFT was conditionally registered on September 15, 1998. The conditional registration was extended on April 11, 2002 and unconditionally registered on October 8, 2004 (Montague, 2012). IFT is currently registered as a Restricted Use Pesticide due to non-target phytotoxicity concerns. In contrast to General Use Pesticides, IFT must be applied by or under the supervision of a certified applicator. At present, EPA is conducting a registration review for IFT (EPA, 2010c). The results of multiple ecological and human-health risk assessments may be found in Appendix A. In summary, risk to aquatic plants, birds, mammals, invertebrates, and fish were below the EPA level of concern (LOC). Additionally, the EPA human-health risk assessment determined that there is no unreasonable dietary risk surrounding IFT residues at its established tolerances (EPA, 2011b).

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

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

The No Action and Preferred Alternatives were analyzed with respect to EO 12898 and EO 13045. Neither alternative is expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

Available mammalian toxicity data associated with the 2mEPSPS and HPPD W336 proteins establish the safety of FG72 soybean and its products to humans, including minorities, low-income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken.

Based on the information submitted by the applicant and reviewed by APHIS, FG72 soybean is agronomically, phenotypically, and biochemically comparable to conventional soybean except for the introduced 2mEPSPS and HPPD W336 proteins. The information provided in the Bayer CropScience petition indicates that the two proteins, 2mEPSPS and HPPD W336, expressed in FG72 soybean are not expected to be allergenic, toxic, or pathogenic in mammals (Bayer, 2011c; Rouquié et al., 2010). Bayer CropScience initiated the consultation process with FDA for the commercial distribution of FG72 soybean and submitted a safety and nutritional assessment of food and feed derived from FG72 soybean to the FDA on December 3, 2009. FDA is currently evaluating the submission, and as of March 16, 2012, has not completed the consultation.

Human toxicity has also been evaluated by the EPA in its development of pesticide labels for both herbicides (62 FR 17723; 76 FR 235). Pesticide labels include use precautions and restrictions intended to protect workers and their families from exposures. It is reasonable to assume that growers will adhere to these EPA herbicide use precautions and restrictions. As discussed in Subsection 4.5, Human Health, the potential use of glyphosate and IFT on FG72 soybean at the proposed application rates would be no more than rates currently approved by the EPA and should not to have adverse impacts to human health when used in accordance with label instructions. It is expected that EPA would monitor the use of FG72 soybean to determine impacts on agricultural practices, such as chemical use, as they have done previously for herbicide-tolerant products.

Based on these factors, a determination of nonregulated status of FG72 soybean is not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

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

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

Soybean is not listed in the U.S. as a noxious weed species by the Federal government (ASA, 2011), nor is it listed as an invasive species by major invasive plant data bases. Cultivated soybean seed does not usually exhibit dormancy and requires specific environmental conditions to grow as a volunteer the following year (OECD, 2010). Any volunteers that may become established do not compete well with the planted crop and are easily managed using standard weed control practices. Soybean does not possess characteristics such as the tolerance for a variety of habitat conditions, rapid growth and reproduction, aggressive competition for resources, and the lack of natural enemies or pests (USDA-APHIS, 2012b) that would make it a successful invasive plant. Non-engineered soybeans, as well as other herbicide-tolerant soybean varieties, are widely grown in the U.S. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by APHIS, FG72 soybean plants are sufficiently similar in fitness characteristics to other soybean varieties currently grown and are not expected to become weedy or invasive.

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

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

Migratory birds may be found in soybean fields. While soybean does not meet the nutritional requirements for many migratory birds (Krapu et al., 2004), they may forage for insects and weed seeds found in and adjacent to soybean fields. As discussed in Sections 4.4.1 and 4.6, data submitted by the applicant has shown no difference in compositional and nutritional quality of FG72 soybean compared with other conventional soybean, apart from the presence of the

2mEPSPS and HPPD W336 proteins. FG72 soybean is not expected to be allergenic, toxic, or pathogenic in mammals. Both 2mEPSPS and HPPD proteins have a history of safe consumption in the context of other food and feeds (Bayer, 2011c). Based on APHIS' assessment of FG72 soybean, it is unlikely that a determination of nonregulated status of FG72 soybean would have a negative effect on migratory bird populations.

The environmental effects associated with IFT have been analyzed by the EPA (EPA, 2011b, 2011d). Testing indicates that ecological toxicity of IFT does not exceed the agency's acute or chronic level of concern. Glyphosate is considered no more than slightly nontoxic to birds (EPA, 1993). Based on these factors, it is unlikely that the determination of nonregulated status of FG72 soybean would have a negative effect on migratory bird populations.

7.2 International Implications

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

APHIS has given this 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 FG72 soybean. All existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new soybean cultivars internationally apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340.

Any international trade of FG72 soybean 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).

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.

7.3 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the potential changes in soybean production associated with a determination of nonregulated status of FG72 soybean (Section 4.2) and determined that the cultivation of FG72 soybean would not lead to the increased production or acreage of soybean in U.S. agriculture. The herbicide tolerance conferred by the genetic modification to FG72 soybean would not result in any changes in water usage for cultivation. As discussed in Section 4.3.2 and 4.3.3, there are no expected negative impacts to water resources or air quality from potential use of glyphosate or IFT associated with FG72 soybean production. Based on these analyses, APHIS concludes that a determination of nonregulated status of FG72 soybean would comply with the CWA and the CAA.

7.4 Impacts on Unique Characteristics of Geographic Areas

A determination of nonregulated status of FG72 soybean is not expected to impact unique characteristics of geographic areas such as park lands, prime farmlands, wetlands, wild and scenic areas, or ecologically critical areas.

Bayer CropScience has presented results of agronomic field trials for FG72 soybean. The results of these field trials demonstrate that there are no differences in agronomic practices between FG72 and conventional soybean. The common agricultural practices that would be carried out in the cultivation FG72 soybean are not expected to deviate from current practices, including the use of EPA-registered pesticides. The product is expected to be deployed on agricultural land currently suitable for production of soybean and replace existing varieties, and is not expected to increase the acreage of soybean production.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of FG72 soybean. This action would not convert land use to nonagricultural use and, therefore, would have no adverse impact on prime farmland. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to FG72 soybean, including the use of EPA-registered pesticides. The Applicant's adherence to EPA label use restrictions for all pesticides is expected to mitigate potential impacts to the human environment.

With regard to pesticide use, a determination of nonregulated status of FG72 soybean is likely to result in changes to the use of IFT on soybean. The potential changes in herbicide use are discussed in Section 4.2.2. IFT is currently registered by the EPA as a restricted use pesticide in soybean and other crops. APHIS assumes that the EPA label would provide for label use restrictions intended to mitigate potential impacts to the human environment, including potential impacts to unique geographic areas. As noted above, APHIS further assumes that the grower will closely adhere to EPA label use restrictions for all pesticides.

Potential impacts to geographic areas have been considered by the EPA in its evaluation of IFT. IFT is currently under registration review by the EPA (EPA, 2011b). With regard to the current registration, EPA conducted both human and environmental risk assessments. Although some risks were identified, the EPA determined that these risks could be mitigated by implementing label use restrictions (EPA, 1997, 2011c, 2011d, 2012b). Additional details regarding the current status of the EPA registration review for IFT may be found in Appendix A.

All pesticides distributed or sold in the U.S. are subject to registration by the EPA under authority of FIFRA. Glyphosate was first registered for use by the EPA in 1974, and has been assessed several times since then by the EPA and other Federal Agencies (EPA, 2009c). At present, glyphosate is currently undergoing registration review by the EPA; in 1993, EPA determined that all currently registered pesticide products containing glyphosate would not pose unreasonable risks or adverse effects to humans or the environment, thus permitting its eligibility for the EPA pesticide reregistration program (EPA, 2009c). A preliminary problem formulation has been conducted as part of the registration review of glyphosate by the EPA, identifying what is currently known and uncertainty regarding the ecological risk, environmental fate, endangered species, and drinking water assessment of glyphosate and its transformation products (EPA, 2009c). EPA produced an estimated timeline for the completion of the glyphosate registration review, with a final decision due in 2015 (EPA, 2009a). Submittals that are relevant to the EPA registration review of glyphosate can be submitted under the docket designation EPA-HQ-2009-0361 at the Regulations.gov website.

Based on these findings, including the assumption that EPA label use instructions are in place to protect unique geographic areas and that those label use instructions are adhered to, a determination of nonregulated status of FG72 soybean is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

7.5 National Historic Preservation Act of 1966 as Amended

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

APHIS' proposed action, a determination of nonregulated status of FG72 soybean is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

APHIS' Preferred Alternative would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of scientific, cultural, or historical resources. This action is limited to a determination of non-regulated status of FG72 soybean.

APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for increased noise on the use and enjoyment of a historic property during the operation of tractors and other mechanical equipment close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the soybean production regions. The cultivation of FG72 soybean is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

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10 APPENDIX A: ISOXAFLUTOLE – DESCRIPTION AND CURRENT USES

Description and Mode of Action

Isoxaflutole (IFT) is a systemic, broad-spectrum herbicide initially developed for the control of problematic broadleaf and grass weeds in corn (*Zea mays*) and sugarcane (RSC, 2011). Degradation of IFT yields two sequential metabolites and may be mediated through metabolic or physical/chemical pathways (Figure A1). Following foliar absorption or root uptake, a rapid and non-enzymatic process sequentially converts IFT into a diketonitrile (DKN) derivative (Pallett et al., 1998). DKN is the major bioactive principle of IFT, and thus, primarily responsible for the herbicidal activity of IFT. DKN is further degraded into a benzoic acid derivative (Pallett et al., 1998). Degradation or metabolism of IFT into DKN and the benzoic acid derivative is known to occur in soil, plants, and animals (EPA, 2011c).

IFT is classified as a Group F2 bleaching herbicide (isoxazole chemical family) under the Herbicide Resistance Action Committee (HRAC). This is a relatively novel group of herbicides and includes the triketone (e.g., mesotrione and sulcotrione) and pyrazole (e.g., benzofenap, pyrazolynate, and pyrazoxyfen) chemical families (HRAC, 2012). In contrast to other carotenoid-inhibiting herbicide groups (e.g., F1 and F3), IFT possesses a unique mode of action (MoA). IFT, through degradation to its bioactive principle, targets 4-hydroxy phenylpyruvate dioxygenase (4-HPPD). Competitive inhibition of 4-HPPD by DKN reduces availability of cellular plastoquinone, an essential co-factor for phytoene desaturase activity in carotenoid biosynthesis (Figure A2). Consequently, a depletion of carotenoids impairs chloroplast development, leading to the typical bleaching of emerging foliar tissue and stunting of IFT-susceptible plant species (Pallett et al., 2001). Tolerance to IFT may be conferred by more rapid degradation of DKN benzoic acid derivative *in planta* (Pallett et al., 1998; RSC, 2011).

Herbicidal activity requires IFT or DKN. Field soil half-life of IFT and DKN are 0.4 – 4.5 and 10 – 39 days, respectively (Table A1). Aquatic photolysis half-life of IFT is 6.7 days; DKN is relatively stable in laboratory aquatic conditions, though dissipation half-life from sediment/water systems is 66 – 89 days (Ramanarayanan et al., 2005). The benzoic acid derivative is not considered toxicologically significant, and thus, does not display herbicidal activity against plants (EPA, 2011c).

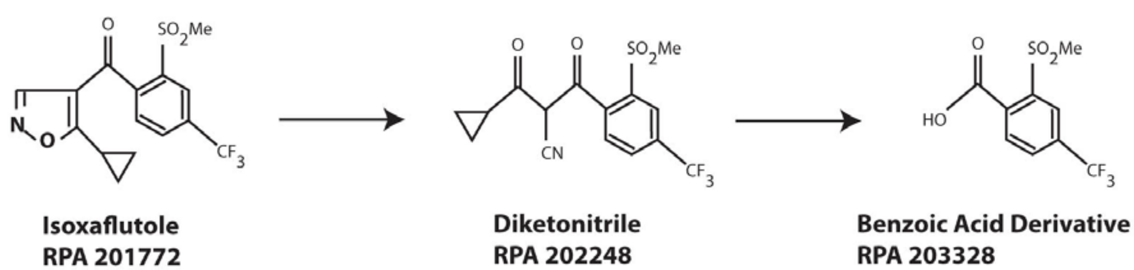


Figure A1. Metabolic/degradative fate of isoxaflutole (IFT) in plants and soil. Reproduced from Pallett et al. (2001).

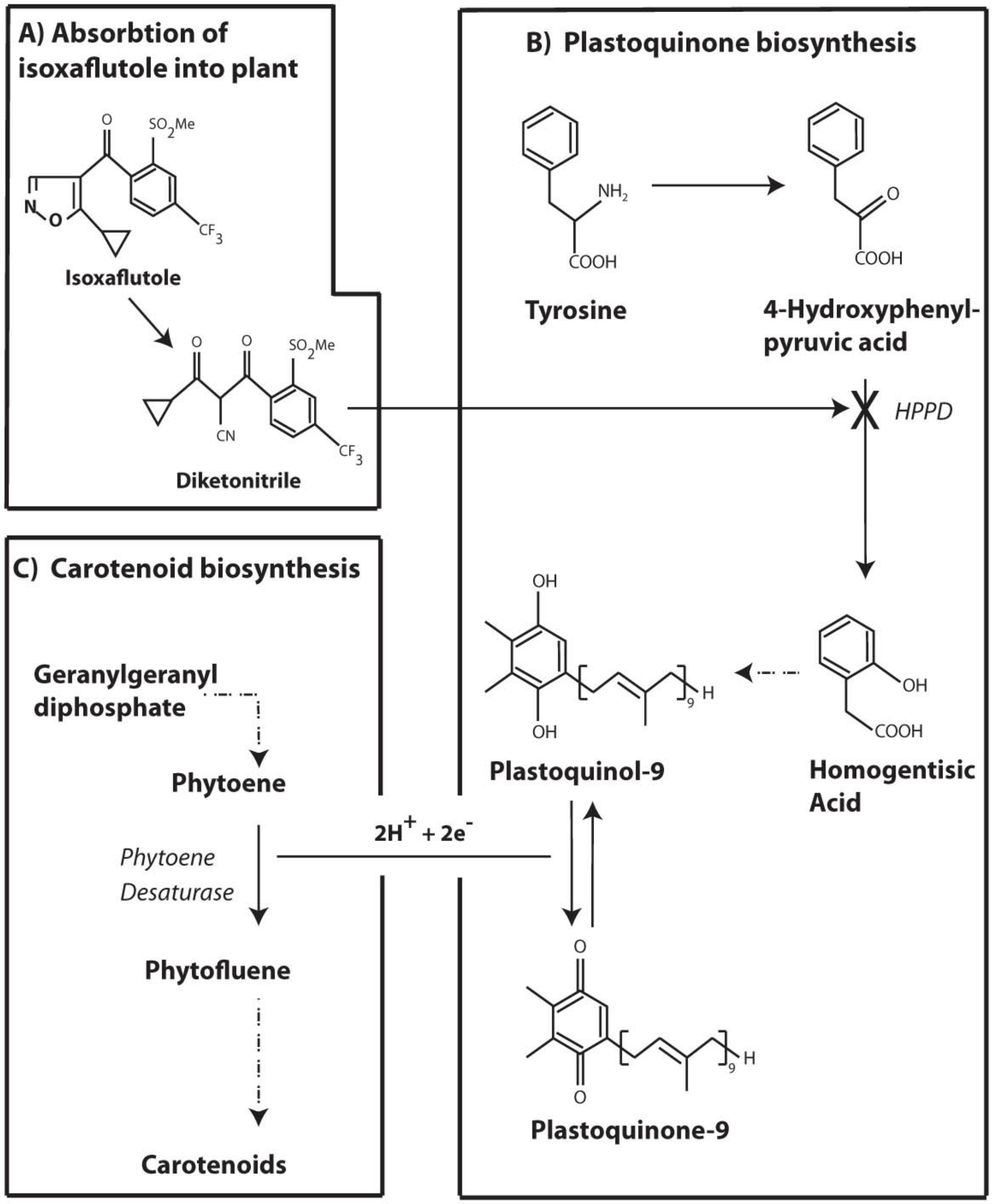
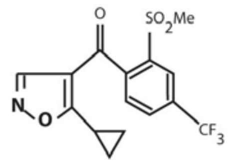
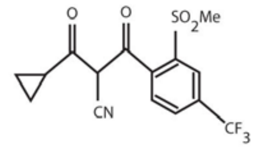


Figure A2. Activity of isoxaflutole (IFT) in plants. (A) Degradation of isoxaflutole yields a diketonitrile derivative *in planta*. (B) The diketonitrile derivative reduces carotenoid biosynthesis through inhibition of the 4-HPPD enzyme, thus precluding the production of the plastoquinol-9 cofactor necessary for (C) phytoene desaturase activity. Adapted from Pallett et al. (1998).

Table A1. Summary of environmental fate information for IFT and DKN.

Property	IFT	DKN
mol structure		
mol wt (g/mol)	359	359
water solubility (mg/L)	6.2	325
octanol/water partition coefficient (log P)	2.32	-0.40
vapor pressure (pa)	1.0 x 10-6 (at 25C)	N/A
soil Koc at initial soil conc (~0.29 ppm)	102-227	62-204
lab aerobic soil half-life (days)	0.3-4.3	10-39
field dissapation half-life (days)	0.4-4.5	6.5-21
hydrolysis half-life at pH 7 (days)	0.84	stable
dissapation half-life from water phase in sediment/water systems (days)	0.5-0.6	66-89
aquatic photolysis half-life (natural sunlight at pH 7) (days)	6.7	stable

Reproduced from Ramanarayanan et al. (2005).

<u>Regulatory Status of Isoxaflutole</u>

The following is a summary of the Environmental Protection Agency (EPA) document entitled *Isoxaflutole Summary Document Registration Review: Initial Docket June 2011* (EPA, 2011a). Additional section-specific information may be found in that document.

All pesticides distributed or sold in the U.S. are subject to registration by the EPA under authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Registration of a pesticide is dependent on consideration of scientific data demonstrating that a particular pesticide will not cause unreasonable risks to human health, workers, or the environment when used as directed on a product label. IFT was first conditionally registered on September 15, 1998. The conditional registration was extended on April 11, 2002 and unconditionally registered on October 8, 2004 (Montague, 2012). IFT is currently registered as a Restricted Use Pesticide due to non-target phytotoxicity concerns. In contrast to General Use Pesticides, IFT must be applied by or under the supervision of a certified applicator. At present, active EPA registrations include:

- 8 Section 3 Registrations.
- 20 Section 24(c) Special Local Need Registrations.
- 1 Section 5 Experimental Use Permit (for use on IFT-tolerant soybean).

The Food Quality and Protection Act of 1996 mandated that the EPA conduct registration reviews of all pesticides distributed or sold in the U.S. every 15 years. Pursuant to Section 3(g) of FIFRA, EPA initiated a registration review for isoxaflutole in June 2011 (Docket Number:

EPA-HQ-OPP-2010-0979). EPA has developed an estimated timeline for the isoxaflutole registration review process. This is reproduced below in Table A2:

Table A2. Estimated isoxaflutole (IFT) registration review timeline.

Registration Review for Isoxaflutole - Projected Registration Review Timeline	
Activities	**Estimated Date**
Opening the Docket	
Open Docket and Public Comment Period	2011 - June
Close Public Comment	2011 - August
Case Development	
Final Work Plant	2011 - November
Issue DCI	2012 - July - Sep.
Data Submission	2014 - July - Sept.
Open Public Comment Period for Draft Risk Assessment	2016 - Jan. - March
Close Public Comment Period	2016 - April - June
Registration Review Decision	
Open Public Comment Period for Proposed Registration Review Decision	2016 - July - Sept.
Close Public Comment Period	2016 - Oct. - Dec.
Registration Review Decision and Begin Post-Decision Follow-up	2017
Total (years)	6

Conclusions from Previous Isoxaflutole Assessments

The following is a summary of the EPA document *Preliminary Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments in Support of the Registration Review of Isoxaflutole* (EPA, 2011c). Additional information specific to this section may be found in that document.

An ecological risk assessment was completed by the EPA Environmental Fate and Effects Division (EFED) on May 2, 1997 (DP barcodes 225503+) for the proposed registration of IFT as a pre-plant or pre-emergence herbicide for the control of grassy and broadleaf weeds in field corn. A brief summary of the risks from the proposed use of IFT is provided below:

- There is a phytotoxic risk to non-target aquatic and terrestrial plants from runoff of parent IFT and its degradation products.
- There is a phytotoxic risk to non-target terrestrial plants from found spray drift of parent IFT.
- Minimal adverse effects to non-target plants are expected from ground spray drift.
- Endangered plant species may be directly affected by the use of isoxaflutole.

- Chronic risks to birds, mammals, shrimp, and estuarine fish cannot be determined because data on the degradation products have not been received. [Note that data submitted subsequent to the 1997 assessment has indicated that only the Agency's level of concern (LOC) for chronic risk to estuarine invertebrates is exceeded at rates of application at corn sites. Chronic risks LOCs to birds, mammals, and fish are not exceeded.]
- EFED expects that degradation products will persist and accumulate in surface water and shallow ground water surrounding treated areas. [Note that updated data since the 1997 assessment supports this finding. Laboratory studies suggest that DKN and the benzoic acid derivative are stable to hydrolysis and photolysis in aqueous systems and hence pose a possible environmental concern.]
- There is a potential risk to other crops from the presence of potentially phytotoxic degradation products in irrigation water. However, the major areas of corn production that use irrigation (Western U.S. corn belt) have deep aquifers with slow recharge rates that are not likely to have sufficient concentrations of the degradation products to adversely affect other crops. In other parts of the U.S., where corn is also grown and where shallow ground water is used for irrigation, sporadic irrigation is used for other crops. Crops such as soybean, which are rotated with corn and are sensitive to irrigation waters containing IFT residues, could be adversely affected. Estimated maximum concentration of IFT residues in ground water exceeded the phytotoxic triggers to non-target plants (e.g., other crops) up to 4,500 times, presuming that the degradation products are as toxic as parent IFT. [Note that updated data since the 1997 assessment indicate that IFT's terminal metabolite, the benzoic acid derivative, does not demonstrate phytotoxicity for terrestrial plants. A developmental toxicity study in rats conducted with the benzoic acid derivative has been submitted to the Agency (MRID 45655906). The results of the study show that in the presence of maternal toxicity at the highest doses tested (750 mg/kg/day), there was no teratogenicity or developmental toxicity. These results and those of other toxicology studies and plant studies on the compounds suggest that the benzoic acid derivative of IFT is not toxicologically significant.]

On April 16, 2010, EFED completed an ecological risk assessment for an Experimental Use Permit (EUP) request from Bayer CropScience for IFT use on IFT-tolerant soybean. Additionally, EFED conducted another ecological risk assessment expanding the geographic extent of corn and considered the use of IFT on soybean. In these ecological risk assessments, IFT and its bioactive principle, DKN, were assessed for potential risk to non-target organisms. The conclusions are briefly summarized below:

- The Agency's LOC for terrestrial non-target plants was exceeded for runoff and spray drift exposure routes.
- Runoff from soybean and/or corn fields may contain residues of IFT and DKN. These waters, if used for irrigation on non-target plants (crops) may exceed the Agency's LOC for non-target plants by up to 310X.
- The Agency's LOC for aquatic non-target plants was not exceeded for listed and non-listed species near soybean fields.
- The Agency's acute or chronic LOCs for birds and mammals (listed and non-listed) were not exceeded.

- The Agency's acute or chronic LOCs for fish or invertebrates (freshwater or estuarine) (listed and non-listed) were not exceeded.

On September 9, 2011, the EPA Health Effects Division (HED) completed a human-health risk assessment entitled *Isoxaflutole. Section 3 Registration for Use on Soybeans. Human-Health Risk Assessment* (EPA, 2011b) as a result of a request from Bayer CropScience to amend 40 CFR 180.537 by establishing tolerances for combined residues of IFT and DKN in or on soybean. Additional information specific to this section may be found in that document. Acute and chronic toxicity profiles are presented below in Tables A3 and A4.

Table A3. Acute toxicity profile of isoxaflutole (IFT) and degradation products.

Guideline No./Study Type	MRID No.	Results	Toxicity Category
Isoxaflutole Technical			
870.1100/Acute oral toxicity	43573212	LD_{50} >5000 mg/kg	IV
870.1200/Acute dermal toxicity	43573213	LD_{50} >2000 mg/kg	III
870.1300/Acute oral toxicity	43573214	LC_{50} >5.23 mg/L	IV
870.2400/Primary eye irritation	43573215	Non-irritating	IV
870.2500/Primary dermal irrigation	43573216	Non-irritating	IV
870.2600/Dermal sensitivity	43573217	Non-sensitizer	N/A
DKN Technical			
870.1100/Acute oral toxicity	43904810	LD_{50} >5000 mg/kg	IV
Benzoic Acid derivative Technical			
870.1100/Acute oral toxicity	43904812	LD_{50} >5000 mg/kg	IV

Table A4. Subchronic and chronic toxicity and genotoxicity profile: Isoxaflutole (IFT) and products.

Guideline No./Study Type	MRID No. (Year)/Doses/Classification	Results
Isoxaflutole		
870.3250 21-day dermal (rat)	43573219 0, 10, 100, or 1000 mg/kg/day. **Acceptable (guideline)**	NOAEL = 1000 mg/kg/day. LOAEL not observed.

Guideline No./Study Type	MRID No. (Year)/Doses/Classification	Results
870.3700 Developmental toxicity (rat)	43573220 0, 10, 100, or 1000 mg/kg/day. **Acceptable (guideline)**	Maternal NOAEL = 1000 mg/kg/day. Maternal LOAEL = 500 mg/kg/day based on increased incidence of clinical signs and decreased body weight, body-weight gains and food consumption. Developmental NOAEL = 10 mg/kg/day. Developmental LOAEL = 100 mg/kg/day base on decreased fetal body weights and increased incidences of skeletal anomalies.
Developmental toxicity (rabbit)	43904808 0, 5 , 20, 100 mg/kg/day. **Acceptable (guideline)**	Maternal LOAEL = 100 mg/kg/day based on increased incidence of clinical signs, decreased body weight gains, and food consumption. Developmental NOAEL not observed. Developmental LOAEL = 5 mg/kg/day base on increased incidence of fetuses with 27th pre-scaral vertebrae.
870.3800 2-generation reproduction (rat)	43904809 0/0, 0.45/0.46, 1.76/1.79, 17.4/17.7, or 414/437 mg/kg/day (M/F). **Acceptable (guideline)**	Maternal NOAEL = 1.76 mg/kg/day. Maternal LOAEL = 17.4 mg/kg/day based on increased liver weights and hypertrophy in both sexes and generations. Reproductive NOAEL = 437 mg/kg/day. Reproductive LOAEL not observed. Offspring NOAEL = 1.76 mg/kg/day. Offspring LOAEL = 17.4 mg/kg/day based on reduced litter survival in both generations (F_1 and F_2 pups).
870.4100 Chronic toxicity (dogs) 870.4200 Carcinogenicity (mice)	43573218 0, 240, 1200, 12000, or 30000 ppm (0, 8.56/8.41, 44.81/45.33, 453/498, or -/1254 mg/kg/day [M/F]). **Acceptable (guideline)** 43904807 0, 25, 500, or 7000 ppm (0/0, 3.2/4, 64.4/77.9, or 977.3/1161.1 mg/kg/day [M/F]). **Acceptable (guideline)**	Maternal NOAEL = 20 mg/kg/day. Maternal LOAEL = 100 mg/kg/day based on increased incidence of clinical signs, decreased body weight gains, and food consumption. Developmental NOAEL not observed. Developmental LOAEL = 5 mg/kg/day base on increased incidence of fetuses with 27th pre-scaral vertebrae. NOAEL = 25 ppm (3.24/4 mg/kg/day (M/F). LOAEL = 500 ppm (64.4/77.9 mg/kg/day (M/F), based on decreased body weight gains, increased liver weights, and increased incidences of histopathological liver changes. Liver tumors observed at HDT.

Guideline No./Study Type	MRID No. (Year)/Doses/Classification	Results
870.4300 Chronic toxicity/ Carcinogenicity (rats)	43904806 0, 0.5, 2, 20, or 500 mg/kg/day. **Acceptable (guideline)**	NOAEL = 2 mg/kg/day. LOAEL = 20 mg/kg/day, based on liver, thyroid, ocular, and nervous system toxicity (M) and liver toxicity (F). Liver and thyroid tumors observed at HDT.
870.5100 *In vitro* bacterial reverse mutation (*S. typhimurium*)	43588002 Up to insoluable (≥ 500 µg/plate) concentrations =/- S9. **Acceptable (guideline)**	Negative.
870.5300 *In vitro* mammalian gene mutation (L5178Y mouse lymphoma)	43573222 Up to insoluable (≥ 150 µg/plate) or soluable (≤ 75 mg/plate) concentrations +/- S9. **Acceptable (guideline)**	Negative.
870.5375 *In vitro* mammalian chromosomal aberration (lymphocytes)	43573221 Up to insoluable (≥ 300 µg/ml -S9; ≤ 600 µg/ml +S9. **Acceptable (guideline)**	Negative.
870.5395 *In vivo* mammalian cytogenetics (mouse micronucleus)	43573223 Up to 5000 mg/kg. **Acceptable (guideline)**	Negative.
870.6200 Acute neurotoxicity (rat)	43904804 0, 125, 500, or 2000 mg/kg/day. **Acceptable (guideline)**	NOAEL = 125 mg/kg/day. LOAEL = 500 mg/kg/day based on significant decreases in hind limb grip strength and landing food splay on day 15.

Guideline No./Study Type	MRID No. (Year)/Doses/Classification	Results
870.6200 Subchronic neurotoxicity (rat)	43904805 0, 25, 250, or 750 mg/kg/day. **Acceptable (guideline)**	NOAEL = Not observed. LOAEL = 25 mg/kg/day based on significant decreases in mean hind limp grip strength during both trials and week 13 and a non-significant decrease in mean forelimb grip strength at week 13.
870.6300 Developmental Neurotoxicity (rat)	45215701 (2000) 0, 5, 25, or 250 mg/kg bw/day. **Unacceptable (guideline) -** morphometric measurements not performed	Maternal NOAEL = 25 mg/kg/day. Maternal LOAEL = 250 mg/kg/day based on increased incidence of clinical signs, decreased body weight, body-weight gains, and food consumption Tentative offspring NOAEL = 25 mg/kg/day. Tentative offspring LOAEL = 250 mg/kg/day based on decreased body weight and brain weight (no effects at lower doses).
870.7485 Metabolism (rat)	43573224 1 and 100 mg/kg (single dose) 1 mg/kg/day (15-day repeated dosing). **Acceptable (guideline)** 43904815 Comparative metabolism study **Unacceptable (non-guideline)**	Rapidly and extensively absorbed and metabolized. DKN represented 70% or more of the radioactivity excreted in the urine and feces. The benzoic acid derivative was more polar. Elimination was rapid and dose dependent. The majority of the radiolabel was eliminated in the first 24 and 48 hours for the low and high dose groups, respectively. The extensive systemic clearance of the radiolabel was reflected in the low levels of radioactivity found in tissues at 168 hours post-dosing. Sex-related differences were observed in the excretion and distribution pattern among high-dose rats. The elimination half-lives were similar among single low and high dose groups, with an estimated mean blood half-life of 60 hours. No sex differences were observed in the metabolism of ^{14}C-isoxaflutole.

Guideline No./Study Type	MRID No. (Year)/Doses/Classification	Results
870.7600 Dermal penetration	44044702 0.865, 7.32, or 79 mg/cm^2. **Acceptable (guideline)**	3.46% absorption at 0.865 mg/cm^2 after 10 hours.
870.7800 Immunotoxicity	48283101 0, 160, 800, or 4000 ppm (0. 6. 57. or 279 mg/kg/day). **Acceptable (guideline)**	NOAEL = 4000 ppm (279 mg/kg/day). LOAEL = not identified.
Mechanistic studies	43904816-43904820	Investigated ocular toxicity, tyrosinemia, and mode of action of liver and thyroid tumor formation in rats and mice
	DKN	
870.5100 *In vitro* bacterial reverse mutation (*S. typhimurium*)	43904811 Up to 500 μg/plate +/- S9.	Negative.
	Acceptable (guideline)	
	Benzoic Acid derivative	
870.3100 28-day oral rat (range-finding)	43904813 (1995) 0, 150, 500, 5000, or 15000 ppm (0.0, 11,14/12.68, 37.57/42.7, 376.96/421.53 or 1117.79/1268.73 mg/kg/day [M/F]) **Acceptable (guideline)**	NOAEL = 15000 ppm (1117.79/1268.73 mg/kg/day [M/F]). LOAEL not observed.
870.3100 90-day oral (rat)	45655903 (1998) 0, 1200, 4800, or 12000 ppm (0/0. 73.2/93.1, 306/371, or 769/952 mg/kg/day [M/F]). **Acceptable (guideline)**	NOAEL = 12000 ppm (769/952 mg/kg/day [M/F]). LOAEL not observed.

Guideline No./Study Type	MRID No. (Year)/Doses/Classification	Results
870.3700 Developmental toxicity rats (gavage)	45655906 0, 75, 250, or 750 mg/kg/day. **Acceptable (guideline)**	Maternal NOAEL = 75 mg/kg/day. Maternal LOAEL = 250 mg/kg/day based on clinical signs (salivation and piloerection around time of treatment), decreased body-weight change, decreased corrected body-weight change, and decreased food consumption. Developmental NOAEL = 750 mg/kg/day. Developmental LOAEL not observed.
870.5100 *In vitro* bacterial reverse mutation (*S. typhimurium*)	43904814 Up to cytotoxic concentrations ($\geq$ 2500 µg/plate) +/- S9. **Acceptable (guideline)**	Negative.
870.5300 *In vitro* mammalian gene mutation (CHO/HGPRT)	4454303 Up to $\geq$ 2700 µg/ml +/- S9. **Acceptable (guideline)**	Negative.
870.5375 *In vitro* mammalian chromosomal aberration (CHO cells)	44545301 Up to $\geq$ 2710 µg/ml +/- S9. **Acceptable (guideline)**	Negative.
870.5395 *In vivo* mammalian cytogenetics (mouse micronucleus)	44545301 0, 500, 1000, or 2000 mg/kg. **Acceptable (guideline)**	Negative.

As a result of this human-health assessment, HED determined that there is no residue chemistry, toxicological or occupational/residential exposure issue that would preclude establishment of an unconditional registration for IFT and its metabolites. These tolerances include:

- HED-recommended tolerance for the combined residue of IFT and DKN on soybean is 0.05 ppm.
- HED-recommended tolerance the combined residue of IFT and DKN on aspirated grain fractions of soybean is calculated as 0.30 ppm.

Current Use and Usage Information

At present, IFT is registered as a Restricted Use Pesticide (RUP) in field corn by the EPA under authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (EPA, 2011a). In contrast to General Use Pesticides, IFT may only be applied by certified applicators or under the supervision of a certified applicator (EPA, 2012). Additionally, an experimental use permit for use of IFT on IFT-tolerant soybean was approved on April 27, 2010 (Bayer, 2011a).

IFT may be found in the following herbicide formulations: Balance Pro®; Balance Flexx® (IFT + cyprosulfamide); Corvus™ (IFT + thiencarbazone + cyprosulfamide); and Radius™ (IFT + flufenacet) (Bayer, 2011c). Additionally, DuPont also produces Prequel™ (IFT + Rimsulfuron) (DuPont, 2012).

IFT registrations for field corn can only be used in the following states: Arkansas, Colorado, Illinois, Indiana, Iowa, Kansas, Kentucky, Missouri, Montana, Nebraska, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota, Tennessee, Texas, and Wyoming (Bayer, 2011b). The listed states participate in developing/following label restrictions to mitigate the possibility of adverse effects to non-target plants. An example of restrictions for use in field corn is presented in Table A5. More label information can be found at:
http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1:1863164510650266

IFT registration for IFT-tolerant soybean can be used in the same states as field corn, except Arkansas, Oklahoma, and Texas (Bayer, 2011a). The listed states also participate in developing/following label restrictions to mitigate the possibility of adverse effects to non-target plants. Table A6 presents a summary of proposed IFT use in IFT-tolerant soybean and an example of restrictions for use in IFT-tolerant soybean is presented in Table A7. Restrictions for IFT use in soybean are the same as corn, including the maximum application rate of 3.0 fluid ounces/year. More label information can be found at:
http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1:1863164510650266

Table A5. Specific use directions for Balance® PRO herbicide alone as part of a planned sequential weed control program. Source: Bayer (2011b).

Application Timing	Amount of BALANCE® PRO Herbicide per Acre					
	Soil Texture					
	Coarse Soils Sand, Loamy sand, Sandy loam		Medium Soils** Loam, Silt loam, Silt, Sandy clay loam		Fine Soils Silty clay loam, Clay loam, Sandy clay, Silty clay, Clay	
	< 1.5% O.M.	> 1.5% O.M.	< 1.5% O.M.	>1.5% O.M.	< 1.5% O.M.	> 1.5% O.M.
Early Preplant (Surface Applied or Incorporated) 8 to 30 days prior to planting	Not Recommended (See Below)*	2.25 to 3.0 fluid ounces	3.0 fluid ounces	3.0 fluid ounces	3.0 fluid ounces	3.0 fluid ounces
Preplant (Surface Applied or Incorporated) 0 to 7 days prior to planting or preemergence	Not Recommended (See Below)*	1.5 to 1.88 fluid ounces	1.88 to 2.6 fluid ounces	2.25 to 3.0 fluid ounces	2.25 to 3.0 fluid ounces	2.25 to 3.0 fluid ounces

O.M. = Organic Matter by weight

Within rate ranges in the rate tables, use the lower rate on soils that are relatively coarse-textured or low in organic matter. Use the higher rate on soils that are relatively fine-textured or high in organic matter or when the preplant application is made further from planting.

*Use on **coarse soils** of less than 1.5% organic matter by weight or pH greater than 7.5 may result in adverse crop response.

When BALANCE® PRO Herbicide is applied preemergence to **medium soils with a pH greater than 7.5, reduce the rate by 0.25 fluid ounce from the recommended rate.

Table A6. Proposed directions for use of isoxaflutole (IFT) on isoxaflutole-tolerant soybean varieties. Source: EPA (2011b).

Summary of Proposed Directions for Use of Isoxaflutole.							
Commodity	Trade Name (EPA Reg. No.)	Application Equipment	Application Rate[1] (lb ai/A)	Maximum Number Applications Per Season	Maximum Seasonal Application Rate (lb ai/A)	PHI[2] (days)	Use Directions and Limitations
Isoxaflutole-Tolerant Soybean Varieties	Balance® PRO (264-600)	Groundboom sprayer	0.094	1	0.094	21 days	Min. spray volume: 10 GPA[2]

[1] Maximum application rate from label. Label recommends varying rates according to soil texture and timing of application.
[2] PHI = pre-harvest interval, GPA = gallons per acre.

Table A7. Specific use directions for Balance® PRO herbicide applied alone, as a tank-mix, or as part of a planned sequential program for weed control in isoxaflutole (IFT) tolerant soybean varieties. Source: Bayer (2011a).

Application Timing[1]	Fluid Ounces of BALANCE® PRO Herbicide per Acre per 365 Days				
	Soil Texture				
	Coarse Soils Sand, Loamy sand, Sandy loam		Medium Soils Loam, Silt loam, Silt, Sandy clay loam		Fine Soils Silty clay loam, Clay loam, Sandy clay, Silty clay, Clay
	1.5% O.M.[2] or less	> 1.5% O.M.	1.5% O.M. or less	>1.5% O.M.	
Preplant (Surface Applied or Incorporated): Early - 8 to 30 days prior to planting	Not Recommended (See Below)[3]	2.5	3.0		
Preplant (Surface Applied or Incorporated): 0 to 7 days prior to planting. Preemergence Early postemergence	Not Recommended (See Below)[3]	2.0	2.5	3.0	

[1]BALANCE® PRO Herbicide may be applied up to 30 days prior to planting when used in a planned sequential application program such as BALANCE® PRO Herbicide followed by glyphosate or other post applied herbicides when plants are also tolerant to such herbicides.

[2]O.M. = Organic Matter by weight

[3]BALANCE® PRO Herbicide applications to **coarse soils** with organic matter of less than 1.5% by weight **or** pH greater than 7.5 may cause adverse crop response. The use of BALANCE® PRO Herbicide is not recommended on soils that have organic matter of less than 1.5% **and** a pH greater than 7.5. Use on clay knolls, eroded hill sides, terracing with scraped exposed subsoil, or other areas of coarser and/or lower organic matter soils, may cause adverse crop response. To prevent off-site movement of soil containing this product to non-target areas, do not apply BALANCE® PRO Herbicide to areas receiving less than 15 inches of average annual precipitation unless supplemented to at least the equivalent of 15 inches of annual precipitation with irrigation water

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11 APPENDIX B: GLYPHOSATE – SUMMARY OF ENVIRONMENTAL FATE AND TOXICITY PROFILE

Glyphosate acid is non-selective, systemic foliar herbicide used to control weeds in agricultural and non-agricultural sites, including forestry, greenhouse, and residential sites. Glyphosate functions as a specific inhibitor of the enzyme, 5-enolpyruvylshikimate 3-phosphate synthase (ESPS), effectively precluding plant aromatic amino acid synthesis (e.g., tyrosine, tryptophan, and phenylalanine) and leading to plant cell death (EPA, 2009, 2011).

The following is a summary of the environmental fate and toxicity profile from the EPA document *Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Glyphosate and its Salts* (EPA, 2009). Additional information form this section may be found in that document.

- Based on the EPA Reregistration Eligibility Decision in 1993 (EPA, 1993), EPA concluded that direct risks to birds, mammals, invertebrates, and fish would be minimal. Under certain conditions, glyphosate may pose a risk to aquatic plants. Additionally, endangered plants and the Houston Toad may be at risk from glyphosate use.

- In 2003, the USDA Forest Service conducted a risk assessment for glyphosate (USDA-FS, 2003). Based on the available data, USDA-FS concluded that the risks due to glyphosate were minimal for mammals, birds, fish, invertebrates, and aquatic plants. However, at an application rate of 7 lbs. a.e./acre, the acute exposure slightly exceeded the acute LC_{50} and exceeded the LC_{50} by a factor of two for more tolerant and less tolerant freshwater fish, respectively. These values were determined, however, from a worse-case scenario where severe rainfall occurred in an area where runoff is favored. Additionally, tolerant terrestrial plants did not appear at risk from low-boom spray application of glyphosate at distances of 25 feet or greater. For more sensitive plants, this distance increased to approximately 1000 feet. No risks to terrestrial plants from runoff were expected, due to the high sorption of glyphosate to soil particles.

- In 2004, EPA assessed the potential of glyphosate to affect 11 federally listed Pacific salmonids (Patterson, 2004). The conclusion of that assessment was that glyphosate may, but is not likely, to negatively affect the salmonids based on acute toxicity to fish for application rates above 5 lbs. a.i./acre. The EPA also concluded that there would be no effect from glyphosate on salmonids at application rates below 5 lbs. a.i./acre.

- In 2008, EPA assessed the potential direct and indirect effects on the California red-legged frog (*Rana aurara draytonii*) resulting from the use of glyphosate on agricultural and non-agricultural sites (Carey et al., 2008). The EPA concluded that there was no direct effect on the aquatic-phase California red-legged frog for any terrestrial or aquatic uses of glyphosate. The terrestrial phase California red-legged frog may be at risk following direct chronic exposure to glyphosate at application rates of 7.5 lbs. a.e./acre and above. Additionally, terrestrial-phase amphibians may be at risk following acute exposure to one particular formulation (Registration number 524-424) at 1.1 lbs formulation/acre. Indirect effects to the aquatic phase California red-legged frog, based on reduction in the prey base, may occur with aquatic non-vascular plants that are managed at an application rate of 3.75 lbs. a.e./acre. Indirect effects to the California red-legged frog, based on reduction in prey base, may occur with small insects at any registered rate; large insects at an application rate of 7.95 lbs. a.e./acre; terrestrial phase amphibians following chronic exposure glyphosate at application rates of 7.5 lbs. a.e./acre and above; at an acute exposure to the formulation listed above; and, mammals following chronic exposure at application rates of 3.84 lbs. a.e./acre. Indirect effects to both the aquatic- and terrestrial-phase California red-legged frog, based on habitat effects, may occur following the management of aquatic plants with glyphosate.

Table B1. Physical and chemical properties of glyphosate.

Physical/Chemical Property	Value
Molecular Formula	$C_3H_8NO_5P$
Molecular Weight	170.8 g/mole
Melting Point	210-212° C (tech.) 215-219° C (pure)
Solubility in water, 25° C	12,000 mg L^{-1}
Vapor Pressure, Pa	1.3×10^{-7} (25° C)
Henry's Law Constant, Pa $\cdot m^3 \cdot mol^{-1}$	2.1×10^{-9}
Log K_{ow}	< -3
Dissociation Constants	$pKa_1 = 0.8$ $pKa_2 = 2.35$ $pKa_3 = 5.84$ $pKa_4 = 10.48$

Table B2. Environmental fate data for glyphosate.

Study	Value	Major Degradates[1], Comments	MRID #
Abiotic Hydrolysis Half-life	Stable (at 25° C for at least 30 days)	None	00108192; 44320642
Direct Aqueous Photolysis	Stable (for at least 30 days)	None	41689101; 44320643
Soil Photolysis Half-life	Stable (for at least 30 days)	Degradation in dark control was equal to that in irradiated samples	44320645.
Aerobic Soil Metabolism Half-life	1.8 and 5.4 days (sandy loam) 2.6 days (silt loam)	AMPA (max 29% at 40 d) CO_2 (≥70% after 1 year)	42372501; 44320645
Anaerobic Aquatic Metabolism Half-life	208 days (Water- silty clay loam sediment system)	AMPA (max 25% at 15 d) CO_2 (≥ 35% after 1 year) Initial degradation was rapid but slowed considerably. Non-linear modeling predicts DT_{50} = 8.1 day and DT_{90} > 1 yr	41723701; 42372502
Aerobic Aquatic Metabolism Half-life	14.1 days (Water- silty clay loam sediment)	AMPA (19-25% at 7-30 d) CO_2 (≥ 23% after 30 d)	41723601; 42372503

Study	Value						MRID #
Batch Equilibrium (mL/g)	*Soil*	*Avg K_d*	*Avg K_{oc}*	*K_F*	*1/n*	*K_{Foc}*	44320646
	sand	170	58,000	64	0.75	22,000	
	sandy loam	18	3,100	9.4	0.72	1,600	
	sandy loam	230	13,000	90	0.76	5,000	
	silty clay loam	680	33,000	470	0.93	21,000	
	silty clay loam	1,000	47,000	700	0.94	33,000	

Table B2 continued.

Study	Value		MRID #
Terrestrial Field Dissipation Half-life	<u>Glyph.</u> <u>AMPA</u> 1.7 d 131 d (TX) 7.3 d 119 d (OH) 8.3 d 958 d (GA) 13 d 896 d (CA) 17 d 142 d (AZ) 25 d 302 d (MN) 114 d 240 d (NY) 142 d no data (IA)	Bare ground studies. Glyphosate and AMPA were found predominantly in the 0 to 6 inch layers	42607501; 42765001
Aquatic Field Dissipation	7.5 days	In a farm pond in Missouri. At 3 sites (OR, GA, MI), half-lives could not be calculated due to recharging events.	40881601
	Water: Dissipated rapidly immediately after treatment. Sediment: Glyphosate remained in pond sediments at ≥ 1 ppm at 1 year post treatment.	In ponds in Michigan and Oregon and a stream in Georgia Accumulation was higher in the pond than in the stream sediments	41552801.
Forestry Dissipation	Foliage: < 1 day Ecosystem: Glyphosate: 100 d AMPA: 118 d	3.75 lb ae/A, aerial application	41552801.

[1] Major degradates are defined as those which reach >10% of the applied.

Table B3. Aquatic toxicity profile for glyphosate and/or its salts.

Assessment Endpoint	Species	Toxicity Values	Toxicity Category[1]	Citation MRID # /Date	Comment
Acute Toxicity to Freshwater Fish	Bluegill sunfish (*Lepomis macrochirus*)	96-hr. LC_{50}: 43 mg a.e./L*	Slightly toxic	44320630/1995	
Chronic Toxicity to Freshwater Fish	Fathead minnow (*Pimephales promelas*)	NOAEC: 25.7 mg a.e./L (highest concentration tested)		00108171/1975	
Acute Toxicity to Freshwater Invertebrates	Midge (*Chironomus plumosus*)	48-hr LC_{50}: 53.2 mg a.e./L	Slightly toxic	00162296/1979	
Chronic Toxicity to Freshwater Invertebrates	Water flea (*Daphnia magna*)	NOAEC: 49.9 mg a.e./L		00124763/1982	LOAEC: 95.7 mg a.e./L based on reduced reproductive capacity.
Acute Toxicity to Marine/Estuarine Fish	Sheepshead minnow (*Cyprinodon variegatus*)	96-hr. LC_{50}: 240 mg a.e./L	Practically nontoxic	44320632/1996	
Acute Toxicity to Marine/Estuarine Invertebrates	Mysid (*Americamysis bahia*)	LC_{50}: 40 mg a.e./L	Slightly toxic	44320634/1996	
Acute Toxicity to Non-vascular Aquatic Plants	Green algae (*Selenastrum capricornutum*)	4-day EC_{50}: 12.1 mg a.e./L		40236901/1987	
Acute Toxicity to Toxicity to Vascular Aquatic Plants	Duckweed (*Lemna gibba*)	14-day EC_{50}: 11.9 mg a.e./L		44320638/1996	

*a.e. = expressed in terms of acid equivalents for glyphosate

[1]Categories of **acute toxicity for aquatic organisms** (U.S. EPA, 2004) based on LC_{50} (mg/L): < 0.1 very highly toxic; 0.1-1 highly toxic; >1-10 moderately toxic; >10-100 slightly toxic; >100 practically nontoxic. Toxicity categories for aquatic plants have not been defined.

Table B4. Terrestrial toxicity profile for glyphosate and/or its salts.

Endpoint	Species	Toxicity Value	Toxicity Category[1]	Citation MRID#/Date	Comment
Acute Avian Oral Toxicity	Bobwhite quail (*Colinus virginianus*)	LD_{50}: >3196 mg a.e./kg bw	Slightly toxic	00108204/1978	
Acute Avian Dietary Toxicity	Bobwhite quail (*Colinus virginianus*)	LC_{50}: >4971.2 PPM	Slightly toxic	44320628/1997	
Chronic Avian	Bobwhite quail (*Colinus virginianus*)	Reproduction study NOAEC: 830 PPM		108207/1978	LOAEC: >830 PPM (highest concentration tested).
Acute mammalian	Rat (*rattus norvegicus*)	LD_{50} >4800 mg/kg bw	Practically non-toxic	43728003/1989	
Chronic mammalian	Rat (*rattus norvegicus*)	NOAEL: 500 mg/kg bw/day; NOAEC: 10000 ppm		41621501/1990	Reproduction study parental/pup LOAEL: 1500 mg/kg bw/day; LOAEC: 30000 ppm (soft stools, decreased body weight gain and food consumption in parents and decreased body weight gain during lactation in pups).
Acute terrestrial invertebrate	Honey bee (*Apis mellifera*)	48 hr LD_{50} (O): >100 µg/bee		00026489/1972	
Terrestrial Plants	Seedling Emergence Monocots	EC_{25}: >5 LB/A		40159301/1987	
	Seedling Emergence Dicots	EC_{25}: > 5 LB/A		40159301/1987	
	Vegetative	EC_{25}: 0.16 LB/A		44125715/45045	

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12 APPENDIX C: SUPPLEMENTAL FIGURES AND TABLES

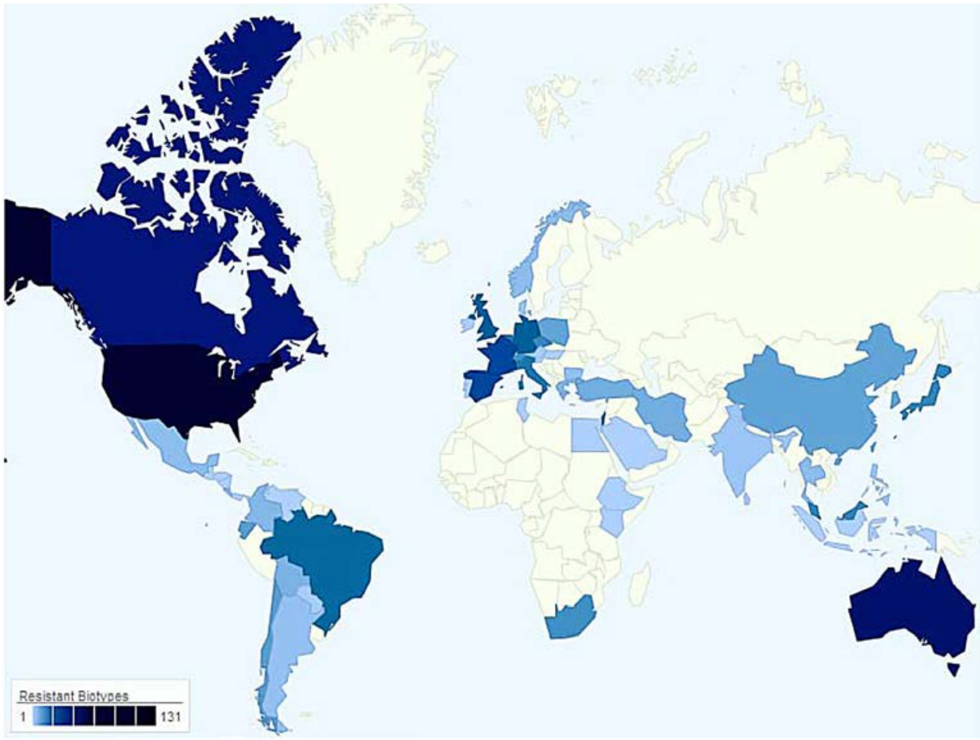

Figure C1. Global distribution of herbicide-resistant biotypes, 2010. Color intensity is associated with an increasing number of herbicide-resistant biotypes. Reproduced from Heap (2012).

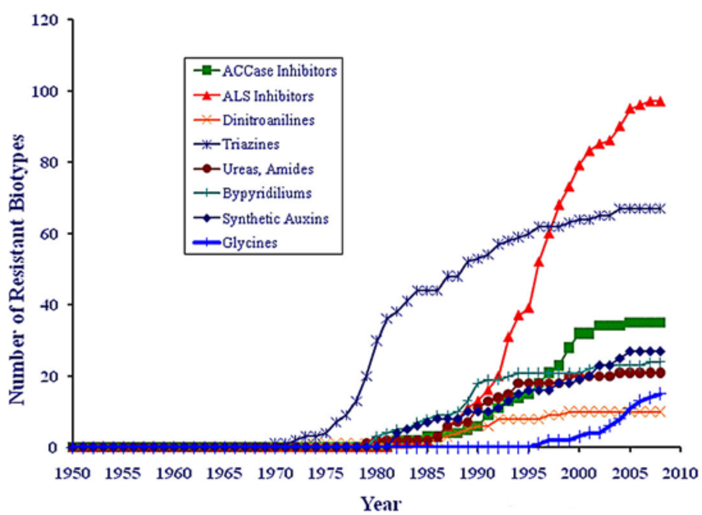

Figure C2. Global herbicide-resistant biotypes by mode of action, 1950 – 2010. Reproduced from Heap (2012).

Table C1. Soybean acreage in U.S. states, 2010.

State	2000	2005	2010
Alabama	160,000	145,000	345,000
Arkansas	3,150,000	3,000,000	3,150,000
Colorado	-	-	-
Connecticut	-	-	-
Delaware	213,000	182,000	173,000
Florida	15,000	8,000	23,000
Georgia	140,000	175,000	255,000
Illinois	10,450,000	9,450,000	9,050,000
Indiana	5,480,000	5,380,000	5,330,000
Iowa	10,680,000	10,000,000	9,730,000
Kansas	2,500,000	2,850,000	4,250,000
Kentucky	1,160,000	1,240,000	1,390,000
Maine	-	-	-
Maryland	515,000	470,000	465,000
Massachusetts	-	-	-
Michigan	2,030,000	1,990,000	2,040,000
Minnesota	7,150,000	6,800,000	7,310,000
Mississippi	1,580,000	1,590,000	1,980,000
Missouri	5,000,000	4,910,000	5,070,000
Montana	-	-	-
Nebraska	4,575,000	4,660,000	5,100,000
New Jersey	98,000	91,000	92,000
New Mexico	-	-	-
New York	132,000	188,000	279,000
North Carolina	1,360,000	1,460,000	1,550,000
North Dakota	1,850,000	2,900,000	4,070,000
Ohio	4,440,000	4,480,000	4,590,000
Oklahoma	290,000	305,000	475,000
Oregon	-	-	-
Pennsylvania	385,000	420,000	495,000

State	2000	2005	2010
South Carolina	430,000	420,000	455,000
South Dakota	4,370,000	3,850,000	4,140,000
Tennessee	1,150,000	1,100,000	1,410,000
Texas	260,000	230,000	185,000
Vermont	-	-	-
Virginia	480,000	510,000	540,000
Washington	-	-	-
West Virginia	15,000	17,000	18,000
Wisconsin	1,500,000	1,580,000	1,630,000
U.S. Total	72,408,000	71,251,000	76,610,000

Source: USDA-NASS (2011a).

Table C2. Irrigation of soybean acres in U.S. states, 2007.

State	Acreage	Irrigated acreage	Percent irrigated acreage
Alabama	179,673	2,124	1.18
Arkansas	2,819,478	1,843,478	65.38
Colorado	2,948	1,882	63.84
Connecticut	294	(D)	-
Delaware	155,548	24,528	15.77
Florida	12,066	212	1.76
Illinois	8,293,711	70,513	0.85
Indiana	4,783,821	82,454	1.72
Iowa	8,612,810	50,481	0.59
Kansas	2,591,428	261,588	10.09
Maine	766	-	-
Maryland	386,604	20,663	5.34
Massachusetts	247	-	-
Michigan	1,715,427	66,556	3.88
Minnesota	6,273,919	92,688	1.48
Mississippi	1,431,085	483,004	33.75

State	Acreage	Irrigated acreage	Percent irrigated acreage
Missouri	4,672,738	365,094	7.81
Montana	409	(D)	-
Nebraska	3,834,855	1,570,110	40.94
New Jersey	79,218	4,730	5.97
New Mexico	(D)	-	-
New York	199,775	(D)	-
North Carolina	1,380,792	13,830	1
North Dakota	3,073,792	13,830	0.45
Ohio	4,236,337	1,056	0.02
Oklahoma	180,878	12,497	6.91
Oregon	(D)	(D)	-
Pennsylvania	431,053	(D)	-
South Carolina	442,461	8,943	2.02
South Dakota	3,222,872	52,661	1.63
Tennessee	976,011	4,077	0.42
Texas	93,453	16,269	17.41
Vermont	2,011	-	-
Virginia	490,396	8,007	1.63
Washington	725	385	53.10
West Virginia	13,717	-	-
Wisconsin	1,363,124	24,855	1.82
U.S. Total	63,915,821	5,237,075	8.19

Source: USDA-NASS (2011b).

Table C3. Common soybean insect pests.

Common name (Scientific name)	
Pod, stem, and seed feeders	
Southern green stink bug (*Nezara viridula*)	Three-cornered alfalfa hopper (*Spissistilus festinus)*
Green stink bug (*Acrosternum hilare*) Brown Stink Bug (*Euschistus servus/Euschistus spp.*)	Lesser cornstalk borer (*Elasmopalpus lignisellus*) *Dectes* stem borer (*Dectes texanus taxanus*)
Bean leaf beetle (*Ceratoma trifurcata*)	Seedcorn maggot (*Delia plautura*)
Corn earworm (*Helicoverpa zea*)	
Foliage feeders	
Soybean looper (*Pseudoplusia includens*)	Twospotted spider mite (*Tetranychus urticae*)
Velvetbean caterpillar (*Anticarsia gemmatalis*)	Mexican bean beetle (*Epilachna varivestis*)
Green cloverworm (*Plathypena scabra*)	Potato leafhopper (*Emopasca fabae*)
Beet armyworm (*Spodoptera exigua*)	Silverleaf whitefly (*Bemisia argentifolii*)
Fall armyworm (*Spodoptera frugiperda*)	Bandedwinged whitefly (*Trialeurodes abutilonea*)
Yellow striped armyworm (*Spodoptera ornithogalli*)	Grasshopper (*Melanoplus spp.*)
Yellow woolybear (*Spilosoma virginica*)	Soybean thrips (*Neohydatothrips variabilis*)
Root and nodule feeders	
Soybean nodule fly (*Rivellia quadrifasciata*)	White grubs (*Phyllophaga spp.*)
Banded cucumber beetle (*Diabrotia balteata*)	Grape colaspis (*Colaspis brunnea*)

Source: Boethel (2004).

Table C4. Common weeds in soybean production: Midwest Region. Reproduced From Monsanto (2010). Number provided in parentheses is the number of states out of the thirteen total states in the Midwest Region that reported each weed.

Foxtail spp. (12)	Ragweed, giant (3)	Dandelion (1)
Pigweed spp. (11)	Shattercane (3)	Johnson grass (1)
Velvetleaf (11)	Quackgrass (3)	Milkweed, honeyvine (1)
Lambsquaters (10)	Buckwheat, wild (2)	Nightshade, hairy (1)
Cocklebur (9)	Crabgrass, spp (2)	Oats, wild (1)
Ragweed, common (7)	Kochia (2)	Pokeweed, common (1)
Smartweed spp (6)	Mustard, wild (2)	Prickly sida (1)
Morning glory spp. (5)	Nightshade, Eastern black (2)	Proso millet, wild (1)
Sunflower, spp (5)	Palmer amaranth (2)	Sandbur, field (1)
Waterhemp spp. (5)	Canada thistle (1)	Venice mallow (1)
Horseweed (marestail) (3)	Chickweed (1)	Volunteer cereal (1)
Panicum, fall (3)	Cupgrass, woolly (1)	Volunteer corn (1)

Table C5. Common weeds in soybean production: Eastern coastal Region. Reproduced From Monsanto (2010). Number provided in parentheses is the number of states out of the thirteen total states in the Eastern Coastal Region that reported each weed.

Ragweed, common (8)	Jimson weed (4)	Dandelion (1)
Cocklebur (7)	Sicklepod (3)	Goosegrass (1)
Morning glory spp. (7)	Florida pusely (2)	Nightshade, Eastern Black (1)
Crabgrass spp. (6)	Johnson grass (2)	Panicum, Texas (1)
Foxtail spp. (6)	Palmer amaranth (2)	Prickly sida (1)
Lambsquaters (6)	Quackgrass (2)	Shattercane (1)
Pigweed spp. (6)	Arrowleaf sida (1)	Signalgrass, broadleaf (1)
Velvetleaf (6)	Beggarweed, Florida (1)	Smartweed spp (1)
Nutsedge spp. (5)	Burcucumber (1)	
Panicum, fall (5)	Canada thistle (1)	

Table C6. Common weeds in soybean production: Mid-south Region. Reproduced From Monsanto (2010). Number provided in parentheses is the number of states out of the thirteen total states in the Mid-south Region that reported each weed.

Morning glory spp. (5)	Pigweed spp. (3)	Ragweed, common (1)
Prickly sida (5)	Crabgrass spp. (2)	Ragweed, giant (1)
Johnson grass (4)	Palmer amaranth (2)	Red rice (1)
Sicklepod (4)	Cocklebur (1)	Smartweed (1)
Signalgrass, broadleaf (4)	Copperleaf, hophorn (1)	Spurge, nodding/hyssop (1)
Barnyard grass (3)	Florida pusely (1)	Spurge, prostrate (1)
Hemp sesbania (3)	Horseweed (marestail) (1)	
Nutsedge spp. (3)	Poinsettia, wild (1)	

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13 APPENDIX D: SOYBEAN COMMODITY PRODUCTION

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 may be 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.

Animal Feed Users: Animal feeds are the major use for soybean meal, consuming about 77 percent of the total meal produced (Soy Connection, 2011a). 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, 2010). 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 derived from soybean (Soy Connection, 2011b). 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 soy nuts. 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. 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. 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 was estimated at $18 billion (US Census Bureau, 2009).

The second industry comprises the many value-added businesses which may employ starting feedstocks from soy seed 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 are useful in making solid fat products such as baking shortenings (O'Brian, 2009a), while oils low in saturated fats are useful for salad oils (O'Brian, 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 (Table D1), with production at 1,192 million liters in 2010 (USB, 2011). 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, 2009). Soaps, amines, fatty acids and oleo chemicals is the second largest consumer of industrial soybean oil at 140,000 metric tons (see Table D1) (USB, 2011). 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.

Table D1. 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 (2011).

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