Syngenta and Bayer Petition 12-215-01p for Determination of Non-regulated Status of Herbicide Tolerant Event SYHT0H2 Soybean (*Glycine max*)

OECD Unique Identifier: SYN-ØØØH2-5

Environmental Assessment

July 2014

Table of Contents

APPENDICES

LIST OF TABLES

LIST OF FIGURES

ACRONYMS AND ABBREVIATIONS

μg/g	Micrograms per gram
A	Acre
ACHP	Advisory Council on Historic Properties
ai	Active ingredient
AIA	Advanced Informed Agreement
AMS	Agricultural Marketing Service (also USDA-AMS)
AOSCA	Association of Official Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service (also USDA-APHIS)
ARMS	Agricultural Resource Management Survey
ARS	Agricultural Research Services (also USDA-ARS)
ATTRA	Appropriate Technology Transfer for Rural Areas
BRS	Biotechnology Regulatory Service
C	Centigrade
CAA	*Clean Air Act* (also, *Clean Air Act Amendments*)
CBD	*Convention on Biological Diversity*
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
CH_4	Methane
CO	Carbon monoxide
CO_2	Carbon dioxide
CODEX	Codex Alimentarius Commission
CRP	Conservation Reserve Program
CWA	*Clean Water Act* (formally, *Federal Water Pollution Control Act*)
DKN	Diketonitrile
DNA	Deoxyribonucleic acid
EA	Environmental Assessment
EFSA	European Food Safety Agency
EIQ	Environmental Impact Quotient
EIS	Environmental Impact Statement
EO	Executive Order
EPA	Environmental Protection Agency (also USEPA)
ERS	Economic Research Service (also USDA-ERS)
ESA	*Endangered Species Act*
EPSP	5-enolpyruvylshikimate 3-phosphate
ESPS	Early soybean production system
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FARRP	Food Allergy Research and Resource Program
FATUS	Foreign Agricultural Trade of the United States
FAS	Foreign Agricultural Service (also USDA-FAS)
FDA	Food and Drug Administration (also USDHHS-FDA)
FFDCA	*Federal Food, Drug, and Cosmetic Act*
FFP	Food, feed, or processing
FIFRA	*Federal Insecticide, Fungicide, and Rodenticide Act*
FIFRA-FESTF	*Federal Insecticide, Fungicide, and Rodenticide Act* - Endangered Species Task Force
fl oz	Fluid ounces
FONSI	Finding of No Significant Impact
FQPA	*Food Quality Protection Act*
FR	Federal Register

ACRONYMS AND ABBREVIATIONS (CONTINUED)

FWS	Fish and Wildlife Service (also USFWS)
GHG	Greenhouse gases
IMS	Information Management System
IDP	Identity Preservation
IPCC	Intergovernmental Panel on Climate Change
HPPD	*p*-Hydroxyphenylpyruvate dioxygenase
lb	Pound
LMO	Living modified organisms
LOC	Level(s) of Concern
Mg/kg bw	Milligrams per kilogram of body weight
MG	Maturity group
N_2O	Nitrous oxide
NAPPO	North American Plant Protection Organization
NASS	National Agricultural Statistics Service (also USDA-NASS)
NEPA	*National Environmental Policy Act*
NHPA	*National Historic Preservation Act*
NMFS	National Marine Fisheries Service
NOAEL	No observable adverse effect level
NOP	National Organic Program
NPS	Nonpoint source
NRC	National Research Council
NRCA	Natural Resources Conservation Service (also USDA-NRCS)
OECD	Organization for Economic Cooperation and Development
OTA	Organic Trade Association
PAT	Phosphinothricin acetyltransferase
PIPs	Plant-incorporated protectants
PM	Particulate matter
PPA	*Plant Protection Act*
PPRA	Plant Pest Risk Assessment
PRA	Pest Risk Analysis
pts	pints
SO_X	Sulfur oxides
TSCA	*Toxic Substances Control Act*
US	United States
USACE	United States Army Corps of Engineers
USC	United States Code
USDA	United States Department of Agriculture
USDHHS	United States Department of Health and Human Services
USEPA	United States Environmental Protection Agency (also EPA)
USFWS	United States Fish and Wildlife Service (also FWS)
WHO	World Health Organization

1 PURPOSE AND NEED

1.1 Background

Syngenta Seeds, Inc. and Bayer CropScience AG, who collectively are the Petitioners (referred hereafter as Syngenta-Bayer), submitted petition number 12-215-01p to the United States Department of Agriculture (USDA) Animal and Plant Health Service (APHIS) on July 31, 2012 seeking approval of the petition for nonregulated status for SYHT0H2 soybean (hereafter referred to as SYHT0H2 soybean), the genetically engineered (GE) mesotrione- isoxaflutole- and glufosinate- herbicide resistant[1] soybean (Glycine max) event SYHT0H2. The Petition was revised in response to APHIS' request for additional information and resubmitted on September 17, 2012 (Syngenta, 2012c). Field trials of SYHT0H2 soybean have been conducted in multiple States within U.S. soybean growing regions and in Puerto Rico. Data resulting from these field trials are described in the Syngenta petition (Syngenta and Bayer, 2012b) and analyzed for plant pest risk in the USDA-APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2014b).

In the event of approval of the petition for nonregulated status, the nonregulated status would include SYHT0H2 soybean, any progeny derived from crosses between SYHT0H2 soybean and conventional soybean, and crosses of SYHT0H2 soybean with other biotechnology-derived soybean that are no longer subject to the regulatory requirements of 7 CFR (Code of Federal Regulations) Part 340 or the plant pest provisions of the Plant Protection Act of 2000 (PPA).

1.2 Purpose of Product

The Petitioners have co-developed SYHT0H2 soybean, a new cultivar that has been genetically modified to tolerate herbicides that inhibit p-hydroxyphenylpyruvate dioxygenase (HPPD)[2] and glutamine synthetase. Most soybeans currently grown in the United States are glyphosate-tolerant transgenic varieties. SYHT0H2 soybean is a new cultivar that is tolerant of three herbicides: mesotrione, isoxaflutole, and glufosinate-ammonium (hereafter, glufosinate). SYHT0H2 *s*oybean will offer growers much-needed flexibility to use herbicides with two

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[1] Resistance to herbicides is defined by HRAC (Herbicide Resistance Action Committee) as the inherited ability of a plant population to survive and reproduce following repeated exposure to a dose of herbicide normally lethal to the wild type HRAC, Guideline to the Management of Herbicide Resistance, 2013, Herbicide Resistance Action Committee, Available: http://www.hracglobal.com/Publications/ManagementofHerbicideResistance.aspx, January 22 2013.. Resistance may be induced by genetic engineering or selection of variants produced by tissue culture or mutagenesis HRAC, Guideline to the Management of Herbicide Resistance.. This is to be distinguished from tolerant, which is defined by HRAC as the inherent ability of a plant to survive and reproduce after herbicide treatment. This implies that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant HRAC, Guideline to the Management of Herbicide Resistance..

[2] Common HPPD inhibitor herbicides include mesotrione, isoxaflutole, pyrasulfatole, tembotrione, topramezone

alternative modes of action in their weed management programs and will help minimize or delay the evolution of herbicide resistance in weed populations.

SYHT0H2 soybean contains the transgene avhppd-03 encoding an HPPD enzyme that is more than 99.7 percent identical in amino acid sequence to the native HPPD in common oat (*Avena sativa*). In comparison with the native soybean HPPD, the HPPD isozyme from oat has lower binding affinity for HPPD-inhibiting herbicides, such as mesotrione and isoxaflutole, and confers tolerance to herbicide application rates that would otherwise injure soybean. SYHT0H2 soybean also contains the transgene pat derived from *Streptomyces viridochromogenes*, a ubiquitous soil microbe. The gene *pat* encodes phosphinothricin acetyltransferase (PAT), an enzyme that inactivates glufosinate herbicide, an inhibitor of glutamine synthetase. Expression of *pat* confers a glufosinate-tolerance phenotype.

The extensive use of glyphosate-based weed-control programs in corn, cotton, and soybean over the past 15 years has resulted in selection for glyphosate-resistant weeds and a shift in weed populations to species that are inherently more resistant to glyphosate, thus making weed control with glyphosate more difficult (Owen, 2008). Twenty-four glyphosate-resistant weed species have been identified globally, 14 of which are found in the US (Heap, 2013a). Cultivation of SYHT0H2 soybean (also known as MGI soybean) will provide growers with an opportunity to use a glutamine synthetase-inhibitor herbicide (glufosinate) and two HPPD-inhibitor herbicides (mesotrione and isoxaflutole) for control of problematic weeds in soybean production systems.

Mesotrione and isoxaflutole are systemic, translocated herbicides with soil residual activity that are used for pre-emergence and post-emergence control of predominantly dicot weed species in a number of crops, including corn, which has a natural tolerance of these herbicides. Glufosinate is a contact herbicide that is applied to crops post-emergence and has no soil residual activity. Glufosinate controls a broad spectrum of monocot and dicot weed species. Glufosinate and mesotrione/isoxaflutole have distinct herbicidal modes of action, both of which differ from that of glyphosate. Using herbicide mixtures and alternating herbicides with different modes of action are cornerstones of an integrated weed management program. Both Syngenta and Bayer plan to provide stewardship programs for the products as part of comprehensive integrated weed management programs which will be offered to growers through training and education opportunities for use with SYHT0H2 (MGI) soybean seed.

1.3 Coordinated Framework Review and Regulatory Review

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

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

1.3.1 USDA-APHIS

USDA-APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the PPA, as amended[3] regulates the introduction (i.e., importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340, when USDA-APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under 7 CFR 340 when USDA-APHIS has reason to believe that the GE organism may be a plant pest or USDA-APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

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

1.3.2 Environmental Protection Agency

The EPA is responsible for regulating the sale, distribution, and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology. The EPA regulates plant incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[4] and certain biological control organisms under the Toxic Substances Control Act (TSCA)[5]. Before planting a crop containing a PIP, a company must seek an experimental use permit from EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 registration with EPA.

[3] United States Code [USC.] title 7, sections 7701 through 7772
[4] 7 U.S.C. 136 et seq
[5] 15 U.S.C. 53 et seq

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

EPA also sets tolerances (maximum residue levels) or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA)[6]. A tolerance is the amount of pesticide residue that can remain on or in food for human consumption or animal feed. Before establishing a pesticide tolerance, EPA is required to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the FQPA. FDA enforces the pesticide tolerances set by EPA.

1.3.3 Food and Drug Administration

FDA regulates GE organisms under the authority of the FFDCA[7] . The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, on May 29, 1992 (57 FR 22984, 1992). Under this policy, FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of bioengineered food. This voluntary consultation process provides a way for developers to receive assistance from FDA in complying with their obligations under Federal food safety laws prior to marketing.

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

[6] 21 USC 301 et seq.
[7] 21 USC. 301 et seq.

1.4 Purpose and Need for APHIS Action

As noted in the previous section, any party can petition USDA-APHIS to seek a determination of nonregulated status for a GE organism that is regulated under 7 CFR 340. As required by 7 CFR 340.6, USDA-APHIS must respond to petitioners that request a determination of the regulated status of GE organisms, including GE plants such as SYHT0H2 Soybean. When a petition for nonregulated status is submitted, USDA-APHIS must determine if the GE organism is unlikely to pose a plant pest risk. The petitioner is required to provide information under §340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

USDA-APHIS must respond to the petition from Syngenta requesting a determination of nonregulated status for SYHT0H2 Soybean. USDA-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) National Environmental Policy Act of 1969 (NEPA) regulations and the USDA and USDA-APHIS NEPA implementing regulations and procedures (40 CFR Parts 1500-1508, 7 CFR Part 1b, and 7 CFR Part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[8] that may result from a determination of nonregulated status for BASF SYHT0H2.

1.5 Public Involvement

USDA-APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. USDA-APHIS does this through a notice[9] published in the Federal Register. On March 6, 2012, USDA-APHIS published a notice in the Federal Register advising the public that APHIS is implementing changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for GE organisms to allow for early public involvement in the process. As identified in this notice, USDA-APHIS will publish two separate notices in the Federal Register for petitions for which USDA-APHIS prepares an EA. The first notice will announce the availability of the petition, and the second notice will announce the availability of USDA-APHIS' decision making documents. As part of the new process, with each of the two notices published in the Federal Register, there will be an opportunity for public involvement:

First Opportunity for Public Comment

Once USDA-APHIS deems a petition complete, the petition will be made available for public comment for 60 days, providing the public an opportunity to raise issues regarding the petition

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

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

itself and give input that will be considered by the Agency as it develops its EA and PPRA. USDA-APHIS will publish a notice in the Federal Register to inform the public that USDA-APHIS will accept written comments regarding a petition for a determination of nonregulated status for a period of 60 days from the date of the notice. This availability of the petition for public comment will be announced in a Federal Register notice.

Second Opportunity for Public Comment

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

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

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

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

USDA-APHIS solicits comments on its draft EA and draft PPRA for 30 days through the publication of a Federal Register notice. USDA-APHIS reviews and evaluates comments and other relevant information, then revises the PPRA as necessary and prepares a final EA. Following preparation of these documents, USDA-APHIS approves or denies the petition, announcing in the Federal Register the regulatory status of the GE organism and the availability of USDA-APHIS'

final EA, PPRA, NEPA decision document (either a FONSI or notice of intent (NOI) to prepare an EIS), and regulatory determination.
Enhancements to public input are described in more detail in the Federal Register notice published on March 6, 2012.

1.6 Public Comment Period for Petition 12-15-01p

USDA-APHIS decided this EA will follow Approach 1 because this is the second EA prepared for soybean genetically engineered for resistance to HPPD inhibitor herbicides and multiple other EAs for engineered resistance to glufosinate (*see* Table 2-1, as ‘phosphinothricin’ resistant). The Syngenta petition was published for public comment on February 27, 2013, with comments accepted until April 29, 2013. A total of 27 public submissions were made to the docket. Some of the submissions to the docket contained multiple comments combined together gathered by organizations from their members. Counting these individual comments, the 26 submissions contained a total of 584 public comments. The public comments in response to the petition may be viewed at the federal website, regulations.gov. APHIS evaluated the issues raised and the submitted documentation. The majority of the comments were supportive of the petition, and were from growers and grower organizations, university extension staff, state departments of agriculture or regional business councils. The remainder expressed a general dislike of the use of GE organisms or were form letters with concerns about concerns for weed resistance, for the direction of modern farming, and for unknown health risks. Many of the unfavorable comments raised issues that are outside the scope of this EA. The Syngenta Environmental Assessment was published for public comment on May 30, 2014, with comments accepted until June 30, 2014. There were a total of five comments received on the EA during the public comment period. Four of the comments were generally against granting nonregulated status to SYHT0H2 soybean and GE plants in general but did not provide support for their position. The fifth comment, from an organization that incorrectly identified the petition 12-215-01 as being one for a GE crop whose HPPD resistance trait had never been assessed previously by APHIS, did not articulate a specific concern with the EA for not assessing possible environmental or agronomic impacts of the soybean. The commenting organization requested an extension of the comment period. APHIS has included a discussion of issues relative to this petition in the EA or in the response to comments attached to the National Environmental Policy Act Decision and in the Finding of No Significant Impact document.

1.7 Issues Considered

The list of resources considered in this EA was developed in accordance with the requirements of NEPA and consistent with previous APHIS EAs regarding similar products. The evaluation considers potential environmental impacts to resources relevant to transgenic field crops like SYHT0H2 soybean, as well as concerns and issues raised in public comments submitted for other EAs of transgenic organisms. The evaluation also addresses concerns raised in previous and unrelated court decisions, as well as questions that have been raised by various stakeholders in the past. The resources considered in this EA are listed below.

- Soybean Production
  - Acreage and areas of soybean production
  - Agronomic practices
  - Commercial soybean production and uses
    - Seed production
    - Raw and processed soybean commodities
    - Organic soybean production
    - Specialty soybean systems
- Physical Environment
  - Soil
  - Water quality and use
  - Air quality
  - Climate
- Natural Biological Communities (Non-target organisms)
  - Animals
  - Plants
  - Soil microorganisms
  - Biodiversity
  - Gene movement in the natural environment
- Public Health
  - Human health
  - Animal (livestock) health
  - Worker safety
- Socioeconomic Factors
  - Domestic trade environment
  - Foreign trade environment
  - Social and economic environment
- Cumulative Effects
- Threatened and Endangered Species

2 AFFECTED ENVIRONMENT

This Chapter describes soybean biology, soybean production, and the environmental and human resources that could potentially be affected by a determination of nonregulated status for SYHT0H2 soybean.

2.1 Soybean Biology

Soybean is one of the oldest cultivated crops in the world (OECD, 2000a); it was domesticated in China sometime between the 17th and 11th centuries BC (Hymowitz, 1970). Soybeans were first introduced into the US in 1765 (Hymowitz, 1990). Soybeans yield oil for a variety of uses and meal for human food and livestock feed. They are the most extensively grown oilseed in the world, representing 56 percent of world oilseed seed production in 2011 (Soystats, 2012a).

Cultivated soybean, *Glycine max* (L.) Merr., is a diploidized tetraploid in the family *Fabaceae*, subfamily *Papilionoideae*, tribe *Phaseoleae*, genus *Glycine* Willd. and subgenus *Soja* (Moench) (OECD, 2000a). The subgenus consists of 12 wild perennial species which are indigenous to Australia; West, Central and South Pacific Islands; China; Russia; Japan; Indonesia; Korea; Papua New Guinea; the Philippines; and Taiwan (OECD, 2000a). *G. max* has never been found in the wild (Hymowitz, 1970), and does not exist naturally anywhere. In addition to *G. max*, subgenus *Soja* subgenus also contains *G. soja* (OECD, 2000a). *G. soja* is the ancestor of *G. max*, and grows in fields, hedgerows, roadsides, and riverbanks in many Asian countries. Some taxonomists consider *G. max* and *G. soja* to be conspecific, as *G. max* ssp. *soya* and *G. max* ssp. *max* (Heatherly and Elmore, 2004). *G. max* has a relatively large seed size that does not produce a persistent seedbank, does not have wild or weedy compatible relatives in the US, and does not have feral populations in the US (Mallory-Smith and Zapiola, 2008), eliminating the potential for gene flow of transgenic traits to related species.

Domesticated soybean is a self-pollinated annual species, propagated commercially by seed (OECD, 2000a). Artificial hybridization is used for cultivar breeding (OECD, 2000a). Flowers are typically cleistogamous but, in some cultivars and under some conditions, may be chasmogamous and insects may transfer pollen (Ahrent and Caviness, 1994; Chiari et al., 2005; Erickson, 1975; Ray et al., 2003). Cross pollination is usually less than 1 percent under typical agricultural conditions (Caviness, 1966; Ray et al., 2003; Yoshimura et al., 2006) but may be higher in some cultivars, under some climatic conditions which favor chasmogamy. In experimental studies, outcrossing rates of 0.41 percent were found with a 90-cm row spacing and up to 6.3 percent with a 15-cm row spacing (Ray et al., 2003), and up to 2.5 percent outcrossing with a 102-cm row spacing (Ahrent and Caviness, 1994). Several studies of soybeans in Japan and China, using various DNA analysis methods (chloroplast DNA, single-sequence repeats, single-nucleotide polymorphism) have detected low levels of the *G. max* genome in some wild *G. soja* populations (Hasegawa et al., 1999; Kuroda et al., 2009; Li et al., 2010), attributed to post-domestication hybridization. A phenotypic analysis of *G. soja* populations in China suggested introgression with *G. max* (Wang et al., 2010). However, a study in Japan, under field conditions, did not detect any gene flow based on nuclear microsatellite data (Kuroda et al., 2009).

Soybean grows in a symbiotic association with the bacterium *Bradyrhizobium japonicum* (Kirchner) Jordan, which carries out nitrogen fixation within the plant roots (Farooq and Vessey, 2009). Similar to other legumes, soybeans develop root nodules to house *B. japonicum* in a microaerobic environment to produce nitrogenase, the enzyme complex responsible for nitrogen reduction in plants (Gage, 2004). Soybean can obtain up to 75 percent of its nitrogen requirements from the air via the nitrogen-fixing bacteria while providing the bacteria with carbohydrates (Pedersen, 2007). Because the nitrogen-fixing bacteria are not native to US soils and would not normally be found in these soils, soybeans are frequently inoculated with these bacteria prior to planting, especially if soybean has not been grown in the field for 3 to 5 years (Pedersen, 2007).

Soybean seeds will germinate when the soil temperature reaches 10°C (OECD, 2000a). The soybean plant responds strongly to day length in its phasic development (Hodges and French, 1985; Hymowitz, 1990). Soybeans are not frost tolerant, and they do not survive freezing winter conditions (OECD, 2000a). This erect, bushy herbaceous summer annual can reach a height of 5 feet (OECD, 2000a). Under very dry conditions, water stress may affect development (Hodges and French, 1985).

In North America, soybeans are classified into 13 maturity groups (MGs) based upon the effects of day length on the time to the appearance of first flowers (Hymowitz, 1990). The MGs for soybean cultivars are based on bands of adaptation that run east-west across the continent, determined by latitude and day length: MG 000 is in the north (at 45° latitude) and MG X is near the equator. In Canada and northern parts of the US, most cultivars are indeterminate[10] and have relatively short crop durations; they are classified as MG 000, MG 00, and MG 0 (Hymowitz, 1990). Cultivars from MG II, MG III, MG IV, and MG V are grown in the central US states. The cultivars adapted to the subtropical and tropical zones are often determinate,[11] have relatively long crop durations, and are classified in MG IX and MG X (Helsel and Minor, 1993; Hodges and French, 1985).

Transgenic soybean products were introduced in the US market by seed companies beginning in 1996, adding new genetic traits such as pest resistance and herbicide tolerance to modern soybean varieties.[12] In 2012, approximately 93 percent of soybean acreage was planted with transgenic varieties, virtually all being herbicide tolerant (USDA-NASS, 2012b). Transgenic soybean cultivars representing 17 different transformation events have been determined to have nonregulated status by APHIS (USDA-APHIS, 2013). Twelve of these cultivars are tolerant to herbicides, as listed in Table 2-1.

10 A growth characteristic by which a plant's roots or meristem shoot can keep growing as long as it is alive.

11 A growth characteristic by which the plant stops growing after it reaches a certain size.

12 Some varieties of soybeans were developed through selection to display nontransgenic tolerance of certain herbicides.

Table 2-1. Transgenic Soybean Cultivars with Herbicide Tolerance 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 of 2000.

Cultivar[1]	Filed By / Petition Number	Herbicide Tolerance	NEPA Status (by APHIS)
40-3-2	Monsanto / petition 93-258-01p	Glyphosate	FONSI and EA issued May 18, 1994
W62, W98, A2704-12, A2704-21, A5547-35	AgrEvo[2] / petition 96-068-01p	Phosphinothricin[3]	FONSI and EA issued August 13, 1996
A5547-127	AgrEvo / petition 98-014-01p	Phosphinothricin	FONSI and EA issued May 1,1998
GU262	AgrEvo / petition 98-238-01p	Phosphinothricin	FONSI and EA issued October 16, 1998
MON 89788	Monsanto / petition 06-178-01p	Glyphosate	FONSI and EA issued July 23, 2007
DP-356043	Pioneer / petition 06-271-01p	Glyphosate and acetolactate synthase-inhibiting	FONSI and EA issued July 15, 2008
MON 87705	Monsanto / petition 09-201-01p	Glyphosate	FONSI and EA issued October 7, 2011
MST-FGØ72-2	Bayer CropScience / 09-328-01p	Glyphosate and isoxaflutole	FONSI and EA issued August 21, 2013

Source: (USDA-APHIS, 2013)
1- Bold type denotes cultivars in commercial production in the US.
2- AgrEvo is now Bayer CropScience.
3- Phosphinothricin is also known as glufosinate or glufosinate-ammonium.

2.2 Agricultural Production of Soybean

This section describes areas and acreages of soybean production in the US, current agronomic practices, specialty production systems, raw and processed soybean commodities, and soybeans' persistence in the environment and weediness potential.

2.2.1 Current and Projected Acreage and Range of Soybean Production

Historically, US soybean acreage reached 70 million acres in 1980 but declined to under 60 million acres by 1989 (USDA-ERS, 2011c). Acreage expanded through the 1990s as federal farm program changes increased planting flexibility and encouraged more farmers to incorporate the crop in their rotations (USDA-ERS, 2011c). Planted soybean acreage in the US has been relatively stable recently (USDA-NASS, 2012d). In 2012, 76.1 million acres of soybeans were planted in the US, up 1 percent from 2011 and the third highest on record (USDA-NASS, 2012b). Total harvested acreage in 2012 was estimated to be 76.1 million acres (USDA-NASS, 2013a), equivalent to the planted acreage, also the third highest on record, and up 3 percent from 2011. As of March, planted soybean acreage for the 2013 season was forecasted to be 77.1 million acres (USDA-NASS, 2013c), down slightly from 2012 but the fourth highest on record. Planted area is projected to be down across the Great Plains with the exception of North

Dakota. The largest declines are expected in Nebraska and Minnesota, while Illinois and North Dakota are expecting the largest increases.

Fluctuations in soybean acreage are due to environmental, agronomic, and economic factors, as well as programs such as the USDA Conservation Reserve Program (CRP) or ethanol mandates imposed by the US government, which drive acreage into source crops for ethanol.

Growth in the US soybean industry could slow over the next 10 years as it faces stronger foreign competition and US farmers shift acreage into feed grains for economic reasons (USDA-ERS, 2011c). Soybean planted acreage is expected to stabilize around 76 million acres in 2014 and remain at that level through 2019 (USDA-ERS, 2011c).

Soybean is profitably grown on high quality agricultural land (USDOE-EIA, 2007), much of which in the US is already committed to agricultural production (USEPA, 2007). In the 2007 Census of Agriculture,[13] the USDA Economic Research Service estimated that only 4.1 percent of US cropland was idle (USDA-NASS, 2009a). To satisfy greater soybean demand, additional soybean acreage is generally planted at the expense of alternative crops, such as cotton or hay, with minor contributions from land exiting CRP agreements (O'Donoghue et al., 2011) resulting in a decrease in total US agricultural acreage (USDOE-EIA, 2007). It is unlikely that previously uncultivated land will be managed for future soybean production; rather, increased soybean production will likely compete with other crops (USDA-ERS, 2011c).

Soybeans are cultivated in 31 states (USDA-NASS, 2012b). Table 2-2 presents an overview of the 2011 and 2012 acreage of soybeans planted by state. The top two producing states in 2012 were Iowa and Illinois, with 9.5 million and 8.6 million acres planted, respectively (USDA-NASS, 2012b). More than 80 percent of the US soybean acreage is concentrated in the upper Midwest (USDA-ERS, 2010a), between 35 and 45 degrees north latitude (Hymowitz, 1970). Figure 2-1 depicts the soybean planted acreage by county in selected states based on 2010 data .

Soybean yield varies by region and variety. Soybean yields range from 26 to 47 bushels per acre, with a trend towards higher yields in recent years (USDA-ARS, 2006). The upward trend in yield is largely a result of new varieties that perform better under climate and pest pressures. The average yield per acre in 2012 was estimated at 39.6 bushels (USDA-NASS, 2013a), 2.3 bushels below the previous year's yield.

13 The USDA-ERS conducts the Census of Agriculture every 5 years. The 2012 Census was conducted from December 2012 through February 2013, and will be published at some future date. It is therefore not available for this report.

Table 2-2 Soybean Acreage by State, 2011 and 2012

	Acres Planted (thousands)	
State	2011	2012
Alabama	300	330
Arkansas	3,330	3,250
Delaware	170	180
Florida	18	25
Georgia	155	190
Illinois	8,900	8,600
Indiana	5,300	5,000
Iowa	9,350	9,500
Kansas	4,000	3,600
Kentucky	1,490	1,400
Louisiana	1,020	1,140
Maryland	470	480
Michigan	1,950	2,000
Minnesota	7,100	7,000
Mississippi	1,820	2,130
Missouri	5,350	5,300
Nebraska	4,900	5,100
New Jersey	88	95
New York	280	340
North Carolina	1,380	1,670
North Dakota	4,000	4,600
Ohio	4,550	4,600
Oklahoma	440	410
Pennsylvania	500	530
South Carolina	370	420
South Dakota	4,100	4,500
Tennessee	1,290	1,330
Texas	165	100
Virginia	560	550
West Virginia	20	20
Wisconsin	1,610	1,690
Total Acreage	**74,976**	**76,080**

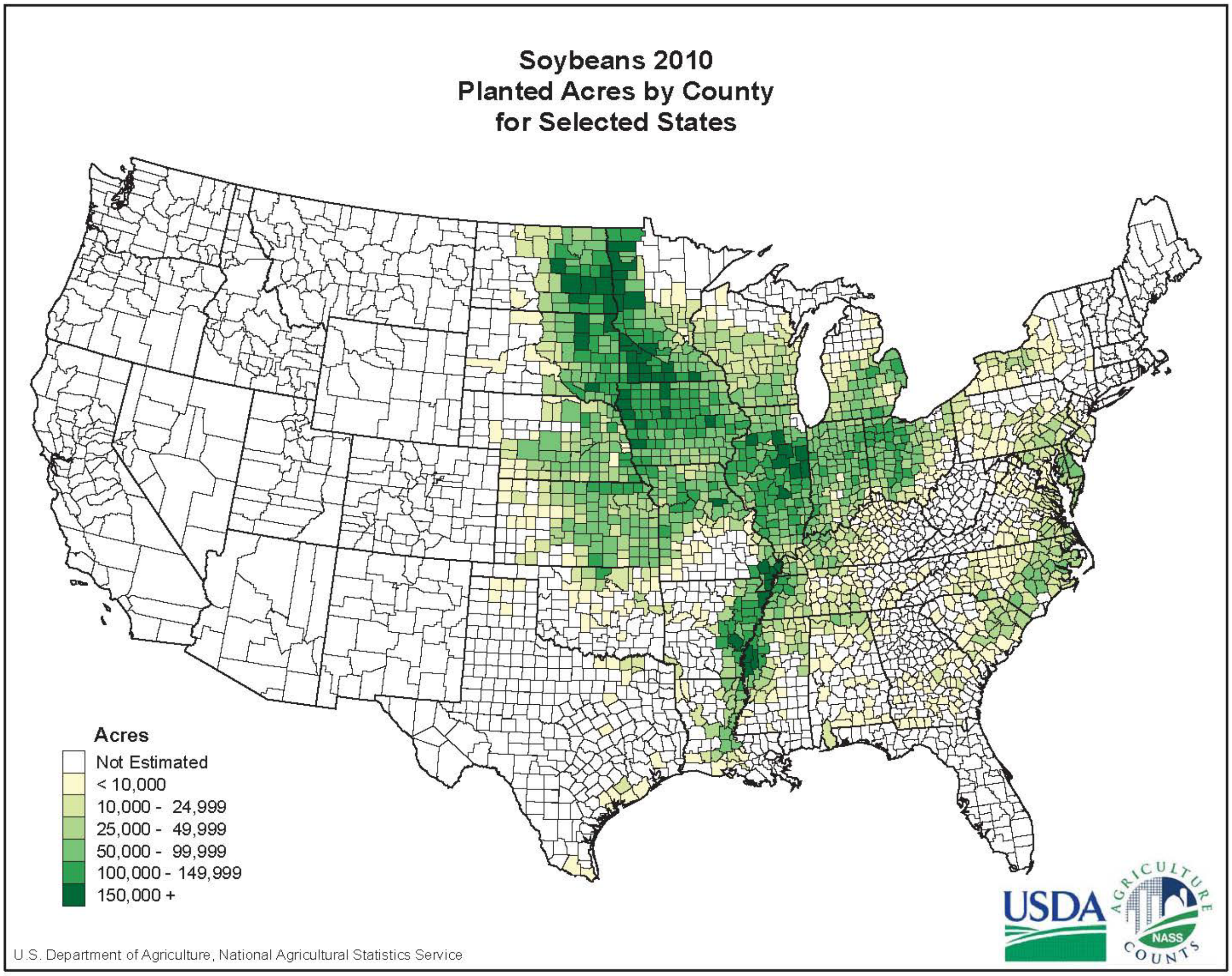
Source: (USDA-NASS, 2012b)

2.2.2 Agronomic Practices

Soybean growers choose agronomic practices that have economic or environmental benefits. Cropping practices include planting cover crops, rotating crops, and using a variety of tillage techniques to maximize yield, control weeds or other pests, and minimize environmental impacts. Other agronomic practices include supplemental irrigation and pest (insect, disease, and weed) management. Proper seedbed preparation, appropriate variety selection, appropriate planting dates and plant population, and good integrated pest management practices are important for optimizing the yield potential and economic returns of soybean. While agronomic practices may be dependent on the soybean maturity group and variety cultivated, common management strategies are shared across regions.

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, such as occasional use to regular inputs of synthetic pesticides and fertilizers. Given that most soybeans planted in the US are transgenic, conventional farming now also includes the use of genetically engineered varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA.

Figure 2-1 Soybeans Planted Acres in 2010 by County for Selected States



As described in Section 2.1, soybean varieties in specific maturity groups are developed and adapted to certain geographical zones (Helsel and Minor, 1993). Additionally, genetically engineered herbicide-tolerant soybean varieties represent the most common soybeans cultivated in the US, accounting for 93 percent of soybean varieties planted in 2012 (USDA-NASS, 2012b). The broad adoption of genetically engineered herbicide-tolerant soybean varieties is attributed to simplified herbicide application practices and positive contributions to productivity and yield (Carpenter and Gianessi, 1999; Fernandez-Cornejo and McBride, 2000). Among the various genetically engineered herbicide-tolerant soybean varieties commercially available, glyphosate-tolerant varieties represent the vast majority that are planted in US soybean fields (NRC, 2010).

2.2.2.1 Cropping Practices

Although the US Midwest is referred to as the Corn Belt, soybeans are commonly planted in this region as well. Rotating corn with soybean supplies the biodiversity, nutrients, and ideal temporal sequence that make corn agriculture successful (Gardner and Payne, 2003). Other soybean cropping practices that directly or indirectly benefit both soybeans and corn include cover crops and tillage and planting techniques.

Crop Rotation

Soybean crop rotation can improve yield and profitability over time, control weeds, break disease cycles, limit insect and other pest infestations, provide an alternative source of nitrogen, reduce soil erosion, increase soil organic matter, improve soil tilth, limit the potential for weeds to develop tolerance to herbicides, and reduce runoff of nutrients and chemicals, as well as the potential for contamination of surface water (Al-Kaisi et al., 2003). Crop rotation also affects the densities of soilborne pathogens and antagonistic microorganisms (Garbeva et al., 2004).

The majority of the US soybean acreage (nearly 70 percent) is rotated with corn (Heatherly et al., 2009) in a 2-year cycle. Other crops in rotation with soybean are wheat, cotton, rice, and sorghum (*see* Table 5.5). Minor rotational crops that follow soybean production include barley, oats, and dry beans. The crop rotation sequence can be modified to take advantage of a particular economic or market opportunity.

Approximately 15 percent of the soybean acreage is in continuous (i.e., non-rotation) soybean production {USDA-NASS, 2013 #317}, a practice that is discouraged by most soybean specialists (Quinby et al., 2006). Planting soybeans after soybeans each year increases the incidence of diseases, nematodes, soil insects, and possibly herbicide residues (Al-Kaisi et al., 2003; Whitaker et al., 2010). The result is generally decreased yields or increased production costs.

Cover Crops

Using cover crops in a soybean system has environmental benefits in conserving and/or improving soil and water resources (Heatherly et al., 2009) by reducing erosion and sequestering nutrients (Mischler et al., 2010), but does not necessarily result in increased soybean yield. Cover crops may be grown in the soybean off-season or simultaneously for managing weeds (Mischler et al., 2010) by competing for limited resources such as sunlight and nutrients, and by suppressing weed emergence when mulched. In the Corn Belt, cover crops are used on approximately 10 percent of soybean fields; winter wheat, cereal rye, and oats are the species most used (Heatherly et al., 2009).

Tillage and Planting Techniques

Prior to planting, soil must be stripped of weeds that would otherwise compete with soybean for space, water, and light. As described in Section 2.2.2.5, *Management of Weeds*, tillage is an economical means of removing biennial and perennial weeds (Byrd et al., 2003) and reincorporating crop residue into the soil. Crop residues are materials left in a field after the crop has been harvested, including stalks and stubble (stems), leaves and seed pods (USDA-NRCS, 2005). These residues aid in conserving soil moisture and reduce wind- and water-induced soil erosion (Heatherly et al., 2009) (USDA-NRCS, 2005). In conventional tillage, postharvest crop residue is integrated into the soil using moldboard plows, heavy disks, and chisel plows, leaving less than 15 percent of crop residue on the surface to prepare a clean bed for planting and to reduce the growth of weeds (Heatherly et al., 2009).

Conservation tillage employs methods that disturb soil less and leave more crop residues on the surface (at least 30 percent), whereas no-till farming only disturbs the soil for planting seed (USDA-NRCS, 2005). Conservation tillage (including no-till farming) results in decreased soil erosion, dust, and pesticide run-off and in increased soil moisture retention and improved air and water quality. Conservation tillage also conserves fuel and water, but may rely heavily on chemical weed control (Loux et al., 2008). Above average management is required to attain good crop stands and weed control (Whitaker et al., 2010).

Since the 1990s, no-till farming has increased more than any other reduced tillage system, with nearly all of the increase in adoption occurring in herbicide-tolerant crop production (i.e., soybean, cotton, canola) (Fawcett and Towery, 2002). In a survey conducted in 1997, it was found that farmers already using no-till practices were more likely to adopt herbicide-tolerant soybeans as an effective weed control practice than farmers using conventional tillage techniques, although the study also found that the commercialization of herbicide-tolerant soybean did not itself encourage the adoption of no-till practices (Fernandez-Cornejo and McBride, 2000). A subsequent survey conducted between 1996 and 2001 found that growers using herbicide-tolerant seed varieties were more likely to use conservation tillage practices over conventional methods and to practice conservation tillage to a greater degree than growers that did not use herbicide-tolerant crops (Fawcett and Towery, 2002). A survey of 1,195 producers undertaken between November 2005 and January 2006 revealed that 25 percent of farmers that had been using conventional tillage switched to no-till and 31 percent switched to reduced-till after adopting glyphosate-tolerant genetically engineered crops (Givens et al., 2009). According to the USDA Agricultural Resource Management Survey (ARMS), approximately 35 percent of US cropland (88 million acres) planted to eight major crops used no-till practices in 2009, and that percentage appears to be increasing over time (USDA-ERS, 2012d). USDA data indicate that soybean fields, 93 percent of which are planted with herbicide tolerant transgenic varieties, exhibit the highest rate of no-till adoption of major crops, increasing from 35 to 45 percent between 2002 and 2006 (the latest data available) (USDA-ERS, 2013a).

In summary, the trend of increasing adoption of conservation tillage practices by US soybean growers continued following the introduction of glyphosate-tolerant soybean in 1996. Conservation tillage adoption facilitates broad-spectrum herbicide use, due to the capacity of these herbicides to control 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., 2002), most evidence suggests a relationship between grower adoption of herbicide-tolerant crops and conservation tillage (NRC, 2010).

Soybean planting techniques commonly include row spacings of 36 inches (OECD, 2000a). Narrower row spacings (20 to 30 inches) help insure full canopy development, which can reduce soil moisture loss and suppress late emerging weeds (Whitaker et al., 2010). In new areas of soybean production, growers may inoculate with *B. japonicum* for optimum efficiency of the nodulated root system. Other considerations made by farmers regarding planting and tilling are seasonal or regional:

- Adequate soil moisture and warm temperatures facilitate rapid seed germination and emergence. However, waiting for soils to reach the ideal soil temperature will delay planting beyond the optimum planting date that will maximize yield (Pedersen and Lauer, 2004).
- Planting date has the greatest impact on yield. In the upper Midwest states, highest yields are generally obtained when planting is done in early to mid-May (Pedersen and Lauer, 2004). In the Southern US, yields are highest when soybean is sown in May or early June.

- The early soybean production system (ESPS) consists of planting an early-maturing soybean variety 4 to 6 weeks before common late-maturing varieties to reduce the risk of drought stress that often occurs during July through September in Southern US states (McPherson et al., 2001; Whitaker et al., 2010). Early planting also helps avoid harvesting the crop during excessively wet conditions that can occur during the fall.

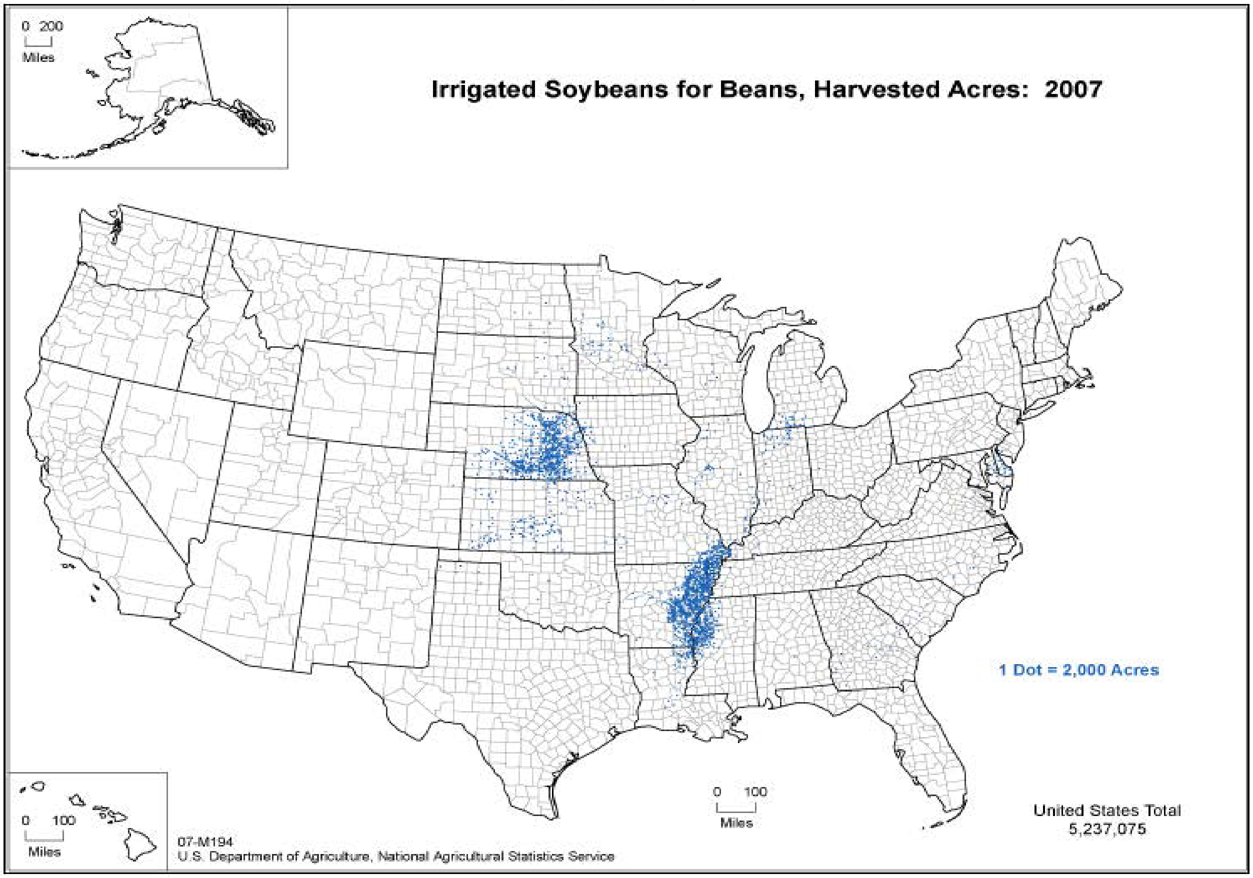
2.2.2.2 Irrigation

The general water requirement for a high-yielding soybean crop (40 to 50 bushels per acre) is approximately 20 to 25 inches of water during the growing season (UA, 2006). Irrigation can alleviate the effects of drought stress, which is the most damaging abiotic stress to soybean in the US (Heatherly et al., 2009). Extended drought during the "critical fruiting period" in dryland farming can result in yield variation from about 5 to 50 bushels per acre (Whitaker et al., 2010). Timely irrigation can stabilize soybean yields at 45 to 50 bushels per acre or more, and improve average yields about 20 bushels per acre (Whitaker et al., 2010).

Irrigated soybean systems are the most productive in the US, providing consistent and sustainable soybean production in the long term (Heatherly et al., 2009). When irrigation is combined with crop rotation, net returns in soybean-corn or soybean-wheat sequences are greater than nonirrigated or irrigated continuous soybean systems (Heatherly et al., 2009). In 2006, an average of approximately 8.4 inches of water per irrigated acre was used, producing an average of over 51 bushels of soybeans per irrigated acre (USDA-ERS, 2012e). This yield was approximately 19 percent higher than the national average (42.9 bushels per acre) for that year (USDA-NASS, 2011a).

Over 9 percent of the soybean crop in the US is irrigated (USDA-NASS, 2010). The majority of the irrigated soybean acreage is in the Midwestern and Midsouthern states, as depicted in Figure 2-2, where summer weather patterns may result in drought stress that makes dryland production risky (Heatherly et al., 2009). Approximately 73 percent of irrigated soybean farms occur in the Missouri and Lower Mississippi Water Resource Regions, with soybean farms in the states of Nebraska, Arkansas, Mississippi, Missouri, and Kansas accounting for 85 percent of all irrigated acres (USDA-NASS, 2010). The soils and climate in the Eastern, Midwestern, and portions of the Great Plains region of the US provide sufficient water supplies under normal climatic conditions to produce a soybean crop.

Figure 2-2 Irrigated Soybeans for Beans; Harvested Acres in 2007



2.2.2.3 Fertilization

USDA-ERS estimates that less than 40 percent of soybean acres in the US receive nitrogen fertilizer (USDA-ERS, 2012g). A 2006 survey of 19 states (USDA-NASS, 2007) found that nitrogen, phosphate, potash, and sulfur were applied to soybeans as summarized in Table 2-3.

Table 2-3 Fertilizer Primary Nutrient Applications to Soybeans in 2006

Primary Nutrient	Area Applied (percent)	Applications (number)	Rate per Application (lb/A)	Rate per Crop Year (lb/A)	Total Applied (millions of pounds)
Nitrogen	18	1.1	15	16	212.4
Phosphate	23	1.0	45	46	772.8
Potash	25	1.0	79	80	1,454.7
Sulfur	3	1.1	10	11	20.0

Source: (USDA-NASS, 2007)

Note: States surveyed: Arkansas, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Ohio, South Dakota, Tennessee, Virginia, and Wisconsin; totaling 72.9 million acres.

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). The nitrogen requirement of soybean is often provided through fertilization of the previous rotation crop or through the 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, nodulating bacteria inoculants are often applied to soybean seeds just before planting (Beuerlein, 2005).

2.2.2.4 Management of Insects

US soybean fields generally face little economic 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 (PSE, 2011). This recalcitrance to insect damage is evident in the low use of insecticides on soybean fields. Historically, only about 2 percent of US soybean acres were treated with insecticides (Gianessi, 2009). However, since the advent of the soybean aphid in 2000 in the Midwest, approximately 16 percent of US soybean acres have been treated with insecticides (USDA-ERS, 2012e).

Numerous kinds of insects occur in soybean fields; most are beneficial or harmless, but some can cause yield loss and even crop failure if not controlled. Insect pests are capable of severely damaging soybeans through defoliation and pod eating (Whitaker et al., 2010). The soybean aphid eats stems; heavy infestations of this pest have occurred since 2000 and caused economic yield losses up to 45 percent in some untreated fields (Gianessi, 2009). The most damaging defoliators are velvetbean caterpillar, soybean looper, green cloverworm, Mexican bean beetle, and bean leaf beetle. Foliage-eating insects are present in practically all soybean fields throughout the growing season, but most fields suffer no yield loss since the number of foliage feeders usually remains at low to moderate levels (NCCES, 2012). The most damaging pod feeders are southern green stink bug, green stink bug, corn earworm, and bean leaf beetle (Gianessi, 2009). Insects which attack the pods are the major reason for treating soybeans with insecticides (NCCES, 2012).

Soybean growers have several tools available to manage insects; integrated pest management approaches incorporate two or more of these tools:

- Soybean varieties with native resistance to some insect pests are available.
- Natural enemies provide considerable control of insect pests in most regions (Gianessi, 2009); beneficial pests that prey on targeted insects may be introduced by the grower;
- Conventional chemical insecticides afford consistent, economical, and effective suppression of insect outbreaks on soybean (Gianessi, 2009); and
- Trap cropping has been proven to be a cost effective means of managing insects in soybeans (Whitaker et al., 2010). Soybean field borders are planted using a soybean variety at least two maturity groups earlier than the rest of the field. Treating only the trap area for pest insects controls the pest without disrupting beneficial insect populations in the rest of the field.

Insect infestation thresholds have been established to indicate when insecticide applications are necessary (Higgins, 1997). The thresholds are commonly based on number of insects found in field sampling surveys and/or in established standard defoliation thresholds, such as those provided by the National Information System of the Regional Integrated Pest Management Centers in pest management strategic plans (USDA-NIFA, 2012).

Table 2-4 presents summary data of the latest available chemical insecticide usage statistics for US soybeans from a 2006 survey (USDA-NASS, 2007). The survey found that insecticides were applied to 16 percent of the 72.9 million soybean acres planted in the surveyed states. No single insecticide exceeds 6 percent of chemically treated acreage (USDA-NASS, 2007). Of the 12 reported insecticides, the three most common (lambda-cyhalothrin, chlorpyrifos, and esfenvalerate) were applied to 6 percent, 5 percent, and 3 percent of the planted acres, respectively (USDA-NASS, 2007).

Table 2-4 Insecticide Applications to Soybeans in 2006[1]

Insecticide	Area Applied (percent)	Average Number of Applications	Rate per Application (lb/A)	Rate per Crop Year (lb/A)	Total Applied (millions of pounds)
Acephate	1	1.3	0.72	0.934	0.546
Benzoic acid	<0.5	1.1	0.051	0.056	0.009
Carbaryl	<0.5	1	0.633	0.633	0.091
Chlorpyrifos	5	1.1	0.454	0.48	1.663
Cyfluthrin	<0.5	1.1	0.028	0.03	0.01
Diflubenzuron	<0.5	1.7	0.037	0.062	0.01
Esfenvalerate	3	1.1	0.035	0.037	0.07
Gamma-cyhalothrin	<0.5	1	0.011	0.011	0.003
Lambda-cyhalothrin	6	1.1	0.02	0.021	0.097
Methyl parathion	<0.5	1.1	0.529	0.565	0.066
Permethrin	<0.5	1	0.065	0.065	0.012
Thiodicarb	<0.5	1	0.32	0.32	0.039
Zeta-cypermethrin	1	1	0.022	0.022	0.014

Source: (USDA-NASS, 2007)

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

2.2.2.5 Management of Disease and Other Non-Insect Pests

Other economically important pest problems for soybeans include a wide range of fungi, bacteria, nematodes, and viruses (Carpenter et al., 2002; Whitaker et al., 2010). Soybean foliar diseases (ISUE, 2010) include:

- Alfalfa mosaic virus
- Bacterial blight (*Pseudomonas syringae*)
- Bacterial pustule (*Xanthomonas axonopodis* pv. *glycines*)
- Bean pod mottle virus
- *Cercospora* leaf blight and purple seed stain (*Cercospora kikuchii*)

- Downy mildew (*Peronospora manshurica*)
- Frogeye leaf spot (*Cercospora sojina*)
- *Phylosticta* leaf spot (*Phylosticta sojicola*)
- Powdery mildew (*Microsphaera diffusa*)
- *Septoria* brown spot (*Septoria glycines*)
- Soybean mosaic virus
- Soybean rust (*Phakopsora pachyrhizi*)

Soybean stem and root diseases (ISUE, 2010) include:

- Anthracnose stem blight (*Colletotrichum truncatum* and several related species)
- Brown stem rot (*Phialophora* [*Cadophora*] *gregata*)
- Charcoal rot (*Macrophomina phaseolina*)
- *Fusarium* wilt and root rot (*Fusarium* species)
- *Phytophthora* root and stem rot (*Phytophthora sojae*)
- Pod and stem blight and *Phomopsis* seed decay (*Diaporthe phaseolorum* var. *sojae* and *Phomopsis longicolla*)
- *Pythium* root rot (*Pythium* species)
- *Rhizoctonia* root rot (*Rhizoctonia solani*)
- *Sclerotinia* stem rot (white mold) (*Sclerotinia sclerotiorum*)
- Soybean cyst nematode (*Heterodera glycines*)
- Stem canker (*Diaphorthe phaseolorum* var. *caulivora* [northern stem canker] and *D. phaseolorum* var. *meridionalis* [southern stem canker])
- Sudden death syndrome (*Fusarium virguliforme*)

Some plant diseases can be prevented or managed by planting disease resistant cultivars. Besides selecting cultivars with resistance to diseases prevalent in a grower's particular region (Dorrance et al., 2007), a healthy soybean crop starts with planting disease-free seed (Jardine, 1997), implementing best management practices such as crop rotation to reduce disease carryover from crop to crop, and providing adequate nutrients and water to grow healthy plants (Nelson, 2011). Tillage practices can also affect disease risk: no-till soils may have higher soil moisture and lower soil temperatures than could increase risk. Tilling may improve drainage to lower risk, but conservation tillage practices should be used to maintain soil quality (ISUE, 2010). Conversely, some infestations, such as of soybean cyst nematode, may be managed by no-till methods. A grower may chose to plant seeds treated with fungicides to enhance soybean seed germination success (Jardine, 1997).

When diseases of fungal origin do occur despite taking such measures, fungicides are used (Jardine, 1997; Padgett et al., 2011). The most commonly applied fungicides on soybean (azoxystrobin, propiconazole, pyraclostrobin, tebuconazole, and trifloxystrobin) were applied to only 4 percent of the planted soybean acreage in the 19 states surveyed in 2006 (USDA-NASS, 2007). Of these fungicides, pyraclostrobin and azoxystrobin were the only two applied on more than 0.5 percent of the planted acres. Pyraclostrobin was applied to 2 percent of the planted acres at an average rate of 0.112 lb/A per year, whereas azoxystrobin was applied to 1 percent of planted acres at an average rate of 0.106 lb/A per year (USDA-NASS, 2007).

Some varieties of soybeans are more susceptible to certain bacterial or viral diseases than others, and resistant varieties are marketed as such (ISUE, 2010). Bacterial and viral diseases may be transmitted by aphids (such as *Aphis glycines*) or bean leaf beetles (*Cerotoma trifucata*). Insecticides may be effective in controlling these insects, as described in Section 2.2.2.4, *Management of Insects*, and therefore minimize disease transmittal from these vectors. Some diseases may be transmitted in or on seeds; fungicide-treated seeds are available to growers.

2.2.2.6 Management of Weeds

Weed control is one of the biggest challenges for soybean growers; poorly controlled weeds substantially decrease crop yield and quality (Carpenter et al., 2002) since weeds compete with soybeans for light, nutrients, and soil moisture. Weeds can harbor insects and diseases, and can interfere with harvest, causing extra wear on harvest equipment (Loux et al., 2008). Soybean yield losses can range from 12 to 80 percent if weeds are uncontrolled for an entire season (Barrentine, 1989; Dalley et al., undated).

If weeds are left uncontrolled, soybean cannot be grown economically (Hartzler, 2012). Growers make choices to use certain herbicides based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, fuel costs, worker safety, potential for crop injury, and ease and flexibility of the system (Gianessi, 2005). Glyphosate-tolerant soybeans have allowed growers to use a broad spectrum herbicide, glyphosate, in place of an array of over 70 selective herbicides targeted toward specific weeds. Recent trends suggest a decrease in glyphosate use and slight increase in selective herbicide use, as described in the Herbicide discussion below.

The primary factors affecting soybean yield loss from weed competition are the species, density, and the duration and time period of the competition. The later the weeds emerge, the less impact the weeds will have on yield. Soybean plants withstand early-season weed competition longer than corn as the plant canopy closes earlier in soybean than in corn (Mallory-Smith and Zapiola, 2008). The extent of canopy closure regulates the availability of light to weeds and other plants that grow below the soybean. Canopy closure occurs much sooner when soybean is drilled or planted in narrow rows as compared to the standard 36-inch row spacing.

Problem weed species in US soybean fields include common cocklebur (*Xanthium strumarium*), jimsonweed (*Datura stramonium*), velvetleaf (*Abutilon indica* or *A. theophrasti*), morning glories (*Ipomoea* spp.), Johnsongrass (*Sorghum halapense*), and foxtails (*Setaria* spp.) (Carpenter et al., 2002). Growers in the Midwest consider giant ragweed (*Ambrosia artemisiifolia*), lambsquarters (*Chenopodium album*), Canada thistle (*Cirsium arvense*), common cocklebur, and velvetleaf to be the top five most problematic weeds in corn and soybean (Nice and Johnson, 2011). The most frequently reported common weeds in the Southeast region are morning glory, prickly sida (*Sida spinosa*), Johnsongrass, sicklepod (*Cassia obtusifolia*), and broadleaf signalgrass (*Brachiaria platyphylla*) (Webster, 2005). Soybean itself may be considered a weed when volunteers grow in crop rotation fields in subsequent years; herbicide-tolerant soybean does not have any characteristics that promote volunteerism.

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

Soybean growers can use a variety of weed control strategies, but the most effective weed management programs have used a combination of cultural (cropping practices), mechanical, and chemical control strategies (Whitaker et al., 2010) in an Integrated Weed Management approach. The effectiveness of any weed control program depends largely upon timeliness (Loux et al., 2008). Good weed control within the first 4 to 6 weeks after crops are planted is critical in order to avoid a yield reduction from weed competition. Weeds that emerge just prior to or at the same time as the soybeans cause greater yield losses than later emerging weeds (Whitaker et al., 2010). Volunteer soybeans, if herbicide-tolerant, would be controlled by cultural and mechanical means.

With increased rates of conservation tillage, there has been a decrease in summer annual weeds and an increase in perennial, biennial, and winter annual weed species (Durgan and Gunsolus, 2003; Green and Martin, 1996) that are not controlled by limited-tillage practices. Winter perennial weeds are particularly competitive and difficult to control, as these weeds regrow every year from rhizomes or root systems. Recent surveys of US agronomic crop producers suggest that pigweed species (*Amaranthus* spp.), morning glory species, Johnsongrass, ragweed species (*Ambrosia* spp.), foxtail species, and velvetleaf are among the most problematic weeds (Heatherly et al., 2009). Palmer amaranth, especially glyphosate resistant populations, is an important problem weed of Mid-South States {Riar, 2013 #318} and recently also in the Upper Midwest States {United-Soybean-Board, 2013 #319}

Cropping Practices for Weed Control

Cropping practices, as described in Section 2.2.2.1, improve weed control by enhancing the competitive ability of the soybeans. Any practice that optimizes early and vigorous crop growth helps give crops a competitive edge over weeds (Loux et al., 2008). Crop rotation is one of the most effective practices for long-term weed control (Loux et al., 2008). Crop rotation aids in controlling weeds by allowing rotation of herbicides with alternative modes of action appropriate for the alternating crops, and providing the opportunity to plant highly competitive crops that prevent weed establishment. However, crop rotation is not effective against seedbanks for all weed species (Jordan et al., 1995).

Soybeans planted in narrow rows, 15 inches or less wide, may have benefits such as higher yield potential and increased crop competitiveness with weeds (Dalley et al., undated). Planting crops in narrow rows increases the amount of shading by the crop canopy, suppressing weed growth. A cover crop grown simultaneously performs similarly and can help reduce herbicide inputs (Mischler et al., 2010).

Herbicides

Herbicides provide effective and economical control of weeds in soybean that cultivators cannot reach (Byrd et al., 2003). Often the combination of shallow, flat cultivation with directed herbicide sprays is the least expensive and most effective weed treatment. Herbicides are applied at various points of the growing season (Carpenter et al., 2002):

- Pre-plant (during field preparation);
- Pre-emergence (during or immediately after planting); and
- Post-emergence (during crop growth).

A traditional soybean weed control program includes a pre-emergence herbicide application followed by one or more post-emergence applications about 4 to 6 weeks after the crop has emerged (Byrd et al., 2003). Yield losses from weed competition may occur when herbicide application is delayed (Dalley et al., undated). A timely application of a post-emergent herbicide in narrow row soybeans may be sufficient for season-long weed control.

The efficacy of herbicides is influenced by environmental and soil conditions, specifically precipitation and soil composition (Stewart et al., 2010). In selecting an herbicide, a grower must also consider whether an herbicide can legally be used on the crop (herbicides are registered by the EPA for specific uses/crops; some states evaluate and authorize or prohibit the use of herbicides separately), the potential adverse effects on the crop, residual effects that can limit crops that can be grown in rotation, effectiveness on expected weeds, and cost. Herbicide use is not regulated by APHIS but is regulated by EPA under FIFRA and its amendments.

Herbicides have different ways of acting on plant physiology (i.e., modes of action) to affect the health of a given plant and are active at one or more target sites within a plant (Prather et al., 2000). Target sites are enzymes, proteins, or places in the plant where herbicides bind and thereby disrupt normal plant functions. Some common modes of herbicide action include auxin growth regulators, amino acid inhibitors, chlorophyll pigment inhibitors, lipid biosynthesis inhibitors, and glutamine synthase inhibitors (UW, undated).

By the early 1990s, there were over 70 individual herbicides or combination products registered for weed control in soybean (Byrd et al., 2003). At that time, pre-emergence herbicides commonly used on soybean were 2,4-dichlorophenoxy acetic acid (2,4-D), chlorimuron, metolachlor, metribuzin, pendimethalin, and trifluralin. Commonly used soybean post-emergence herbicides included acifluorfen, basagran, bentazon, clethodim, cloransulam, fluazifop, fomesafen, glyphosate, imazethapyr, quizalofop, and sethoxydim. These herbicides typically control either broadleaf or grass species, but rarely both. Several species of weeds are usually present in any particular field and growers need to control both grassy and broadleaf weeds using different herbicides (Carpenter et al., 2002). A combination of herbicides may be necessary, but tank mixing some herbicides can result in antagonism between the compounds. Sequential spraying may be required, in some cases necessitating multiple passes to apply the different herbicides.

Table 2-5 lists the most commonly applied herbicides to US soybeans and the corresponding percent of acres treated in 1995 (USDA-NASS, 1996), in comparison to use of these herbicides in 2001 (USDA-NASS, 2002), and 2006 (USDA-NASS, 2007)[14]. Figure 2-3 graphs the usage trends of the top 10 herbicides from 1995 in terms of percent planted acres treated in t`hose same 3 years. Glyphosate has become the most often-used herbicide on US soybean. The graph shows that from 1995 to 2006 glyphosate-applied acres increased to 92 percent in 2006 but also that the number of acres to which other herbicides were applied significantly declined (NRC, 2010).

14 USDA-NASS no longer collects these data.

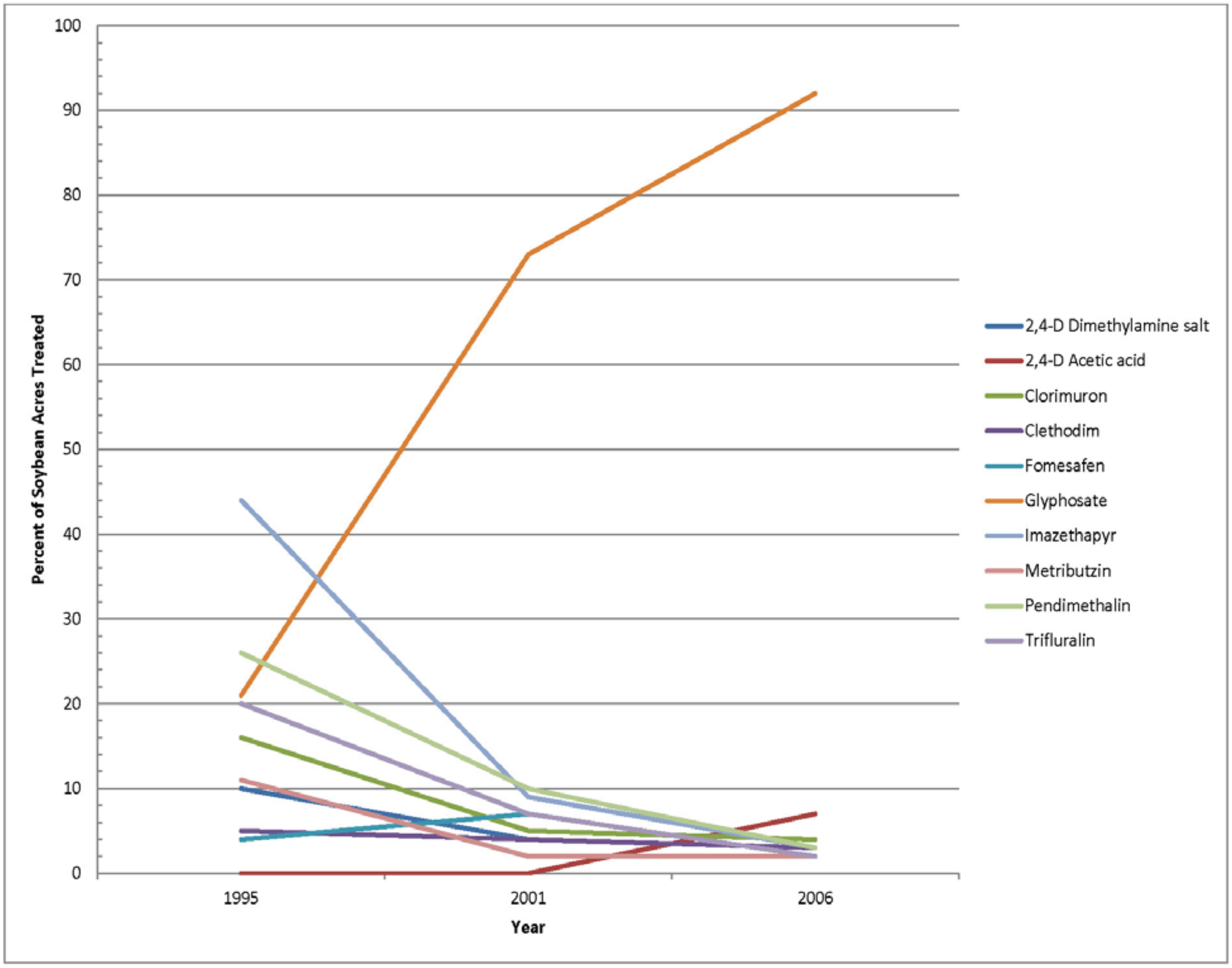
Table 2-5. Percent of US Soybean Acres[1] Treated With Herbicides; 1995, 2001, 2006, 2012

	Percent Soybean Acres Treated per Year					Percent Soybean Acres Treated per Year			
Herbicide	**1995**	**2001**	**2006**	**2012**	**Herbicide**	**1995**	**2001**	**2006**	**2012**
2,4-D[2]	10	4	3	4	Fluthiocet-methyl		--	--	2
2,4-DB[3]	1	<1	<1	--	Glufosinate	--		--	3
2,4-DEHE			7	11	Glyphosate	20	73	92	98
Acifluorfen	12	3	<1	1	Imazaquin	15	2	1	--
Alachlor	4	<1	<1	--	Imazethapyr	44	9	3	6
Bentazon	12	1	<1	--	Lactofen	5	1	<1	2
Chlorimuron-ethyl	16	5	4	11	Linuron	2	--	--	--
Clethodim	5	4	3	9	Metolachlor, (*S*)Metolachlor	7	<1	--	--
Clomazone	4	<1	--	--	Metribuzin	11	2	2	3
Dimethenamid	1	--	--	1	Paraquat	2	--	1	3
Ethalfluralin	1	--	--		Pendimethalin	26	10	3	2
Fenoxaprop-ethyl	6	3	<1	--	Quizalofop-ethyl	6	<1	<1	2
Fluazifop-P-butyl	10	3	1	3	Sethoxydim	7	1	<1	--
Flumetsulam	2	<1	<1	--	Thifensulfuron	12	2	1	5
Fomesafen	4	7	2	8	Trifluralin	20	7	2	2

Sources: (USDA-NASS, 1996; USDA-NASS, 2002; USDA-NASS, 2007; USDA-NASS, 2013a)
1- Survey states:
1995: Arkansas, Georgia, Illinois, Indiana, Iowa, Kentucky, Louisiana, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, Ohio, and Tennessee.
2001: Arkansas, Illinois, Indiana, Iowa, Minnesota, Missouri, Nebraska, and Ohio.
2006: Arkansas, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Ohio, South Dakota, Tennessee, Virginia, and Wisconsin.
2012: Alabama, Arkansas, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Ohio, Pennsylvania, South Carolina, South Dakota, Tennessee, Wisconsin.
2- Dimethylamine salt formulation of 2,4-dichlorophenoxy acetic acid
3- 4-(2,4-dichlorophenoxy)butyric acid
-- = no value.
4-2-ethylhexyl ester

While total herbicide use trends are subject to debate, it is clear that an herbicide-substitution effect has occurred in US soybean production (Benbrook, 2009; Fernandez-Cornejo et al., 2009). With the 1996 commercial introduction of glyphosate-tolerant soybean, a major shift occurred with an increased use of glyphosate for soybeans concurrent with the increased planting of glyphosate-tolerant soybean. Although other herbicide-tolerant soybeans are cultivated, glyphosate-tolerant varieties continue to dominate the market in the US. Glyphosate is the active ingredient in a broad-spectrum Roundup® herbicide introduced by Monsanto in 1974 (Monsanto, 2005). It works by disrupting the 5-enolpyruvylshikimate 3-phosphate (EPSP) synthase enzyme, which is involved in the production of amino acids that are essential to plant growth. Glyphosate products are among the world's most widely used herbicides.

Figure 2-3 Percent of US Soybean Acres Treated with the 10 Most Used Herbicides; 1995, 2001, and 2006[1]



Source: (USDA-NASS, 2007)

1- Survey states:

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

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

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

In 2006 (the latest year for which data are available), based on soybean farmers surveyed in selected states, it was estimated that 98 percent of the planted soybeans were treated with at least one type of herbicide, indicating the importance of weed control in maximizing soybean yield. As shown in Table 2-6, application rates ranged from 0.004 to 1.931 lbs/A per crop year (USDA-

NASS, 2007). Table 2-7 lists the most common troublesome weeds in herbicide-treated soybean fields in 2006, 2007, and 2008, and the number of acres treated with herbicides each year.

Table 2-6 Total Applications of Herbicides to Soybeans, 2006[1]

Herbicide	Area Applied (percent)	Applications (number)	Rate per Applications (lb/A)	Rate per Crop Year (lb/A)	Total Applied (1,000 lb)
2,4-D (2-EHE)	7	1.0	0.493	0.503	2,505
2,4-D (BEE)	<0.5	1.1	0.426	0.459	68
2,4-D (DMA)	3	1.0	0.462	0.475	953
Acifluorfen, sodium	<0.5	1.0	0.287	0.296	47
Alachlor	<0.5	1.0	1.931	1.931	485
Bentazon	<0.5	1.0	0.687	0.687	70
Carfentrazone-ethyl	<0.5	1.2	0.038	0.046	10
Chlorimuron-ethyl	4	1.0	0.017	0.017	52
Clethodim	3	1.1	0.096	0.102	190
Cloransulam-methyl	1	1.0	0.019	0.019	17
Dicamba, digly salt	<0.5	1.0	0.250	0.250	16
Fenoxaprop	<0.5	1.0	0.031	0.031	9
Fluazifop-P-butyl	1	1.0	0.099	0.099	43
Flufenacet	<0.5	1.0	0.265	0.265	80
Flumetsulam	<0.5	1.0	0.048	0.048	8
Flumiclorac-pentyl	1	1.4	0.020	0.028	17
Flumioxazin	3	1.0	0.066	0.066	138
Fomesafen	2	1.2	0.190	0.233	330
Glyphosate	4	1.7	0.630	1.044	2,841
Glyphosate, ammonium salt	<0.5	1.5	0.489	0.745	142
Glyphosate, isopropyl amine salt	92	1.7	0.802	1.330	88,903
Imazamox	<0.5	1.0	0.030	0.030	9
Imazaquin	1	1.0	0.061	0.062	66
Imazethapyr	3	1.0	0.053	0.053	100
Imazethapyr, ammonium	<0.5	1.0	0.048	0.048	5
Lactofen	<0.5	1.0	0.110	0.110	23
(*S*)-Metolachlor	1	1.0	1.023	1.023	837
Metribuzin	2	1.0	0.255	0.260	437
Paraquat	1	1.0	0.492	0.511	335
Pendimethalin	3	1.0	0.920	0.926	1,894
Quizalofop-P-ethyl	<0.5	1.1	0.038	0.041	14
Sethoxydim	<0.5	1.0	0.153	0.153	10
Sulfentrazone	1	1.0	0.087	0.091	70
Sulfosate	1	1.8	0.967	1.701	970
Thifensulfuron	1	1.1	0.004	0.004	3
Tribenuron-methyl	1	1.0	0.008	0.008	5
Trifluralin	2	1.0	0.818	0.818	1,454

Source: (USDA-NASS, 2007)

1- Survey States: Arkansas, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Ohio, South Dakota, Tennessee, Virginia, and Wisconsin; totaling 72.9 million planted acres.

Table 2-7 Common Troublesome Weeds in Treated Soybean Fields; 2006-2008

Weed Species	Total Soybean Acres Treated 2006	2007	2008
Annual Broadleaf Weeds			
Buckwheat, Wild	1,167,746	855,879	1,331,675
Chickweed	1,652,712	1,259,096	1,823,638
Cocklebur, Common	23,657,980	22,389,376	23,962,063
Horseweed	2,188,359	3,159,712	3,470,274
Kochia	4,859,759	3,671,795	5,317,528
Lambsquarters, Common	21,859,614	24,459,895	28,242,972
Marestail	4,044,060	5,382,190	11,257,267
Morning glory spp.	10,711,087	11,432,904	11,011,185
Mustard, Wild	2,019,346	1,975,291	2,688,590
Nightshade, Black	1,766,649	1,277,416	1,385,751
Pigweed, Redroot	21,093,224	21,788,121	26,715,150
Pigweed, Smooth	188,160	801,569	1,322,732
Ragweed, Common	9,417,252	9,438,871	9,518,051
Ragweed, Giant	13,369,296	14,684,000	16,565,209
Sicklepod	2,024,031	1,650,086	2,535,829
Sida, Prickly	1,639,261	1,567,275	2,432,701
Smartweed, Pennsylvania	2,366,851	1,835,825	3,529,114
Sunflower, Volunteer	1,089,460	1,007,691	1,913,860
Sunflower, Wild	5,558,526	5,759,216	5,709,292
Velvetleaf	23,820,731	23,373,573	26,786,349
Waterhemp, Common	18,399,609	15,970,794	21,364,980
Waterhemp, Tall	2,301,380	2,926,358	3,826,647
Annual Grass Weeds			
Barnyardgrass	4,189,156	3,967,425	3,805,391
Corn, Volunteer	2,292,705	2,088,371	3,704,330
Crabgrass	5,170,684	5,928,919	7,424,879
Cupgrass, Woolly	1,765,244	2,470,437	2,108,135
Foxtail spp.	24,409,043	18,489,746	18,446,420
Foxtail, Giant	11,817,612	17,513,493	17,804,622
Foxtail, Yellow	10,870,761	11,217,512	13,947,018
Foxtail, Green	5,629,880	7,109,316	7,610,855
Oat, Wild	1,792,389	1,478,890	2,886,300
Panicum, Fall	2,251,014	2,241,088	1,852,417
Shattercane	2,408,592	2,715,388	1,879,416
Perennial/Biennial Weeds			
Dandelion	1,578,579	1,528,332	2,154,008
Johnsongrass	10,152,393	11,057,825	10,368,155
Quackgrass	2,628,187	2,570,688	2,786,633
Thistle	1,479,038	647,315	1,513,566
Thistle, Canada	4,123,437	3,584,676	4,840,383

Source: (Dow, 2010)

Herbicide use (as measured in terms of pounds of active ingredient applied per acre [lb. ai/A]) on soybeans has been relatively stable since transgenic varieties with herbicide tolerance were introduced in the mid-1990s, although there has been a slight increase in recent years (Brookes et al., 2012).

The diversity of herbicides available to US soybean growers has not decreased; rather, the diversity of herbicides used in US soybean production fields has gradually increased while applied quantities of those same herbicides (except glyphosate) have generally decreased, as indicated in Figure 2-3 and Table 2-5. However, total herbicide use may not be an effective metric to measure environmental impact, as this does not effectively permit a comparison of different herbicides, which may have different environmental effects, across time or across management strategies (Fernandez-Cornejo et al., 2009).

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

Weed Resistance to Herbicides

Transgenic Crops for Herbicide Tolerance

Herbicide-tolerant soybean was introduced in 1996 to provide growers with additional options to improve crop safety and/or improve weed control. Soybean's natural tolerance to herbicides that would normally damage the crop has been developed through conventional and mutation breeding, with biotechnology adding transgenic traits (Carpenter et al., 2002). Variability in the natural tolerance of soybean to commercially available herbicides such as 2,4-DB, metribuzin, and glyphosate was recognized in the 1980s (Barrentine et al., 1982). At that time, efforts to screen soybean germplasm for commercial levels of tolerance to glyphosate had not been successful. The first transgenic traits put into soybean were herbicide tolerance, with glyphosate tolerance being the most prevalent (Sleper and Shannon, 2003).

The adoption of herbicide-tolerant soybeans has been particularly rapid in the US, increasing from less than 10 percent of soybean acreage in 1996 (Lin et al., 2001) to 93 percent of soybean acreage in 2012 (USDA-NASS, 2012b). Farmers have widely adopted herbicide-tolerant soybean because of lowered production costs, reduced crop injury, simplicity and flexibility in weed management, and because farmers can use one herbicide to control a broad spectrum of weeds instead of using multiple herbicides (Carpenter et al., 2002). However, using a single broad-spectrum herbicide intensifies selection of weed populations against the herbicide's mode of action because repeated use of a single, broad-spectrum mode of action replaces use of multiple modes of action and tillage (Vencill et al., 2012).

2.2.3 Commercial Soybean Production and Uses

This section describes the commercial production of soybean seeds, raw and processed soybean commodities, organic soybeans, and specialty products.

2.2.3.1 Seed Production

Seed quality (including genetic purity, vigor, and presence of weed seed, seed-borne diseases, and inert materials such as dirt) is a major factor in crop yields. If variability in seed production is not carefully controlled, the value of a new variety or cultivar may be lost (Hartmann et al., 2011). Genetic purity in commercial seed production is generally regulated through a system of seed certification that is intended to ensure that the desired traits in the seed are maintained throughout all stages of cultivation.

Seed laws and certification agencies ensure that purchasers who receive certified seed can be assured that the seed meets established seed quality standards (Bradford, 2006). The *US Federal Seed Act of 1939*[15] recognizes seed certification and official certifying agencies. Implementing regulations further recognize land history, field isolation, and varietal purity standards. Soybean seed is commonly separated into three classes: Foundation, Registered, and Certified (MCIA, 2012). Each class of seed is identified to designate the seed generation from the original breeder source (Hartmann et al., 2011).

Foundation, Registered, and Certified seed production is controlled by public or private certification programs (AOSCA, 2003). Commercially certified soybean seed must meet state and Federal seed standards and labeling requirements. State seed certification standards vary slightly from state to state and can be more restrictive than the seed standards of the Association of Official Seed Certifying Agencies (AOSCA). All soybean seed sold may not be officially certified; however, commercial soybean seed sold and planted for normal soybean production is produced predominately to meet or exceed Certified seed standards. No program can ensure 100 percent purity of seeds, given the potential for accidents and human error. However, the existing standards provide a reasonable level of confidence in seed products based on the cost and feasibility of implementing the certification programs.

2.2.3.2 Raw and Processed Soybean Commodities

Soybean plants are grown for their seed, which is processed to yield oil for a variety of uses and meal for human dietary products and livestock feed. Soybean is the most extensively grown oilseed in the world, with approximately 210 million metric tons of harvested seed produced in 2009, representing 56 percent of world oilseed production (Soystats, 2012a). Unprocessed soybeans have no human food and limited animal feed use since they contain anti-nutrient factors, such as trypsin inhibitors and lectins. Adequate heat processing inactivates these factors.

Approximately 85 percent of the world soybean seed supply is crushed to produce soybean meal and oil (Soyatech, 2012). The first modern US soybean production facility was established in 1922,

15 7 USC 1551.

and soybean production for oil and animal feed increased substantively during World War II (Hymowitz, 1990). In the late 1940s and early 1950s, the US overtook China as the world leader in soybean production (Hymowitz, 1970). Most of the seed is used to supply the feed industry for livestock use or the food industry for edible vegetable oil and soybean protein isolates. A large portion of the world soybean seed supply is traded to other geographies, with China, the European Union (EU), Japan, and Mexico being the top soybean seed importers (Soystats, 2010). The remainder of the soybean seed produced is used as certified seed, feed, or stocks.

A bushel (27.2 kilograms) of soybeans yields about 21.8 kilograms of protein-rich meal and 5.0 kilograms of oil (OECD, 2001b). Soybean oil makes up 94 percent of the soybean food ingredients consumed by humans (OECD, 2001b). The essential amino acids required for the human diet are present in soybean proteins. Soy protein is added to a number of meat, dairy, bakery, and cereal products as a protein extender (OECD, 2000a).

A significant fraction of the soybean market is dedicated to production of purified oil for food use and industrial applications (Cahoon, 2003). The domestic food use of soybean oil is mainly in frying oils, salad and cooking oils, and margarines (Soystats, 2010). In 2009, these three categories represented approximately 85 percent of the soybean oil market in the US, with industrial uses consuming the remaining 15 percent (Soystats, 2010; USSEC, 2006). Soybean oil industrial uses include plastics, lubricants, coatings, printing inks and adhesives, emulsifiers, surfactants (industrial detergents and cleaners as well as solvents), resins, and biodiesel, among others. Soybean is also a carbon/nitrogen source in the production of yeasts via fermentation (Cahoon, 2003). Soy-based industrial oil products have many advantages compared to petroleum oils, including being inherently biodegradable, having low ecotoxicity, and being derived from renewable resources (USSEC, 2006).

Extracting oil from soybeans also creates a highly valued solid, soybean meal, which is used for animal feed in all livestock sectors (swine, beef, poultry, dairy, and fish) and human food protein (CAST, 2009). Tofu, soy milk, soy sauce, miso, meat substitutes, protein powder, soynuts, soy sprouts, baked or roasted soybeans, and soy flour are the soy-based products present in the human diet. Processed soybeans are the largest source of protein for livestock in the world (USDA-ERS, 2010a), accounting for nearly 69 percent of world protein meal supplies (Soystats, 2010). Globally, most soybean meal, 97 percent, is used in animal feed, with 46 percent going to poultry, 32 percent to swine, and 9 percent each going to dairy and beef cattle feed, respectively. About 2 percent is used in pet food (OECD, 2001b).

Although honeybees have been reported to forage for nectar in soybean fields (Erickson, 1975), soybeans are not reported to be commercial honey sources (Morse and Calderone, 2000).

2.2.3.3 Organic Soybean Production

In the US, only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2010). Organic certification is a process-based certification, not a certification of the end product. The certification process specifies and audits the methods and procedures by which the product is produced. The NOP was established by the *Organic Foods Production Act of 1990*[16] and implementing USDA regulations (USDA, 2012).

Organic production operators must develop and maintain an organic system plan approved by an accredited certifying agent (USDA, 2012).[17] The plan describes how the operation will achieve and document compliance with the NOP's National Organic Standards. Before an operation is certified to sell organic soybeans the cropland must be managed organically for a minimum of 36 months (USDA, 2012)[18]. The NOP requires organic farming operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management (USDA, 2012)[19]. The NOP regulations preclude the use of excluded methods in crop production. Excluded methods are defined at 7 CFR §205.2 as:

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

Use of synthetic insecticides, fertilizers, and transgenic crops is excluded from certified organic production systems. Natural products are allowed. Since organic certification is process-based, the presence of a detectable residue of a product of excluded methods (including genetically modified organism residues; e.g., transgenic soybean) does not by itself constitute a violation of the NOP regulations (USDA-AMS, 2011). The NOP regulations do not specify an acceptable threshold level for the adventitious presence of genetically engineered materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used the excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche, 2006; USDA-AMS, 2010).

To prevent gene flow between conventional crops and to produce genetically pure seed, different types of crops should be separated from each other by an adequate isolation distance (Carpenter et al., 2002). Common practices organic growers may use to prevent gene flow from genetically engineered organisms include planting only organic seed, planting earlier or later than neighboring farmers who may be using transgenic crops so that the two crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields (Baier, 2008; Bradford, 2006; NCAT, 2003; Sundstrom et al., 2002). Isolation distances vary between crops based on the type of pollination. Isolation distances for soybean are usually not required because the crop is

16 Title 21 of Public Law 101-624, the *Food, Agriculture, Conservation, and Trade Act of 1990*, as amended.

17 Section 201

18 Section 205.202(b)

19 Section 205.202(c)

predominantly self-pollinated; however, as described in Section 2.1, insect-mediated outcrossing may occur over short distances in some cultivars if the different cultivars have synchronized flowering.

Organic soybean production practices include crop rotation, use of cover crops, green and animal manures, application of rock minerals such as lime, other soil additives, mechanical weed control, biological control of pests, and disease control primarily through management practices (Heatherly et al., 2009; Kuepper, 2003; USDA-AMS, 2011). Based on 2006 ARMS data, more than 90 percent of organic soybean producers planted in standard width rows, as compared to 60 percent of other soybean producers (McBride and Greene, 2008). The standard row spacing may be utilized by organic farmers to facilitate mechanical weed control that would be hindered by narrow row spacing where weed control is accomplished by chemical means that are prohibited in organic systems. Further, organic soybean operations rotated crops more often, and 40 percent of the farmers incorporated a 1-year fallow into their organic soybean rotation.

Weed control in organic systems is accomplished with delayed seeding to avoid spring weeds, applying fertilizer to growing plants to outcompete weeds, increasing seeding rates, sowing cover crops, rotating crops, intercropping, flame weeding, hand weeding, and tilling (Heatherly et al., 2009; Kuepper, 2003). Organic crop production historically employed mulch and ridge tillage practices (NCAT, 2003); no-till practices may be unsustainable in some long-term organic systems because of increasingly poor weed control. Field evaluations of several tillage methods in organic systems conducted over 9 years found that factors contributing to poor weed control included uneven seeding beds produced by chisel-tilling in a cover crop and animal manure, variable ground cover occurring in mowed cover crop residue, insufficient disruption of weed roots by sweep-type cultivators, and the short grain crop rotation system used was unsuitable for maintaining a low weed seedbank (Teasdale et al., 2007).

Pest control in organic systems is accomplished with application of natural pesticides, integrated pest management techniques such as introduction of beneficial organisms (predator and parasitic organisms), and some of the practices described for conventional weed control (crop rotation, intercropping, and use of cover crops) (NCAT, 2003). Diseases are primarily controlled in organic systems by planting disease-resistant varieties, using management practices that promote healthy soil, rotating crops, diligently removing diseased plant material, and managing plant canopy. When physical, mechanical, or biological controls are not sufficient for controlling weeds, pests, or disease, only a biological, botanical, or synthetic substance approved on the national list may be used (USDA-AMS, 2011).

Organic soybeans represent between 0.17 and 0.22 percent of US soybean production (USDA-ERS, 2010c). In 2011, certified organic soybeans were harvested from 96,080 acres in 28 states, resulting in 2.9 million bushels of soybeans (USDA-NASS, 2012a). Table 2-8 indicates the acreage of organic soybean produced in each state.

Organic soybean field yields are lower or equal to conventional soybean yields (Cavigelli and Conklin, undated). Organic soybean producers had an average yield in 2006 of 31 bushels per acre, as compared to 47 bushels per acre for conventional soybean yield (McBride and Greene, 2008). Lower yields are generally attributed to competition with weeds in organic systems.

In 2006, the total estimated additional costs for producing organic relative to conventional soybeans were $0.82 per bushel for operating costs alone, $2.61 per bushel for operating and capital costs together (including transition costs), and $6.20 per bushel for total economic costs (McBride and Greene, 2008).

Table 2-8 US Certified Soybean Acreage by State, 2011

State	Acres	State	Acres
Arkansas	(D)	Missouri	5,505
Delaware	(D)	Nebraska	6,211
Georgia	(D)	New Jersey	(D)
Idaho	(D)	New York	8,621
Illinois	6,633	North Carolina	(D)
Indiana	945	North Dakota	3,288
Iowa	12,659	Ohio	5,634
Kansas	1,311	Pennsylvania	1,280
Kentucky	(D)	South Dakota	3,962
Louisiana	(D)	Tennessee	(D)
Maine	(D)	Texas	(D)
Maryland	1,090	Vermont	527
Michigan	11,699	Virginia	150
Minnesota	16,150	Wisconsin	7,622

Source: (USDA-NASS, 2012a)

(D) = Withheld to avoid disclosing data for individual operations. Total area in this table is therefore 84,666 acres, less than the US total of 96,080 acres.

2.2.3.4 Specialty Production Systems

Specialty production refers to specialized agronomic practices as compared to those described in Section 2.2.2, *Agronomic Practices*, and unique soybean commodities as compared to those described in Section 2.2.3.2, *Raw and Processed Soybean Commodities*. Specialty soybean varieties are produced on approximately 12 percent of the US soybean acreage.

The Identity Preservation (IDP) production and distribution systems accommodate differences between commodity and specialty soybean. Distinct identity-preserved specialty soybean with such traits as clear hilum or high protein have been grown and successfully marketed for specific food uses in domestic and export markets for many years (Cui et al., 2004). The specialty soybean market produces soybeans that have specific physical or chemical characteristics to meet specific buyer requirements. A separate specialty soybean production channel has developed for the specialty soybean product that involves much smaller volumes than commodity soybean. Specialty soybeans can be grouped into several broad, but overlapping, categories, as listed below.

- Altered seed composition

- Low saturated fat
- High sucrose
- High oleic fatty acid
- Low linolenic fatty acid
- High protein

- Unique physical characteristics or uses
  - Clear hilum
  - Tofu
  - Natto
  - Soy milk

The categories are not exclusive. Soybeans of all specialty categories are often derived from varieties produced according to certified seed production practices, as described in Section 2.2.3.1, *Seed Production*.

Specialty soybeans often earn premiums (Pritchett et al., 2002). The greatest premium received by producers is for tofu soybeans, but these have higher production costs related to seed cost, technology fees, and transportation costs. Seed soybeans have additional costs related to more intensive production/management requirements and herbicide costs, although the seed technology fees and additional transportation costs remain important factors.

Product differentiation and market segmentation in the specialty soybean industry includes mechanisms to keep track of the grain (traceability) for IDP and quality assurance processes (e.g., ISO9001-2000 certification), as well as contracts between growers and buyers that specify delivery agreements (Sundstrom et al., 2002). Systems used by specialty soybean growers and end users to maintain identity of the production include:

- **Contracts –** written agreements detailing responsibilities and duties of both parties including premiums for reaching goals and penalties for failing to attain specifications.
- **Tracking and Traceability Systems –** correct labeling of all products (planting seeds and harvested material) and testing procedures for identifying and detecting acceptability of materials.
- **Quality Assurance Processes –** oversight on handling procedures, testing planting seeds, and testing harvested materials to determine acceptability of use and product requirements, and assuring testing procedures are appropriate.
- **Closed-Loop Systems –** the end-user supplies the planting seeds and guarantees to purchase final products. This may also require that the end-user conduct intermediate procedures such as planting, providing oversight during the growing season, harvesting, and transportation to processing plant.
- **Identity Preservation Systems –** using systems of identity preservation that have been shown to be successful in the past such as the seed certification systems conducted by members of the AOSCA. To maintain the purity of the soybean product, this production

system is based on controlling, tracking and documenting each step from seed production to end use (processing plants) (AOSCA, 2003).

The IDP practices used in specialty soybean production require that all equipment and storage facilities for specialty soybean must be clean of seed from other soybean varieties or plants, dirt, pathogens, and other foreign material. Some soybean contracts may require a special inspection of the handling and storage facilities. The specialty soybean for soybean foods may require special harvesting equipment because some of these soybeans are harvested before full maturity (e.g., edamame or vegetable soybean) (Cui et al., 2004). Weed control is extremely important for specialty soybean to maintain a high yield potential.

2.3 Physical Environment

Soil, water, and air affect, and are affected by, soybean agriculture. This section describes water quality, soil characteristics, and air quality impacted by soybean agriculture. Climatic conditions, in the context of potential climate change, are also discussed.

2.3.1 Soil

Soil consists of solids (minerals and organic matter), liquids, and gases. This body of inorganic and organic matter is home to a wide variety of fungi, bacteria, and arthropods, and is the growth medium for terrestrial plant life (USDA-NRCS, 2004). Soil is characterized by its layers that can be distinguished from the initial parent material due to additions, losses, transfers, and transformations of energy and matter (USDA-NRCS, 1999b). It is further distinguished by its ability to support rooted plants in a natural environment. Soil plays a key role in determining the capacity of a site for biomass vigor and production in terms of physical support, air, water, temperature moderation, protection from toxins, and nutrient availability. Soils also determine a site's susceptibility to erosion by wind and water, and flood attenuation capacity. Soil properties change over time: temperature, pH, soluble salts, amount of organic matter, the carbon-nitrogen ratio, and the numbers of microorganisms and soil fauna all vary seasonally, as well as over extended periods of time (USDA-NRCS, 1999b). Soil texture and organic matter levels directly influence its shear strength, nutrient holding capacity, and permeability.

Soil taxonomy was established by scientists to classify soils according to the relationship between soils and the factors responsible for their character (USDA-NRCS, 1999b). Soils are differentiated based on characteristics such as particle size, texture, and color, and classified taxonomically into soil orders based on observable properties such as organic matter content and degree of soil profile development (USDA-NRCS, 2010). From an ecological perspective, organic matter is probably the most vital component in maintaining quality soil; it is instrumental in maintaining soil stability and structure, reduces the potential for erosion, provides energy for microorganisms, improves infiltration and water holding capacity, and is important in nutrient cycling, cation exchange capacity[20], and the breakdown of pesticides (USDA-NRCS, 1996).

20 Soil cation exchange capacity is the ability of soil anions (negatively charged clay, organic matter and inorganic minerals such as phosphate, sulfate, and nitrate) to adsorb and store soil cation nutrients (positively charged ions such as potassium, calcium, and ammonium).

The interactions between the below-ground community of microorganisms and arthropods, plant root structure, and organic residues in the soil are central to soil ecological processes including decomposing organic material, subsequent nutrient cycling and release, and maintaining soil structure and composition. Cultivation directly impacts these biological attributes. Agronomic practices such as conventional tillage and mechanized harvesting machinery may disturb and expose the top soil surface layer, leaving the land prone to degradation or, conversely, improving soil health. Soil degradation can lead to a decline in water quality and contribute to the greenhouse effect by releasing sequestered carbon dioxide (CO_2) (Lal and Bruce, 1999). A decline in soil quality and soil resilience enhances the greenhouse effect through emissions of radiatively active gases (CO_2 and nitrous oxide, N_2O). Land that is prone to degradation is also more likely to adversely impact water quality and communities of organisms dependent on those water resources. While practices such as tillage, fertilization, pesticide application, and other management tools can improve soil health, they can also cause substantial damage if not properly used. Inappropriate agricultural practices can lead to increased erosion, soil compaction, degradation of soil structure, nutrient loss, increased salinity, change in pH, and reduced biological activity (USDA-NRCS, 2001).

Soybeans are grown in managed agricultural fields and are best suited to fertile, well-drained medium-textured loam soils, yet can be produced in a wide range of soil types (Berglund and Helms, 2003). Soybeans need a variety of macronutrients (such as nitrogen, phosphorus, potassium, calcium, magnesium, and sulfur) at various levels (NSRL, undated). They also require smaller amounts of micronutrients such as iron, zinc, copper, boron, manganese, molybdenum, cobalt, and chlorine. These micronutrients may be deficient in poor, weathered soils, sandy soils, alkaline soils, or soils excessively high in organic matter. As with proper nutrient levels, soil pH is critical for soybean development. Soybeans grow best in soil that is slightly acidic (pH 5.8 to 7.0); more alkaline soils (pH 7.3 or greater) negatively affect yield (Cox et al., 2003). Similarly, soils that are high in clay and low in humus may impede plant emergence and development (NSRL, undated). Soils with some clay content may retain moisture during periods of low precipitation than those with no clay content (Cox et al., 2003).

Conservation tillage methods (as described in Section 2.2.2.1, *Cropping Practices*) leave a crop mulch on the ground to provide a protective cover to the soil between seasons and improve soil fertility by maintaining nutrient-rich organic matter on the field. As conservation practices are adopted, soil organic matter increases help bind soil nutrients and significantly reduce the loss of cropland soil from runoff, erosion, and leaching over time (USDA-NRCS, 2006a; USDA-NRCS, 2006b). Organic matter builds up in the soil, absorbing CO_2 and helping to reduce a significant amount of greenhouse gas.

One of the most effective soil conservation methods to reduce wind and water erosion is through management of crop residue, which also benefits air and water quality and wildlife (USDA-NRCS, 2006a). Residue management that uses intensive tillage and leaves low amounts of crop residue on the surface results in greater losses of soil organic matter as compared to conservation tillage methods. Intensive tillage turns the soil over and buries the majority of the residue, stimulating microbial activity and increasing the rate of residue breakdown (USDA-NRCS, 1996). The residues left after conservation tillage increase organic matter and improve infiltration, soil stability and structure, and soil microorganism habitat (Fawcett and Caruana, 2001; USDA-NRCS, 2005).

The residue left over from conservation tillage practices increases organic matter in the top 3 inches of the soil and protects the surface from erosion while maintaining water-conducting pores. Soil aggregates in conservation tillage systems are more stable than those of conventional tillage due to the products of organic matter decomposition and the presence of soil bacteria and fungal hyphae (filamentous structures that composes the main growth) that bind aggregates and soil particles together (USDA-NRCS, 1996). Although soil erosion rates are dependent on numerous local conditions such as soil texture and crop, a comparison of 39 studies contrasting conventional and no-till practices concluded that, on average, no-till practices reduce erosion 488 times over conventional tillage (Montgomery, 2007). This reduction is enough to balance soil production with losses from erosion. From 1982 through 2003, erosion on US cropland dropped from 3.1 billion tons per year to 1.7 billion tons per year (USDA-NRCS, 2006a). This can partially be attributed to the increased effectiveness of weed control through the use of herbicides and the corresponding reduction in the need for mechanical weed control (Carpenter et al., 2002). Another factor is the Conservation Reserve Program described in Section 2.2.2.1, which provides financial incentives to farmers to use conservation tillage techniques or set aside land from agricultural use (USDA-FSA, 1999). Conservation tillage also minimizes soil compaction due to the reduced number of tillage trips.

While conservation tillage does have several benefits for soil health, some management concerns are associated with its use in certain circumstances. Under no-till practices, soil compaction may become a problem as tillage is useful for breaking up compacted areas (USDA-NRCS, 1996). Likewise, not all soils (such as wet and heavy clay soils) are suited for no-till. No-till practices may lead to increased pest occurrences that conventional tillage is better suited to managing (NRC, 2010) as described in Section 2.2.2.5, *Management of Disease and Non-Insect Pests*.

Other methods to improve soil quality include:

- Careful management of fertilizers and pesticides;
- Use of cover crops to increase plant diversity and limit the time soil is exposed to wind and rain; and
- Increase landscape diversity with buffer strips, contour strips, wind breaks, crop rotations, and varying tillage practices (USDA-NRCS, 2006a).

There are a multitude of organisms associated with soils, ranging from microorganisms to larger invertebrates such as worms and insects. The microorganisms that make up the soil community include bacteria, fungi, protozoa, and nematodes, as discussed in Section 2.4.3, *Soil Microorganisms*. These organisms are responsible for a wide range of activities that impact soil health and plant growth. Pesticide (including herbicide) use has the potential to affect soil quality due to potential impacts to the soil microbial community. The length of time that herbicides persist in soil is dependent on the concentration and rate of degradation by biotic and abiotic processes (Carpenter et al., 2002). Persistence is measured by the half-life or dissipation time, which equates to the length of time needed for the herbicide to degrade to half of its original concentration. Herbicide persistence in soil for mesotrione, isoxaflutole, and glufosinate (the three herbicides of which SYHT0H2 soybean is tolerant) is discussed in detail in the appendices.

2.3.2 Water Quality

The primary cause of agricultural nonpoint source (NPS) pollution is increased sedimentation from soil erosion, which can introduce sediments, manure, fertilizers, and pesticides to nearby lakes and streams (USEPA, 2005). Water quality risks from herbicide use are assessed by the EPA during the herbicide registration (and re-registration review) process and are addressed, as warranted, through EPA requirements such as application methodology and buffer zones between fields and water bodies, as well as monitoring for herbicide residues in surface and ground water. There are no federal water quality standards for the enzymes present in transgenic herbicide-tolerant plant varieties.

Additionally, add the following to the reference cited above:
Although meteorological (precipitation, temperature), morphological (land use, soil type), and environmental fate drivers affect water quality, anthropogenic practices (product use and management) are the most relevant, as these are generally under direct grower control on a soybean farm (Ramanarayanan et al., 2005). Certain agronomic practices, including conservation tillage and reduced fertilizer or pesticide application rates, may reduce adverse impacts. The EPA recommends several Best Management Practices for protecting water quality from agricultural NPS pollution (USEPA, 2008a):

- **Conservation Tillage** - leaving crop residue (plant materials from past harvests) on the soil surface reduces runoff and soil erosion, conserves soil moisture, helps keep nutrients and insecticides on the field, and improves soil, water, and air quality;
- **Crop Nutrient Management** - fully managing and accounting for all nutrient inputs helps ensure that nutrients are available to meet crop needs while reducing nutrient movement off of fields. It also helps prevent excessive buildup in soils and helps protect air quality;
- **Pest Management** - varied methods for keeping insects, weeds, disease, and other pests below economically harmful levels while protecting soil, water, and air quality; and
- **Conservation Buffers** - from simple grassed waterways to riparian areas, buffers provide an additional barrier of protection by capturing potential pollutants that might otherwise move into surface waters.

Conservation tillage (including no-till practices) has been shown to minimize surface water runoff and soil erosion. As discussed in Section 2.3.1, *Soil*, reduced tillage agricultural practices result in improved soil quality having high organic material that binds nutrients within the soil. An increased amount of plant residue on the soil surface reduces the effects of pesticide usage on water resources by forming a physical barrier to erosion and runoff, allowing more time for absorption into the soil, and slowing down soil moisture evaporation (Locke et al., 2008). Improving soil quality increases soil organic matter that promotes nutrient, pesticide, and herbicide binding to soil and prevents their loss to surface waters and groundwater from runoff, erosion, and leaching. Farmers planting genetically engineered herbicide-tolerant soybean varieties are more likely to use conservation tillage over conventional agricultural practices (Givens et al., 2009). The shift to genetically engineered varieties has resulted in reduced surface water run-off and soil erosion (Locke et al., 2008).

2.3.3 Air Quality

Agriculture is an important market sector impacting air quality. Agricultural air emission sources include: smoke from agricultural burning, vehicle exhaust from equipment used in tillage and harvest, soil particulates (dust) from tillage, pesticide drift from spraying, and N_2O emissions from the use of nitrogen fertilizer (Aneja et al., 2009). Certain pesticides may volatilize after application to soil or plant surfaces and may also move as constituents of dust in wind eroded soils (Vogel et al., 2008). Agricultural air pollution also contributes to odor. After deposition of reactive nitrogen in waterways, eutrophication and acidification can result and affect biodiversity. Air quality can be improved by using conservation tillage methods in place of conventional (intensive) tillage as less dust is produced and fewer pollutants are emitted from farm equipment.

2.3.4 Climate

Agriculture is responsible for an estimated 6.3 percent of all human-induced greenhouse gas (GHG) emissions in the US (USEPA, 2012a), the second-highest source. Agricultural soil management practices, including nitrogen-based fertilizer application and cropping practices, are the largest source of N_2O emissions in the US, accounting for 67.9 percent of the total N_2O emissions attributable to agricultural land uses (USEPA, 2012a). Agriculture sources of methane (CH_4) emissions are primarily associated with enteric emissions of gas from cattle and manure management, and are responsible for 29 percent of CH_4 emissions from anthropogenic activities in the US (USEPA, 2012a). CO_2 is also a significant GHG associated with particular classes of crops planted, geographic location and soil types, and energy consumption (Cole et al., 1997).

GHGs may be affected by the class of crop planted and soil types; trees, grasses and field crops each play a slightly different role in the global cycle of GHGs (Cole et al., 1997). For example, emissions of N_2O, produced naturally in soils through microbial nitrification and denitrification, can be dramatically influenced by fertilization, introduction of grazing animals, cultivation of nitrogen-fixing crops and forage, retention of crop residues (i.e., no-till conservation), irrigation, and fallowing of land (USDS, 2010). These agricultural practices can influence the decomposition of carbon-containing organic matter sequestered in soil, resulting in CO_2 loss to the atmosphere.

In agricultural soils, mineral and organic soils sequester approximately six times as much carbon as is emitted from these soils through liming and urea fertilization (USEPA, 2012a). The mineral soil carbon sequestration is largely due to the conversion of cropland to permanent pastures and hay production, a reduction in summer fallow areas in semi-arid areas, an increase in the adoption of conservation tillage practices, and an increase in the amounts of organic fertilizers (i.e., manure and sewage sludge) applied to agriculture lands. EPA has identified regional differences in GHG emissions associated with agricultural practices on different soil types (USEPA, 2012a). Mineral soils contain from 1 to 6 percent organic carbon by weight; conversion of such soils from their native state to agricultural uses can cause as much as 50 percent of the natural organic carbon to decompose and be released to the atmosphere. In contrast to mineral soils, organic soils may contain as much as 20 percent carbon by weight. When such soils are prepared for agricultural use, they are aerated, accelerating decomposition and release of CO_2 to the atmosphere.

Tillage contributes to the release of GHGs from soil because of the loss of CO_2 to the atmosphere from the exposure and oxidation of soil organic matter (Baker et al., 2005). Reduced tillage can limit the loss of CO_2 to the atmosphere by preventing exposure and oxidation of soil organic matter (Baker et al., 2005; CAST, 2009). In general, conservation tillage strategies are associated with more stable and increased carbon sequestration due to a net reduction in CO_2 emissions (Lal and Bruce, 1999; West and Marland, 2002). Recent literature, however, suggests that the relationship between conservation tillage and increased carbon sequestration requires more study, as soil depth level and seasonal sampling bias may inadvertently affect measurements (Baker et al., 2007; Potter et al., 1998). Increased N_2O emissions as a result of conservation tillage strategies may offset any gains achieved through increased carbon sequestration (Gregorich et al., 2005). A broad generalization regarding the impact of tillage strategy and N_2O emissions is difficult to make, 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).

The impacts of genetically engineered crop varieties on climate change are dependent on many variables including cropping systems, production practices, geographic distribution of activities, and individual grower decisions. Agriculture influences emissions that may contribute to climate change, and climate change, in turn, potentially affects agriculture through shifts in precipitation patterns and temperature ranges. The production of genetically engineered soybeans is expected to result in lower GHG emissions because fuel use would be reduced due to less frequent herbicide applications and soil cultivation (Brookes and Barfoot, 2010). Most studies of corn, rice, sorghum, soybean, wheat, common forages, cotton, some fruits, and irrigated grains project likely climate-related yield increases of 5 to 20 percent (Field et al., 2007). However, this positive impact would not be observed evenly across all regions as certain areas of the US are expected to be negatively impacted by substantially reduced water resources (i.e., increased drought). In addition, the current range of weeds and pests of agriculture is expected to change in response to climate change (USGCRP, 2009).

2.4 Biological Resources

The biological resources described in this section include animals, plants, soil microorganisms, biodiversity, and soybean gene movement. Threatened and endangered species are discussed in Chapter 5.

2.4.1 Animal Communities

Soybean fields are host to many animal species. During the spring and summer months, soybean fields provide browse for rabbits, deer, rodents, other mammals, and birds such as upland gamebirds. Fields also provide a forage base for insects (Palmer et al., undated). During the winter months, leftover and unharvested soybeans provide a food source for wildlife; however, soybeans are poorly suited for meeting nutrient needs of wildlife, such as waterfowl, that require a high-energy diet (Krapu et al., 2004b).

As discussed in Section 2.2.2.1, *Cropping Practices*, farmers that have shifted from conventional agricultural practices to conservation tillage and no-till practices have also been more inclined to plant genetically engineered herbicide-tolerant soybean varieties than farmers retaining conventional practices (Givens et al., 2009). The increased use of conservation tillage practices has benefitted wildlife through improved water quality, availability of waste grain, retention of cover in fields, and increased populations of invertebrates (Sharpe, 2010). Conservation tillage practices that leave greater amounts of crop residue serve to increase the diversity and density of birds and mammals (USDA-NRCS, 1999a). Increased residue also provides habitat for insects and other arthropods, increasing this food source for insect predators. Insects are important during the spring and summer brood rearing season for many upland game birds and other birds, as they provide a protein-rich diet to fast growing young, as well as a nutrient-rich diet for migratory birds (USDA-NRCS, 2003).

Insects and other invertebrates can be beneficial to soybean production, providing biological services such as nutrient cycling and preying on plant pests. Although soybean is typically cleistogamous and not insect-pollinated, some varieties may be chasmogamous and insect-mediated pollination has been reported (Ahrent and Caviness, 1994; Erickson, 1975). Soybean cultivars vary in their rate of nectar secretion and some varieties have been reported to be attractive to honeybees (Ahrent and Caviness, 1994). Conversely, there are many insects and invertebrates that are detrimental to soybean crops (Palmer et al., undated; Whitworth et al., 2012), including:

- Bean leaf beetle (*Cerotoma trifurcata*)
- Beet armyworm (*Spodoptera exigua*)
- Blister beetle (*Epicauta* spp.)
- Corn earworm (*Helicoverpa zea*)
- Grasshopper (*Acrididae* spp.)
- Green cloverworm (*Hypena scabra*)
- Seed corn beetle (*Stenolophus lecontei*)
- Seed corn maggot (*Delia platura*)
- Soybean aphid (*Aphis glycines*)
- Soybean looper (*Pseudoplusia includens*)
- Soybean stem borer (*Dectes texanus*)
- Spider mites (*Tetranychus urticae*)
- Stink bug (green [*Acrosternum hiliare*] and brown [*Euschistus* spp.])
- Velvetbean caterpillar (*Anticarsia gemmatalis*)

As described in Section 2.2.2.4, *Management of Insects*, insects are considered less problematic than weeds in US soybean production; however, insect injury can impact yield, plant maturity, and seed quality. Consequently, insect pests are sometimes managed during the growth and development of soybean to enhance soybean yield (Aref and Pike, 1998).

2.4.2 Plant Communities

Soybean fields are typically bordered by other agricultural fields, pastures, woodlands, or grasslands; natural plant communities adjacent to fields may be important to biodiversity. From an agronomic perspective, the most important members of a surrounding plant community are those that can behave as weeds when they have invaded fields, as discussed in Section 2.2.2.6, *Management of Weeds*. Soybean agronomic performance can be reduced by weed competition for water, nutrients, and light. Adjacent natural or native plant communities that do not behave as weeds are important from an ecological perspective but not agronomically.

Plants are classified as annuals, biennials, or perennials. An annual is a plant that completes its lifecycle in 1 year or less and reproduces only by seed. Biennials are plants that complete their life cycles in 2 years. Perennials are plants that live for more than 2 years. Plants are also classified as broadleaf (dicots) or grass (monocots). Plants can reproduce by seeds, rhizomes (underground creeping stems), or other underground parts. Many plant species occur as weeds in fields.

Weed Resistance to Herbicides

Herbicide *resistance* is generally defined by the Weed Science Society of America (WSSA)[21] as "the inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type. In a plant, resistance may be naturally occurring or induced by such techniques as genetic engineering or selection of variants produced by tissue culture or mutagenesis" (WSSA, 2013). Increasing the intensity of herbicide use (frequency and number of acres treated) increases the probability of selecting an herbicide-resistant plant (Boerboom and Owen, 2006) from a population of a weed species. WSSA defines herbicide *tolerance* as "the inherent ability of a species to survive and reproduce after herbicide treatment. This implies that there was no selection or genetic manipulation to make the plant tolerant; it is naturally tolerant" (WSSA, 2013). A number of crops and weeds exhibit natural tolerance to some herbicides by preventing their absorption and/or translocation, or by rapidly metabolizing the herbicide to a non-toxic form (Loux et al., 2008). Natural herbicide tolerance has been observed in weed species such as waterhemp, common cocklebur, Powell amaranth, ragweed (common and giant), and kochia (Carpenter et al., 2002).

Herbicides do not cause the mutations that result in weeds developing resistance. Rather, an extremely rare genetic trait that allows a weed to survive any given herbicide may exist in the natural population. That gene is more likely to be found and increase in occurrence when one herbicide is used frequently. Repeated use of that herbicide will expose the weed population to selection pressure that may lead to an increase in the number of surviving resistant individuals in the population (HRAC, 2011). In other words, plants susceptible to the applied herbicide will die or have decreased reproduction; those few having some type of natural resistance will survive and reproduce. Resistant weeds that initially appear as isolated plants or patches in a field can quickly spread to dominate the population and the soil seed bank (Vencill et al., 2012).

21 www.wssa.net

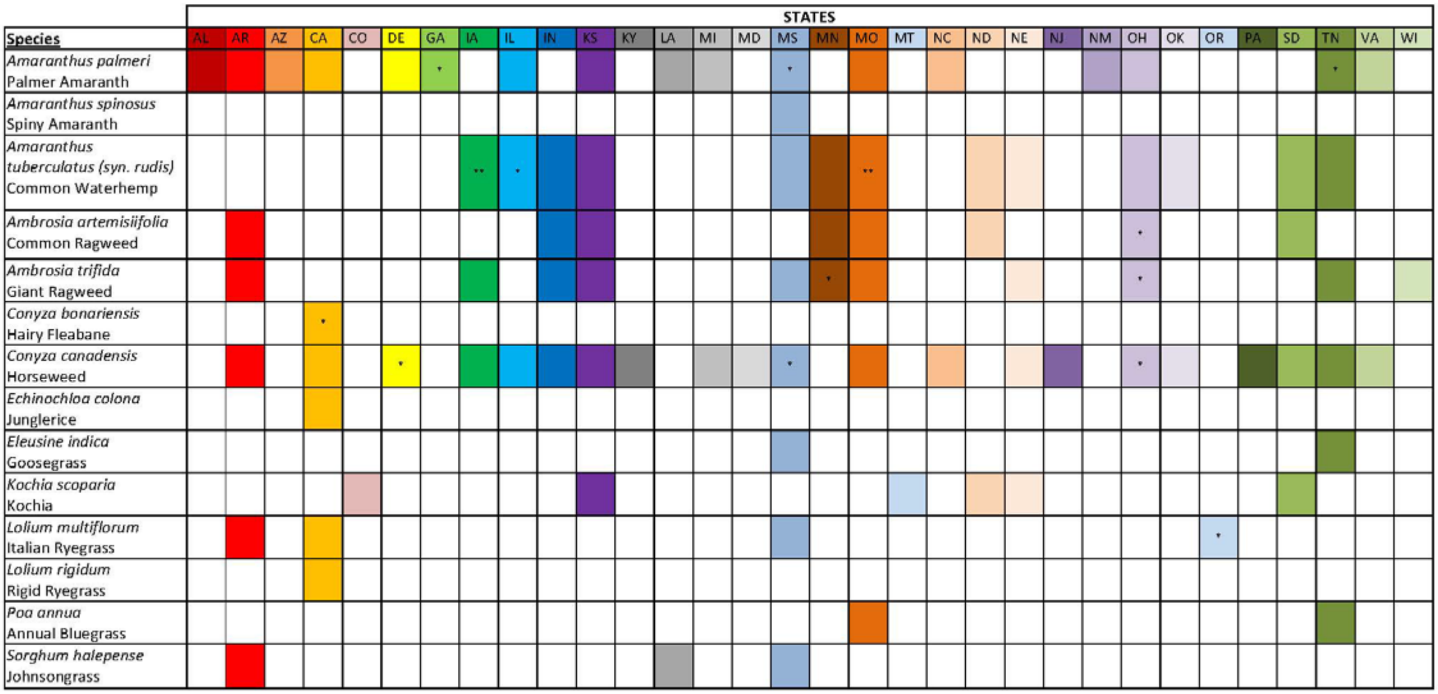
The reproductive biology of the particular weed species appears to be a factor contributing to the spread of resistant biotypes. For example, resistant biotypes of marestail (*Conyza canadensis*), which produces a large number of wind dispersed seeds contributing to a rapid distribution, have been found in many states in the Northeast, Midwest, and South. Other species such as common ragweed (*Ambrosia artemisiifolia*) produce seeds that do not have features that allow for such easy distribution by the wind. As a consequence, biotypes of resistant ragweed have been found in only seven sites in the Midwest, North and South compared to 24 sites for *C. canadensis* (Heap, 2013a).

The risk of weeds developing resistance to herbicides and the potential impact of resistance on the usefulness of an herbicide varies greatly across different modes of action and depends on a combination of factors including selection pressure, herbicide soil residual activity, herbicide chemistry, the rate of seed production, and the level of genetic variation in plants. Another major factor contributing to the development of herbicide-resistant weeds is poor weed control management practices by the growers. These include application of herbicides at rates below those indicated on the EPA-approved label for the weed species and reliance on a single herbicide for weed control without the use of other cultural control methods (i.e., pre-plant and in-crop tillage) (Peterson et al., 2007). Weed management programs that integrate the use of herbicides with different modes of action and short residual activity times in soil reduce selection pressure (Prather et al., 2000). Growers have been successfully managing herbicide-resistant weeds for decades by using alternative herbicides and cultural methods such as tillage or crop rotation (and often necessarily incorporating rotation of herbicide modes of action). The occurrence of an herbicide-resistant weed biotype generally does not end the useful lifespan or preclude the effective use of the herbicide in question as part of an overall weed management system.

Globally, 397 weed biotypes have developed resistance to 21 herbicide modes of action (Heap, 2013a). In the US, 142 weed biotypes have developed resistance to herbicides. Some populations of certain weed species have developed resistance to multiple herbicide classes (Boerboom and Owen, 2006). For example, some tall waterhemp plants are known to be resistant to up to four herbicide modes of action (McMullan and Green, 2011; Tranel, 2010). Most herbicides affect a single specific site of action, and that site is usually under the control of a single gene, or at most a few genes. Annual weeds are more likely to evolve resistance because they typically produce abundant seeds and have more genetic diversity than species that reproduce vegetatively.

For many years, growers were able to effectively control or suppress virtually all weeds in soybean with glyphosate alone. However, a number of weed species have developed resistance to glyphosate, and the number of acres infested with resistant biotypes has been increasing. To date, 24 weed species resistant to glyphosate have been identified globally, 14 of which are found in the US (Heap, 2013c). Glyphosate-resistant weed biotypes in US soybean fields vary by state (Figure 2-4). Each of these species is generally controlled by mesotrione, isoxaflutole, or glufosinate except hairy fleabane, Italian ryegrass, and rigid ryegrass (Syngenta, 2012c), which are not, however, typically problematic in soybean fields (see Table 2-7, *Common Troublesome Weeds in Treated Soybean Fields, 2006-2008*). Other herbicides are available to control these species, and could be appropriately used in an integrated weed management program.

Figure 2-4 Glyphosate-Resistant Weeds in US Soybean Fields



Source: (Heap, 2013d)

Note that presence of a population is unrelated to prevalence.

* indicates at least one population in that state possesses resistance to glyphosate and another herbicide.

**indicates at least one population in that state possesses resistance to glyphosate and two other herbicides.

All of the weed species that are resistant to glyphosate are fully or partially controlled by one or more of the herbicides to which SYHT0H2 soybean is tolerant, as discussed in the appendices. However, certain biotypes of three weed species have developed resistance to HPPD-inhibiting herbicides (including mesotrione and/or isoxaflutole) or glufosinate when applied to the weed post-emergence:

- Certain common waterhemp (*Amaranthus tuberculatus* (*syn. rudis*)) populations have evolved resistance to post emergence applications of HPPD-inhibiting herbicides including mesotrione and isoxaflutole in US fields where full rates of an HPPD herbicide have been used in multiple years during seed corn production (Heap, 2013b);
- Two Palmer amaranth (*Amaranthus palmeri*) populations have recently been reported to be resistant to HPPD inhibitors (Heap, 2013b); and
- Certain Italian ryegrass (*Lolium multiflorum*) populations in US fields have been shown to be resistant to glufosinate (Heap, 2013c).

The conditions leading to populations of these weeds evolving resistance to these herbicides occurred during a time of less diversity in herbicide usage and cultural practices. In an Illinois biotype of common waterhemp found to be resistant in 2009, for example, an absence of crop rotation and herbicide rotation, and failure to use mixed products containing multiple modes of herbicidal action in a corn seed production field contributed to the development of HPPD-inhibitor resistance

(Hausman et al., 2011). Crop management practices in seed corn production fields are not representative of fields in which corn hybrids or soybean varieties are grown commercially.

Modeling predicts that herbicide-resistant weeds can evolve after only 4 or 5 years of continuous herbicide use (Neve et al., 2011a; Neve et al., 2011b). This prediction is consistent with observations based on actual glyphosate use. Implementing additional weed management strategies, such as diversity of herbicide modes of action providing full, effective season-long weed control, could delay or mitigate herbicide resistance in Palmer amaranth, for example, for at least 20 years (Neve et al., 2011a).

Plant communities adjacent to agricultural fields may be affected by spray drift or volatilization of herbicides applied to the nearby crops. Spray drift and volatilization are managed by adherence to the application requirements stated on EPA-approved herbicide labels.

2.4.3 Soil Microorganisms

Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva et al., 2004). The main factors affecting microbial population size and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (as providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva et al., 2004), as described in Section 2.3.1, *Soil*. Plant roots, including those of soybeans, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere. Microbial diversity in the rhizosphere may be extensive and different from the microbial community in bulk soil (Garbeva et al., 2004).

Decomposers (such as bacteria, actinomycetes [filamentous bacteria], and saprophytic fungi) degrade plant and animal remains, organic materials, and some pesticides (USDA-NRCS, 2004). Other organisms (such as protozoa, mites, and nematodes) consume the decomposer microbes and release macro- and micronutrients, making them available for plant usage. Mutualists (mycorrhizal fungi, nitrogen-fixing bacteria, and some free-living microbes) have co-evolved with plants and supply nutrients to and obtain food from their plant hosts (USDA-NRCS, 2004).

Members of the bacterial families *Rhizobiaceae* and *Bradyrhizobiaceae* form a highly complex and specific symbiotic relationship with leguminous plants, including soybean (Gage, 2004). The nitrogen-fixing plant/microbe symbiosis results in the formation of root nodules, providing an environment in which differentiated bacteria (bacteroids) are capable of reducing (fixing) atmospheric nitrogen. The product of nitrogen fixation, ammonia, then can be used by the plant. In soybean, atmospheric nitrogen is fixed into ammonia through a symbiotic association with the bacterium *B. japonicum* (Farooq and Vessey, 2009). Since neither soybean nor *B. japonicum* is native to North America, if a field has not been planted with soybean in the last 3 to 5 years, either the seed or seed zone must be inoculated with the bacteria prior to soybean planting (Berglund and Helms, 2003; Pedersen, 2007).

2.4.4 Biodiversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem, and provides valuable genetic resources for crop improvement (Harlan, 1975). With reference to agriculture, biodiversity supports pollination, biological control, and nutrient recycling. These processes support competition against pests by natural enemies, improve soil structure, facilitate soil and water conservation, suppress disease, control the local microclimate and local hydrological processes, and detoxify noxious chemicals (Altieri, 1999).

Relative to any natural ecosystem, species abundance and richness will generally be less in intensively managed agroecosystems.[22] However, biomass may be higher as a result of introduced fertilizers and additional water that would not be present naturally. The degree of biodiversity in an agroecosystem depends on four primary characteristics (Altieri, 1999; Palmer et al., undated):

- Diversity of vegetation within and around the agroecosystem;
- Permanence of various crops within the system;
- Intensity of management; and
- Extent of isolation of the agroecosystem from natural vegetation.

Tillage, seed bed preparation, monoculture crop planting, pesticide use, fertilizer use, and harvest may all limit the diversity of plants and animals in an agricultural field (Lovett et al., 2003). Herbicide use in agricultural fields may impact biodiversity by decreasing weed species and other non-weedy plants present in the field and the insects, birds, and mammals that utilize those weeds.

Reducing biodiversity may result in a need for costly management practices in order to provide the biological functions of pollination, genetic introgression, biological control, and nutrient recycling (Altieri, 1999). Woodlots, fencerows, hedgerows, wetlands, and the like have been used to introduce biodiversity into large scale monocultures. Other enhancement strategies in agroecosystems include intercropping (planting of two or more crops simultaneously to occupy the same field), agroforestry, crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically for the purpose of incorporating it into the soil in order to provide nutrients and organic matter), addition of organic matter (compost, green manure, animal manure, etc.), and windbreaks (Altieri, 1999).

Agriculture interacts with biodiversity at the crop, farm, and/or landscape level (Carpenter, 2011). In this EA, crop diversity refers to the absence of genetic uniformity within crops, farm level diversity refers to the level of complexity of organisms within the boundaries of a farm, and landscape level diversity refers to land use patterns beyond the farm boundaries (Carpenter, 2011). Each of these levels is described in further detail below.

2.4.4.1 Crop Diversity

Genetic diversity in crops is beneficial as it may improve yields, pest and disease resistance, and quality in agricultural systems. Greater varietal and intra-species diversity enables growers to maintain productivity over a wide range of conditions (Krishna et al., 2009). The adoption of genetic

22 An agroecosystem is the organisms and environment of an agricultural area when considered as an ecosystem.

engineering technology might reduce grower demand for crop genetic diversity because breeding programs could concentrate on a smaller number of high value cultivars, which could reduce the availability of, and demand for, non-genetically engineered varieties (Carpenter, 2011; Krishna et al., 2009). However, several studies involving genetically engineered soybeans and cotton have found this not to be the case, indicating that the introduction of genetically engineered cultivars has not decreased crop species diversity (Carpenter, 2011; Krishna et al., 2009).

Concern about the loss of genetic variability for crops has led to the establishment of a worldwide network of gene banks. The USDA Soybean Germplasm Collection, which is part of the National Plant Germplasm System, acquires, maintains, and evaluates soybean germplasm and distributes seed samples to scientists in 35 states (Peregrine, 2003). Nationwide, there are over 21,850 soybean varieties (USDA-ARS, 2012) that provide a vast reservoir of genetic diversity for crop development.

2.4.4.2 Farm-Level Biodiversity

As noted previously, agricultural practices have the potential to impact biodiversity at the farm level by affecting local biota, including birds, wildlife, invertebrates, soil microorganisms, and other plant populations. For example, increased adoption of conservation tillage practices is associated with the use of genetically engineered herbicide-tolerant crops (Givens et al., 2009). Less tillage provides more wildlife habitat by allowing other plants to establish between crop rows; this benefits biodiversity but may adversely affect crop productivity. Conservation tillage also leaves a higher rate of plant residue and increases soil organic matter, which benefit soil biota by providing additional food sources (energy) (USDA-NRCS, 1996) and increasing the diversity of soil microorganisms, as discussed in Section 2.4.3, *Soil Microorganism*s. In addition, invertebrates that feed on plant detritus and the other animals (invertebrates, birds, reptiles, and mammals) that prey on them may benefit from conservation tillage practices (Carpenter, 2011).

Herbicide use in agricultural fields may impact biodiversity by decreasing weed or non-weed plant quantities or causing a shift in weed or non-weed plant species present in the field, which could affect the insects, birds, and mammals that utilize these species. The quantity and type of herbicide use associated with crops is dependent on many variables, including cropping systems (including non-genetically engineered and genetically engineered varieties), type and abundance of weeds, production practices, and individual grower decisions.

2.4.4.3 Landscape-Level Biodiversity

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

The use of herbicides also has the potential to impact biodiversity at the landscape level. Increased conservation tillage practices associated with herbicide-tolerant crops at the farm scale but implemented over large areas may regionally increase certain populations of invertebrates and wildlife that benefit from conservation tillage, whereas the species dependent on the targeted weeds may be negatively impacted. For example, it has been suggested that reductions in monarch butterfly (*Danaus plexippus*) populations overwintering in Mexico might be attributed in part to loss of host milkweed (*Asclepias syriaca*) plants in the Corn Belt from the extensive use of glyphosate on corn and soybean fields (Brower et al., 2011; Pleasants and Oberhauser, 2012). Other factors implicated in the decline in overwintering populations include loss of wintering habitat in Mexico (Brower et al., 2011). However, monarch populations are very dynamic because of the high reproductive potential of this species and population shifts cannot be easily correlated with one factor (Davis, 2011). Potential reductions in landscape-level biodiversity can also result from the effects of herbicides on non-target plant species. Such potential impacts on non-target plants are managed by adherence to the application requirements stated on EPA-approved herbicide labels.

The crop protection industry has taken a proactive approach to helping farmers protect and enhance farm-level and landscape-level biodiversity through extensive outreach and education programs. For example, along several programs sponsored or supported by one or both companies, Syngenta and Bayer provide support to the Coalition for Urban/Rural Environmental Stewardship[23] and the Center for Integrated Pest Management.[24] These programs promote environmental stewardship and provide information and guidance on biodiversity issues such as conservation buffers, wildlife habitat, wildlife stewardship, and pollinator health and protection.

2.4.5 Gene Movement in the Natural Environment

For a description of gene flow relating to soybean production, see APHIS PPRA for this petition, 12-215-01. Gene flow is the movement of genes from one population to another, conferring new traits – the biophysical characteristics of the source organism – to individuals of the recipient population (Quist, 2010). This happens by cross-pollination (also called hybridization): the pollination of members of one population or genetic pool with pollen from another. Vertical gene transfer is genetic information that is passed 'down' from parents to offspring or related species. Horizontal gene transfer is the passage of genes from one organism to an unrelated one by means other than inheritance. Vertical gene flow often results in introgression, the establishment of alleles (gene variants), or wholly new genes (as is the case with transgenes) in the recipient population. There is no evidence that horizontal gene transfer can naturally occur between unrelated plant species (Stewart et al., 2003).

Characteristics that favor natural hybridization between two populations of related species include (Mallory-Smith and Zapiola, 2008):

- Presence of feral populations and uncontrolled volunteers;
- Presence of a high number of highly compatible relatives;
- Self-incompatibility;

23 http://curesworks.org

24 http://pesticidestewardship.org

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

None of these characteristics occur in soybeans. Soybean is not native to the US and there are no feral or weedy relatives. Soybean is a self-pollinated species, propagated by seed (OECD, 2000a), and does not require insects to pollinate flowers. Flowers are typically cleistogamous but, in some cultivars and under some conditions, may be chasmogamous and insects may transfer pollen (Ahrent and Caviness, 1994; Chiari et al., 2005; Erickson, 1975; Ray et al., 2003). Insect-mediated cross-pollination to adjacent plants may occur through pollinating insects such as honeybees. Incidental pollen transfer by nonpollinating insects occurs at very low frequency (typically less than 1 percent with narrow row spacing) (Caviness, 1966; Ray et al., 2003; Yoshimura et al., 2006). There is little potential for gene flow from one plant to another.

Gene movement can be enabled by dormancy or volunteer characteristics, which can allow the plant to survive outside of normal agriculture. Cultivated soybean seed rarely displays any dormancy characteristics and only under certain environmental conditions grows as a volunteer in the year following cultivation (OECD, 2000a). Volunteer soybean seed is typically not viable after the winter period in the northern US. In the southern US soybean seed may remain viable over the winter and germinate the following spring (Carpenter et al., 2002; OECD, 2000a). However, volunteers do not compete well with the succeeding crop and are easily controlled mechanically or chemically. There is a wide range of herbicides available to control volunteers of herbicide-tolerant soybean (York et al., 2005). As described in Section 2.1, *Soybean Biology, Glycine max* is not weedy in character and is not found outside of cultivation in North America.

2.5 Public Health

Public health concerns related to soybeans stem from human consumption of soybean and soybean food products, animal (livestock) consumption of soybean feed products, and the indirect effect on human health and worker safety from laborers' exposure to agricultural chemicals.

2.5.1 Human Health

Soybean oil makes up 94 percent of the soybean food ingredients consumed by humans (OECD, 2001b). The essential amino acids required by humans are present in soybean proteins. Soy protein products are added to a number of meat, dairy, bakery, and cereal products as protein extenders. Soy sprouts, baked soybeans, roasted soybeans, soy flour, and traditional soy foods (miso, soy milk, soy sauce and tofu) round out the soy-based products present in the human diet.

Soybeans also contain several antinutrients, with potential effects on humans, that are offset by heating or processing (OECD, 2001b):

- Protease inhibitors are active against trypsin and chymotrypsin, and interfere with the digestion of proteins resulting in decreased animal growth. The activity of these inhibitors is destroyed when the bean or meal is toasted or heated during processing.
- Lectins are proteins that bind to carbohydrate-containing molecules. Lectins in raw soybeans can inhibit growth and cause death in animals and, potentially, in humans. Lectins are rapidly degraded upon heating.
- Soybeans naturally contain a number of isoflavone compounds reported to possess biochemical activity, including estrogenic, anti-estrogenic, and hypocholesterolemic effects, in mammalian species. Processing significantly reduces isoflavone isomers in the final soy products.
- The low molecular weight carbohydrates stachyose and raffinose are considered antinutrients due to the gas production and resulting flatulence caused by their consumption. Further processing of soybean meal into concentrate or isolate reduces or removes these oligosaccharides.
- Phytic acid chelates mineral nutrients (including calcium, magnesium, potassium, iron, and zinc), rendering them unavailable to humans consuming the soybeans.
- Saline extracts of soybeans have been reported to contain several antigenic proteins which can orally sensitize humans. The presence of these allergenic proteins in the diet of hypersensitive individuals can cause severe adverse reactions in the gastrointestinal tract.

Nontransgenic soybean varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the US for human food or animal feed safety prior to release in the market. Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from genetically engineered soybean must be in compliance with all applicable legal and regulatory requirements.

Genetically engineered organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market (USDHHS-USFDA, 1992). Although voluntary, thus far all applicants who have wished to commercialize a genetically engineered variety of a plant that would be included in the food supply have completed a consultation with the FDA. In such a consultation, a developer who intends to commercialize a bioengineered food consults with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food (USDHHS-USFDA, 1997). This process includes the developer's submission of the following information to the FDA:

- The purpose or intended technical effect of the modification, and its expected effect on the composition or characteristic properties of the food or feed.
- The identity and function of expression products encoded by the introduced genetic material, including an estimate of the concentration of any expression product in the bioengineered crop or food derived thereof.

- Any known or suspected allergenicity or toxicity of expression products and the basis for concluding that foods containing the expression products can be safely consumed.
- Comparison of the composition or characteristics of the bioengineered food to that of food derived from the parental variety or other commonly consumed varieties with special emphasis on important nutrients and toxicants that occur naturally in the food.
- Discussion of the whether the potential for the bioengineered food to induce an allergic response has been altered by the genetic modification.
- Any other information relevant to the safety and nutritional assessment of the bioengineered food.

FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require. Several international agencies also review safety associated with food and feed items derived from genetically engineered crops; these agencies include the European Food Safety Agency (EFSA) and the Australia and New Zealand Food Standards Agency (ANZFS).

Foods derived through biotechnology also undergo a comprehensive safety evaluation before entering the world market, including reviews under standards set by the CODEX, the EFSA, and the World Health Organization (FAO and WHO, 2009; Hammond and Jez, 2011). Food safety reviews compare the compositional characteristics of the genetically engineered crop with nontransgenic, conventional varieties of that crop (FAO and WHO, 2009). This comparison also evaluates the composition of the modified crop under actual agronomic conditions, including various agronomic inputs. Composition characteristics evaluated in these comparative tests include moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and antinutrients.

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

2.5.2 Worker Safety

Workers engaged in soybean production may encounter insecticides, herbicides, fungicides, or fertilizers that do not pose a worker health or safety risk when used in accordance with the agriculture-specific requirements established by EPA in the Worker Protection Standard (WPS) that protects field workers from the hazards of chemical exposure (USEPA, 1992). The Occupational Safety and Health Administration requires all employers to protect their employees from hazards associated with chemicals.

Most soybean acreage in the US is treated with pesticides; herbicides are the most commonly applied pesticides, but some acres are treated with insecticides and/or fungicides. Changes in acreage, crops, or farming practices can affect the amounts and types of pesticides used and thus change the risks to workers. Registered pesticides must have use restrictions that, if followed, have been determined to be protective of worker health.

EPA-approved measures to limit worker exposure to pesticides are listed on product labels. The WPS requires certain actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protection to more than 2.5 million agricultural workers who work with pesticides at more than 600,000 workplaces on farms, forests, nurseries, and greenhouses (USEPA, 2012c). 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.

2.5.3 Animal (Livestock) Health

Animal agriculture consumes 98 percent of the soybean meal produced in the US (GINA, 2011; Soyatech, 2012). Poultry consume more than 48 percent of domestic soybean meal (13 million tons), with soy oil increasingly replacing animal fats and oils in broiler diets (Soystats, 2010). Other animals fed domestic soybean (by crop volumes consumed) include swine (26 percent), beef cattle (12 percent), dairy cattle (9 percent), other (e.g., farm-raised fish; 3 percent), and household pets (2 percent) (Soystats, 2010). Soybean can be the dominant component of livestock diets: for example, upwards of 66 percent of poultry protein intake is derived from soy (Waldroup and Smith, undated).

Because of the presence of anti-nutritional factors in raw soybean, there is very limited consumption of the unprocessed bean. Most livestock is fed the protein-enriched seed meal left after extraction of soybean oil. Treated whole beans, hulls and the vegetative parts of the plant in a fresh or conserved state are also used to a limited extent, primarily for cattle. Soybean has a long history in the US as a nutritious grazing forage, hay, and silage crop for livestock (Blount et al., 2009). Soybean may be harvested for hay or grazed from the flowering stage to near maturity; the best soybean for forage is in the beginning pod stage. For silage, it should be harvested at maturity before leaf loss, and mixed with a carbohydrate source, such as corn, for optimal fermentation characteristics. Varieties of soybean have been developed specifically for grazing and hay, but use of the standard grain varieties are recommended by some because of the whole plant feeding value (Weiderholt and Albrecht, 2003).

Similar to the regulatory control for direct human consumption of soybean under the FFDCA, it is the responsibility of livestock feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from genetically engineered 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 genetically engineered plants in animal feed into the market, following the process described above. Thus far all applicants who wish to commercialize a genetically engineered variety that will be included in the feed supply have completed a consultation with the FDA.

2.6 Socioeconomic Factors

See APHIS EA for 11-202-01 for discussion of socioeconomic issues related to soybean production, including domestic economic environment, and foreign economic environment.

2.6.1 Domestic Trade Environment

In 2010, 76 million acres of soybeans were cultivated in the US, yielding 3.3 billion bushels at a value of $38.9 billion (USDA-NASS, 2011a). The top ten producing states (Iowa, Illinois, Minnesota, Indiana, Nebraska, Ohio, Missouri, South Dakota, Kansas, and North Dakota) accounted for more than 80 percent of this production. US inventory in 2010 (2009 remaining stocks plus 2010 production) totaled 3.5 billion bushels. Almost all of the US soybean supply (95.6 percent in 2009/10) comes from domestic production and almost all of this supply (96.8 percent) is either exported or crushed for meal and oil (O'Donoghue et al., 2011; USDA-ERS, 2011a; USDA-ERS, 2011c). Approximately 43 percent of US soybean is destined for the export market (USDA-ERS, 2010b) and the remaining 57 percent of US soybean is 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. Only a small proportion of the soybean crop is consumed directly by humans (GINA, 2011).

Managing production costs is a major component of the economics of producing a soybean crop. Key cost decisions include the choice of which soybean varieties to plant, the amount of fertilizer to apply, and which herbicide program to use. USDA-ERS conducts production cost surveys every 4 to 8 years for each commodity as part of the annual Agricultural Research Management Survey (ARMS). Forecasted total 2012 operating costs were $144.21 per planted soybean acre and forecasted 2013 operating costs were $146.40. The projected 2013 total costs were comprised of purchased seed ($61.48), fertilizer and soil amendments ($22.91), other chemicals ($17.54), fuel, lubricant, and electricity ($22.18), repairs ($14.71), other variable expenses ($0.15), and interest on operating capital ($0.55) (USDA-ERS, 2012c). The rise in crop production input prices is attributed to the increased use of more expensive seeds with complex genetic traits, increased use of fertilizer that has increased in price primarily in response to rising natural gas prices, and a rise in pesticide costs coupled with an increase in overall crop acreage (USDA-ERS, 2012a).

The USDA-ERS recognizes resource regions that vary in terms of land productivity and cost of production. The most productive of these regions are the Heartland and Northern Crescent; the least productive are the Eastern Uplands, Southern Seaboard, and Mississippi Portal (Fernandez-Cornejo and McBride, 2000). While the Heartland and Northern Crescent regions have high production costs, their higher productivity results in greater profitability. In 2010, the US total gross average value of soybean production per planted acre was $449.32 and the average price of a bushel of soybeans at harvest was $9.56 (USDA-ERS, 2011b). Economic returns since 1948 (when record-keeping began) have increased from $48 per acre to $486 per acre in 2011, as shown in Figure 2-5.

The US soybean market represents approximately 8 percent of the total value of agricultural sector production (USDA-ERS, 2012h) and 25 percent of the value of all field crops (USDA-NASS, 2012c). Cash receipts from US soybean sales are expected to experience a decline in 2013 from 2012 values, from $42.6 billion to $38.1 billion (USDA-ERS, 2013d). However, the value of production is expected to increase from $39.4 billion to $40.5 billion, due in part to the higher forecast price described below.

Figure 2-5 Return per Acre of Soybeans, 1948-2011

Source: (USDA-ERS, 2011b)
Note: Excluding government payments

Prices paid to farmers ranged between $4 and $8 per bushel from 1986 until 2006, but in subsequent years were in the range of $12 per bushel (Soystats, 2011a). As of early March 2013, soybeans prices were at $14.73 per bushel (RCG, 2013) and the price range forecast by USDA-ERS for the 2012/2013 season was $13.55 to $15.05 per bushel (USDA-ERS, 2013b).

There is a niche market for nontransgenic food and feed in the US, as is evident from private labeling initiatives such as the Non-GMO Project.[25] This initiative offers third-party product verification and labeling for nontransgenic products. There also is a niche market for organic products in the US. Sales of organic products have been growing quickly, from $1 billion in 1990 to $26.7 billion in 2010, with a 7.7 percent increase between 2009 and 2010 alone (OTA, 2011). To satisfy the demand for organic soybean, producers have adopted specific production practices to maintain and prevent the use of excluded methods as dictated by the NOP. To offset the increase in investment related to these more extensive practices, premiums are often paid for nontransgenic or organic soybean. For example, the price for non-organic soybean (the majority of which is used for livestock feed) in early March 2013 was nearly $14.75 per bushel, as mentioned above, whereas organic soybean for livestock feed ranged between $25.00 and $27.25 per bushel (USDA-AMS, 2013).

There is consistent evidence that farmers obtain substantial financial and non-financial benefits as a result of adoption of genetically engineered crops as opposed to nontransgenic (but not "organic") crops (Duke and Powles, 2009; Fernandez-Cornejo et al., 2002; Fernandez-Cornejo and McBride, 2000). These benefits include:

25 http://www.nongmoproject.org/.

- An opportunity to increase income from off-farm labor;
- Increased flexibility and simplicity in the application of pesticides;
- An ability to adopt more environmentally friendly farming practices;
- Increased consistency of weed control;
- Increased human safety;
- Equipment savings; and
- Labor savings.

2.6.2 Foreign Trade Environment

The US was the largest soybean seed producing country in 2011 (the latest year for which complete data are available), followed by Brazil and Argentina (Table 2-9). These three exporters account for approximately 81 percent of the global soybean exports in the form of harvested seed, meal, or oil (USDA-ERS, 2011c). Currently, the US produces approximately 33 percent of the global soybean supply (Soystats, 2012a).

Table 2-9 World Soybean Production, 2011

Country	Production (millions of metric tons)	Percent of Market
United States	83.2	33%
Brazil	72.0	29%
Argentina	48.0	19%
China	13.5	5%
Canada	4.2	2%
India	11.0	4%
Paraguay	6.4	3%
Other	13.1	5%
Total	251.5	100%

Source: (Soystats, 2011b)

Table 2-10 presents the leading exporters of bulk soybean, meal, and oil products in 2011/2012 (the latest season for which complete data are available). Forecasts for the 2012/2013 season show Brazil exceeding US exports (USDA-ERS, 2013b). The US, along with Brazil, Argentina, Paraguay, and Canada, accounted for 97 percent of the bulk soybean exported, while Argentina, Brazil, the US, India, and Paraguay accounted for 94.1 percent of the soybean meal exported. Argentina, the US, and Brazil are the dominant countries in terms of soybean oil exports, accounting for 80.2 percent in 2011/2012.

Table 2-10 World Soybean Exports in 2011/12

	Soybean Product		
	Bulk	Meal	Oil
Location	Exports (thousand metric tons)		
Argentina	7.37	26.02	3.78
Bolivia	--[1]	--	0.32
Brazil	36.32	14.68	1.89
Canada	2.93	--	--
EU-27[2]	--	--	0.68
India	--	4.60	--
Paraguay	3.10	0.90	0.18
Russia	--	--	0.17
United States	37.06	8.84	0.66
Other	3.55	3.95	0.81

Source: (USDA-FAS, 2012)
1 -- = no data
2 European Union 27 member countries

Table 2-11 presents the top 10 US export markets for soybean by volume for the 2011/2012 marketing season in comparison to the previous three marketing seasons. China, Mexico, and the European Union 27 member countries (EU-27) were the top three importers in the last marketing season (USDA-FAS, 2013). US soybean exports are projected to increase to approximately 1.5 billion bushels (33.2 million metric tons) in 2020 (USDA-OCE, 2011).

Table 2-11 Top 10 US Soybean Export Markets in 2011/2012 Compared to Previous Years

	Marketing Season			
	2011/2012	2010/2011	2009/2010	2008/2009
Location	Exports (metric tons)			
China	489,598	303,154	-388	105,832
Germany	75,845	0	65,995	0
Indonesia	20,489	64,059	70,992	80,200
Israel	31,912	0	-22,432	8,000
Japan	63,395	24,874	75,438	50,510
Malaysia	3,057	223	26,160	0
Mexico	113,057	29,816	13,510	33,819
Saudi Arabia	72,575	0	0	0
Thailand	34,105	603	6,240	0
Turkey	27,705	38,235	3,847	18,000

Source: (USDA-FAS, 2013)

US soybean and soy product exports exceeded $21.5 billion in 2011. China was the largest customer for US soybeans with purchases exceeding $10.4 billion. Mexico was the second largest market for US soybeans with purchases of nearly $1.6 billion. Other significant buyers included Japan with purchases of $954 million and Indonesia with purchases of $859 million. Soybeans produced in China and India are primarily for domestic use, but China's imports of soybean are expected to account for more than 78 percent of the projected global gain in production by 2019/2020. For the top ten US export customers, the value of soybean and soybean products (meal and oil) in 2011 (the most recent year for which detailed data are available) is shown in Table 2-12.

Table 2-12 US Export Markets for Soybean and Soybean Products (2011)

Soybean Exports		Soybean Meal Exports		Soybean Oil Exports	
Location	**Value ($M)**	**Location**	**Value ($M)**	**Location**	**Value ($M)**
China	10,453	Canada	375	Morocco	336
Mexico	1,651	Mexico	369	Mexico	194
Japan	954	Venezuela	260	China	129
Indonesia	859	Philippines	229	Colombia	77
Taiwan	704	Morocco	221	Algeria	72
Egypt	301	Dominican Republic	145	Dominican Republic	71
Germany	286	Japan	119	Venezuela	57
South Korea	267	Guatemala	110	Guatemala	52
Spain	194	Ecuador	84	Canada	47
Thailand	176	South Korea	71	Peru	36
Other	1,720	Other	720	Other	196
Total	17,564	Total	2,702	Total	1,268

Source: (Soystats, 2012b)

2.6.3 Social and Economic Environment

Social issues related to soybeans include farmer and consumer choice, as well as the sustainability of US soybean farms. Farmers can select from a range of options in agronomic practices, seed products (nontransgenic, transgenic, and organic), and markets for their products. Consumers have a range of soybean products to choose from in a free market system such as the US.

The rotation of crops between soybean and corn drives much of the economic environment for US farmers. Soybean acreage planted in the last 3 years has hovered around 76 to 77 million acres, as described in Section 2.2.1, *Current and Projected Acreage and Range of Soybean Production*. Higher per-bushel prices, as described in Section 2.6.1, *Domestic Trade Environment*, may result in the forecasted rebound in soybean plantings for 2013.

As described in Section 2.2.2.6, *Management of Weeds*, millions of corn and soybean acres in the US are now infested with glyphosate-resistant weeds (Boerboom and Owen, 2006). Nearly 40 million acres are expected to be infested in the US in 2013. The economic impact of these resistant weed populations can be significant for growers. One economic analysis places this cost in the range of $12 to $18 per acre (Mueller et al., 2005).

Genetically engineered traits such as herbicide tolerance, as described in Section 2.2, *Agricultural Production of Soybean*, offer opportunities for making agriculture more sustainable, as is evident by their rapid adoption. The introduction of glyphosate-tolerant soybeans in the US in 1996 revolutionized the way that growers managed weeds in their soybean fields. Growers rapidly adopted the technology because of its effectiveness and ease of use, and by 2012 93 percent of soybean acres in the US were planted with genetically engineered varieties, virtually all with herbicide tolerance traits (USDA-NASS, 2012b).

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3 ALTERNATIVES

The EA analyzes the potential environmental consequences of a determination of nonregulated status of SYHT0H2 soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that SYHT0H2 soybean is unlikely to pose a plant pest risk.Based on its PPRA (USDA-APHIS, 2014b), APHIS has concluded that SYHT0H2 soybean is unlikely to pose a plant pest risk. Therefore, APHIS must determine that SYHT0H2 soybean is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Two alternatives were evaluated in this EA: (1) no action and (2) determination of nonregulated status of SYHT0H2 soybean. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section.

3.1 No Action: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. SYHT0H2soybeans and progeny derived from SYHT0H2 soybeans 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 SYHT0H2 soybeans 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 SYHT0H2 soybean.

This alternative is not the preferred alternative because APHIS has concluded through a Plant Pest Risk Assessment that SYHT0H2soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

3.2 Preferred Alternative: Determination that SYHT0H2 Soybean is No Longer a Regulated Article

Under the Preferred Alternative, SYHT0H2 soybean and its progeny would no longer be regulated articles under the regulations at 7 CFR part 340. SYHT0H2 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of SYHT0H2 soybean and progeny derived from this event. The preferred alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the PPA. Because the agency has concluded that SYHT0H2 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of SYHT0H2 soybean is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

3.2.1 Alternatives Considered, Not Included in Detailed Analysis

APHIS has assembled a list of alternatives that might be considered for SYHT0H2 soybean. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the PPA, 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 SYHT0H2 soybean. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

3.2.1.1 Prohibit Any SYHT0H2 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 SYHT0H2 soybean, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that SYHT0H2 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012).

In enacting the PPA, Congress listed findings in Section 402(4), including the following one:

> "[D]ecisions affecting imports, exports, and interstate movement of products regulated under this title [the Plant Protection Act] shall be based on sound science;"

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 agencies that develop and implement policies for oversight of emerging technologies such as genetic engineering. In accordance with this memorandum, agencies should adhere to guidance in Executive Order 13563, and, consistent with it, apply the following principle, among others to the extent permitted by law when regulating emerging technologies:

> "Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandate of each agency."

Based on the PPRA (USDA-APHIS, 2012), and the scientific data evaluated therein, APHIS concluded that SYHT0H2 soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of SYHT0H2 soybean.

3.2.1.2 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 SYHT0H2 soybean is unlikely to pose a plant pest risk, (USDA-APHIS, 2013), and it is the only line described in the petition, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3.2.1.3 Isolation Distance between SYHT0H2 Soybean and Non-GE Soybean Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating SYHT0H2 soybean from conventional or specialty soybean production. However, because APHIS has concluded that SYHT0H2 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012), an alternative based on requiring isolation distances would be inconsistent with statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of SYHT0H2 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 SYHT0H2 soybean, there are no geographic differences associated with any identifiable plant pest risks for SYHT0H2 soybean (USDA-APHIS, 2012). This alternative was rejected and not analyzed in detail because APHIS has concluded that SYHT0H2 soybean does not present a plant pest risk, and will not exhibit a greater plant 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 PPA 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 PPA. However, individuals might choose on their own to geographically isolate their non-GE production systems from SYHT0H2 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 SYHT0H2 soybean is available from the Association of Official Seed Certifying Agencies (AOSCA, 2011).

3.2.1.4 Requirement of Testing for SYHT0H2 Soybean

During the comment periods for other petitions for nonregulated status, some comments requested USDA to require and provide testing for GE products in non-GE production systems. APHIS notes that 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 SYHT0H2 soybean does not pose a plant pest risk (USDA-APHIS, 2012), the imposition of any type of testing requirement 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 SYHT0H2 soybean would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

3.3 Comparison of Alternatives

Table 3-1 summarizes the potential impacts associated with selection of either of the Alternatives evaluated in this Environmenal Assessment. The impact assessment is presented in Section 4.

Table 3-1: **Summary of Environmental Consequences and Regulatory Compliance**

	Alternative	
Attribute/Measure	**No Action**	**Preferred**
Meets Purpose and Need, and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied through plant pest risk assessment
Soybean Production		
Acreage and areas of soybean production	The size and distribution of soybean production will not change much over the next 10 years	SYHT0H2 is not expected to change extent of soybean production
Cropping practices	Continuing use of same rotation crops in various growing regions depending upon economics, markets and convenience.,	SYHT0H2 will not generally alter current practices, although plantback times may increase for some crops and lead to changes in rotations
Pesticide use	Patterns of herbicide use may see increased use of althernatives to glyphosate to respond to resistant weeds	Growers with glyphosate resistant weeds may begin to use SYHT0H2 and increase use of mesotrione, glufosinate and isoxaflutole and decrease glyphosate use with little overall change in weed management practices. .
Organic soybean production	Organic soybean will continue increase in production but be a small part of total US soybean production	SYHT0H2 will not impact organic soybean any differently than does conventional soybean.
Specialty soybean production	Identity preserved soybean will continue to respond to specialized market requirements	SYHT 0H2 will have no impacts on specialty soybean different from those of current varieties
Physical Environment		
Water quality	Current use of conservation tillage reduces runoff of nutrients and pesticides	SYHT0H2 will not deleteriously affect water quality as current tillage and irrigation practices are continued for production and weed control
Soil	Use of conservation tillage will continue except in some circumstances in which tillage	Soil practices will remain unchanged, especially since growers will have an additional

	is the only control for herbicide resistant weeds	MOA for resistant weeds to allow continued use of conservation tillage
Air quality	Conservation tillage which reduces air particulates will continue unchanged	No changes expected with production of SYHT0H2 soybean
Climate	Greenhouse gas production from tillage and vehicle emissions will likely remain unchanged	Production of GHGs will not be altered by use of SYHT0H2 soybean, although in some cases where resistant weeds exist, additional spraying may be needed which increases GHGs
Biological Environment		
Animals	Agricultural impacts to crop associated animals in general will remain unchanged	SYHT0H2 will not change impacts on animal populations.
Plants	Weeds will continue to develop resistance and growers will respond with other herbicides and cultural or mechanical techniques	Management techniques may change mostly by use of additional herbicide MOAs for growers of SYHT0H2 soybean. Cumulative use of mesotrione, isoxaflutole and glufosinate on corn could increase exposure of weeds to these herbicides and increase possibilities of resistance. However, increased use of multiple herbicides can potentially deter such resistance development.
Soil Microorganisms	Soil microorganisms will continue to be impacted by conventional agricultural practices with little consequence to soybean production	SYHT0H2 will not alter populations of soil microorganisms differently than do conventional soybean varieties
Biodiversity	A variety of EIQs from the use of different herbicides may impact biodiversity	The EIQs of the three new herbicides that would be used for soybean in SYHT0H2 are slightly lower than for glyphosate, but would likely not change biodiversity.
Gene movement	No gene flow expected	SYHT02 would not change gene flow between other varieties of soybean
Public Health		
Human health	Existing varieties have no impacts on health	The proteins avHHPD-03 and PAT are unlikely to be allergens and are not toxic
Animal (livestock) health	Current varieties and herbicides used on them have no health impacts on animals that feed on soybean	The SYHT0H2 soybean and herbicides applied to it when used under EPA restrictions are safe for animals exposed to the variety
Worker safety	Worker exposure to herbicides is regulated by EPA for safety	Use of EPA registered herbicides will convey no health risks to workers when used according to

		label requirements.
Social and Economic Factors		
Domestic trade environment	Growers will continue to choose varieties based on maximizing profits and environmental benefits	Additional choices of herbicides to improve weed control could provide economic benefit to growers, increasing price competiton for seed and herbicides
Foreign trade environment	Additional soybean varieties will continue to be developed and available to foreign trade	No change in trade is expected, although potential exists for increasing efficiency in production and possible profit increases for growers
Social and economic environment	No social or economic effects are anticipated	Consumer choice or regulatory decisionmaking on GE soybean would not change
Threatened and Endangered Species	Mesotrione, isoxaflutole and glufosinate are all registered for use on other crops including corn, and were approved for use following restrictions that should mitigate possible impacts on T&E species	No new herbicides would be used on SYHT0H2 other than those approved by EPA at similar rates for other crops. EPA label requirements that take T&E species into account will not change possible impacts of existing herbicides.
Other Regulatory Approvals		
US	Unchanged for existing non regulated varieties	FDA consultation is pending
Compliance with Other Laws		
CWA, CAA, ESA, EOs	Fully compliant	Fully compliant

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4 ENVIRONMENTAL CONSEQUENCES

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this environmental assessment. A cumulative effects analysis is presented for each potentially affected environmental concern.

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for SYHT0H2 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 3.0). Impacts may be categorized as direct, indirect, or cumulative. A direct effect[26] is an effect that results solely from a proposed action without intermediate steps or processes. Examples could include soil disturbance, air emissions, and water use. An indirect effect[27] may be an effect that is related to but removed from a proposed action by an intermediate step or process. Examples could include surface water quality changes resulting from soil erosion due to increased tillage, and worker safety impacts resulting from a change in herbicide use.

The EA describes the potential environmental consequences of the two alternatives under consideration: the No Action Alternative and the Preferred Alternative. As described in Chapter 3, under the No Action Alternative SYHT0H2 soybean would continue to be a regulated article as defined by the PPA. Environmental releases of SYHT0H2 soybean would be regulated by APHIS, as they have been since 2008.[28] Limited field tests would be allowed, but the product would not be marketed. Under the Preferred Alternative, APHIS would determine that SYHT0H2 soybean does not pose a plant pest risk. SYHT0H2 soybean would no longer be regulated under the PPA and the Petitioners would market this product as a stand-alone product or in breeding stacks with other transgenic soybean traits.

A likely indirect effect of deregulating SYHT0H2 soybean is a change in herbicide use, since the product includes a unique trait of tolerance to HPPD-inhibiting herbicides (mesotrione and isoxaflutole) as well as tolerance to the glutamine synthetase-inhibiting glufosinate (also known as glufosinate-ammonium or phosphinothricin). Mesotrione and isoxaflutole[29] are not currently used on soybeans commercially[30]; glufosinate is currently used on some non regulated herbicide-resistant soybean varieties but only at 3% of total acreage (*2012 data*, see Table 2-5). The use of

26 (CEQ, 1978) Section 1508.8, *Effects*, Paragraph (a), those “which are caused by the action and occur at the same time and place.”

27 Section 1508.8, *Effects*, Paragraph (b), those “which are caused by the action and are later in time or farther removed in distance, but are still reasonably foreseeable. Indirect effects may include growth inducing effects and other effects related to induced changes in the pattern of land use, population density or growth rate, and related effects on air and water and other natural systems, including ecosystems.”

28 Appendix A of the Petition lists permits/authorizations in chronological order.

29 Bayer CropScience’s FG72 soybean (OECD Unique ID MST-FGØ72-2) is a transgenic variety with tolerance to isoxaflutole (and glyphosate); APHIS has determined non-regulated status for this product.

30 Mesotrione is currently registered for pre-emergence use on certain soybean varieties that exhibit natural tolerance to mesotrione, however this use is currently not on any marketed label and is not being used commercially.

herbicides on the SYHT0H2 variety has not yet been approved by EPA, but APHIS will assess the potential for increase of herbicide usage as an indirect consequence of the decision for nonregulated status. However, APHIS has no direct responsibility for regulating herbicides or herbicide impacts. Descriptions of these three herbicides and their uses and potential impacts on human health and the environment have been summarized (Appendices A, B, C{Syngenta and Bayer, 2013 #287}. These appendices are based primarily on EPA studies and regulatory actions since herbicide usage is regulated by EPA, not APHIS.

A cumulative effects analysis is also included for each environmental issue 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 SYHT0H2 soybean with other events that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340,or impacts result from third-party actions (e.g. EPA, growers). If there are no direct or indirect impacts identified for a resource area, then there can be no cumulative impacts. Where it is not possible to quantify impacts, a qualitative assessment of potential impacts can be provided. Certain aspects of this product and its cultivation may be no different between the alternatives; those are described below.

This Chapter provides an evaluation of the direct and indirect effects of the No Action Alternative and the Preferred Alternative. A cumulative effects analysis is provided in Chapter 5 for selected resources, and an evaluation of the potential impacts to threatened or endangered species is provided in Chapter 6.

4.1.1 Scope of the Environmental Analysis

In this section, *Environmental Consequences*, environmental issues are assessed individually. However, it should be noted that APHIS has regulatory authority over the MGI soybean plants (which is the name Syngenta and Bayer give to seed expressing the SYHT0H2 event), but EPA has regulatory authority over herbicides that are applied to the crop. The scope of this EA covers the possible direct and indirect impacts that would result primarily from the cultivation and use of the plant. EPA, in its registration process, is considering any direct and indirect impacts from the use of the herbicide on MGI resistant plants. The USDA is relying on EPA's authoritative assessments and will not duplicate the assessment prepared by EPA. The EA will provide informative assessments, but not the determinative document for any impacts of herbicide usage, since that analysis will have been completed by EPA under their regulatory authority. USDA also considers in this EA (*Section 5),* cumulative effects that result in the event that USDA approves the petitions for non-regulated status to MGI resistant soybean, and EPA registers the use of herbicides on these crops.

The Affected Environment section (*Section 2*) previously described the the resources potentially impacted, including soybean production practices as well as physical, biological, public health, and socioeconomic resources. The resources analyzed are of public interest or are potentially affected by the Preferred Alternative and are commonly addressed in APHIS's NEPA evaluations of their plant pest risk decisions. Resources that have no potential to be affected by the Preferred Alternative, such as coastal zones or ambient noise, are not addressed in this assessment.

The Preferred Alternative's potential direct or indirect effects from SYHT0H2 soybean are discussed as a stand-alone crop (i.e., not combined with other transgenic traits through breeding). Potential impacts on the analyzed resources deriving from stacked traits are addressed in *Section 5, Cumulative Impacts* and were compared to how those resources may be affected if the No Action Alternative is selected. Any impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-federal) or person undertakes such other actions (40 CFR ~ 1508.7) are also discussed in *Cumulative Impacts*. Direct effects were considered to be the impacts that may result from SYHT0H2 soybean itself; indirect effects were considered to be the impacts that may result from other actions (such as changes in herbicide use) that could be induced by introducing SYHT0H2 soybean. As noted, APHIS has no authority to regulate these herbicide usages or their consequences to agriculture or the environment. Consequently, APHIS has no federal requirement under NEPA to assess these indirect effects.

4.1.2 Assumptions

The analysis of the potential environmental consequences of the No Action Alternative was based on the assumption that regulated field trials of SYHT0H2 soybean on small plots of land would continue, as described in the Petition. The analysis of the potential environmental consequences of the Preferred Alternative was based on the assumption that there would be commercialization of SYHT0H2 soybean to U.S. growers to the extent noted below in this *Section 4.1.2, Assumptions*. As noted above, the analyses of direct or indirect effects of the Proposed Action are based on SYHT0H2 soybean in the absence of stacking with other transgenic traits. The cumulative effects analysis provided in Section 5 was based on an assumption that SYHT0H2 soybean will be marketed as seed stacked with other transgenic traits.

The environmental consequences of the two alternatives were analyzed under the assumption that the majority of farmers who grow transgenic, nontransgenic, or organic soybean are using reasonable, commonly accepted best management practices for their chosen system and varieties during soybean production. These management practices include conventional planting dates, typical seeding rates, appropriate harvest times, and acceptable pest management methods as well as preservation and coexistence measures. It is assumed that herbicides will be applied in accordance with EPA-approved label requirements. It is also assumed that the stewardship plan provided in Appendix F of the Petition will be implemented by the Petitioners and that growers will comply with the plan in accordance with the Technology Use Agreement provisions for growers.

The environmental consequences of both the No Action Alternative and the Preferred Alternative were evaluated in the context of conventional soybean and existing transgenic soybeans developed with traits conferring herbicide tolerance. No other transgenic soybean cultivars containing the oat-derived transgene *avhppd-03,* which conveys tolerance of mesotrione and isoxaflutole, have been deregulated by APHIS.[31] Table 2-1 lists deregulated transgenic soybean products and shows that seven are tolerant of phosphinothricin (also known as glufosinate or glufosinate-ammonium) and four are tolerant of glyphosate (USDA-APHIS, 2011). Most of these crops are marketed as single

31 APHIS has determined nonregulated status for MST-FGØ72-2 soybean, which has an HPPD gene from another source.

trait products; one product contains both a glyphosate-tolerance trait and an acetolactate synthase-inhibiting trait. Another product contains both an isoxaflutole resistant trait (another HPPD inhibitor, as is mesotrione) and a glyphosate resistant trait. Some of these cultivars are currently on the market and some have been discontinued or were never commercialized.

It is also assumed that mesotrione, isoxaflutole, and glufosinate may replace some portion of the current glyphosate use on soybeans. As described in Section 2.2.2.6, *Management of Weeds*, herbicide-tolerant soybean varieties now comprise some 93 percent of US plantings, and phosphinic acid herbicides (e.g., glyphosate) were used on 77 percent of those fields in 2006 (the most recent year for which data are available) (USDA-ERS, 2012f). It is not possible to accurately predict what portion of the glyphosate use may be replaced by mesotrione, isoxaflutole, and/or glufosinate. However, we will assume the estimates of use (12-15% of growers will grow plants expressing the traits by five years post launch) provided by the developers do represent a reasonable approximation for the adoption rate of SYHT0H2 (Syngenta, 2013). The indirect effects analysis of this Section therefore presents the potential impacts from changes in herbicide use at these levels.

4.2 Soybean Production

This section describes the potential impacts of the preferred alternative to areas and acreage of soybean production, agronomic practices, raw and processed soybean commodities, specialty soybean systems, and soybean's persistence in the environment/weediness potential.

4.2.1 Acreage and Areas of Soybean Production

Substantive changes in soybean production acreage and areas are more likely to result from market conditions and changes in federal policies than any other source. Domestic and international demand for soybean products, coupled with relatively high soybean commodity prices, is increasing (USDA-ERS, 2012g). In response, total US 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-OCE, 2011). Approximately 93 percent of the current acreage is planted with transgenic varieties, virtually all being herbicide tolerant (USDA-NASS, 2011b). In order to accommodate the increase of US soybean acreage in spite of a net decrease in available US agricultural land (USDOE-EIA, 2007), growers are likely to plant additional soybean acreage at the expense of other crops, such as cotton or hay (USDA-ERS, 2011c). The use of existing agricultural land in lieu of previously uncultivated land for additional soybean acreage is a land-use decision made by growers, as soybean is profitably grown on high quality arable land but not on land of lower productivity (USDOE-EIA, 2007).

Arable land for increased soybean planting acreage could also result from the return of CRP lands to agricultural production. Although CRP funding has been steady at approximately $1.9 billion per year through 2011 (USDA-ERS, 2012b), the 2008 US Farm Bill[32] reduced CRP lands from 39.2 million acres to 32 million acres.[33] This year growers were offered payments for new

32 *Food, Conservation, and Energy Act of 2008*. Public Law 110-234.
33 Section 2103, Paragraph (3)

enrollments on only about 58% of the land that was retired from CRP (Doane-Advisory-Services). Following recent trends of enrollment, it is likely that the size of CRP will only be about 24 million acres in 2014 (Doane-Advisory-Services). Available acreage for soybean production could increase by this federal policy change. However, most soybeans are planted in fields that have been in crop production for years, rather than in converted CRP lands. A more likely scenario is that other crops displaced by soybean, such as hay or cotton, would be grown on converted CRP lands.

No Action Alternative

The acreage and areas of soybean production would not change as a direct or indirect result of the No Action Alternative. Conventional production practices that use transgenic varieties would continue to increase under the No Action Alternative, based on current acreage trends. Seed with transgenic traits and nontransgenic varieties would continue to be available under the No Action Alternative. Soybean is currently produced in 31 states (see Table 2-2) and under the No Action Alternative the range of production would be unchanged. CRP acreage converted to soybean production would not be affected by this alternative. Current trends in the acreage and areas of production are likely to continue to be driven by market conditions and federal policy even if SYHT0H2 soybean continues to remain a regulated article. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no effect on the acreage and areas of soybean production.

Preferred Alternative

The acreage and areas of soybean production would not change as a direct or indirect result of the Preferred Alternative. SYHT0H2 soybean is unlikely to disrupt the relationship between market forces and soybean acreage, which is affected by growing demand for soybean commodity products (USDA-ERS, 2010b; USDA-ERS, 2010c). SYHT0H2 soybean would not expand soybean acreage beyond projected values because it requires similar management conditions as other soybean varieties, does not present any yield gains over other soybean varieties, and exhibits no phenotypic characteristics that would be indicative of an improved capacity to grow outside an agricultural environment (Syngenta, 2012c). Similar to currently available soybean varieties, SYHT0H2 soybean will 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. SYHT0H2 soybean is unlikely to be cultivated on land not previously used for agriculture, maintaining the trend to shift agricultural land away from other crops toward soybean production to satisfy market demand (USDA-ERS, 2010b; USDA-ERS, 2010c).

Growers are not expected to change the acreage or areas of soybean production as a result of deregulating SYHT0H2 soybean. CRP acreage converted to crop production would not be affected by this alternative. Current trends in the acreage and areas of soybean production are likely to continue to be driven by market conditions and federal policy if SYHT0H2 soybean is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000.

4.2.2 Agronomic Practices

Potential changes in agronomic practices, including cropping practices, irrigation, fertilization, and pesticide use, are described below for the No Action Alternative and the Preferred Alternative.

4.2.2.1 Cropping Practices

Various cropping practices are used by soybean growers to improve the performance of their operations; some of these practices directly or indirectly control weeds. Growers make choices to plant certain varieties and select cropping practices based on factors such as yield, weed and disease pressures, cost of seed and other inputs, technology fees, worker safety, potential for crop injury, and ease and flexibility of the production system (Gianessi, 2005). Transgenic soybean varieties offer a range of herbicide tolerance traits to assist growers in weed management that complement cropping practices and other weed management methods, but do not replace those methods. Cropping practices are unlikely to change as a result of introducing a new herbicide-tolerant transgenic soybean variety to the market.

As described in Section 2.2.2., Agronomic *Practices*, crop rotation can improve yield and profitability over time, control weeds, break disease cycles, limit insect and other pest infestations, provide an alternative source of nitrogen, reduce soil erosion, increase soil organic matter, improve soil tilth, limit the potential for weeds to develop tolerance to herbicides, and reduce runoff of nutrients and chemicals, as well as the potential for contamination of surface water (Al-Kaisi et al., 2003). Approximately 85 percent of the soybean-planted acreage is in some form of a crop rotation system (Quinby et al., 2006); transgenic soybean (with herbicide tolerance traits) accounts for 93 percent of all soybean fields in the US (USDA-NASS, 2011b), and most of the US soybean acreage (approximately 70 percent) is rotated with corn (Heatherly et al., 2009). The economics of soybean production drive changes in crop rotation practices as farmers seek the most profitable crop and production method. Given the predominance of crop rotation practices and transgenic soybeans, any changes in rotation practices are more likely to result from economic and market conditions than other factors. Introducing a new transgenic soybean tolerant of a different class (or classes) of herbicides is unlikely to have any effect on crop rotation practices.

Other cropping practices that provide some weed control are cover crops and tillage. Both of these practices are used in conjunction with other weed control methods, including herbicide use, as part of integrated weed management programs. Cover crops are selected for a variety of reasons; compatibility with herbicides used on the fields is one factor. Introducing a new transgenic soybean tolerant of a different class of herbicides could indirectly affect decisions on which cover crops may be planted.

Tilling practices under a full (conventional) tillage protocol prepares a field for planting and is used in large part for weed control. Farmers increased the use of reduced (conservation) tillage before and contemporaneously with the adoption of glyphosate-tolerant soybean varieties (Bonny, 2011a; Owen, 2008). Adoption of conservation tillage for soybeans grew (but at a decreasing rate) from about 25 percent of the soybean acreage in 1990 to 48 percent in 1995, the 5-year period previous to the introduction of herbicide-tolerant soybeans (Fernandez-Cornejo and McBride, 2002). Conservation tillage continued to increase following the commercialization of glyphosate-tolerant soybean in 1996, and totaled 63 percent of soybean acreage by 2007 (Bonny, 2011b). These trends are likely to be sustained by the continued use of broad-spectrum herbicides (Carpenter and Gianessi, 1999). Using a broad-spectrum herbicide such as glyphosate allows less intensive tilling, replacing conventional tillage as an economic alternative for weed control (Givens et al., 2009; USDA-ERS, 2010a). Farmers already using no-till find herbicide-tolerant seeds can be easily incorporated into their weed management program, but the commercialization of herbicide tolerant soybeans does not necessarily encourage adoption of no-till practices (Fernandez-Cornejo and McBride, 2002). Introducing a new transgenic soybean tolerant of a different class of herbicides could indirectly affect decisions on what types of tilling techniques may be used by facilitating conservation tillage.

Some soybean growers may return to conventional tillage to manage glyphosate-resistant weed populations (NRC, 2010) if use of that herbicide becomes less effective. However, in the absence of alternatives the majority of US growers are likely to continue using glyphosate at increased rates or frequencies rather than reincorporate conventional tillage into their weed management strategies because:

- Conventional tillage is relatively high cost (USDA-NRCS, 2012);
- Growers are familiar with glyphosate (NRC, 2010); and
- Glyphosate-tolerance systems are simple and convenient to implement (Owen, 2010).

Alternative broad-spectrum herbicides with different modes of action than glyphosate may control glyphosate-resistant weeds, allowing reductions in glyphosate use and facilitating the continued or increased use of conservation tillage practices by controlling weeds through chemical, rather than mechanical means.

No Action Alternative

Cropping practices would not change as a direct or indirect result of the No Action Alternative. Cover crop use, crop rotations, and tillage practices are likely to continue to be driven by economic and market conditions, or convenience and environmental factors, even if SYHT0H2 soybean continues to remain a regulated article. Various cropping practices would be chosen to meet the economic and marketing strategies or the convenience and environmental considerations of the particular farmer. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no effect on cropping practices.

Preferred Alternative

Cropping practices such as cover crops, crop and herbicide rotation, and tillage would not change as a direct result of the Preferred Alternative. SYHT0H2 soybean exhibits similar agronomic performance relative to its nontransgenic parent variety (“Jack”) and would benefit from currently practiced soybean crop rotation practices. No differences in disease susceptibility were observed between SYHT0H2 soybean and its nontransgenic parent variety in experimental plots (Syngenta, 2012c).

Soybean growers may change their use of cropping practices as an indirect result of introducing SYHT0H2 soybean because it is tolerant of a different class of herbicides than the most commonly used product, glyphosate. Introduction of SYHT0H2 soybean with mesotrione, isoxaflutole, and glufosinate tolerance would have an indirect effect on cropping practices by allowing farmers to use a broader range of herbicides to minimize weed development of tolerance to any specific chemical. These herbicides are applied at different stages of the crops’ life cycles, and successive crops should not be planted when residual concentrations may be present in the fields. Each of the herbicides that contains mesotrione, isoxaflutole, or glufosinate as an active ingredient has time constraints on when crops may be planted in fields to which these herbicides have been applied. Rotation crop plant-backtimes[34] for each of the three herbicides when applied to corn are provided in Table 4-1; soybean and the most common crops grown in rotation with soybean are indicated in bold type. The time constraints for applications of mesotrione and isoxaflutole to soybean fields are for nontransgenic soybean (i.e., cultivars that have not been genetically engineered to be tolerant of these herbicides) as no soybean varieties tolerant of these herbicides are currently marketed.[35] The time constraints for applications of glufosinate take into consideration soybean varieties tolerant of this herbicide: these varieties may be planted immediately. Although these constraints limit herbicide choice by farmers, they also facilitate herbicide rotation, which is an integral component of herbicide resistance management.

As noted above, approximately 70 percent of soybean fields are in a crop rotation program with corn, which can be planted immediately after an herbicide containing any of these three herbicides has been applied. Soybean is grown continuously on up to 15 percent of the fields, and the balance of soybean fields are in rotation with a range of crops (wheat, cotton, rice, sorghum, barley, oats, and dry beans). A basic tenet of integrated weed management is that herbicides should be rotated along with crops, to minimize the potential for development of herbicide-resistant weed biotypes. Depending upon which herbicide is used, an indirect effect of the Preferred Alternative is that crop and herbicide rotation practices should be altered to accommodate these planting restrictions and integrated weed management recommendations. Syngenta's Resistance Fighter™ program[36] and Bayer's Respect the Rotation™ program[37] describe the companies' recommended strategies to manage herbicide resistance. These recommendations are encapsulated in the SYHT0H2-specific stewardship plan provided in Appendix F to the Petition (Syngenta, 2012c).

A determination of nonregulated status of SYHT0H2 soybean would not directly impact tillage. Crop and herbicide rotation practices may be altered as an indirect result of the Preferred Alternative, which would improve weed resistance management practices. A determination of nonregulated status of SYHT0H2 soybean would indirectly prevent a shift towards conventional tillage in soybean caused by needs to control glyphosate resistant weeds. SYHT0H2 soybean is tolerant of herbicide modes of action other than the predominant herbicide, glyphosate, and therefore allows control of weeds resistant to glyphosate with additional herbicides. Some of these problem fields haveneeded to be controlled by means other than herbicides, including tillage, since soybean has fewer options for weed control than do some other crops such as corn.

34 There are slight variations in rotational crop information for different products with other concentrations or mixtures of herbicides.

35 Some varieties of soybean display a natural tolerance of mesotrione, but are not actively marketed as such.

36 http://www.resistancefighter.com/

37 http://www.bayercropscience.us/news/respect-the-rotation

Table 4-1 Examples of Crop Rotation Plant-Back Intervals

Planting allowed after:	Herbicide (example product)		
	Mesotrione (Callisto)	**Isoxaflutole (Balance Pro)**	**Glufosinate (Liberty)**
	Crop		
0 days	**Corn (all types)**, asparagus, cranberry, flax, millet (pearl), grasses grown for seed (Kentucky bluegrass, perennial ryegrass, and tall fescue), **oats**, rhubarb, **sorghum (grain and sweet)**, and sugarcane	**Corn (field)**	Canola, **corn**, **cotton**, **rice**, **soybeans**, and sugar beets
70 days			Root and tuber vegetables, leafy vegetables, brassica leafy vegetables and small grains (**barley**, buckwheat, **oats**, rye, teosinte, triticale, and **wheat**)
120 days (4 months)	Small grains	**Wheat**	
6 months		**Soybeans**, **barley**, **sweet corn**, **popcorn**, potato, **grain sorghum**, and sunflower	All other crops
10 months	Alfalfa, blueberry, canola, **cotton**, lingonberry, peanuts, potatoes, **soybeans**, sunflowers, and tobacco. If applied post-emergence following a mesotrione-containing pre-emergence herbicide, only corn (all types) or grain sorghum may be replanted the year following application.	**Cotton**, peanuts, **rice**; **dry beans** and sugar beets east of the Mississippi River, and alfalfa in all geographic areas	
18 months	Sugar beets, peas, **dry beans**, snap beans, cucurbits, red clover, and all other rotational crops	**Dry beans** and sugar beets west of the Mississippi River, and all other crops in all geographic areas	

Sources: (Bayer, 2012; Bayer, 2013; Syngenta, 2011a)
Note: **Bold type** denotes soybean and the most common crops grown in rotation with soybean

4.2.2.2 Irrigation

Supplemental irrigation is used in some soybean production areas, such as the western and midsouthern states where summer weather patterns result in drought stress that makes dryland production risky. Irrigation rates are affected by local climate conditions (seasonal rainfall), and climate change could increase or decrease irrigation rates in some areas.

Herbicide-tolerant soybeans, cultivated on 94 percent of soybean acreage, have facilitated increased adoption of conservation tillage practices (NRC, 2010). Conservation tillage plays a major role in water conservation (USDA-NRCS, 2006a) by reducing evaporation rates and irrigation requirements. As discussed previously, conservation tillage trends are not expected to change in US soybean production from what is currently practiced; the impacts of conservation tillage on irrigation rates are also not expected to change.

No Action Alternative

Irrigation practices would not change as a direct or indirect result of the No Action Alternative. Even if SYHT0H2 soybean continues to remain a regulated article, irrigation rates are likely to continue to be driven by local weather and climate conditions, as well as increasing adoption of conservation tillage techniques. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no effect on irrigation rates.

Preferred Alternative

Irrigation rates are likely to continue to be driven by local weather and climate conditions, and continued adoption of conservation tillage techniques; these factors would not change as a direct or indirect result of the Preferred Alternative.

4.2.2.3 Fertilization

Compared to other crop plants, soybean cultivation requires less nitrogen fertilization because of the natural nitrogen-fixing aspect of legumes. USDA-ERS estimates that less than 40 percent of soybean acres in the US receive nitrogen fertilizer (USDA-ERS, 2012e; USDA-ERS, 2012g). The percentage of soybean acreage treated with nitrogen fertilizer, along with application rates of nitrogen fertilizer, has remained relatively constant since 1992. Transgenic soybeans with herbicide tolerance traits do not affect fertilization rates.

No Action Alternative

Under the No Action Alternative, current rates of fertilizer use in US soybean production would not change. Even if SYHT0H2 soybean continues to remain a regulated article, fertilization rates are likely to continue to be driven by agricultural production needs and the natural characteristics of soybean. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no effect on fertilization rates.

Preferred Alternative

A determination of nonregulated status of SYHT0H2 soybean would not change fertilization patterns in US soybean production. SYHT0H2 soybean has agronomic performance similar to the nontransgenic parent soybean, and only standard agricultural practices are required for the cultivation of SYHT0H2 soybean (Syngenta, 2012c).

4.2.2.4 Pesticide Use

Pests that adversely affect soybean production include insects, nematodes, diseases (which may be caused by fungi, bacteria or viruses), and weeds. Yield losses in all crops due to pests were substantial and widespread until the introduction and adoption of crop protection chemicals in the 1960s. Growers may use pesticides to control many of these pests: insecticides, nematicides, fungicides, and herbicides, as described in the EA to which APHIS referred. Insect injury can impact yield, plant maturity, and seed quality; insect pests are therefore managed during the growth and development of soybean to enhance soybean yield (Aref and Pike, 1998). Insect injury in soybean seldom reaches levels that cause significant economic loss, as indicated by the low percentage (16 percent) of soybean acreage that receives an insecticide treatment (USDA-NASS, 2007).

No Action Alternative

The continued emergence of glyphosate resistant weeds under the No Action Alternative will result in growers' selecting appropriate modifications of crop management practices to address these weeds. Growers are expected to become less reliant on glyphosate for the control of weeds if it is no longer effective in controlling those weeds. However, growers will likely continue to use the herbicide because it is still effective on hundreds of weed species. Choices for growers will be to seek other management plans based on combinations of present herbicides, use cultivation or cultural techniques or seek new herbicide resistant crops that can provide additional options for integrated weed management practices.

Selection of glyphosate resistant weeds is expected to continue where glyphosate is used especially in those regions where such weeds have already become widely prevalent. Furthermore, because other non-glyphosate herbicides will still be used to manage glyphosate resistant weeds, weeds resistant to non-glyphosate herbicides will continue to be selected. For many of the non-glyphosate herbicides, resistant weeds have already been selected and are widely prevalent. As a result, herbicide options for weed management may become less attractive under the No Action Alternative and growers may be forced to return to more aggressive tillage systems to maintain soybean yields (Prince et al., 2012a).

Other herbicide-tolerant varieties of soybeans may continue to be developed, marketed, and planted regardless of whether or not SYHT0H2 soybean continues to remain a regulated article. Soybean growers are likely to continue to use the available herbicides and any of the other herbicide-tolerant cultivars that are currently available, as listed in Table 2-1, *Transgenic Soybean Cultivars with Herbicide Tolerance 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 of 2000,* or any that may be developed and marketed in the future. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no effect on herbicide use.

Preferred Alternative

EPA has regulatory authority over herbicides that are applied to the crop. This EA covers the possible direct and indirect impacts that would result primarily from the cultivation and use of the plant. EPA, in its registration process, is considering any direct and indirect impacts from the use of the herbicide on MGI resistant plants (*see* Appendix B). The USDA is relying on EPA's authoritative assessments and will not duplicate the assessment prepared by EPA. This EA will provide informative assessments, but not the determinative document for any impacts of herbicide usage, since that analysis will have been completed by EPA under their regulatory authority.

SYHT0H2 soybean is agronomically equivalent to the nontransgenic parent soybean, with equal susceptibility to insects, nematodes and disease pathogens. Use of insecticides, nematicides and fungicides would not change as a result of deregulating SYHT0H2 soybean. Because SYHT0H2 soybean incorporates herbicide tolerance traits, this section focuses on potential changes in herbicide use that would indirectly result from a determination of nonregulated status of this product.

If APHIS approves the petion for nonregulated status of SYHT0H2 soybean, overall herbicide use trends are likely to continue even as mesotrione and isoxaflutole are added to the range of approved products for use on soybeans and glufosinate use is expanded. These three herbicides would continue to be used on crops grown in rotation with soybeans and potentially replace some glyphosate or other approved soybean herbicides. Soybean growers would have a new cultivar to plant in addition to conventional varieties and the other herbicide-tolerant varieties that are currently available, as listed in Table 2-1, *Transgenic Soybean Cultivars with Herbicide Tolerance 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 of 2000,* or any others that may be developed, no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000, and marketed in the future.

SYHT0H2 soybean would facilitate the use of two other broad-spectrum herbicides, as additional options available within an integrated weed management program. Glyphosate use may be reduced but mesotrione, isoxaflutole, and glufosinate use would likely increase. Unlike glyphosate, mesotrione and isoxaflutole have residual activity and may be applied pre-emergence for early-season weed control. This allows for greater flexibility in choice and timing of any post-emergence herbicide applications. They are also compatible with other herbicides in formulations and tank mixes as catalogued on labels for these herbicides. Mesotrione, isoxaflutole, and glufosinate are effective against a broad spectrum of weeds (dicots and grasses), including several weed biotypes that have developed resistance to glyphosate, acetolactate synthase (ALS) inhibitors, protoporphyrinogen oxidase (PPO) inhibitors, or triazine herbicides. Growers will make herbicide choices based on a broad range of factors that cannot be accurately predicted; it is not feasible to quantify future changes in herbicide use.

The addition of another SOA for soybean would provide potential for reducing development of new resistant weeds (Green, 2014)(J. McMillan, Alabama Commisioner of Agriculture, public comment, Docket APHIS-2012-0090) especially within comprehensive management programs that include multiple SOAs in tank mixes and applications during several crop stages (Norsworthy et al., 2012). Alternative weed control options available by planting SYHT0H2 soybean will likely reduce the use of glyphosate for soybean weed control, and potentially reduce selection pressure for additional development of glyphosate resistant weeds. Still other herbicides currently used for soybean weed control, including PPO-inhibiting herbicides such as fomesafen, may also see reduced selection pressure with MGI crops (Syngenta, 2013). Another weed management concern is the need for circumventing “rescue treatments” for crops with large Palmer amaranth and horseweed populations that are becoming resistant; these late applied treatments or high dose applications stress crops and reduce yield (Hartzler, 2012). The injurious effects may be averted if

MGI soybean were widely available for growers (Steckel, L., Univ. Tenn. Agric. Extension, Docket APHIS-2012-0090).

Replacing glyphosate use with mesotrione, isoxaflutole, or glufosinate is likely to reduce the pounds of active ingredients of herbicides applied to soybean fields since each of the herbicides to which SYHT0H2 soybean is tolerant is applied at lower rates than glyphosate. Based on herbicide labels, a comparison of the application rates for glyphosate, mesotrione, isoxaflutole, and glufosinate is provided in Table 4-2. Because commercial labels for mesotrione and isoxaflutole herbicides do not currently specify rates for use on soybean fields, application rates for these herbicides are provided as the proposed rates for use on tolerant soybean. These proposed rates have been submitted by Bayer and Syngenta to EPA for approval.

Table 4-2 Maximum Herbicide Application Rates for Herbicide Tolerant Soybean

	Maximum Application Rate (lb. ai/acre)	
Herbicide (Formulation)	**Single**	**Annual Total**
Glyphosate (e.g., RoundUp[1])	1.56	5.95
Mesotrione (Callisto[2])	0.20	0.31
Isoxaflutole (Balance Pro[3])	0.094	0.094
Glufosinate (Liberty[4])	0.53	1.188

NS: Not Specified.
Sources: 1 (Monsanto, 2012a) Glyphosate is reported as pounds acid equivalent per acre
2 Syngenta proposed soybean use rate
3 Bayer proposed soybean use rate
4 (Bayer, 2012)

As SYHT0H2 soybean is tolerant to a new mode of action (HPPD inhibition) only recently available in soybean (MST-FGØ72-2 soybean, which has been determined as nonregulated), two new broad-spectrum herbicides (mesotrione and isoxaflutole) would be available for soybean growers to incorporate into an integrated weed management program. Agricultural extension programs are both acknowledging the usefulness of the development of new synthetic auxin resistant crops and HPPD resistant crops, but suitably reserved about the prospects, noting that these "will provide good opportunities to manage some glyphosate-resistant weeds but expectations must be set appropriately and an understanding of the potential issues addressed to maximize the benefits and minimize the risks" (Iowa-State-Extension, 2014). However, new herbicide chemistries are not being introduced, and consequently, greater diversity of weed management is needed to respond to emerging problem weeds (Young, B., Purdue Agronomy Extension, public comments Docket APHIS-2012-0090) such as offered by crops with new herbicide resistance. Additional flexibility in management programs is also offered by mesotrione and isoxaflutole because these are both foliar active and soil active, in contrast to the foliar-only effectiveness of glyphosate and glufosinate. Proposed patterns of use of mesotrione were made by Syngenta and accumulated in more comprehensive plans for weed management and are found in Appendix C.

As noted in Section 3.2, Appendix F of the Petition (Syngenta, 2012c) includes a stewardship program as an integral part of the Preferred Alternative. The stewardship program includes the following elements:

- Technology use grower agreements;
- Integrated weed management and herbicide resistance recommendations;
- Customer education and training;
- Product use information and support; and
- Monitoring of grower use of herbicides.

Specific management recommendations for weed control in soybean and corn to minimize the development of herbicide-resistant weed biotypes are:

- Always use a full rate of a residual pre-emergence herbicide as specified on the product label.
- Do not rely solely on post-emergence applications of HPPD-inhibiting herbicides for control of target weeds; integrate other herbicides that are active on the target weeds such as glufosinate-ammonium, metribuzin and fomesafen for soybeans or glufosinate-ammonium, glyphosate, atrazine, and/or dicamba for corn.
- For post-emergence herbicide applications, use full labeled rates with recommended adjuvants on small weeds.
- Use herbicide combinations with several modes of action with overlapping efficacy on target weeds (i.e., chose herbicide combinations in which each active ingredient is effective against the most difficult-to-control target weeds).
- Strive for full and effective season-long weed control. Control weeds that have escaped herbicide treatment, and do not allow weeds to go to seed.

When herbicides are used in accordance with the stewardship program, SYHT0H2 soybean is expected to indirectly minimize the potential development of weed resistance to any one herbicide. The availability of other herbicides as additional components of integrated weed management would reduce the selection pressure on weed species to develop resistance to other methods of control.

Survival of soybean volunteers in the season subsequent to planting may occur with varying impacts; usually these are not serious crop competitors, but in some years may reduce yield in corn (Jhala et al., 2013). Syngenta-Bayer recommends that these multiply resistant MGI volunteers that arise be treated with suitable synthetic auxins such as 2,4-D, or with another soybean selective herbicide such as atrazine (Syngenta, 2012). These WSSA Class 4 and Class 5 herbicides have numerous alternative herbicide choices for applications to those crops that are frequently rotated with soybean.

4.2.3 Commercial Soybean Production and Uses

This section describes the potential impacts to commercial production of soybean seeds, raw and processed soybean commodities, organic soybeans, and specialty soybean products that may occur from the No Action and Preferred Alternatives.

4.2.3.1 Seed Production

As described in Section 2.2.3.1, *Seed Production*, seed purity is accomplished using contracts, tracking and traceability systems, quality assurance processes, closed loop systems, and identity preservation systems. Seed soybean production differs from commercial soybean production because seed companies impose strict requirements to maintain seed identity and high levels of genetic purity of the final product. These practices minimize to the extent practical the chance of commingling SYHT0H2 soybean seed with other seed. The practices used to maintain seed purity do not vary substantively between transgenic and nontransgenic varieties.

No Action Alternative

The availability of methods used to produce seed soybean under the No Action Alternative would be the same as in current seed soybean production systems.

Preferred Alternative

Seed soybean production methods would not change as a direct or indirect result of the Preferred Alternative. If APHIS approves the petition for nonregulated staus of SYHT0H2 soybean, specialty soybean products would continue to be protected by the identity systems established in the industry. SYHT0H2 soybean would be produced in a manner similar to other seed soybean varieties, which are typically produced under identity preservation systems that include contracts with growers, traceability, product tracking, and process verification. These procedures minimize chances of commingling SYHT0H2 soybean seed with other seed to the same degree as existing seed production systems.

4.2.3.2 Raw and Processed Soybean Commodities

As described in Section 2.2.3.2, *Raw and Processed Soybean Commodities*, soybean seeds are processed into a variety of industrial (oil), human dietary, and livestock products. Raw soybeans have no human or livestock feed use as they contain anti-nutrient factors; these factors are removed by heat processing. There are no differences in handling requirements for processing transgenic and nontransgenic soybean.

No Action Alternative

Raw and processed soybean commodities would not change as a direct or indirect result of the No Action Alternative. Raw and processed soybean commodities would continue to be handled in accordance with regulatory standards and industry practices even if SYHT0H2 soybean continues to remain a regulated article. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no effect on raw or processed commodities.

Preferred Alternative

Raw and processed soybean commodities would not change as a direct result of the Preferred Alternative. Based on data described in the Petition, SYHT0H2 soybean is not materially different from conventional soybean in composition or nutritional value (Syngenta, 2012c). Apart from the expected weed control benefits associated with tolerance to mesotrione, isoxaflutole, and glufosinate herbicides, SYHT0H2 soybean varieties are agronomically equivalent to their nontransgenic counterparts (Syngenta, 2012c). If SYHT0H2 soybean is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000, raw and processed soybean commodities would continue to be handled in accordance with regulatory standards and industry practices.

A determination of nonregulated status of SYHT0H2 soybean would likely result in changes of herbicide use types and rates, as described above. Raw and processed soybean commodities may be indirectly impacted by deregulating SYHT0H2 soybean as a result of different herbicide applications. Depending upon the extent of adoption of the product and application of the herbicides, some portion of the commodities would have residual concentrations of mesotrione, isoxaflutole, or glufosinate instead of glyphosate. EPA registration of herbicides (including mesotrione, isoxaflutole, and glufosinate) includes establishing limits of residual concentrations of the herbicides on food and feed commodities to protect human health and the environment. Current and proposed residual concentration limits (tolerances) for registered and new uses of these herbicides are described in the appendices.

4.2.3.3 Organic Soybean Production

Organic farming operations coexist with farming operations using nontransgenic and transgenic varieties for herbicide tolerance. As described in Section 2.2.3.3, *Organic Soybean Production*, the National Organic Program (NOP) requires that organic farms have distinct, defined boundaries and buffer zones separating adjoining land not under organic management to prevent unintended contact with substances not used in organic fields. Organic production operations must also develop and maintain an organic production system plan. Excluded production methods include methods used to genetically modify organisms or otherwise influence their growth and development by means not possible under natural conditions or processes.

In organic systems, the use of synthetic pesticides and fertilizers is strictly limited, and transgenic crops and inputs are prohibited. SYHT0H2 soybean would not be approved for use in organic systems because it is transgenic.

Organic soybean acreage represents less than 0.2 percent of the US soybean acreage (USDA-NASS, 2009a). In contrast to other US organic crops, US organic soybean production has not kept pace with demand (USDA-ERS, 2010c), which has generally been met by increasing imports from international organic soybean producers (USDA-NASS, 2009a). Organic farmers may benefit from proximate transgenic crops with herbicide tolerance traits: neighboring fields would not be seed banks for weeds that could infest the organic fields, easing their weed management needs.

No Action Alternative

Organic farming practices, including field management to avoid excluded methods and gene movement, would not change as a direct or indirect result of the No Action Alternative. Organic soybean seed availability would be unaffected by the No Action Alternative. Organic production systems and non-organic production systems would continue to coexist in accordance with NOP requirements. Organic soybean production would continue to be driven by market conditions if SYHT0H2 soybean continues to remain a regulated article.

The amount of transgenic soybean and organic soybean production in the US is increasing, and current trends suggest that both production practices will likely continue to increase. The use of coexistence measures is expected to continue. Organic farms would continue to benefit from the weed suppression provided by proximate farms with transgenic crops and low weed populations. The availability of seed for soybean varieties that are transgenic, nontransgenic, or used for organic production would remain the same. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no effect on organic farming.

Preferred Alternative

Organic farming practices, including field management to avoid excluded methods and gene movement, would not change as a direct or indirect result of the Preferred Alternative. Soybean is primarily a self-pollinated plant (OECD, 2000a), and there is no reason to expect that the biology of SYHT0H2 soybean will increase its potential to outcross with soybean varieties utilized in organic soybean production (Syngenta, 2012c). Studies of SYHT0H2 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 (Syngenta, 2012c).

Organic soybean seed availability would be unaffected by a determination of nonregulated status of SYHT0H2 soybean; the seed certification programs described above would continue to operate at their current level of effectiveness. Consistent with NOP standards and practices, organic and non-organic soybean production systems would continue to coexist. Organic farms would continue to benefit from the weed suppression provided by proximate farms with transgenic crops of herbicide tolerant varieties, including SYHT0H2 soybean. Organic soybean production would continue to be regulated by the NOP and driven by market conditions if SYHT0H2 soybean is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000. A determination of non-regulated status for SYHT0H2 soybean would not change current practices of organic soybean producers or the growth of organic soybean production.

Currently, the production of organic and transgenic soybean varieties are both increasing due to market demands (although organic production is unable to keep up with demand), and these markets would likely continue to increase under the Preferred Alternative. A determination of nonregulated status of SYHT0H2 soybean would not increase risks of contamination, via either pollinators or post-harvest processing, because the overall percentage of transgenic soybean is not expected to increase. SYHT0H2 soybean would not present new and different issues than existing herbicide-tolerant soybean cultivars (see Table 2-1) with respect to impacts on organic farmers.

APHIS has determined as non-regulated the products listed in Table 2-1 based on a finding that these other products do not pose a plant pest risk. Availability of SYHT0H2 seed will not lead to a decline in availability of organic or non-GE soybean seed for growers, nor to loss of choices for consumers. A determination of nonregulated status of SYHT0H2 soybean is unlikely to affect US organic soybean production.

4.2.3.4 Specialty Soybean Systems

Potential changes in specialty soybean systems, such as identity preservation, are described for the No Action Alternative and the Preferred Alternative in this section.

As with the purity processes described above for seed production, specialty soybean growers and end users maintain the identity of their products by contracts, tracking and traceability systems, quality assurance programs, closed loop systems, and identity preservation systems.

No Action Alternative

Other specialty soybean production systems would not change as a direct or indirect result of the No Action Alternative. Specialty products are likely to continue to be protected by the identity-preservation systems established in the industry even if SYHT0H2 soybean continues to remain a regulated article. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no effect on other specialty soybean production systems.

Preferred Alternative

Other specialty soybean production systems would not change as a direct or indirect result of the Preferred Alternative. If APHIS approves the petition for nonregulated status of SYHT0H2 soybean, specialty products would continue to be protected by the identity-preservation systems established in the industry.

4.3 Physical Environment

This section describes the potential impacts to soil, water quality, air quality, and climate that may result from the No Action Alternative and the Preferred Alternative as compared to the existing conditions described in Chapter 2.

4.3.1 Soil

As described in Section 2.3.1, *Soil*, agronomic practices such as crop type, tillage, and pest management regimes have greater effects on the biology of the soil than the type of soybean cultivated. In particular, tillage can adversely or beneficially impact soil quality (Holland, 2004; NRC, 2010). Degraded soil structure and composition may lead to decreased water retention, a decrease in soil carbon aggregation and net positive carbon sequestration, and increased greenhouse gas emissions. Conservation tillage methods can reduce these adverse effects and have been increasingly adopted by soybean growers, partially enabled by the capacity to apply a broad-spectrum herbicide (glyphosate) over a tolerant soybean variety (glyphosate-tolerant soybean). As discussed in Section 4.2.2, *Agronomic Practices*, conservation tillage in US soybean is generally associated with 30 percent or greater remaining plant residue and reduced soil erosion and compaction.

There may be a relationship between the introduction of herbicide-tolerant soybean varieties and an increase in the practice of no-till or conservation tillage by US growers. In 1995, before the introduction of glyphosate-tolerant soybeans, approximately 27 percent of the US soybean acres used no-till production. Approximately 50 percent of soybean acres were planted in no-till systems by 2009 (Horowitz et al., 2010).

Soil quality may be impacted by the application of herbicides on crops, as an indirect effect of transgenic soybean with herbicide tolerance traits, depending upon the chemicals' persistence in soil. Pre-emergence herbicide application would be directly on the soil and post-emergence application may result in some portion of the herbicides reaching the ground surface. Plant material could transfer herbicide residues into soil via biological activity of the plant or decay after harvest.

No Action Alternative

Soil characteristics would not change as a direct or indirect result of the No Action Alternative. The adoption of herbicide-tolerant soybean varieties is expected to continue. The increasing use of conservation tillage in US soybean production, an effect attributed to the glyphosate-tolerant soybean system, is not expected to change under the No Action Alternative. Insecticide use will remain as it is currently practiced and limited to a small percentage of total US soybean acreage (USDA-NASS, 2007). Glyphosate is anticipated to remain the most widely applied herbicide in US soybean production, continuing the current trend.

Soybean growers would continue current agronomic practices, and further adoption of conservation tillage methods is expected even if SYHT0H2 soybean continues to remain a regulated article. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no effect on soil characteristics.

Preferred Alternative

Soil characteristics would not change as a direct result of the Preferred Alternative. The new proteins expressed in SYHT0H2 soybean would not impact soil quality: compositional analysis of SYHT0H2 soybean tissue demonstrates that it is not substantially different from conventional soybean (Syngenta, 2012c).

SYHT0H2 soybean production would not change land acreage or cultivation practices for transgenic or nontransgenic soybean. Growers would continue current agronomic practices and continue to adopt conservation tillage methods regardless of whether SYHT0H2 soybean is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 or not. Continued adoption of conservation tillage would be facilitated by the addition of other broad-spectrum herbicides to the range of weed management tools used by growers. SYHT0H2 soybean is tolerant to mesotrione, isoxaflutole, and glufosinate. Thus, conservation tillage trends, and its direct beneficial effects on soil quality, are likely to continue as currently practiced.

Soil characteristics would not change as an indirect result of the Preferred Alternative. Mesotrione and isoxaflutole would be applied to pre-emergence or to SYHT0H2 soybean fields post-emergence, but would not adversely affect soil quality. Glufosinate would be applied to SYHT0H2 soybean fields post-emergence. As described in the appendices, these herbicides degrade rapidly through biotic or abiotic processes. Although the DKN degradate of isoxaflutole is more persistent than the parent chemical, soil quality will not be impacted when isoxaflutole is used in accordance with EPA label requirements. As a prerequisite to its registration of herbicides (including their degradates), EPA determines that there is no unreasonable environmental risk if the end user adheres to the label use restrictions during application. Application of isoxaflutole has conditions required for soil type, soil organic content, soil water saturation condition or water table height in 15 of 22 states registered by EPA to further protect soil and potential for either runoff or soil leaching (see label for (Bayer, 2013)).

4.3.2 Water Quality and Use

As described in Section 2.3.2, *Water Quality*, the primary cause of agricultural nonpoint source (NPS) pollution is increased sedimentation from soil erosion, which can introduce sediments, manure, fertilizers, and pesticides to nearby lakes and streams. Transgenic soybean is not a sediment, fertilizer, or pesticide and therefore is not a major component of agricultural NPS pollution. Soybean plant matter could be transferred to water bodies after field harvest, potentially accumulating in stream or lake sediments.

Water quality may be indirectly impacted by herbicide-tolerant crops as a result of changes in herbicide type and usage rates, as discussed in Section 4.2.2, *Agronomic Practices*. As described in Section 2.3.2, *Water Quality*, risks to water quality from herbicide use are assessed by the EPA during the herbicide registration (and re-registration review) process and are addressed, as warranted, through EPA requirements such as application methodology and buffer zones between fields, riparian areas, and water bodies, as well as monitoring for herbicide residues in surface and ground water.

No Action Alternative

Selection of glyphosate resistant weeds as well as non-glyphosate weeds as a consequence of growers using weed management practices not meeting best management practices is likely to continue. ;Subsequently, herbicide options for weed management may become less attractive under the No Action Alternative. One weed management alternative for growers is a return to more aggressive tillage systems to maintain soybean yields, and this has been observed in the Southern States(Prince et al., 2012a). When tillage is increased, runoff of soils and any chemicals in soil can also be expected to end up in water resources, such as rivers, lakes and ocean bodies. Regions where glyphosate resistant weeds have already become widely prevalent are most at risk. Furthermore, because other non-glyphosate herbicides will still be used to manage glyphosate weeds, these also may become more frequently represented in water resources.

Other factors have possible impacts on water quality would continue to be regulated by federal programs (some of which have been delegated to certain states) and agronomic practices to protect water quality would continue to be implemented even if SYHT0H2 soybean continues to remain a regulated article. Herbicide use would continue to evolve as transgenic soybean products with herbicide tolerance traits are developed, approved, marketed, and adopted, as described in Section 4.2.2, *Agronomic Practices*. Overall herbicide concentrations in water may change and water quality as well, independent of the regulatory status of SYHT0H2 soybean. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no effect on water quality.

Preferred Alternative

EPA evaluates risks to water quality when conducting ecological risk assessments as part of the herbicide registration review process, as described in the appendices for each of the herbicides that would be used on SYHT0H2 soybean. Identified risks are managed by EPA requirements for application methods and buffer zones, as specified in EPA-approved labels on each herbicide product. As previously noted in 4.3.1 Soil, at one time, nearly 70% of States allowing use of isoxaflutole placed restrictions on applied water, soil water conditions and soil qualities for application of the herbicide to crops, although that percentage may presently be changing (Syngenta, 2013). Labels for herbicides containing isoxaflutole, glufosinate, or mesotrione will be submitted by Bayer and Syngenta to EPA for approval of use on SYHT0H2 soybean fields. Based on these precautions, increased use of these products is unlikely to result in a substantive adverse impact to water quality.

Water quality could potentially show small improvements as an indirect result of the Preferred Alternative. SYHT0H2 soybean does not contain any substances that have the potential to affect water quality, but the availability of SYHT0H2 could potentially decrease the numbers of herbicides applied to control glyphosate resistant crops. Additionally, the availability of more cost efficient or effective herbicides that may be used with MGI soybean may delay the adoption of non-chemical management strategies under the Preferred Alternative. Fewer growers would be expected to adopt aggressive tillage when herbicides remain effective for weed control. Water quality would continue to be regulated by federal programs (some of which have been delegated to certain states) and agronomic practices to protect water quality would continue to be implemented if SYHT0H2 soybean is determined as nonregulated.

A summary of mesotrione's chemical persistence in water is found in Appendix A. The three herbicides to which SYHT0H2 soybean is resistant degrade rapidly and are therefore not persistent in surface or groundwater but the degradates may persist under certain conditions (i.e., suboxic conditions such as groundwater). The longest persistence was noted for DKN: the aqueous degradation half-life of DKN was calculated to be 103 days. As described in the appendix, the herbicides and their degradates are unlikely to concentrate or bioaccumulate.

EPA evaluates risks to water quality when conducting ecological risk assessments as part of the herbicide registration review process, as described in the appendices for each of the herbicides that would be used on SYHT0H2 soybean. Identified risks are managed by EPA requirements for application methods and buffer zones, as specified in EPA-approved labels on each herbicide product. As previously noted in 4.3.1 Soil, nearly 70% of States place restrictions on applied water, soil water conditions and soil qualities for application of isoxaflutole to crops. Labels for herbicides containing isoxaflutole, glufosinate, or mesotrione will be submitted by Bayer and Syngenta to EPA for approval of use on SYHT0H2 soybean fields. Based on these precautions, increased use of these products is unlikely to result in a substantive adverse impact to water quality.

Making available additional options for growers to control glyphosate resistant weeds may have additional consequences on water resources. In some Southern States, when resistant weed infestations and seed production attain high levels, soybean growers who do not have effective herbicide alternatives are deep-tilling the seeds to bury them. When these fields, formerly farmed as no-till or conservation-till fields, are changed to full tillage, soil water loss is enhanced, and additional surface irrigation is needed; in States such as Georgia, supplemental irrigation can deleteriously impact water resources (B. Tolar, Georgia Agribusiness Council, personal communication). A determination of nonregulated status for SYHT0H2 could improve water availability in some regions of soybean cultivation.

4.3.3 Air Quality

As described in Section 2.3.3, *Air Quality*, agricultural activities such as burning, tilling, harvesting, applying pesticides, and fertilizing can directly affect air quality by emitting vehicle exhaust, dust, and herbicide sprays. With regard to transgenic soybean with herbicide tolerance traits, burning, harvesting, and fertilizing practices do not vary between transgenic and nontransgenic agricultural varieties. Air quality impacts from aerial application of herbicides may vary slightly between transgenic soybean varieties with herbicide tolerance traits and nontransgenic varieties because different herbicides would be used for transgenic varieties. Aerial application of herbicides has the potential to impact air quality from drift, diffusion, and volatilization of the chemicals, as well as motor vehicle emissions from airplanes or helicopters. Potential impacts are managed by adherence to the application requirements stated on EPA-approved herbicide labels, including consideration of wind speed when spraying.

Section 4.2.2.4, *Pesticide Use*, explains that herbicide use can be changed by transgenic herbicide tolerant crops, potentially benefitting air quality if chemical use and motorized equipment use can be reduced. As discussed in Section 4.2.2.2, *Cropping Practices*, conservation tillage increases with the use of transgenic crops, resulting in lower dust emissions and farm equipment exhaust emissions.

No Action Alternative

Air quality would not change as a direct or indirect result of the No Action Alternative. Soybean growers would continue current trends in agricultural activities even if SYHT0H2 soybean continues to remain a regulated article. Application of herbicides and adoption of conservation tillage practices would continue on current trend lines as additional herbicide-tolerant products are adopted by growers, reducing impacts to air quality from agricultural activities. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no effect on air quality.

Preferred Alternative

Air quality would not change as a direct result of the Preferred Alternative because the SYHT0H2 plant does not display any characteristics that would impact air quality. Agronomic practices that may affect air quality may be altered as a result of using a different suite of herbicides on SYHT0H2 soybean fields: additional passes across the fields may be required in certain instances to apply a range of herbicides at different times, as part of an integrated weed management program. Vehicle exhaust emissions and dust generation may increase, but it is not possible to quantify the extent. The herbicides to which SYHT0H2 soybean is tolerant are not volatile and therefore would not impact air quality.

4.3.4 Climate

As described in Section 2.3.4, *Climate*, agriculture-related activities are recognized as both direct (e.g., exhaust from motorized equipment) and indirect (e.g., agriculture-related soil disturbance, fertilizer production) sources of greenhouse gases (GHGs). Transgenic crops in general have reduced the release of GHGs from agriculture, equivalent to removing 5 million cars from the roads each year (Brookes and Barfoot, 2005), by reducing equipment use and allowing adoption of conservation tillage methods. The permanent CO_2 savings arising from reduced fuel use in the US attributable to transgenic herbicide-tolerant soybeans in 2008 was 290 million kilograms of CO_2 (Brookes and Barfoot, 2010).

The climate can also affect agricultural crop production, and climate change could affect soybean yields either positively or negatively. Transgenic soybeans with herbicide tolerance traits are not expected to differ from nontransgenic soybean in response to climate change.

No Action Alternative

The climate would not change as a direct or indirect result of the No Action Alternative. Soybean growers would continue current trends in agricultural activities even if SYHT0H2 soybean continues to remain a regulated article. GHG emission reductions would continue as other transgenic varieties are adopted by growers and they seek more energy-efficient methods of agriculture. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no effect on the climate. Increases or decreases in soybean yields resulting from climate change would not be affected by the No Action Alternative.

Preferred Alternative

The climate would not change as a direct or indirect result of the Preferred Alternative. SYHT0H2 soybean production would not change land acreage or cultivation practices for transgenic or nontransgenic soybean. As described in the Petition (Syngenta, 2012c), SYHT0H2 soybean requires management strategies similar to those for conventional soybean production, and would not affect agricultural activities that may impact climate change. Growers would continue current trends in agricultural activities if SYHT0H2 soybean is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000. GHG emission reductions would continue as SYHT0H2 soybean and other transgenic varieties are adopted by growers and they seek more energy-efficient methods of agriculture. Increases or decreases in soybean yields resulting from climate change would not be affected by the Preferred Alternative.

4.4 Natural Biological Communities (Non-Target Organisms)

This section describes the potential impacts to animals, plants, soil microorganisms, biodiversity, and gene movement in the natural environment that may result from the No Action Alternative and the Preferred Alternative as compared to the existing conditions described in Chapter 2. Potential impacts to threatened and endangered species are separately described in Chapter 6.

4.4.1 Animals

As described in Section 2.4.1, *Animals*, soybean fields may be temporarily or permanently occupied by many animals including invertebrates, birds, and mammals. Aquatic animals may reside in water bodies adjacent to soybean fields. Animals can have positive, negative, or no effect on soybean production; herbicide-tolerant soybean varieties do not affect animals but the herbicides applied to these crops may.

Most herbicides used on soybeans are only slightly toxic to birds and mammals (Palmer et al., undated). Cultural practices that decrease the need for herbicides include rotating crops, selecting resistant varieties (when possible), planting and harvesting at the proper time, and using integrated pest management techniques. Potential impacts to wildlife are minimized by applying herbicides in accordance with EPA label requirements.

No Action Alternative

Animals would not be affected as a direct or indirect result of the No Action Alternative. Animal exposure to genetically modified crops containing enzymes tolerant of herbicides would be nearly identical to current conditions even if SYHT0H2 soybean continues to remain a regulated article. Approved transgenic soybean cultivars would continue to be used by growers and there would be no change in animal exposure rates outside of controlled environments (i.e., agriculture). Regulated field trials of SYHT0H2 soybean would only impact small plots of land with controlled animal incursions.

Preferred Alternative

Animals are not likely to be affected as a direct result of the Preferred Alternative. If SYHT0H2 soybean is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000, animal exposure to genetically modified crops with herbicide tolerance would be similar to current conditions. As described in Section 4.2.1, *Agronomic Practices*, land use and agricultural production of SYHT0H2 soybean under the Preferred Alternative is likely to continue as currently practiced. There would be no direct impact to animal communities as a result of soybean production practices under the Preferred Alternative.

Consumption of SYHT0H2 soybean would also not affect animals. Toxicological assessments of the two enzymes conferring herbicide tolerance to mesotrione, isoxaflutole, and glufosinate are described in the Petition (Syngenta, 2012c). As presented in Section VI.D.3, *Conclusions of the Toxicological Assessment of AvHPPPD-03*, of the Petition,

> "The source organism for *avhppd-03*, oat, is a safely consumed food crop, and the enzymatic mode of action of AvHPPD-03 is a native feature of *A. sativa* HPPD, with no toxicological significance to mammals. The bioinformatic analysis showed that AvHPPD-03 is most similar to other HPPD proteins in common food crops and does not have sequence similarity to any known or putative toxins. In mice, AvHPPD-03 was not acutely toxic when administered orally (NOAEL = 2000 mg/kg b.w.[38]). Therefore, AvHPPD-03 is considered to be nontoxic."

Similarly, as presented in Section VII.E.3, *Conclusions of the Toxicological Assessment of PAT*, of the Petition,

> "The PAT protein in SYHT0H2 soybean is from a source organism that is not known to be toxic. The PAT protein from *S. viridochromogenes* is a member of a well-characterized, safe class of enzymes with a high degree of substrate specificity, and shows significant homology with PAT proteins from other source organisms. Bioinformatic analysis revealed no amino acid sequence similarity to any known toxins or other proteins known to cause adverse effects, and PAT was not acutely toxic to mice. PAT is therefore considered to be nontoxic."

Increased use of mesotrione, isoxaflutole, and glufosinate may be an indirect result of introducing SYHT0H2 soybean that is tolerant of these other herbicides. The potential risks, as identified by EPA's review of toxicological data, to animals and habitat presented by these herbicides are described in the appendices. These risks are managed by proper herbicide application, in accordance with the EPA-approved herbicide labels.

A determination of nonregulated status of SYHT0H2 soybean would not directly or indirectly impact animals. An evaluation of ecosystem effects is provided in Section 4.4.4, *Biodiversity*.

4.4.2 Plants

As described in Section 2.4.2, *Plants*, soybean fields may be bordered by other agricultural fields (including other soybean varieties), woodlands, pasture and grasslands, or wetlands. These bordering areas may be occupied by non-target plants. Transgenic soybean cultivars with herbicide tolerance traits allow growers to change herbicide usage types and application rates to manage target plants (i.e., weeds) within fields. Both target and non-target plants may be affected by herbicides (target plants are addressed in Section 4.2.2). Impacts to non-target plants outside of

38 No Observable Adverse Effect Level equals 2,000 milligrams per kilogram (mg/kg) of body weight.

soybean fields may result from herbicide spray drift and volatilization. Such potential impacts are managed by adherence to the application requirements stated on EPA-approved herbicide labels.

No Action Alternative

Non-target plants would not be affected as a direct or indirect result of the No Action Alternative. Weed management methods would continue following current trends even if SYHT0H2 soybean continues to remain a regulated article. 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. Isoxaflutole, glufosinate, mesotrione, and other approved herbicides would continue to be used on other crops in accordance with label requirements that protect non-target plants. Regulated field trials of SYHT0H2 soybean would only occur on small plots of land with controlled plant exposures. No impacts to non-target plant species are anticipated.

The continued emergence of glyphosate resistant weeds under the No Action Alternative will itself call for growers to modify crop management practices to address these weeds. Growers are expected to become less reliant on glyphosate for the control of weeds if it is no longer effective in controlling problem weeds. However, growers are expected to depend on additional chemical and non-chemical methods to control the glyphosate resistant weeds. Changes in management practices will likely include more use of non-glyphosate herbicides and adjustments to crop rotation and tillage practices (Owen et al., 2011).

Preferred Alternative

Non-target plants would not be affected as a direct result of the Preferred Alternative. SYHT0H2 soybean production would not change land acreage or cultivation practices for transgenic or nontransgenic soybean. Target plants (i.e., weeds) would be affected by the Preferred Alternative, as intended. This alternative, by allowing the use of herbicides with different modes of action than are currently available for use on soybean, will indirectly help prevent or delay the evolution of herbicide resistance among target weed species, and help deter shifts in weed populations to those that are naturally tolerant to present soybean herbicides that are predominately used by growers.

SYHT0H2 soybean would facilitate the new or increased use of some herbicides in US soybean production. Mesotrione, isoxaflutole, and/or glufosinate would likely be applied to fields planted with this herbicide-tolerant variety, possibly in combination with other herbicides registered for use on soybeans. These herbicides would also continue to be used on rotational crops in the same fields. Non-target plants may be potentially affected from herbicide volatilization or spray drift as an indirect result of the Preferred Alternative.

While weed resistance to HPPD inhibitor herbicides appears to be limited (Heap, 2013), a recent report suggests that one weed type may be of increasing importance. The earliest resistance to HPPD inhibitor herbicides arose from repeated applications of two herbicides from this class, and this occurred only in the specialized circumstance of seed corn production. Reports from Iowa now indicate that between 24 and 27% of waterhemp populations have resistance to HPPD class herbicides (Iowa-State-Extension, 2014). The use of this herbicide in soybean production regions with existing HPPD weed resistance will need to take into account that increased probability. Growers will unquestionably need to heed the requirement planned for inclusion in the Technical Use Agreement for MGI seed purchasers, which is to use overlapping herbicide sites of action to target susceptibilities of multiply resistant and principal weeds (Iowa-State-Extension, 2014).

As explained in the appendices for the herbicides that would be used on SYHT0H2 soybean (Sygenta and Bayer, 2013), volatilization is not likely for these compounds due to their low vapor pressure. Spray drift has the potential to impact non-target plants or may affect the quality of stormwater or irrigation water run-off. The potential risks to non-target plants presented by these herbicides (as identified by EPA's review of toxicological data) are described in the appendices. These risks are managed by proper herbicide application, in accordance with the EPA-approved herbicide labels.

There would be no new off-target impacts associated with application of the three herbicides (mesotrione, isoxaflutole, and glufosinate) to SYHT0H2 soybean when they are used in accordance with label directions. EPA has determined that there is no unreasonable environmental risk if the end user adheres to the label use restrictions when applying herbicide formulations. Herbicide labels specify application equipment and methodology to minimize spray drift. For Restricted Use Pesticides (e.g., isoxaflutole), requirements specify that applications must be made by a certified applicator to minimize effects on nearby environments.

4.4.3 Soil Microorganisms

As described in Section 2.4.3, *Soil Microorganisms*, the main factors affecting microbial population size and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (as providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation). Planting transgenic soybeans does not substantively change any of these factors except agricultural management practices. The changes in crop rotation, tillage practices, fertilizer application, and irrigation outlined in Section 4.2.1, *Agronomic Practices*, are not expected to substantively affect soil microorganisms. Herbicide types and application rates can be changed by growers when new herbicide-tolerant cultivars are available; herbicides that persist in soil and are toxic to microbes have the potential to affect soil microorganisms.

Glyphosate can alter the microbial ecology and biology of the rhizosphere environment. Increased fungal populations that develop under glyphosate treatment of glyphosate-resistant soybean may adversely affect plant growth and biological processes in the soil and rhizosphere (Kremer et al., 2005). Field studies conducted in Missouri during the 1997 to 2007 period assessed effects of glyphosate applied to glyphosate-resistant soybean and maize on root colonization and soil populations of *Fusarium* and selected rhizosphere bacteria (Kremer and Means, 2009). Frequency of root-colonizing *Fusarium* increased significantly after glyphosate application during growing seasons in each year at all sites. Roots of soybean and maize treated with glyphosate were heavily colonized by *Fusarium* compared to non-glyphosate-resistant or glyphosate-resistant cultivars not treated with glyphosate. These studies hypothesized that root-exuded glyphosate may serve as a nutrient source for fungi and stimulate propagule germination.

No Action Alternative

Soil microorganisms would not be affected as a direct or indirect result of the No Action Alternative. Soybean cultivation would continue as currently practiced. Microbes in the field would continue to be exposed to common agronomic practices, including herbicide applications to soybean fields. The use of transgenic soybean with herbicide tolerance traits would continue following current trends even if SYHT0H2 soybean continues to remain a regulated article. Regulated field trials of SYHT0H2 soybean would involve only small plots of land with controlled plant exposures. No impacts to soil microorganisms compared to any effects from current agronomic practices are anticipated.

Preferred Alternative

Soil microorganisms would not be affected as a direct result of the Preferred Alternative. As stated in the Petition (Syngenta, 2012c), SYHT0H2 soybean phenotype characteristics do not differ substantively from its nontransgenic parent variety and the new enzymes are not toxic. Soil microbial interaction with plant tissue would not have any effect.

Herbicides have the potential to impact soil microbes if the herbicides are toxic to them. As described in the appendices, studies of mesotrione, isoxaflutole, and glufosinate have found no to minimal impacts to soil microorganisms. The Preferred Alternative would not have an indirect adverse affect on soil microorganisms.

4.4.4 Biodiversity

Biological diversity, or the variation in species or life forms in an area, is highly managed in agricultural fields. Biodiversity in an agroecosystem (the organisms and environment of an agricultural area when considered as an ecosystem) depends (Altieri, 1999) on the:

- Diversity of vegetation within and around the agroecosystem;
- Permanence of crops within the agroecosystem;
- Intensity of management; and
- Extent of isolation from natural vegetation.

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. Farmers want to encourage high yields from their crop, and will intensively manage plant and animal communities through chemical and cultural controls to protect the crop from damage. The biological diversity in agricultural fields is therefore lower than in the surrounding habitats. Although soybean production fields are cultivated as plant monocultures to optimize yield, the adjacent landscape may harbor a wide variety of plants and animals. Most transgenic crops increase the productivity of cultivated lands, so biodiversity is protected because additional land is not needed for the same volume of crop production.

A qualitative and relative comparison of the potential for ecological impacts of herbicides can be made by calculating an "environmental impact quotient" (EIQ) based on the application rate and percentage of active ingredient in marketed products. The EIQ method was developed by integrated pest management specialists at Cornell University to help fruit and vegetable growers of New York State to evaluate low impact pest-control options (Levitan, 1997). A composite EIQ score is calculated for each pesticide active ingredient using an algebraic equation that combines the numerical ratings assigned to eight environmental parameters. The underlying premise of the EIQ method is to screen for potential impacts that might result from the interaction of toxicity and exposure. In conducting EAs of herbicide-tolerant transgenic plants, APHIS has used the EIQ method to compare the environmental effects of herbicide usage on a relative basis (e.g., *Environmental Assessment, Bayer Petition 09-328-01 for Determination of Nonregulated Status of Double Herbicide-tolerant Soybean (Glycine max) Event FG72* and *Final Environmental Impact Statement, Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status*).

In order to assess relative impacts to ecosystems, the calculation provides an "ecological" EIQ based on application rates of herbicide active ingredients, rather than toxicity of the pure compound to fish, birds, bees, and beneficial organisms (NYS-IPM, 2012). Table 4-3 compares the ecological EIQ ratings of the top ten herbicides used on soybeans currently (see Figure 2-3) and the three herbicides of which SYHT0H2 soybean is tolerant (listed in **bold type**), using the maximum annual application rates for soybeans on the referenced product labels, or the proposed rates for the new use on transgenic SYHT0H2 soybean (see Table 4-2). Table 4-3 also provides an overall "field use" EIQ rating, which combines the ecological EIQ with worker and consumer ratings based on toxicity to humans.

These ratings provide a qualitative comparison of the potential overall environmental effect of using these herbicides. Table 4-3 shows that the ecological EIQ can vary considerably from the overall field use EIQ, as the percentage of active ingredient and the application rate substantively affect the final score. The dominant herbicide used on soybeans, glyphosate, has a slightly higher ecological EIQ (indicating higher environmental impact) than the three herbicides of which SYHT0H2 soybean is tolerant.

Table 4-3 EIQ Ecological and Overall Field Use Rating of Selected Herbicides

Herbicide				Environmental Impact Quotient Rating[1]	
Common Name	**Example Formulation**	**Percent active ingredient**	**Maximum Annual Application Rate (per acre)**	**Overall Field Use**	**Ecological**
2,4-D Dimethylamine salt	2,4-D Amine 4[2a]	46.8	2 pts	19.3[2b]	29.0
2,4-D Dichlorophenoxy-acetic acid	Weedone LV6EC[3a]	87.3	1.5 pts	21.8[3b]	44.5
Chlorimuron	Classic[4a]	25.0	1.5 oz	0.5[4b]	1.0
Clethodim	Clethodim 2EC[5a]	26.4	32 fl oz	9.0[5b]	16.4
Fomesafen	Flexstar[6a]	22.1	1.6 pts	8.6[6b]	11.5
Glyphosate	Roundup[7a]	48.7	44 fl oz	20.5[7b]	46.9
Imazethapyr	Pursuit[8a]	22.9	4 oz	1.1[8b]	1.9
Metribuzin	Sencor DF[9a]	75.0	1.34 lb	28.5[9b]	69.4
Pendimethalin	Prowl[10a]	38.7	4.0 pts	46.7[10b]	113.0
Trifuralin	Treflan HFP[11a]	43.0	4.0 pts	32.4[11b]	72.2
Glufosinate	Liberty[12a]	18.2	62 fl oz	14.2[12b]	30.0
Isoxaflutole	Balance Pro[13a]	40.5	3 fl oz	1.8[13b]	3.0
Mesotrione	Callisto[14a]	40.0	10 fl oz	4.7[14b]	8.3

Sources:1- (NYS-IPM, 2012)
2a- (Albaugh, Undated) 2b- (NYS-IPM, 2013b)
3a- (Nufarm, Undated) 3b- (NYS-IPM, 2013a)
4a- (DuPont, 2012) 4b- (NYS-IPM, 2013c) Note: this herbicide is commonly tank-mixed with other herbicides such as glyphosate
5a- (Willowood, 2011) 5b- (NYS-IPM, 2013d)
6a- (Syngenta, 2010b) 6b- (NYS-IPM, 2013e)
7a- (Monsanto, 2012a) 7b- (NYS-IPM, 2013g)
8a- (BASF, 2011) 8b- (NYS-IPM, 2013h)
9a- (Bayer, Undated) 9b- (NYS-IPM, 2013k) Note: this herbicide is not currently marketed in the US; the application rates are for a Canadian formulation
10a- (BASF, 2012) 10b- (NYS-IPM, 2013l)
11a- (Dow, 2008) 11b- (NYS-IPM, 2013m)
12a- (Bayer, 2012) 12b- (NYS-IPM, 2013f)
13a-(Bayer, 2013) 13b- (NYS-IPM, 2013i)
14a- (Syngenta, 2011a) 14b- (NYS-IPM, 2013j)

No Action Alternative

Biodiversity would not be affected as a direct or indirect result of the No Action Alternative. Biodiversity within agroecosystems would continue to be affected by agricultural practices following current trends. Growers would 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 of 2000, and adoption of new transgenic soybean varieties would be expected to continue even if SYHT0H2 soybean continues to remain a regulated article. Animal and plant species that typically inhabit soybean production fields or adjacent land will continue to be affected by currently utilized management plans and systems, which include the use of mechanical, cultural, and chemical control methods. Regulated field trials of SYHT0H2 soybean would only involve small plots of land with controlled animal and plant incursions. No changes in biodiversity compared to effects from current agronomic practices are anticipated.

Preferred Alternative

Biodiversity would be unchanged as a result of the Preferred Alternative. SYHT0H2 soybean is not toxic and does not exhibit any different agronomic traits or require different agronomic practices (Syngenta, 2012c). As described in Section 4.4.1, *Animals,* and Section 4.4.2, *Plants,* animal and plant species that typically inhabit soybean production areas would be managed the same as for other herbicide tolerant soybean products on the market. The four determinants of biodiversity in an agroecosystem listed above are likely to remain unchanged under the Preferred Alternative.

As shown in Table 4-3, isoxaflutole, glufosinate, and mesotrione display relatively low EIQ ratings as compared to the top ten other herbicides used on soybean, and in particular glyphosate. Adding new transgenic soybean cultivars with tolerance of isoxaflutole, glufosinate, and mesotrione would be likely to increase the use of these herbicides but, as demonstrated by the lower EIQ scores than the most commonly used herbicide (glyphosate), would not adversely affect biodiversity.

4.4.5 Gene Movement in the Natural Environment

Soybean is principally a self-pollinated species, propagated by seed (OECD, 2000a). As described in Section 2.4.5, *Gene Movement in the Natural Environment*, there is no evidence that horizontal gene transfer can naturally occur between unrelated plant species. Genetic engineering artificially accomplishes horizontal gene transfer, but does not impart natural gene transfer.

Cross-pollination to adjacent plants of other soybean varieties occurs at a very low frequency (0 to 6.3 percent as measured in experimental treatments) (Caviness, 1966; Ray et al., 2003; Yoshimura et al., 2006). As described in Section 2.2.5, *Persistence in the Environment/Weediness Potential*, cultivated soybean seed rarely displays any dormancy characteristics and only under certain environmental conditions grows as a volunteer in the year following cultivation, minimizing the potential for vertical gene movement. The soybean plant is not weedy, and there are no wild relatives outside of Asia.

No Action Alternative

Soybean's characteristic of limited gene movement in the natural environment would not be affected as a direct or indirect result of the No Action Alternative. Soybean breeding by traditional or transgenic means would continue even if SYHT0H2 soybean continues to remain a regulated article. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with minimal potential for exposure to sexually compatible plants (i.e., other soybean plants) or unrelated plants. No changes in the natural gene movement characteristics of current soybean varieties are anticipated.

Soybean's persistence in the environment and weediness potential would not be affected as a direct or indirect result of the No Action Alternative. Soybean breeding by traditional or transgenic means would continue even if SYHT0H2 soybean continues to remain a regulated article. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with minimal potential for exposure to sexually compatible plants (i.e., other soybean plants). No changes in these characteristics of current soybean varieties are anticipated.

Preferred Alternative

Soybean's characteristic of limited gene movement in the natural environment would not be affected as a direct or indirect result of the Preferred Alternative. As described in the Petition (Syngenta, 2012c), it is theoretically possible that the transgenes *avhppd-03* or *pat* could enter the soil. However, multiple reviews have concluded that there is minimal likelihood of horizontal gene transfer between transgenic plants and soil microorganisms (Keese, 2008). Should *avhppd-03* or *pat* from SYHT0H2 soybean be integrated into a plasmid or chromosome of a bacterium, it is highly unlikely that AvHPPD-03 or PAT proteins will be produced, because the codon use in *avhppd-03* and *pat* is optimized for expression in plants, not bacteria. It is highly unlikely that AvHPPD-03 or PAT will be produced in soil via transformation of bacteria with genes from SYHT0H2 soybean.

Soybean's persistence in the environment and weediness potential would not be affected as a direct or indirect result of the Preferred Alternative. Cultivation of SYHT0H2 soybean will not lead to the transfer of *avhppd-03* and *pat* to wild relatives of soybean because they are not present in the US. The weediness potential of soybean has not been altered by SYHT0H2 soybean. Germination and dormancy characteristics of SYHT0H2 soybean seed are no different than those of conventional soybean seed (Syngenta, 2012c). The introduced traits in SYHT0H2 soybean are not intended to affect the range or frequency of soybean outcrossing, and phenotypic data show no indication that the genetic modification resulted in enhancement of reproductive characteristics of SYHT0H2 soybean compared with conventional soybean (Syngenta, 2012c).

4.5 Public Health

This section describes the potential impacts to human health, animal (livestock) health, and worker safety that may result from the No Action Alternative and the Preferred Alternative as compared to the existing conditions described in Chapter 2.

4.5.1 Human Health

In theory, transgenic products could impact human health because of possible toxic or nutritional effects of the products, or how the product might change the allergenicity of food products. As described in Section 1.1, *Regulatory Authority*, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from transgenic products must be in compliance with all applicable legal and regulatory requirements. Transgenic products for food and feed also routinely undergo a voluntary consultation process with the FDA prior to release onto the market. To date, all transgenic crops marketed in the US have been the subject of pre-marketing consultations with the FDA.

No Action Alternative

Human health would not be affected as a direct or indirect result of the No Action Alternative. Transgenic soybean that are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 would continue to be used as food for human consumption. Human exposure to SYHT0H2 soybean would be limited to those individuals involved in cultivation under regulated conditions even if SYHT0H2 soybean continues to remain a regulated article. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no potential for exposure to the general public. Exposure to existing transgenic and nontransgenic soybean would not change under this alternative.

Preferred Alternative

Human health would not be affected as a direct result of the Preferred Alternative. If SYHT0H2 soybean is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000, the general public would primarily come in contact with the introduced transgenic proteins (i.e., AvHPPD-03 or PAT) through dietary exposure to food and products derived from SYHT0H2 soybean, although most processed products would contain no detectable AvHPPD-03 or PAT residues. The lack of human health effects from the lack of changes in nutritional value, potential exposure to constituents of SYHT0H2 soybean, and potential exposure to herbicides are described below.

The Petition (Syngenta, 2012c) states that an analysis of key nutritional components of forage and seed from SYHT0H2 soybean identified no differences from conventional, nontransgenic soybean that would affect human or animal health. No unintended, adverse consequences of the transformation process or expression of the transgenes in SYHT0H2 soybean were evident in any test. Seed, forage, and soybean meal from SYHT0H2 soybean were found to be similar in composition to those same materials from conventional soybean. SYHT0H2 soybean exhibits a compositional profile similar to that of reference soybean varieties grown concurrently in several locations and other soybean varieties.

Soybean is one of the most commonly implicated sources of food allergy. SYHT0H2 soybean seed was assessed to determine whether its endogenous allergen content differed from that of a nontransgenic, near-isogenic control soybean (variety ‘Jack’) or commercially available nontransgenic soybean reference varieties (Syngenta, 2012c). SYHT0H2 soybean was determined to be comparable to and as safe as conventional soybean varieties and will not pose greater health risks to soybean-allergic consumers than nontransgenic soybean.

The Petition also states that both AvHPPD-03 and PAT are homologous with proteins in many species to which humans and animals are exposed daily without concern (Syngenta, 2012c). AvHPPD- 03 and PAT do not share significant amino acid similarity to known toxins and are not acutely toxic in mice. AvHPPD-03 and PAT are unlikely to be human allergens.

AvHPPD-03 is derived from a safely consumed endogenous protein in a common food crop, oat (Syngenta, 2012c). Oat contains no endogenous proteins that are listed in the Food Allergy Research and Resource Program (FARRP) Allergen Protein Database[39] and therefore is not considered to be a known allergenic food. Oat has been implicated as a potential source of proteins that cause celiac disease in humans; however, a recent review of the literature clarified that this risk has likely been confounded by the use of test materials that were not pure oats (HealthCanada, 2007). Pure oats can be consumed by celiac disease patients who are otherwise sensitive to foods such as wheat and barley (which contain the proteins associated with celiac disease and are listed in the FARRP Allergen Protein Database).

HPPD enzymes, as a group of biochemically and structurally related proteins, are ubiquitous in commonly consumed food plants and animals, and the level of AvHPPD-03 in SYHT0H2 soybean is low (Syngenta, 2012c). AvHPPD-03 is not acutely toxic in mice and has no significant amino acid sequence similarity to known toxins or allergens. Bioinformatic analysis and assays for digestibility, heat inactivation, and glycosylation status provided in the Petition indicate that AvHPPD-03 is unlikely to be a food allergen. AvHPPD-03 is not likely to pose a risk to the health of humans or other mammals through consumption of SYHT0H2 soybean.

PAT has been safely used and consumed in commercially available transgenic crops and has a permanent EPA tolerance exemption in all crops under 40 CFR § 174.522. It has a history of safe use in numerous transgenic crop 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 of 2000. The PAT protein produced in SYHT0H2 soybean has been characterized and tested to determine its potential for causing adverse effects in humans and livestock (Syngenta, 2012c). The PAT protein in SYHT0H2 soybean is from *S. viridochromogenes* (a member of a well-characterized, nonpathogenic group of bacteria), shows a high degree of substrate specificity, and shows significant homology with PAT proteins from other source organisms. Bioinformatic analysis revealed no amino acid sequence similarity to any known toxins or other proteins known to cause adverse effects, and PAT was not acutely toxic to mice. PAT is therefore considered to be nontoxic.

PAT is also unlikely to be a food allergen. It is derived from a source organism that contains no known allergens, it is not significantly similar in amino acid sequence to any known allergens, and, as expressed in SYHT0H2 soybean, it shows no glycosylation (Syngenta, 2012c). Furthermore, PAT is produced at very low levels in soybean seed, its enzyme activity is completely inactivated at 55°C, and it is rapidly degraded in simulated mammalian gastric and intestinal fluids. PAT is not similar to known allergens, and little or no dietary exposure to intact PAT protein would occur in humans or other mammals via consumption of SYHT0H2 soybean.

Human health assessments from potential exposure to herbicides are described in the appendices. Each of the three herbicides that would be applicable to SYHT0H2 soybean (mesotrione, isoxaflutole, and glufosinate) are registered with EPA. EPA's review process has determined that these herbicides and their degradates present no unreasonable risk to human health when used in accordance with EPA-approved label requirements.

39 http://www.allergenonline.org/databasebrowse.shtml

The Petitioners have initiated a pre-market consultation process with FDA and submitted a Safety and Nutritional Assessment for SYHT0H2 soybean (Syngenta, 2012c). The consultation was completed on March 28, 2014 (see FDA Memo BNF 000139) and FDA did not identify any safety or regulatory issues under the FD&C Act that would require further evaluation at this time. Syngenta and Bayer Crop Science have concluded that SYHT0H2 soybean and the foods and feeds derived from it are not materially different in composition, safety, or any other relevant parameter from other soybean varieties now grown, marketed and consumed in the United States. The completed assessment documents a lack of toxicity of the introduced AvHPPD-03 and PAT proteins in SYHT0H2 soybean for human and animal consumption, and a lack of allergenicity concerns for humans. No adverse impacts to human health, either directly or indirectly, are expected from a determination of nonregulated status of SYHT0H2 soybean.

4.5.2 Worker Safety

As described in Section 2.5.3, *Worker Safety,* pesticides, including insecticides, fungicides and/or herbicides, are used on most soybean acreage in the US; herbicides are the most commonly used pesticides on soybean. The EPA's Worker Protection Standard (USEPA, 1992) requires employers to take actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The restrictions and precautions for worker safety associated with most herbicides include:

- Personal Protective Equipment (chemical-resistant gloves and other skin protection, eye protection, respirators, etc.) or other measures (closed-system applications) to minimize applicator exposure;
- Minimum worker reentry intervals post application; and
- Minimum preharvest intervals post application.

Large-scale cultivation of transgenic herbicide-tolerant soybean has increased since its introduction in 1996. As described in Section 2.2.2.6, *Management of Weeds*, the volume of herbicide active ingredients has been trending downward since the introduction of herbicide-tolerant soybeans in 1996, but glyphosate use has been trending upward. The actual health risk that workers experience is based on the specific chemicals to which they may be exposed and the chemical handling procedures used, as described above. Prior to registering a pesticide, EPA conducts an in-depth worker safety evaluation, and imposes strict requirements for personal protective equipment, field reentry intervals, and specific handling instructions for mixing, loading and applying the product.

No Action Alternative

Agricultural workers and pesticide applicators would continue adhere to the restrictions required by the variety of registered herbicides such as those approved by EPA for use on soybeans under the No Action Alternative. Chemical herbicide use rates would likely continue to evolve as new varieties of herbicide-tolerant transgenic soybean are adopted, allowing a more diverse weed management program. Worker exposure to herbicides would be managed by following application requirements listed on product labels. Approved transgenic soybean cultivars would continue to be used even if SYHT0H2 soybean continues to remain a regulated article. Regulated field trials of

SYHT0H2 soybean would only impact small plots of land with limited potential for exposure to agricultural workers. Under the No Action Alternative, agricultural workers and herbicide applicators would continue to be exposed to a variety of chemicals including mesotrione, isoxaflutole, and glufosinate on crops other than soybeans.

Preferred Alternative

The Preferred Alternative would not have a direct impact to worker safety, as the SYHT0H2 soybean does not display any characteristics that pose a risk to workers from exposure. The Preferred Alternative would likely result in the use of different herbicides on soybean fields than currently, potentially indirectly affecting workers. EPA-registered isoxaflutole, glufosinate, and mesotrione herbicides that are currently used on other crops would be available for use by soybean growers under the Preferred Alternative. As described in Section 4.2.2.4, *Pesticide Use*, trends in herbicide use are likely to continue as a direct result of the Preferred Alternative. The addition of a new herbicide-tolerant soybean variety would allow the use of herbicides not currently applicable to soybeans, diversifying the tools available to growers as part of an integrated weed management program. Instead of increasing applications of glyphosate to manage weeds that are developing resistance to this herbicide, these other herbicides could be used. As described in the appendices, EPA's review of toxicological studies has shown that these herbicides present no unreasonable risk to humans. EPA's label requirements are intended to minimize or eliminate risks to workers from exposure during application.

4.5.3 Animal (Livestock) Health

As described in Section 2.5.2, *Animal (Livestock) Health*, livestock ingestion of feed from transgenic crops, with subsequent human ingestion of livestock food products, is a potential concern about transgenic crops. Several whole and processed fractions of soybeans contribute to the total animal diet (OECD, 2001b). The main soybean product fed to animals is defatted/toasted soybean meal, generally not exceeding 15 percent of the animals' diet. Aspirated grain fractions, forage, hay, hulls, seed, silage, and bakery products containing soybean oil are also fed to cattle. Hay and hulls are also fed to poultry, and soybean aspirated grain fractions, hulls, and seeds have been fed to swine.

Section 2.5.2, *Animal (Livestock) Health*, explains that approximately 27 million tons of soybean meal are used annually for animal feed, representing nearly 70 percent of the total annual soybean meal production. As approximately 93 percent of the soybean produced in the US is transgenic, it may be assumed that the majority of soybean livestock feed is also transgenic. As discussed in Section 4.5.1, *Human Health*, soybean has anti-nutrient qualities that can be removed by heat processing, and transgenic soybean does not vary in this regard from nontransgenic soybean. The proteins that convey herbicide tolerance are derived from natural sources, have been tested for safety, and are not expected to be toxic in mammals or poultry. Changes in herbicide use types or rates that could conceivably result from introducing herbicide-tolerant cultivars may indirectly impact livestock if safe exposure levels are exceeded.

No Action Alternative

Animal (livestock) health would not be affected as a direct or indirect result of the No Action Alternative. Livestock would not be exposed to SYHT0H2 soybean if it continues to remain a regulated article. Transgenic soybean that are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 will continue to be used as feed for animal consumption, and adoption of transgenic soybean varieties would be expected to continue. Exposure to existing transgenic and nontransgenic soybean would not change under this alternative. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no potential for exposure to livestock.

Preferred Alternative

Animal (livestock) health would not be affected as a direct or indirect result of the Preferred Alternative. Processing SYHT0H2 soybean for livestock feed would be unchanged from current practices. SYHT0H2 soybean and soybean meal processed from raw SYHT0H2 soybeans are nutritionally and compositionally comparable to raw and processed soybean from conventional varieties (Syngenta, 2012c). SYHT0H2 soybean is expected to provide adequate nutrition as part of formulated diets delivered to growing livestock.

If SYHT0H2 soybean is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000, livestock would primarily come in contact with the introduced AvHPPD-03 and PAT proteins in SYHT0H2 soybean through feed products derived from SYHT0H2 soybean. As described in Section 4.5.1, *Human Health*, these proteins are not toxic. Livestock would not be adversely affected by consuming SYHT0H2 soybean containing these introduced proteins.

The Petitioners have initiated a voluntary pre-market consultation process with FDA and submitted a Safety and Nutritional Assessment for SYHT0H2 soybean in August 2012 (Syngenta, 2012b). The consultation was completed on March 28, 2014 (see FDA Memo BNF 000139) and FDA did not identify any safety or regulatory issues under the FD&C Act that would require further evaluation at this time. Syngenta and Bayer CS have concluded that SYHT0H2 soybean and the foods and feeds derived from it are not materially different in composition, safety, or any other relevan parameter from other soybean varieties now grown, marketed and consumed in the United States. The completed assessment documented a lack of toxicity of the introduced AvHPPD-03 and PAT proteins in SYHT0H2 soybean animal consumption. No adverse impacts to livestock, either directly or indirectly, are expected from deregulating SYHT0H2 soybean.

Different herbicides may be used by soybean growers as a result of deregulating SYHT0H2 soybean, potentially changing livestock exposure to herbicides. Potential impacts to livestock health are minimized by adherence to EPA-approved label requirements. For example, the herbicide labels for Callisto® (containing mesotrione), Balance Pro® (containing isoxaflutole), and Liberty® (containing glufosinate) include precautions on time limits when certain crops may not be used as forage or feed after herbicide application.

4.6 Socioeconomic Factors

This section describes the potential impacts to the domestic trade environment, foreign trade environment, and social and economic environment that may result from the No Action Alternative and the Preferred Alternative as compared to the existing conditions described in Chapter 2.

4.6.1 Domestic Trade Environment

The majority of soybean production in the US is utilized domestically for animal feed, with lower amounts and byproducts used for oil or fresh consumption (GINA, 2011; USDA-ERS, 2010a). As described in Section 2.6.1, *Domestic Trade Environment*, the estimated value of the 2012 US soybean production to meet these demands as well as export requirements (described below) is $34.5 billion. In 2011, transgenic products comprised 93 percent of the planted soybean to satisfy this demand (USDA-ERS, 2011c). The transgenic traits include herbicide tolerance and improved oil content, as described in Section 2.1, *Soybean Biology*. Overall, harvest security and quality are better with herbicide-tolerant soybean. Farm income is positively impacted by herbicide-tolerant soybean by reducing production costs (e.g., reduced tillage for weed management and, potentially, reduced herbicide use). Section 2.2.2.6, *Management of Weeds*, explains that soybean yield losses can range from 12 to 80 percent if weeds are uncontrolled for an entire season.

Economic advantage is a key indicator and useful index for comparing glyphosate-tolerant soybean to conventional weed control programs, and is instructive for anticipating changes to the domestic trade environment that may result from the introduction of other herbicide-tolerant soybean varieties. The unprecedented high rate of acceptance and adoption of glyphosate-tolerant soybean in industrial and developing countries demonstrates the economic advantage of glyphosate-tolerant soybean (Carpenter et al., 2002). A major impact of the introduction of glyphosate-tolerant soybean has been a reduction in weed control costs for soybean farmers. As early as 1997, weed control costs for glyphosate-tolerant soybean adopters were lower than those incurred by nonadopters (Lin et al., 2001). Manufacturers of conventional herbicides soon reacted to their declining market share by decreasing the prices of conventional herbicides, such as imazethapyr and chlorimuron, by as much as 40 percent (Carpenter et al., 2002). The result has been a reduction in weed control costs for both adopters and nonadopters of glyphosate tolerant soybean. It was estimated that in 2000, US soybean farmers would spend $307 million less on weed control than in 1995 (Carpenter and Gianessi, 1999). A recent economic impact for one weed control system (comprised of a combination of herbicides and herbicide-tolerant corn, cotton, and soybean) estimated that adoption of the system could add $1.9 billion in net farm revenue in 2011 alone, with increasing benefits over time (Dow, 2011); this money would be otherwise spent on alternative herbicide and tillage programs to control glyphosate-resistant weeds.

Despite the rapid adoption of herbicide-tolerant soybeans, there was little impact on net farm returns in 1997 and 1998 (Fernandez-Cornejo and Caswell, 2006). It may be that the adoption of herbicide-tolerant soybeans is associated with increased off-farm household income, suggesting that farmers adopt this technology because the simplicity and flexibility of the technology permit them to save management time, allowing them to benefit from additional income from off-farm activities. Herbicide-tolerant soybean varieties offer growers greater flexibility in the timing and choice of herbicide applications. The benefits attributable to herbicide-tolerant soybeans and their distribution are very dependent on the soybean supply elasticity (Fernandez-Cornejo and Caswell, 2006).

No Action Alternative

The domestic trade environment would not be affected as a direct or indirect result of the No Action Alternative. Growers would continue to make choices to plant certain soybean varieties and use certain crop rotation practices based on factors such as yield, weed, disease and other pest pressures, cost of seed and other inputs, technology fees, worker safety, potential for crop injury, and ease and flexibility of the production system (Gianessi, 2005). The No Action Alternative would not affect available options for growers and therefore not affect the domestic trade environment. SYHT0H2 soybean would remain a regulated article and would require an APHIS permit or notification for release into the environment. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no impact on the domestic trade environment.

Preferred Alternative

The Preferred Alternative would not directly impact the domestic trade environment; SYHT0H2 soybean does not offer any agronomic or yield advantages over other soybean cultivars currently on the market. However, the domestic trade environment could be positively affected as an indirect result of deregulating SYHT0H2 soybean, although accurate projections are not possible. Growers would have an additional set of herbicides to use for weed control on soybean fields if SYHT0H2 soybean is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000, potentially reducing economic loss from weed competition and economic cost from weed control. More effective weed management offered by expanding an integrated weed management program would minimize yield losses and help preserve the efficacy of weed management systems.

The Preferred Alternative could also indirectly result in economic benefit from increased competition in the seed and herbicide markets. The availability of multiple herbicide-tolerant products would increase grower choice and price competition, potentially resulting in lower seed prices for growers. The option to use different herbicides may have a similar effect on herbicide prices.

4.6.2 Foreign Trade Environment

As described in Section 2.6.2, *Foreign Trade Environment*, the US produces approximately 33 percent of the global soybean supply and the primary US soybean export destinations include China, Mexico, Japan, and Indonesia. These countries do not have major barriers for importing food or feed commodities produced from transgenic crops, including those with herbicide tolerance traits. Soybean exports to European Union countries have generally declined since the Common Agricultural Policy limited grain imports and EU membership has expanded (USDA-ERS, 2011a); exports to Europe may increase slightly in 2013 due to economic conditions, physical constraints, and climate issues elsewhere (USDA-ERS, 2013c).

No Action Alternative

The foreign trade environment would not be affected as a direct or indirect result of the No Action Alternative. Additional genetically modified soybean varieties would continue to be developed and available in the foreign trade market. SYHT0H2 soybean would remain a regulated article and would require an APHIS permit or notification for release into the environment. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no impact on the foreign trade environment. There would be no change in imports to other countries, including the European Union, as a result of the No Action Alternative.

Preferred Alternative

The foreign trade environment would not be affected as a direct or indirect result of the Preferred Alternative. Worldwide market conditions and destination country approval of transgenic crop commodities would continue to be factors for international soybean prices, without regard to the presence or absence of SYHT0H2 soybean on the market. A determination of nonregulated status of SYHT0H2 soybean would not adversely impact the foreign trade economy and may potentially enhance it through more efficient production of soybean supplies worldwide.

The Petitioners intend to apply to foreign agencies for approval of the unconfined environmental release and food and feed use of soybean commodities and processed goods containing SYHT0H2 soybean. Regulatory filings for SYHT0H2 soybean import approvals have been made in Canada, Argentina, Japan, Republic of China, South Korea, Republic of South Africa, Australia and New Zealand, and the European Union. Regulatory filings in additional countries, including the People's Republic of China, are planned. The foreign trade economic impacts associated with a determination of nonregulated status of SYHT0H2 soybean are anticipated to be very similar to the No Action Alternative.

4.6.3 Social and Economic Environment

As described in Section 2.6.3, *Social and Economic Environment,* farmers have a range of options in agronomic practices, seed products to choose from, and opportunities for sale to customers. Consumers have a range of soy products to choose from. Section 4.2.3.3, *Organic Soybean Production*, explains that growers may choose to grow transgenic, nontransgenic, or organic soybeans, and obtain price premiums for growing varieties of soybean for particular markets. Regulatory agency requirements (under the *Federal Food, Drug, and Cosmetic Act* and the National Organic Program, for example) and consumer advocacy groups promote food product safety and consumer choice.

No Action Alternative

The social and economic environment would not be affected as a direct or indirect result of the No Action Alternative. SYHT0H2 soybean would remain a regulated article and would require an APHIS permit or notification for release into the environment. Regulated field trials of SYHT0H2 soybean would only impact small plots of land with no impact on the social and economic environment.

Preferred Alternative

The social and economic environment would not be affected as a direct or indirect result of the Preferred Alternative. Regulatory programs and consumer choice would be unchanged by a determination of non-regulated status of SYHT0H2 soybean.

Concerns have been raised in public comments about potential mixing of organic with GE soybean and consequent loss of full soybean commodity value. SYHT0H2 will not present a different risk than that of other GE soybean for such admixture, nor does APHIS conclude that there will be more GE soybean produced under the Preferred Alternative. The levels of current admixture for organic soybean as summarized from supply chain testing in the US was undetectable in 95% of 2180 samples tested, between 0.1 and 0.5% in 4% of samples and between 0.51 and 0.99% in 0.8% of samples {Organic-Trade-Association, 2011 #316}. If these values are typical of those found generally, and the rejection threshold for EU acceptability is typical of purchasers (0.9%) then under the Preferred Alternative, APHIS concludes that the rejection rate for organic soybean will be less than 0.8% and unchanged from that under the No Action Alternative.

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5 CUMULATIVE EFFECTS

This Chapter describes the potential cumulative effects that may result from the Preferred Alternative. In accordance with CEQ regulations, this evaluation considers the potential effects that, although individually minor, could have a collectively significant impact on the environment when added to other past, present, and reasonably foreseeable future actions.

5.1 Introduction

The CEQ regulations (CEQ, 1978) define a cumulative effect as "the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time." For example, for USDA-APHIS cumulative effects may include the impacts associated with a determination of nonregulated status of a genetically engineered 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 PPA. A cumulative impact may also result from the use of an herbicide with a similar mode of action to that of the intended herbicides described in the Petition for nonregulated status.

Based on the information provided in Sections 4.2 through 4.6, which is summarized in Table 3-1, the Preferred Alternative would not have substantive direct or indirect adverse impacts to soybean production practices or the physical, natural, social, or economic environment. If SYHT0H2 soybean is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000, some resources may be beneficially impacted to a minor degree, as compared to the No Action Alternative. This cumulative effects evaluation reviews only those resources that may be directly or indirectly impacted by deregulating SYHT0H2 soybean, whether the impacts are adverse or beneficial. Resources that would not be impacted by the Preferred Alternative are not subject to the cumulative effects evaluation.

In the event that APHIS reaches a determination of nonregulated statusof SYHT0H2 soybean this soybean varerity could be combined ("stacked") with nontransgenic and transgenic soybean cultivars that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA. Such transgenic cultivars could include those listed in Table 2-1 as well as other varieties for which Environmental Assessments are in process or petitions for nonregulated status that are in review and subsequently approved . This could result in a plant variety that, for example, may be resistant to additional herbicides and contain other transgenic traits such as increased oil or fatty acid production. APHIS's regulations at 7 CFR part 340 do not provide for agency oversight of transgenic 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 of 2000, nor over stacked varieties combining transgenic cultivars that are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000, unless it can be positively shown that such stacked varieties are likely to pose a plant pest risk. Any herbicides that would be used on a stacked product have been subject to EPA's registration process and review for impacts to human health and the environment; approved herbicides pose little risk when used in accordance with label requirements. This cumulative effects analysis therefore evaluates the combination of the transgenic traits that may occur from SYHT0H2 soybean stacked with other traits, and the combination of additional herbicides that may be used on fields of the stacked product, rather than the individual impacts of other transgenic traits or other herbicides.

The analyses provided in the following sections discuss the potential cumulative impacts to selected resources that may result from the direct and indirect effects of a determination of nonregulated status of SYHT0H2 soybean when combined with other past, present, and reasonably foreseeable future actions. There is no indication in the Petition (Syngenta, 2012c) that SYHT0H2 soybean will be stacked with any particular transgenic variety that is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000, as company plans, third-party licensing negotiations, and market demands play a significant role in those business decisions. Predicting all potential combinations of stacked varieties that could be created using both transgenic soybean cultivars that are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 and nontransgenic soybean cultivars is hypothetical and speculative. Because it is not possible to identify specific varieties of stacked transgenic traits and further changes in herbicide use that may result from such stacks, these potential cumulative impacts are discussed in general terms.

5.2 Agronomic Practices

A determination of nonregulated status of SYHT0H2 soybean is not anticipated to have a cumulative effect on agronomic practices involving either cropping practices or weed management. As described in Section 4.2.2.1, *Cropping Practices,* deregulating SYHT0H2 soybean would not have a direct or indirect adverse impact on cropping practices, though some beneficial changes may result. Transgenic soybean varieties with nonregulated status have not differed substantively from nontransgenic soybean in agronomic requirements and pest sensitivities, and SYHT0H2 soybean is similar as well (Syngenta, 2012c). It is unlikely that there would be any cumulative effect on soybean cropping practices related to growing the plant as a result of stacking SYHT0H2 soybean with any other currently available soybean product.

The potential for adverse impacts to the environment from the expected increased use of HPPD inhibitor herbicides were they to exist, are direct and indirect impacts outside the scope of this EA. Authority to regulate the impacts of herbicide use resides with the EPA under FIFRA. USDA's authority comes from the Plant Protection Act, which limits APHIS authority to the regulation of plant pests and noxious weeds only. Under APHIS's regulations, APHIS can only consider plant pest risks when making a determination of nonregulated status. APHIS has no authority to regulate herbicide use. The EPA's registration process under FIFRA ensures that pesticides will be properly labeled and that, if used in accordance with label specifications, will not cause unreasonable harm to humans and the environment. Thus EPA has the authority to regulate the effects of herbicide use on humans and the environment.

Herbicide use patterns and application rates may change beyond those anticipated in Section 4.2.2.4, *Pesticide Use*. If SYHT0H2 soybean is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000 , farmers may apply any of the three herbicides of which SYHT0H2 soybean is tolerant: mesotrione, isoxaflutole, and glufosinate. These applications would occur in combination with, or possibly in place of, other herbicides registered for use on soybeans. Although HPPD-inhibitor herbicides other than mesotrione and isoxaflutole exist, the developer has not demonstrated that SYHT0H2 soybean has resistance to commercial application rates of other HPPD-inhibitor herbicides registered by EPA. It is therefore unlikely that any other currently registered HPPD-inhibiting herbicides would be substituted for mesotrione or isoxaflutole for use on SYHT0H2 soybean. Further, there are no other glutamine synthetase-inhibiting herbicides besides glufosinate (which is also known as glufosinate-ammonium and phosphinothricin) that could be used on SYHT0H2 soybean.

The additional application of mesotrione and also isoxaflutole to rotation crops following SYHT0H2 soybean can be estimated. Both are also registered for uses on other crops, and some of these crops would also be used in rotation with soybean. The crop with the largest acreage rotation with soybean would be corn. Mesotrione (as Callisto for field corn) is registered in 49 states and Puerto Rico). Usage rates of mesotrione on corn have increased between 2003 and 2005 to 20% of corn acres, but showed a decline in 2010 to 17% (See Table 5-1). The likelihood that mesotrione would be used on corn after mesotrione treatment of SYHT0H2 soybean would be the product of the estimated adoption rate of SYHT0H2 (15%) times percentage of the rotation to corn (70%), and a product of the present usage rate (17%) which would be 1.8%. However, the rate could be much less, since growers are being cautioned by weed scientists not to use the same herbicide site of action (SOA) repeatedly or over time (Hartzler, 2014). Isoxaflutole (as Balance Pro for field corn) is registered in at least 18 states, and BCS indicates the total has risen to 28 states (Syngenta, 2012c). Isoxaflutole use on corn has been much less than that for mesotrione, averaging 7% of acres between 2005 and 2012. The rate of successive season reuse by chance alone would be about 0.7%. Use of two other HPPD inhibitors attained to only 3% of acres on corn, and the repeat rate for next year application of mesotrione to SYHT0H2 soybean would be about 0.3%. The frequency that any HPPD inhibitor would be used on corn following SYHT0H2 would be no more than 2.8%. Thus, a low likelihood exists of repeated application of the HPPD inhibitor herbicides to corn rotated with soybean production acres.

Glufosinate use on soybean according to the most recent survey by USDA-NASS has attained to 3% of acres in 2012 and on corn in 2010 has averaged about 3% of acres over the seven years encompassed by the survey. At the maximal predicted adoption rate, the likelihood of glufosinate corn following glufosinate SYHT0H2 soybean would be between 0.25 and 0.31%. Again it is likely that there would not be a high frequency of repetitive use of the glufosinate which could lead to greatly enhanced development of resistance in weeds exposed to and then surviving the herbicide.

Table 5-1. Corn and Soybean Acres Treated with Glufosinate, Glyphosate, Isoxaflutole, or Mesotrione as a Percentage of Acres Planted

Herbicide		Corn % Acres Treated			Soybean % Acres Treated	
Year	2010	2005	2003	2012	2006	2005
Glyphosate (all salts)	76	33	19	98	96	91
Glufosinate	2	5	3	3	0	0
Isoxaflutole	7	6	8	0	0	0
Mesotrione	17	20	8	0	0	0
Tembotrione	2	NA	NA	-	-	-
Topramezone	1	NA	NA	-	-	-

Source: (USDA-NASS, 2013b)

Application of mesotrione to SYHT0H2 soybean can occur under registered use as late as the R1 stage, and other adjacent crops may also receive incidental application. Corn would be the most frequent rotation crop to receive incidental mesotrione applications (and the EA uses rotation crop statistics as an estimate of the most likely adjacent crop). Corn, however, is not sensitive to mesotrione. Two other crops may follow soybean with a lower frequency (See Table 5-5): soybean at 15% (Table 5-4) and wheat at 11% (Table 5-3). Soybean varieties have variable sensitivity to HPPD inhibitors, and wheat can receive pyrasulfatrole (another HPPD inhibitor herbicide) until flag leaf stage. The other crops have a frequency of around 1-2 % or less, or far less likely to be an adjacent crop, and so would not represent substantial overall risk of crop injury.

At least six herbicides classes are typically reported as sources of herbicide injury, and one of these classes include the HPPD inhibitor herbicides; also glyphosate, and synthetic auxins (such as 2,4-D) are included in the cited classes (Lingenfelter and Curran, 2013). Glyphosate, being applied exceptionally more frequently to soybean and its rotation crops than other herbicides, while capable of causing herbicide injury, and may do so. Glyphosate is applied at later stages in crop development than other herbicides when it is used with glyphosate resistant crops, but it is not cited as particularly prone to herbicide drift issues (Lingenfelter and Curran, 2013). Group 4 (WSSA) herbicides (such as 2,4-D) are more likely to generate alerts for potential drift injuries, but HPPD less so (Lingenfelter and Curran, 2013). However, in the absence of observational data, it cannot be determined if mesotrione or isoxaflutole when incidentally applied are less safe from causing injuries at a later stages to non-MGI soybean or to other crops than at earlier stages. Extension agronomy or weed science publications generally seem not to note recurrent or frequent non target injury herbicide injuries from applied HPPDs. Instead, injuries are noted to occur to the target crop from incorrect herbicide combinations with the HPPD class or from known interactions with insecticides (Clough and Peachey, NA); some cited injuries were consequences of carryover in the soil from the previous season or a same year earlier applications. Correctly following herbicide label directions may avert many of these issues (e.g., see Callisto label).

Table 5-2. Frequency of Crops as a Rotation Crop with Soybean: Crops Registered for Use with Mesotrione and Stages for which They are Sensitive.

Crop	Permitted exposure	Frequency of crop as a rotation following soybean (% of acres compared to soybean)	Use of HPPD inhibitor herbicides (% of acres) in 2011 or 2012 NASS Surveys (Quick Stat)
Corn	Can be used at any POST stage	69	27
Sorghum	Seven days pre-emergence	1.1	7
Oats	Any stage	0.1	0
Flax	Before crop emergence	0.1	0
Millet	Before crop emergence	.05	0

From: Callisto herbicide label and Table 5-5.

Table 5-3. Frequency of Crops as a Rotation Crop with Soybean: Crops Registered for Use with Pyrasulfatrole (Huskie) and Stages at which They are Sensitive

Crop	Permitted exposure	Frequency of crop as a rotation following soybean (% of acres compared to soybean)	Use of HPPD inhibitor herbicides (% of acres) in 2011 or 2012 NASS Surveys (Quick Stat)
Wheat (spring)	First leaf to flag leaf	11.2	0
Barley (spring)	First leaf to flag leaf	.05	N/A
Durum	First leaf to flag leaf	N/A	0
Sorghum	Between 3 leaf stage of growth up 30 inches and/or prior to flag leaf emergence, whichever comes first	1.1	7 (mesotrione)

From: Huskie herbicide label

Table 5-4. Crops not Registered for HPPD Inhibitors but with Greater than 14% Deployment of a Rotation Crop (by Percentage of Crop to National Crop Total Acres) to Soybean

Crop	Susceptibility to exposure	Frequency of crop as a rotation following soybean (% of acres compared to soybean)	Use of HPPD inhibitor herbicides (% of acres) in 2011 or 2012 NASS Surveys (Quick Stat)
Soybean	No yield loss at 11g/a; sensitivity varies by variety	14.5	0
Cotton	Susceptible but undefined	2.1	0
Rice	At least after 5-6 leaf stage	1.4	0
Sugar Beets	Application sensitivity not determined: soil sensitive	0.19	0 (no recent data)

From: (Damalas et al., 2010; Young et al., 2003) and Callisto label

MGI soybean sites on which mesotrione or isoxaflutole may be applied could potentially provide origins for HPPD resistant weeds. Some growers whose corn rotation crops are dependent upon mesotrione (or other HPPD inhibiter) for control of weeds could find the potential presence of mesotrione- resistant weeds difficult to manage. Other crops that may be planted as rotation crops labelled for use of mesotrione include those in Table 5-2 or crops labelled for use of pyrasulfatrole, those in Table 5-3. Corn, which has the highest likelihood of being a rotation crop for soybean, already has considerable use of HPPD inhibitor herbicides, but has more effective herbicide options already than does soybean (K Bradley, Univ. Missouri, personal comment, 2013). Sorghum attains 7% of the total soybean crop acreage as a soybean rotation crop, and represents a small likelihood that it will be planted adjacent to SYHT0H2 soybean and thus be exposed to escapes of mesotrione resistant weeds. The other rotation crops had no major use of HPPD inhibitor herbicides as recently as 2011 or 2012. Other soybean rotation crops as listed in Table 5-4 do not already have a registered use for an HPPD inhibitor herbicide, so growers are at no risk of losing an important herbicide should HPPD inhibitor resistant weeds escape through rotation in subsequent years. Increased use of mesotrione with SYHT0H2 adoption is not likely to result in substantive risks of mesotrione resistant weeds arising in rotation crops that have no available alternative herbicide for their control.

Table 5-5. Crops Planted Following Soybean, with Total Acreage, Percentage of the Crop Compared to the National Total Crop Planting (in 2008) and the Percentage of the Crop Compared to the Total Soybean Acreage.

Rotational Crop Following Soybean[1]	Total Acreage of Rotational Crop Following Soybean (000)[2]	Percent of Rotation Crop Following Soybean[3]	Percent of Rotational Crop as a Fraction of Total Soybean Acreage[4]
Corn	51,500	69%	68.6
Soybean	10,866	14%	14.5
Sorghum	841	21%	1.1
Cotton	1,570	42%	2.1
Wheat	8,396	22%	11.2
Barley	41	2%	0.05
Oats	98	5%	0.1
Rice	1,042	45%	1.4
Alfalfa	162	9%	0.2
Sugar Beets	144	17%	0.19
Potatoes	32	10%	0.04
Dry Beans	35	3%	0.05
Dry Peas	38	7%	0.05
Millet	41	16%	0.05
Flax	76	22%	0.1
Various vegetables	141	31%	0.2

Sources: See Appendix E; (Monsanto, 2010; Monsanto, 2012b; USDA-NASS, 2008; USDA-NASS, 2009b).

Notes:

1. Crops listed have been identified as the primary crops, nationwide, in the soybean rotation strategy.
2. Acres presented represent total acres of rotational crop identified as planted following soybean.
3. Percent of rotation crop following soybean identified as that fraction of the total nationwide planting of rotation crop following soybean.
4. Percent of rotation crop following soybean identified as that fraction of total rotation crop relative to total acreage of soybean, identified in 2008 as 75,037,000 acres.

It is possible that SYHT0H2 soybean could be stacked with other transgenic soybean 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 of 2000 that confer tolerance to herbicides with other modes of action. As described in Section 4.2.2.4, *Pesticide Use*, overall herbicide application rates (as measured in pounds of active ingredient applied per acre of crops) have increased slightly in recent years, even as particular herbicide application rates have risen or fallen. Stacking SYHT0H2 soybean with other traits that confer tolerance to herbicides with different modes of action would offer growers greater choices in herbicide programs and advance integrated weed management practices. Any herbicides that would be used in this scenario would have been registered with EPA and approved for use on soybeans; substantive changes in herbicide application practices are therefore unlikely. Agronomic practices would only be minimally altered by using previously approved herbicides on SYHT0H2 soybean fields. A determination of nonregulated status of SYHT0H2 soybean would not have a cumulative effect on agronomic practices.

Weed populations can change in response to farm-level agronomic practices, including weed management decisions. The development of glyphosate-resistant weeds as a result of the predominant use of glyphosate is one such consequential practice. An integrated weed management system, incorporating a range of herbicides that use different modes of action, could minimize the development of weeds resistant to any one herbicide or herbicide class. Further, herbicide use (and indirectly, the use of herbicide-tolerant crops) should be a component of a broader integrated weed management system (Mortenson et al., 2012). Integrated weed management 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 agricultural environment (Mortenson et al., 2012). Cultivating SYHT0H2 soybean and using a broader range of herbicides as a result of the Preferred Action Alternative will facilitate a more comprehensive approach to weed management than is currently possible (*see* the proposed practice for mesotrione use in Appendix D). Preemptively incorporating integrated weed management measures (as described in the stewardship plan presented as Appendix F of the Petition (Syngenta, 2012c)) may prevent or delay the development of resistant weed populations.

Planted and produced within an integrated weed management system and within the context of best management practices, SYHT0H2 soybean would offer soybean growers new herbicide options and possibly facilitate the control of glyphosate-resistant weed populations. Additionally, HPPD inhibitor-resistant SYHT0H2 may also prevent or delay the rate of development of other herbicide resistant weeds. Syngenta-Bayer's stewardship plan would require signing a Technology Use Agreement (TUA) which requires that the grower practice integrated weed management principles (Syngenta, 2012). While the details of the TUA have not been finalized, they will describe best practice use of SYHT0H2 soybean in terms of several burndown-, soil residual- and post-emergent- applications of residual, foliar active or combinations of herbicides (Syngenta, 2013). The cumulative effect on weed management as a result of deregulating SYHT0H2 soybean could potentially minimize the development of new populations of weed species with herbicide resistance and maintain and preserve herbicide efficacy.

Adoption of MGI soybean could provide growers with an alternative herbicide to glyphosate and also an alternative to intensive tillage practices that might be used to manage herbicide resistant weeds (Prince et al., 2012a). Any additional option for managing weeds and weed resistance in the context of multiple crops with various resistance traits can be useful in a framework of integrated weed management. However, the eventual occurrence of weeds resistant to mesotrione, glufosinate or isoxaflutole could over time limit the use of MGI crops and any benefit to natural resources that may arise. The magnitude of the benefit or the loss of the benefit is uncertain because decisions on crop production management are made by individual growers.

5.3 Water Quality and Use

A determination of nonregulated status for SYHT0H2 soybean is not anticipated to result in an adverse cumulative effect on water quality. As described in Section 4.3.2, *Water Quality and Use*, deregulating SYHT0H2 soybean would not have any direct effect or substantive adverse indirect effect on water resources. Stacking SYHT0H2 soybean with other herbicide tolerance traits would allow other herbicides to be used on SYHT0H2 soybean crops. Any herbicides that would be used in this scenario, such as glyphosate, would have already been registered with EPA and approved for use on soybeans. Glyphosate, currently the most extensively used herbicide, has relatively low impacts to soil and water quality compared to many other herbicides (Cerdeira and Duke, 2010).

As described in Section 4.3.2, *Water Quality*, EPA evaluates risks to water quality when conducting ecological risk assessments as part of the herbicide registration review process. Identified risks are managed by EPA requirements for application methods and buffer zones. Based on these precautions, deregulating SYHT0H2 soybean would not have an adverse cumulative effect on water quality. In some regions, the inability to control herbicide resistant weeds arising on crops and their rotation crops has led to increased tillage or other cultivation. If conventional tillage is increased to control glyphosate- and other herbicide-resistant weeds, there may be an impact on soil quality from increased erosion. A determination of nonregulated status for SYHT0H2 offers an additional postemergent herbicide that could control problem weeds and avert additional tillage to control these problem weeds.

5.4 Soil

A determination of nonregulated status of SYHT0H2 soybean is not anticipated to result in an adverse cumulative impact on soil quality. As described in Section 4.3.1, *Soil*, SYHT0H2 soybean would not have a direct or indirect adverse effect on soil quality. SYHT0H2 soybean will contribute to the continued trend toward conservation tillage, an agricultural practice with strong direct and positive effects on soil quality (Holland, 2004; NRC, 2010). Stacking SYHT0H2 soybean with other transgenic traits that confer herbicide resistance may have a positive effect on this trend. Increasing the range of herbicide products that may be used on SYHT0H2 soybean as part of an integrated weed management program could allow further use of conservation tillage. Any herbicides that would be used in this scenario would already have been registered with EPA and approved for use on soybeans. Soil quality would not expected to be altered by using previously approved herbicides on SYHT0H2 soybean fields. A determination of nonregulated status of SYHT0H2 soybean would not have a cumulative adverse effect on soil.

5.5 Air Quality

A determination of nonregulated status for SYHT0H2 soybean is not anticipated to result in an adverse cumulative effect on air quality. As described in Section 4.3.3, *Air Quality*, deregulating SYHT0H2 soybean would not have any direct or indirect adverse effect on air quality. Stacking SYHT0H2 soybean with other herbicide tolerance traits would allow additional herbicides to be used on SYHT0H2 soybean crops. Any other herbicides that would be used in this scenario would have already been registered with EPA and approved for use on soybeans. Air quality would not be adversely affected by using other previously approved herbicides on SYHT0H2 soybean fields. Air quality could benefit from increased use of conservation tillage practices, decreasing dust emissions. A determination of nonregulated status of SYHT0H2 soybean would not have a cumulative adverse effect on air quality.

5.6 Plants

A determination of nonregulated status of SYHT0H2 soybean is not anticipated to result in an adverse cumulative effect on non-target plants. As discussed in Section 4.4.2, *Plants*, SYHT0H2 soybean would not directly impact non-target plants but could indirectly affect them through changes in herbicide use. The herbicides that would be newly available for use on soybeans are toxic to target plants (weeds) and some non-target plants; these characteristics generally apply to all herbicides. Stacking SYHT0H2 soybean with other herbicide tolerance traits could allow other herbicides to be used on SYHT0H2 soybean crops at lower application rates than under the currently dominant glyphosate use. Any herbicides that would be used in this scenario would have already been registered with EPA and approved for use on soybeans. EPA conducts an in-depth analysis of the potential impacts of pesticides to non-target plants based upon an extensive data set, and sets restrictions to ensure there is no unreasonable harm to non-target plants. When the herbicides are used in accordance with label requirements, non-target plants would therefore be unaffected by using previously approved herbicides, such as glyphosate, on SYHT0H2 soybean fields. A determination of nonregulated status of SYHT0H2 soybean would not have a cumulative adverse effect on non-target plants.

Soybean crops on which mesotrione or isoxaflutole may be applied could potentially be sites for development of HPPD resistant weeds. Growers whose soybean rotation crops (See Table W) are dependent upon mesotrione (or other HPPD inhibiter) for control of weeds might find the potential presence of mesotrione- resistant weeds difficult to control. Other crops that may be planted as rotation crops labelled for use with mesotrione include those in Table Y or with Isoxaflutole in Table Z. Corn, which has the highest likelihood of being a rotation crop for soybean, already has considerable use of HPPD inhibitor herbicides. Sorghum attains 7% of the soybean crop acreage as a rotation crop, and represents a small likelihood that it will be a rotation crop for SYHT0H2 soybean and thus be exposed to escapes of mesotrione resistant weeds. The other crops have no major use of HPPD inhibitor herbicides as recently as 2011 or 2012. Other rotation crops as listed in Table ZZ do not already have a registered use of an HPPD inhibitor herbicide, so are at no risk of losing an important herbicide should mesotrione weeds escape through rotation in subsequent years. Increased use of mesotrione will not result in substantive risks of mesotrione resistant weeds that have no major alternative herbicides for their control in rotation crops.

Potential for Weed Cross-Resistance to other HPPD Inhibitor herbicides. At least four HPPD inibitors have been available on the market for weed control in corn. These are a newer class of herbicides, mesotrione (Callisto), having been released in 2001, and others such as tembotrione (Laudis) in 2006, pyrasulfutole (Huskie for small grains) in 2008 and topramezone (Impact) in 2008. Despite recent market availability, resistance to this class nevertheless has been detected in four US states, but thus far only in two weed species. Heap (2013) reports Palmer amaranth in Kansas has resistance to three herbicide MOAs, and these include three HPPD inhibitors, mesotrione, tembotrione and topramezone; common waterhemp in Illinois has resistance to the same three HPPD inhibitors. The multiple HPPD resistances attain 10-35X resistance compared to susceptible common waterhemp populations (Hausman et al., 2011). Thus, although mechanisms of weed resistance may be common to all those weed populations against HPPD inhibitor herbicides, the weeds in which herbicide resistance has been described are two that have already developed resistance to many other herbicides as well. Also, the frequency of use on corn in 2010 was limited to 27% of corn acreage for all herbicides of the class (Figure 5-1), indicating frequent use, but resistance developed only in those two weeds with an already high proclivity for resistance to several other herbicides.

As described in Section 4.3.2, *Water Quality*, EPA evaluates risks to water quality when conducting ecological risk assessments as part of the herbicide registration review process. Identified risks are managed by EPA requirements for application methods and buffer zones. Based on these precautions, deregulating SYHT0H2 soybean would not have an adverse cumulative effect on water quality. In some regions, the inability to control herbicide resistant weeds arising on crops and their rotation crops has led to increased tillage or other cultivation. If conventional tillage increases to control glyphosate- and other herbicide-resistant weeds, there may be an impact on soil quality from increased erosion; nonregulated status for SYHT0H2 could potentially offer an additional means to use herbicides for postemergent weed control on a crop not previously capable of exposure to these HPPD inhibitor herbicides.

Although a small percentage of soybean fields may be subject to repeated use of mesotrione or isoxaflutole from previous application of one of these to corn (see estimates in Environmental Consequences section), APHIS expects that farmers will use discretion in how frequently the same herbicides or same SOAs are repeatedly used on-farm when SYHT0H2 is commercially available. For example soybean crop consultants indicated in a survey that they valued as important at least seven best management practices[40] (score of 4.5 of 5.0) to manage and prevent herbicide resistant weeds (Riar et al., 2013). Sixty percent of the time consultants perceived that growers actually

[40] Proper herbicide timing. Start clean (no weeds at planting). Apply multiple effective herbicide modes of action targeting most problematic weeds. Use of full labeled herbicide rates. Prevent in-crop weed seed production. Crop rotation. Rotate herbicide-resistant traits.

used the top five[41] of these BMPs. Another larger survey of certified crop advisers in 2012 who were also producers indicated that in the North Central States, 57% believed that the next 'silver bullet' for managing weeds would come from new management strategies rather than new chemicals or soybean traits (Asmus et al., 2013). Multistate grower surveys from 2010 also indicate that growers were increasingly using practices important for weed resistance compared to previous surveys conducted in 2005: 54% of growers were using multiple herbicide SOA chemistries and application of residual chemicals and 75% of those with on-farm resistant weeds were using residuals (Prince et al., 2012b). Other best management practices such as field scouting before and after herbicide application were being used by all those participating up to 65% of the time. From these surveys, APHIS concludes that growers are likely to be much more cautious about using herbicide practices that will avert new resistance development. Following increasingly frequent negative consequences on income, grower reliance on a single herbicide with limited applications as was typical practiced with glyphosate resistant crops is unlikely to continue. Nonregulated status will facilitate the evolving of additional strategies and use of additional herbicide SOAs that can be used to deter resistance and deal with existing herbicide resistant weeds.

The lack of new herbicide chemistries for weed control in soybean has resulted in seed developers repeating an approach to weed control, that is, providing another herbicide resistant crop, as they did glyphosate resistant crops. The strategy has been modified several times using older herbicides that have now proven effective and that have been shown to encourage limited development of weed resistance (Johnson et al., 2012). The usefulness of a new option will be gained by growers with the commercial availability of the other herbicide resistant crops, similar to SYHT0H2, and these benefits include (Johnson et al., 2012):

a. reduction of crop injury associated with use of the herbicide on non-resistant crops
b. control of resistant weeds with a different chemistry
c. continuation of conservation tillage to obviate full tillage for weed control
d. help in avoiding further selection of glyphosate resistant weeds, even though glyphosate as a successful herbicide will continue to an have important role in many weed control programs

As noted by extension weed specialists (Steckel, L, 2013 and Young, B., 2013, petition comments, Docket APHIS-2012-0090) the need for diversity of weed management options is increasing, perhaps more so in soybean for post emergent herbicides than for other crops such as corn (Kevin Bradley, Univ. Missouri, personal communication, 2013).

The availability of a new herbicide resistant crop is not a final solution for control of difficult or resistant weeds. The history of herbicide usage on non-resistant crops is one that typically includes development of weed resistance and the resulting necessity to integrate a variety of measures to avert and remediate such weeds. An important question worth an answer is whether the users of herbicide technology properly perceive the developing problems and respond opportunely and appropriately to them. The necessity for proper management practices that forestall development

[41] Proper herbicide timing. Start clean (no weeds at planting). Apply multiple effective herbicide modes of action targeting most problematic weeds. Use of full labeled herbicide rates.

of resistant weeds is increasingly perceived by growers and by crop advisors, extension staff, and technology developers, as noted earlier. Advice from state weed science practioners, and from state extension agents has become clear in defining the hazards to growers of failure to use weed management BMPs[42]. APHIS concludes that the lessons provided in the increasing populations of weeds resistant to herbicide because of inattention to best management practices, and those provided by the financial losses from not correctly averting resistant weed development will shape future responses of growers to follow their own best interest, and embrace a culture of applying effective BMPs.

Knowing that weed resistance is always a present potentiality argues for the use of herbicide technology only when accompanied by due diligence and the avoidance of any such obvious misuse. Mesotrione resistant waterhemp developed in Nebraska by 2011 on seed corn production acres, and that occurred after five seasons of repetitive use of mesotrione (Knezevic, 2011). Similarly, another population in Illinois after six sequential seasonal applications of multiple HPPD inhibitors once or twice per season, also became resistant to mesotrione (Hausman et al., 2011). Careful planning for both prominent and resistant weed suppression by specific combinations of herbicides and availability and use of all options will facilitate effective control and suppress resistance development. SYHT0H2 can provide a finite number of years of useful weed control when this technology is integrated into a comprehensive and integrated plan for management of weeds.

5.7 Soil Microorganisms

A determination of nonregulated status of SYHT0H2 soybean is not anticipated to result in an adverse cumulative effect on soil microorganisms. As described in Section 4.4.3, *Soil Microorganisms*, deregulating SYHT0H2 soybean would not have a direct or indirect adverse impact on soil microorganisms. Other APHIS-approved transgenic traits potentially stacked with SYHT0H2 soybean do not adversely impact soil microorganisms. Stacking SYHT0H2 soybean with other transgenic traits, including those conferring herbicide tolerance, would not adversely impact soil microorganisms. All herbicides that would be used on a stacked product would have been subject to EPA's registration and review process for impacts to human health and the environment. No overall impact of the suite of potential herbicides is expected on soil microorganisms. A determination of nonregulated status of SYHT0H2 soybean would not have a cumulative adverse effect on soil microorganisms.

[42] For example, "Single pest management techniques no longer are considered reliable to combat most pests. Many management practices have limited periods of effectiveness, while others can create side effects worse than the crop damage. Success in managing crop pests depends on how well economically effective technologies, old and new, can be integrated, while minimizing risk to health and the environment… Simplistic approaches such as routine applications of pesticides are no longer acceptable pest management practices… Using a combination of methods is the best approach to handling most pest problems." Penn-State-University. 2014. Pest Management. C.o. Agriculture, editor. 165-167.

5.8 Biodiversity

A determination of nonregulated status of SYHT0H2 soybean is not anticipated to result in an adverse cumulative effect on biodiversity. Cultivating SYHT0H2 soybean is unlikely to directly or indirectly impact biodiversity, as described in Section 4.4.4, *Biodiversity*. Stacking SYHT0H2 soybean with other transgenic traits, including those conferring herbicide tolerance, could facilitate the use of alternative herbicides. With more herbicide diversity comes reduced potential for impacts of repeated exposure to a single chemical for all organisms in soybean fields. A determination of nonregulated status of SYHT0H2 soybean would not have a cumulative adverse effect on biodiversity.

Using transgenic soybean varieties containing herbicide-tolerance traits may improve biological diversity by facilitating the use of conservation tillage practices (Bonny, 2011a; NRC, 2010), which, in turn, can improve soil porosity, enhance soil fauna and flora, increase the flexibility of crop rotation, and facilitate 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., undated).

5.9 Domestic Trade Environment

A determination of nonregulated status of SYHT0H2 soybean is not anticipated to result in an adverse cumulative effect on the domestic trade environment. As described in Section 4.6.1, *Domestic Trade Environment*, deregulating SYHT0H2 soybean would not have a direct or indirect adverse impact on the domestic trade environment. Domestically produced soybean and soybean products, whether transgenic or not, are produced for a number of markets. Transgenic soybean products comprise 93 percent of the soybean market, and the addition of a stacked SYHT0H2 soybean product is unlikely to substantively affect the market of transgenic products. Market use of soybean is often dependent on the soybean variety, and the resulting nutrient composition. There are compositional differences among some soybean varieties grown for animal feed and those for human consumption. These include the soybean varieties that are intentionally produced to yield a variety of fatty acid profiles (e.g., for food uses). They may include soybeans that have been produced through standard breeding or genetic engineering methods. Market use of SYHT0H2 soybean stacked with other transgenic traits would likely be similar to that of other soybean products currently on the market. This approach would likely have a minor beneficial impact on the domestic trade market as a result of increased competition. A determination of nonregulated status of SYHT0H2 soybean would not have an adverse cumulative effect on the domestic trade environment.

6 THREATENED AND ENDANGERED SPECIES

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

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

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

Once an animal or plant is added to the list, 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 designated critical habitat. To facilitate their ESA consultation requirements, APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS' regulatory authority and effects analysis for petitions for nonregulated status and developed a process for conducting an effects determination consistent with the Plant Protection Act (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 met with USFWS officials on June 15, 2011, to discuss whether APHIS has any obligations under the ESA regarding analyzing the effects 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 or appropriate 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 mesotrione, isoxaflutole, glufosinate, or any other herbicide, by soybean growers. Under APHIS' current Part 340 regulations, APHIS only has the authority to regulate SYHT0H2 soybean or any GE organism as long as APHIS believes they may pose a plant pest risk (7 CFR § 340.1). 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.

After completing a plant pest risk analysis, if APHIS determines that SYHT0H2 soybean seeds, plants, or parts thereof do not pose a plant pest risk, then these articles would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR Part 340, and therefore, APHIS must reach a determination that these articles are no longer regulated. As part of its EA analysis, APHIS is analyzing the potential effects of SYHT0H2 soybean on the environment including, as required by the ESA, 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:

- A review of the biology and taxonomy of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant, including disease and pest susceptibilities, weediness potential, and agronomic and environmental impacts;
- Determination of the concentrations of known plant toxicants (if any are known in the plant);
- Analysis to determine if the transgenic plant is sexually compatible with any threatened 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 SYHT0H2 soybean may have, if any, on federally-listed TES species and species proposed for listing, as well as designated critical habitat and habitat proposed for designation. Based upon the scope of the EA and production areas identified in the Affected Environment section of the EA, APHIS 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, 2014a; USFWS, 2014b).

Prior to this review, APHIS considered the potential for SYHT0H2 soybean to extend the range of soybean production and also the potential to extend agricultural production into new natural areas. APHIS has determined that agronomic characteristics and cultivation practices required for SYHT0H2 soybean are essentially indistinguishable from practices used to grow other soybean varieties, including other herbicide-tolerant varieties (USDA-APHIS, 2014b) (Syngenta and Bayer, 2012b; Syngenta and Bayer, 2013). Although SYHT0H2 soybean may be expected to replace other varieties of soybean currently cultivated, APHIS does not expect the cultivation of these to result in new soybean acres to be planted in areas that are not already devoted to agriculture. Accordingly, the issues discussed herein focus on the potential environmental consequences of the determination of nonregulated status of SYHT0H2 soybean on TES species in the areas where soybean are currently grown.

For its analysis on TES plants and critical habitat, APHIS focused on the agronomic differences between the regulated articles and soybean varieties currently grown; the potential for increased weediness; and the potential for gene movement to native plants, listed species, and species proposed for listing.

For its analysis of effects on TES animals, APHIS focused on the implications of exposure to the novel proteins expressed in the plants as a result of the transformation, and the ability of the plants to serve as a host for a TES. The novel proteins associated with SYHT0H2 soybean are listed in Table 6-1.

Table 6.1. GE Proteins in SYHT0H2 soybean

Regulated Article	Protein	Phenotypic Effects
SYHT0H2 Soybean	*p*-hydroxyphenylpyruvate dioxygenase (*AvHPPD-3*)	Resistance to the HPPD-inhibiting herbicides, such as mesotrione and isoxaflutole
	phosphinothricin acetyltransferase (*PAT*)	Resistance to glufosinate

6.1 Potential Effects of SYHT0H2 Soybean on Threatened or Endangered Species

6.1.1 Threatened and Endangered Plant Species and Critical Habitat

Soybean has been cultivated around the globe without any report that it is a serious weed or that it forms persistent feral populations (USDA-APHIS, 2012). Soybean does not possess any of the attributes commonly associated with weeds (Baker, 1965), such as long persistence of seed in the soil, the ability to disperse, invade, and become a dominant species in new or diverse landscapes, or the ability to compete well with native vegetation. Furthermore, mature soybean seeds have no innate dormancy; germinating seedlings and plants are sensitive to cold, are not expected to survive in freezing winter conditions and do not vegetatively reproduce (OECD, 2000b); (Raper Jr. and Kramer, 1987). Soybeans that volunteer from the previous year's crop are rarely a management issue, as crop losses attributable to interference from soybean volunteers are minimal (Owen and Zelaya, 2005). However, volunteers can be a problem particularly in the South where winters are milder, and particularly if weather events lead to soybean seed loss prior to harvest (York et al., 2005).

Agronomic data provided in the Petition were used in the analysis of weediness potential for SYHT0H2 soybean and further evaluated for the potential to impact threatened or endangered species. Agronomic studies tested the hypothesis that the weediness potential of SYHT0H2 soybean is unchanged with respect to conventional soybean. No differences were detected between SYHT0H2 soybean and conventional soybean in growth, reproduction or interactions with pests and disease, other than the intended effect of herbicide tolerance (Syngenta and Bayer, 2012b); (Syngenta and Bayer, 2013). This herbicide tolerance resulting from presence of the AvHPPD-3 and PAT proteins would not contribute to increased weediness. If volunteers appear in subsequent crops there are effective weed management strategies to control them (OECD, 2000b; York et al., 2005). Based on the agronomic field data and a literature survey on soybean weediness potential, SYHT0H2 soybean is unlikely to affect threatened or endangered species or their habitat as a troublesome or invasive weed.

APHIS evaluated the potential of SYHT0H2 soybean to cross with wild relatives, listed species, and species proposed for listing. As previously discussed in the analysis of Gene Movement in the Natural Environment, APHIS has determined that there is no risk to unrelated plant species from the cultivation of SYHT0H2 soybean. Soybean is highly self-pollinating and can only cross with other members of *Glycine* subgenus *Soja* (OECD, 2000b). 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 nil (OECD, 2000b). After reviewing the list of threatened and endangered plant species in the U.S. states where soybean is grown, APHIS determined that SYHT0H2 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* (USFWS, 2014a; USFWS, 2014b).

Based on agronomic field data, literature surveyed on soybean weediness potential, and no sexually compatibility of TES with soybean, APHIS has concluded that SYHT0H2 soybean will have no effect on threatened or endangered plant species or on critical habitat.

6.1.2 Threatened and Endangered Animal Species

Threatened and endangered animal species that may be exposed to the gene products in SYHT0H2 soybean would be those TES that inhabit soybean fields and feed on SYHT0H2 soybean. To identify potential effects on threatened and endangered animal species, APHIS evaluated the risks from consuming SYHT0H2 soybean.

Soybean commonly is used as a feed for many livestock. Additionally, wildlife may use soybean fields as a food source, consuming the plant or insects that live on the plants, although, 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*), interior least tern

(*Sterna antillarum*), and Sprague's pipit (*Anthus spragueii;* a candidate species) occasionally feed in farmed sites (US Fish and Wildlife Service, 2011). These bird species may visit soybean fields during migratory periods, but would not be present during normal farming operations (Krapu et al., 2004a; US Fish and Wildlife Service, 2011). 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., 2004a). Least terns feed over water, principally on small fish, but also eat aquatic insects (Thompson, 1997). Piping plover also feed entirely on invertebrates (Haig, 2004). None of the listed species are likely to feed on soybean plants or seeds.

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 (US Fish and Wildlife Service, 2008). The squirrel forages for food in woodlots and openings, such as farm fields, with a diet that mainly includes acorns, nuts/seeds of hickory, beech, walnut, and loblolly pine. They also feed on tree buds and flowers, fungi, insects, fruit, and seeds in the spring and mature, green pine cones in the summer and early fall (US Fish and Wildlife Service, 2008). The Louisiana black bear (*Ursus americanus luteolus*), occurring in Louisiana, Mississippi, and Texas, may occasionally forage on soybean; however, other crops such as corn, sugarcane, and winter wheat are preferred by the species (MSU, No Date).

APHIS has examined data on the food and feed safety of SYHT0H2 soybean, evaluating the agronomic and morphological characteristics, including compositional and nutritional characteristics, safety evaluations and toxicity tests, as compared to a conventional hybrid soybean variety grown at eight different sites across the U.S. in 2010 (Syngenta and Bayer, 2012b; Syngenta and Bayer, 2013). The analysis included moisture, protein, fat, ash, carbohydrates, amino acids, fatty acids, fibers, anti-nutrients, vitamin E isoforms, minerals and vitamins, consistent with OECD guidelines (OECD, 2001a) (Syngenta and Bayer, 2012a). SYHT0H2 soybeans had significantly lower (2.7%) potassium (K) and iron (Fe) content (3.5%) than the comparator Jack variety, but not significantly different from the reference varieties used in this study or from the International Life Sciences Institute' (ILSI) crop composition database (Syngenta and Bayer, 2012a). The other compositional and nutritional components described above were not significantly different between SYHT0H2 soybeans and the conventional non-transformed soybean control Jack (Syngenta and Bayer, 2012a).

The potential allergenicity and toxicity of the introduced AvHPPD-03 and PAT proteins (obtained from *Avena sativa* and *Streptomyces viridochromogenes*, respectively) was assessed, according to the recommendations of the Codex Alimentarius Commission (Codex, 2003). For the toxicity analysis, the AvHPPD-03 amino acid sequence was systematically compared with the latest posting of the NCBI Entrez Protein Database (NCBI, 2012). The NCBI Entrez Protein Database search identified 1,394 sequences with significant similarity to the AvHPPD-03 amino acid sequence ($E < 0.4$). None of these sequences corresponded to known or putative toxins (Syngenta and Bayer, 2012a). HPPD proteins are ubiquitous in plants, animals and microbes, and are not novel (Syngenta and Bayer, 2012a). Standard studies in mice exposed to high doses of AvHPPD-03 or PAT demonstrated no toxic effects. The AvHPPD-03 protein is 99.7 percent identical to the native HPPD enzyme from oat (*Avena sativa*) and there is no reason to suspect it would present a risk to non-target organisms (Syngenta and Bayer, 2012a). Data regarding the environmental safety of PAT proteins have been extensively reviewed in international scientific, peer-reviewed journals (Herouet et al., 2005). The PAT protein is expressed in a number of GM crops that have been approved by regulatory agencies (USDA-APHIS, 2014a) (Syngenta and Bayer, 2012a). These GM crops have been consumed by humans and animals since 1995 and have exhibited no significant adverse effects. In addition, the EPA has exempted the PAT enzyme and the genetic material necessary for its production in all raw agricultural commodities (40 CFR Part 180, 1997), (40 CFR Part 180.1151, 2005).

To assess allergenicity potential, the AvHPPD-03 protein and the PAT protein were compared with listings in the FARRP Allergen Protein Database (FARRP, 2012). The AvHPPD-03 protein from SYHT0H2 soybean, differs from native oat (*A. sativa*) HPPD amino acid sequence by a single amino acid residue that is not part of the enzyme's active site. Oat contains no endogenous proteins that are listed in the FARRP Allergen Protein Database (FARRP 2012) and therefore is not considered to be a known allergenic food. Two different bioinformatic comparison searches were performed for the AvHPPD-03 and PAT proteins against the FARRP Allergen Protein Database. Neither search found a significant level of shared amino acid sequence between AvHPPD-03 or PAT and any entry in the FARRP Allergen Protein Database (Syngenta and Bayer, 2012a). An evaluation of the susceptibility of AvHPPD-03 and PAT proteins to degradation in simulated mammalian gastric fluid containing pepsin and in simulated mammalian intestinal fluid containing pancreatin. Results indicated that the PAT protein was completely digested in both SGF and SIF within 0.5 minute, and the AvHPPD-03 in one minute (both the first time point sampled), indicating that PAT and AvHPPD-03 are rapidly and completely degraded by pepsin under mammalian gastric conditions and by pancreatin under simulated mammalian intestinal conditions (Syngenta and Bayer, 2012a). These studies and reviews support the conclusion that AvHPPD-03 and PAT proteins are unlikely to be food allergens.

In addition to establishing that AvHPPD-03 and PAT are nontoxic and not allergenic, studies comparing SYHT0H2 soybean to its nontransgenic counterpart demonstrated no meaningful differences in agronomic or morphological characteristics (Syngenta and Bayer, 2012a). Compositional elements, including proximate and fiber components, vitamins, amino acid and fatty acid content, and antinutrients and isoflavone concentrations, revealed no substantive differences between SYHT0H2 soybean and conventional soybean varieties (Syngenta and Bayer, 2012a). These data indicate there is no substantial difference in the composition and nutritional quality of SYHT0H2 soybean compared with conventional soybean varieties, apart from the presence of the AvHPPD-03 and PAT proteins. These results show that the incorporation of the *avhppd-03* and *pat* transgenes and the accompanying activity of the AvHPPD-03 and PAT proteins in SYHT0H2 soybean do not result in any biologically meaningful differences between SYHT0H2 soybean and non-genetically engineered varieties.

APHIS considered the possibility that SYHT0H2 soybean could serve a host plant for a threatened or endangered species. A review of the species list reveals that there are none that would use soybean as a host plant.

Considering the compositional and agronomic similarities between SYHT0H2 soybean and other varieties currently grown and the lack of toxicity and allergenicity of the AvHPPD-03 and

PAT proteins, APHIS has concluded that exposure and consumption of SYHT0H2 soybean would have no effect on threatened or endangered animal species.

6.2 Conclusion

After reviewing the possible effects of allowing the environmental release of SYHT0H2 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 SYHT0H2 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. Soybean is not sexually compatible with, or serves as a host species for, any listed species or species proposed for listing. Consumption of SYHT0H2 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 SYHT0H2 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 is not required.

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

As required by the CEQ, this Chapter considers the Executive Orders (EOs), standards, and treaties related to the potential environmental impacts of the Preferred Alternative.

7.1 Executive Orders with Domestic Implications

Four EOs have domestic implications that are relevant to the environmental assessment of the petition to deregulate SYHT0H2 soybean.

7.1.1 Executive Order 12898: Environmental Justice

EO 12898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*[43], 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 or low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.

SYHT0H2 soybean is not significantly different from other transgenic or nontransgenic soybean. As described in Chapter 4, Section 4.4.1, *Animals*, the AvHPPD-03 and PAT enzymes do not pose a hazard to humans. A voluntary FDA consultation for food and feed use of SYHT0H2 soybean has been completed by the Petitioners (March 28, 2014, see FDA Memo, BNF 000139). Data and information provided by the Petitioners support the safe use of SYHT0H2 soybean and indicate that it will be as nutritious and wholesome as other soybean currently used as food and feed. Based on these analyses, SYHT0H2 soybean is not expected to have a disproportionate adverse effect on minorities or low-income populations.

As described in Chapter 4, Section 4.2.2, *Agronomic Practices*, the cultivation of previously 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 of 2000 with other herbicide tolerance traits has changed herbicide application patterns and rates. If herbicide applications are reduced or less toxic herbicides are used, there may be a beneficial effect on minority populations. Any effect would be negligible, assuming that the herbicides are used in accordance with label precautions. These populations might include farm workers and their families, and other rural dwelling individuals who are potentially exposed to herbicides through aerial application, groundwater, or other routes of exposure.

43 EO 12898 of February 11, 1994; 59 FR 7629.

7.1.2 Executive Order 13045: Protection of Children

EO 13045, *Protection of Children from Environmental Health Risks and Safety Risks*[44], 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. This EO requires each federal agency (to the extent permitted by law and consistent with the agency's mission) to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

SYHT0H2 soybean is not significantly different from other transgenic or nontransgenic soybean. As described in Chapter 4, Section 4.4.1, *Animals*, the AvHPPD-03 and PAT enzymes do not pose a hazard to humans. A voluntary FDA consultation for food and feed use of SYHT0H2 soybean has been completed by the Petitioners (March 28, 2014, see FDA Memo BNF 000139). Data and information provided by the Petitioners support the safe use of SYHT0H2 soybean and indicate that it will be as nutritious and wholesome as other soybean currently used as food and feed. Based on these analyses, SYHT0H2 soybean is not expected to have a disproportionate adverse effect on children.

As described in Chapter 4, Section 4.2.2, *Agronomic Practices*, the cultivation of 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 of 2000 with other herbicide tolerance traits has changed herbicide application patterns and rates. If herbicide applications are reduced or less toxic herbicides are used, there may be a beneficial effect on children that might be exposed to the chemicals. Any effect would be negligible, assuming that the herbicides are used in accordance with label precautions. Similar to minority populations, these children might include families of farm workers and other rural dwelling individuals who are exposed to herbicide through aerial application, groundwater contamination, or other routes.

7.1.3 Executive Order 13112: Invasive Species

EO 13112, *Invasive Species* [45], requires federal agencies to 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 a highly domesticated plant and is not an invasive species. Both nontransgenic and transgenic soybean varieties that have been determined as non-regulated are widely grown in the US and have not developed weedy or invasive characteristics. As described in Section 4.4.5, *Gene Movement in the Natural Environment*, SYHT0H2 soybean plants are very similar in agronomic characteristics to other soybean varieties that are currently grown and are not expected to become weedy or invasive, and are not toxic to listed species. Accordingly, the Preferred Alternative would not raise concerns addressed by EO 13112, *Invasive Species*.

44 EO 13045 of April 21, 1997; 62 FR 19885.
45 EO 13112 of February 3, 1999; 64 FR 6183.

7.1.4 Executive Order 13186: Migratory Birds

EO 13186, *Responsibilities of Federal Agencies to Protect Migratory Birds*[46], requires each federal agency to avoid and minimize, to the extent practicable, adverse impacts on migratory bird populations when conducting agency actions.

Although migratory birds forage in soybean fields, as described in Section 4.4.1, *Animals*, SYHT0H2 soybean is not expected to have any adverse impacts on migratory birds because the AvHPPD-03 and PAT enzymes do not present a toxicity hazard. Additionally, the Petitioners conducted a feeding study on broiler chickens, in which no harmful effects were observed. Determining non-regulated status for this soybean cultivar therefore is not expected to have a negative effect on migratory bird populations. The Preferred Alternative would be in compliance with EO 13186, *Responsibilities of Federal Agencies to Protect Migratory Birds*.

7.2 Executive Orders with International Implications

EO 12114, *Environmental Effects Abroad of Major Federal Actions* [47], requires federal officials to take into consideration any potential environmental effects outside the US, its territories, and possessions that may result from actions being taken.

All of the existing national and international regulatory authorities and phytosanitary regimes that currently apply to introduction of new soybean cultivars internationally apply equally to those covered by an APHIS determination of non-regulated status under 7 CFR part 340. International trade of SYHT0H2 soybean subsequent to a determination of non-regulated status for the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC, 1997).

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." The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds. The IPPC set a standard for the reciprocal acceptance of phytosanitary certification among the 177 nations that have signed or acceded to the convention[48]. In April 2004, a standard for pest risk analysis (PRA) of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to the existing *International Standard for Phytosanitary Measure No. 11* (IPPC, 2004). The standard acknowledges that 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.

46 EO 13186 of January 10, 2001; 66 FR 3853.
47 EO 12114 of January 4, 1979; 44 FR 1957.
48 https://www.ippc.int/

The *Cartagena Protocol on Biosafety* (the Protocol) (SCBD, 2000) is a treaty under the United Nations *Convention on Biological Diversity* (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which includes those modified through biotechnology. The Protocol came into force on September 11, 2003, and 193 countries are currently parties to it[49]. Although the US is not a party to the CBD and thus not a party to the Protocol, US exporters will still need to comply with domestic regulations that importing countries that are parties to the Protocol have put in place to comply with their obligations.

The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol, and the required documentation. LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the US government has developed a website[50] that provides the status of all regulatory reviews completed for different uses of bioengineered products. These data will be available to the Biosafety Clearinghouse. International trade of SYHT0H2 soybean would be conducted in compliance with the Protocol.

Biosafety and biotechnology consensus documents, guidelines, and regulations, are managed by APHIS in accordance with the requirements of the North American Plant Protection Organization (NAPPO) and the Organization for Economic Cooperation and Development (OECD). The Preferred Alternative is not expected to affect APHIS's participation in NAPPO or the OECD.

The North American Biotechnology Initiative is a forum for information exchange and cooperation on agricultural biotechnology issues for the US, Mexico, and Canada. Bilateral discussions on biotechnology regulatory issues are also held regularly with other countries including Argentina, Brazil, Japan, China, and South Korea.

As described in Section 4.6.2, *Foreign Trade Environment*, the Preferred Alternative is not expected to affect the US soybean export market since the Petitioners are actively pursuing regulatory approvals for SYHT0H2 soybean in countries with functioning regulatory systems for genetically modified organisms and that import soybean from the US or Canada. Regulatory filings for SYHT0H2 soybean import approvals have been made in Canada, Argentina, Japan, Republic of China, South Korea, Australia and New Zealand, the Republic of South Africa and the European Union. Applications for import approvals in additional countries, including the People's Republic of China, will also be made.

7.3 Other Federal Laws

In addition to the *National Environmental Policy Act* and the *Plant Protection Act*, three other federal environmental laws are potentially relevant to the environmental assessment of the petition

49 http://www.cbd.int/convention/parties/list/

50 http://usbiotechreg.nbii.gov

to deregulate SYHT0H2 soybean. Other federal land management laws and regulations address the unique characteristics of certain geographic areas, and are also potentially relevant to a determinationof nonregulated status of SYHT0H2 soybean.

7.3.1 Clean Water Act

The *Federal Water Pollution Control Act*[51] (commonly referred to as the Clean Water Act) and implementing regulations[52] require entities that discharge regulated materials to certain surface water bodies (including wetlands) obtain authorization to do so from federal or state agencies under various permit programs.

As described in Section 4.3.1, *Water Quality and Use*, water quality is not likely to change as a direct or indirect result of the Preferred Alternative. A determination of nonregulated status of SYHT0H2 soybean would not result in a change of agricultural practices or any new discharge of pollutants to surface water bodies. Water quality would continue to be regulated and agronomic practices to protect water quality would continue to be implemented if SYHT0H2 soybean is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000. Cultivating SYHT0H2 soybean would not require Clean Water Act permits different than those already required for agricultural activities.

7.3.2 Clean Air Act

The *Clean Air Act Amendments of 1990*[53] (commonly referred to as the Clean Air Act) and implementing regulations[54] require entities that discharge regulated materials into the atmosphere obtain authorization to do so from federal or state agencies under various permit programs.

As described in Section 4.3.3, *Air Quality*, the Preferred Alternative is not likely to directly change air quality. SYHT0H2 soybean production would not change land acreage or cultivation practices for transgenic or nontransgenic soybean. Air quality would be indirectly improved if conservation tillage is increased. Soybean growers would continue current trends in agricultural activities if SYHT0H2 soybean is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000. Cultivating SYHT0H2 soybean would not require Clean Air Act permits different than those already required for agricultural activities.

7.3.3 National Historic Preservation Act

The *National Historic Preservation Act*[55] (NHPA) and its implementing regulations[56] require federal agencies to:

51 33 USC Sections 1251-1376
52 33 CFR parts 320-332 and 40 CFR parts 230-233
53 40 USC 7401-7671
54 40 CFR parts 50-99
55 16 USC Section 470 *et seq.*
56 36 CFR parts 800-801

- Determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties, and
- 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 Offices, Tribal Historic Preservation Officers), as appropriate.

The Preferred Alternative is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would be undertaken by the tribe or at the tribe's request. The tribes would have control over any potential conflict with cultural resources on tribal properties. The Preferred Alternative would also 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 cause any loss or destruction of significant scientific, cultural, or historical resources.

The Preferred Alternative 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 new visual, atmospheric, or noise elements to areas in which they are used that are different from current agricultural practices and could result in effects on the character or use of historic properties. The cultivation of SYHT0H2 soybean alone or in approved stacks is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

7.3.4 Federal Laws Regarding Unique Characteristics of Geographic Areas

Other federal land management laws and regulations protect park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas. A determination of non-regulated status for SYHT0H2 soybean is not expected to affect unique characteristics of these geographic areas, and the common agricultural practices that would be carried out in the cultivation of SYHT0H2 soybean are not expected to deviate from current practices. As described in Section 4.2.2, *Agronomic Practices,* SYHT0H2 soybean is expected to be deployed on agricultural land currently suitable for soybean production and replace existing varieties, and is not expected to increase the acreage of soybean production.

The Preferred Alternative would not include any major new ground disturbances; new physical destruction or damage to property; alterations of property, wildlife habitat, or landscapes; or prescribed sale, lease, or transfer of ownership of any property. The Preferred Alternative is limited to a determination of non-regulated status of SYHT0H2 soybean. This action would not convert agricultural land use to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, pest control, irrigation, and harvesting of plants would be used on agricultural lands planted to SYHT0H2 soybean, alone or when stacked with other soybean varities that are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act of 2000.

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Appendix A: Mesotrione, Isoxaflutole and Glufosinate: Changes in Application Rates for MGI Soybean

Table 1. Mesotrione use rates (g active ingredient/Ac) for corn and soybean.

Application timing	Corn Use Rate (g ai/Ac)	Proposed Soybean Use Rate (g ai/Ac)
Preplant, preplant incorporated, or preemergence	85.1 – 109.1	90.7
Early postemergence	42.5 – 85.1	42.5 – 90.7
Postemergence	42.5 – 85.1	42.5 – 51.0
Season maximum rate	85.1 – 109.1	141.6

Source: EPA label for Callisto Herbicide and amendment for addition of soybean to the label
Mesotrione soybean use instructions (from EPA label):

i. Mesotrione can be applied from 14 days prior to planting up through and including the R1 growth stage for control of weeds in soybeans.

Table 2. IFT use rates (g active ingredient/Ac) for corn and soybean.

Application timing	Corn Use Rate (g ai/Ac)	Proposed Soybean Use Rate (g ai/Ac)
Early preplant, preplant incorporated (8-30 days prior to planting)	21.3 – 42.6	35.5 – 42.6
Preplant , preplant incorporated (0-7 days prior to planting) or preemergence	21.3 – 42.6	28.4 – 42.6
Early postemergence	None	28.4 – 42.6
Season maximum rate	42.6	42.6

Source: EPA labels for Balance Pro Herbicide and EXP32032A SC Herbicide

Table 2. Glufosinate use rates (g active ingredient/Ac) for corn and soybean.

Application timing	Corn Use Rate (g ai/Ac)	Proposed Soybean Use Rate (g ai/Ac)
Preplant burn down	240 - 298	240 – 298
Postemergence	182	182 - 298
Season maximum rate	365	538

Source: EPA label for Liberty Herbicide and amendment for addition of soybean to the label
Mesotrione soybean use instructions (from EPA label):

i. Mesotrione can be applied from 14 days prior to planting up through and including the R1 growth stage for control of weeds in soybeans.

Appendix B: Mesotrione Description, Uses, and Potential Impacts[57]

[57] Syngenta (2013), Environmental Report

Mesotrione: Description, Uses, and Potential Impact on Human Health and the Environment

1. Introduction

This summary describes the uses of mesotrione and its potential impact on human health and the environment.

2. Product History

This section describes mesotrione's chemical name and structure, development, and regulatory status in the US.

2.4 Chemical Name and Structure

The chemical name for mesotrione is 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione. Mesotrione is a triketone with an empirical formula of $C_{14}H_{13}O_7NS$. Mesotrione degrades in the environment to two non-herbicidally active metabolites:

- 4-(methylsulfonyl)-2-nitrobenzoic acid) (MBNA); and
- 2-amino-4-(methylsulfonyl)benzoic acid (AMBA).

Mesotrione is an acidic herbicide with sulfonyl and nitro groups. MNBA and AMBA are benzene ring-based acids that remain after the connection to the cyclohexanedione ring is broken (USEPA, 2001b). MNBA and AMBA also retain the sulfonyl functional group. The chemical structures of mesotrione and its metabolites are shown in Figure 1.

2.5 Development

Mesotrione is an active ingredient found in several herbicides for control of broadleaf and certain grassy pest weeds. This review focuses on concentrations of mesotrione found in Callisto® herbicide, which is approved for use on many row crops including corn, with an experimental use permitted on soybeans. Pre-emergence use of Callisto on soybean varieties with a degree of native tolerance to mesotrione is an approved use, however, Callisto is not currently marketed for this use. Products containing mesotrione for use on commercial and residential turf include the herbicide Tenacity®, a solo product. Other Syngenta products currently marketed in the US that contain mesotrione are Callisto® Xtra, Halex® GT, Lexar®EZ, Lumax®EZ, and Zemax® herbicides. These herbicides contain mesotrione in combination with one or more of the following: *S*-metolachlor[58], atrazine[59], and glyphosate.[60] These products are used primarily on corn. Glyphosate, *S*-metolachlor, and atrazine are not addressed in this summary.

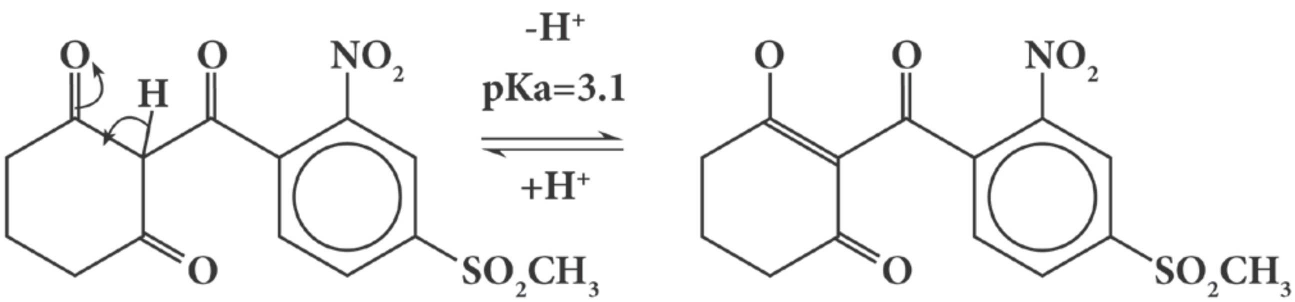
58 The chemical name of *S*-metolachlor is 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(1*S*)-2-methoxy-1-methylethyl]acetamide. It is contained in Callisto® Xtra, Halex® GT, Lexar® EZ and Lumax® EZ herbicides.

59 The chemical name of atrazine is 2-chloro-4-(ethylamino)-6-(isopropylamino)-s-triazine. It is contained in Callisto® Xtra, Lexar® EZ, and Lumax® EZ herbicides.

60 The chemical name of glyphosate is *N*-(phosphonomethyl) glycine. It is contained in Halex® GT herbicide

Figure 1: Chemical Structure of Mesotrione and Degradates

Structure of Mesotrione (associated and dissociated forms)

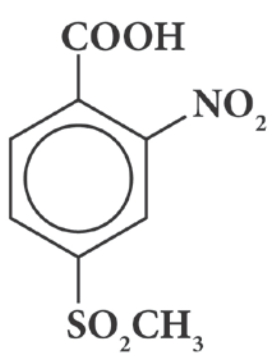


associated (low pH)

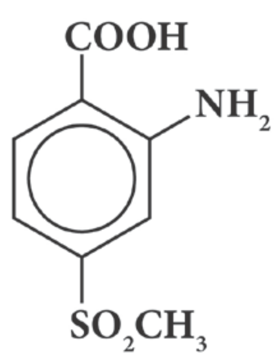
dissociated (high pH)

Structure of Identified Metabolites

<u>MNBA</u>
4-(methylsulfonyl)-2-nitrobenzonic acid
(CAS No. 110964-79-9)



<u>AMBA</u>
2-amino-4-(methylsulfonyl) benzonic acid
(CAS No. Not Available)



2.6 Regulatory Status in the US

All pesticides distributed or sold in the US are subject to registration by the Environmental Protection Agency (EPA) under authority of the *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA). Registration of a pesticide under Section 3 of FIFRA 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. EPA is also responsible for identifying chemicals that pose health hazards, under the *Emergency Planning and Community Response Act*/*Superfund Amendments and Reauthorization Act* (EPCRA SARA) Title III Section 311/312 hazard classification. The US Department of Agriculture and the US Food and Drug Administration (FDA) are responsible for enforcing EPA tolerances for pesticides in food.[61] This section describes the EPA regulatory actions involving mesotrione.

Mesotrione was first registered on June 4, 2001 (USEPA, 2001a). The *Food Quality and Protection Act* of 1996 (FQPA) mandated that the EPA conduct registration reviews of all pesticides distributed or sold in the US every 15 years. EPA's registration review schedule indicates that mesotrione is scheduled for re-evaluation starting in 2014. There are 20 current, active FIFRA Section 3 mesotrione registrations (USEPA, 2012b). One Experimental Use Permit (Syngenta, 2011b), for application on soybeans, was activated in 2009 and has been extended to 2014. There are nine Section 24(c) Special Local Need Registrations (for Callisto use on cranberry, blueberry, ryegrass, and cuphea; and for aerial use of Halex GT) and ten Section 18 Emergency Exemptions have been issued but have since expired.

Several mesotrione uses have been designated as "reduced risk" by EPA. See Section 5 in this paper for information about potential human health effects from mesotrione.

A selected review and regulatory action history of mesotrione within EPA is provided chronologically below.

- On May 29, 1998, EPA issued a notice in the Federal Register (63 FR 29401) announcing the filing of a pesticide petition for tolerances by Zeneca Ag Products (USEPA, 1998). The petition was subsequently transferred to Syngenta Crop Protection, Inc. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the herbicide 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione (mesotrione) and its metabolites or degradates in or on the raw agricultural commodities field corn, field corn fodder, and field corn forage at 0.01 parts per million (ppm).
- On May 7, 2001, EPA issued a memorandum that provided a chemical review for mesotrione's use in preemergence and postemergence broadleaf weed control in corn and the associated environmental fate and ecotoxicity data evaluation records (DERs) (USEPA, 2001b).
- On June 6, 2001, the EPA Office of Prevention, Pesticides, and Toxic Substances published the *Occupational and Residential Exposure and Risk Assessment/Characterization for the Proposed use of Mesotrione on Field Corn* (USEPA, 2001e).
- On June 20, 2001, EPA published a notice in the Federal Register (66 FR 120) establishing the tolerance for residues of mesotrione in or on field corn at 0.01 ppm (USEPA, 2001f).

61 The FDA website does not have any information about enforcement actions in regard to EPA tolerances for mesotrione in food.

- On December 22, 2008, the EPA Office of Prevention, Pesticides, and Toxic Substances published the *Ecological Risk Assessment for Experimental Use Permit (DP Barcode 354510) and Section 3 New Use (DP Barcode 357888) registrations for use of mesotrione on soybeans* (USEPA, 2008c). The Section 3 New Use applied for at that time supported preemergence applications on soybean varieties with a degree of native tolerance to mesotrione.
- On December 18, 2009, EPA published a notice in the Federal Register (74 FR 242) establishing the tolerance for residues of mesotrione in or on soybean seed at 0.01 ppm as a new use of this herbicide (USEPA, 2009b). This tolerance supported preemergence applications of mesotrione on certain soybean varieties exhibiting native tolerance to the herbicide.

In 2013, Syngenta applied to EPA for a new, postemergence use of mesotrione on soybean and amended soybean tolerances (USEPA, 2013). These amendments to the registrations and tolerances will support the intended rates and timing of mesotrione applications on soybean cultivars genetically modified for tolerance of HPPD-inhibitor herbicides.

Tolerance levels for residues of mesotrione (and its metabolites or degradates) are listed in 40 CFR part 180.571. Current tolerance limits are discussed in Section 3.3.1 of this paper.

3. Function

This section describes mesotrione's mode of action, herbicide class, and usage.

3.4 Mode of Action and Herbicide Class

Mesotrione is an inhibitor of 4-hydroxyphenyl-pyruvate-dioxygenase (4-HPPD). The mode of action prevents the biosynthesis of carotenoid pigments that protect chlorophyll from decomposition by sunlight (USEPA, 2001c). HPPD enzymes have also been isolated from bacteria, fungi, animals, and humans (Coats, 2009). HPPD enzymes from diverse origins share a common structure and have several highly conserved amino acid sequences among all HPPD proteins. HPPD activity is implicated in the tyrosine metabolism of microorganisms, plants, and mammals.

In plants, HPPD catalyzes the conversion of p-hydroxyphenyl-pyruvate to homogentisate (which is an aromatic precursor of vitamin E) and plastoquinones (which are antioxidant compounds and elements of the chloroplast electron-transfer chain) (Matringe et al., 2005). This pathway is schematically depicted in Figure 2. Plastoquinone is a critical cofactor for phytoene desaturase, a component of the carotenoid biosynthetic pathway. Depletion of plastoquinone levels by inhibition of HPPD results in depletion of carotenoids, leading to bleaching symptoms. Without carotenoids, light energy destroys the chlorophyll, causing new growth to turn white and disrupting cell membranes, resulting in necrosis and death of susceptible plants (Syngenta, 2008).

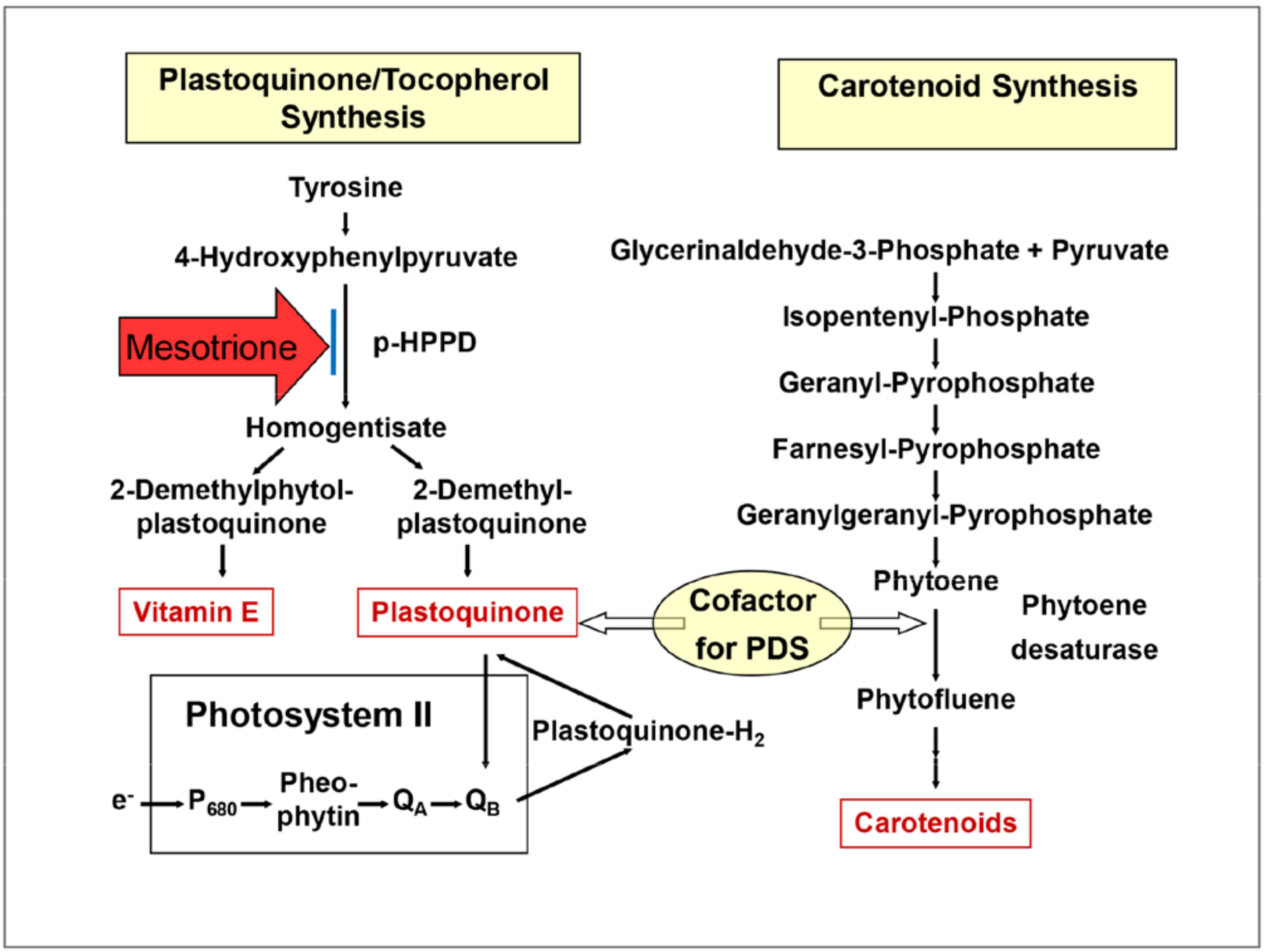
Mesotrione is a benzoylcyclohexanedione (triketone) herbicide. The Herbicide Resistance Action Committee (HRAC) classifies the mesotrione mode of action as F2, a carotenoid biosynthesis inhibitor (inhibition of 4-HPPD) (HRAC, 2013).

3.5 Usage

3.5.4 Current US Uses and Established Tolerances

Syngenta's label for Callisto identifies this product as "a systemic postemergence and preemergence herbicide for the selective contact and residual control of broadleaf weeds in field corn, seed field corn, yellow popcorn, sweet corn, and other listed crops" (Syngenta, 2011a). Other listed crops are cranberry, blueberry, lingonberry, flax, pearl millet, asparagus, Kentucky bluegrass, perennial ryegrass, tall fescue, oats, rhubarb, black raspberry, red raspberry, blackberry, okra, grain sorghum, sweet sorghum, certain tolerant soybean cultivars (i.e., cultivars with native tolerance to pre-emergence Callisto applications), and sugarcane. Use on bluegrass, ryegrass, and fescue is only for when these are grown for seed. Use on soybeans is not currently indicated on the Callisto commercial label. Mesotrione is registered for use on commercial and residential turf (USEPA, 2009b) on the Tenacity® product label.

Figure 2: Mesotrione Mode of Action



Mesotrione is the active ingredient (ai) in the Callisto herbicide and comprises 40 percent of that formulation. Non-active ingredients comprise the remaining 60 percent. The Syngenta label for Callisto states that when this product is used preemergence, weeds take up the product through the soil during their emergence. When used postemergence, susceptible weeds take up the herbicide through the treated foliage and cease growth soon after application. Complete death of the weeds may take up to 2 weeks.

To help prevent the development of weed resistance to Callisto, Syngenta recommends that applicators always use full labeled rates. If applying Callisto postemergence in corn after a mesotrione-containing preemergence herbicide, atrazine should always be added as a tank mix partner. No more than 0.24 pounds of active ingredient per acre (lb ai/A) of corn should be applied per year (equivalent of 7.7 fluid ounces of Callisto per acre per year).

Rotational crop information provided on the Callisto label is:

Immediate: Corn (all types), asparagus, cranberry, flax, millet (pearl), grasses grown for seed (Kentucky bluegrass, perennial ryegrass, and tall fescue), oats, rhubarb, sorghum (grain and sweet), and sugarcane may be replanted immediately.

120 Days: Small grains may be planted 120 days after application.

10 Months: Alfalfa, blueberry, canola, cotton, lingonberry, peanuts, potatoes, soybeans, sunflowers, and tobacco can be planted back the following season but not less than 10 months after the last Callisto application. If Callisto is applied postemergence following a mesotrione-containing preemergence herbicide, only corn (all types) or grain sorghum may be replanted the year following application, or severe crop injury may occur.

18 Months: Sugar beets, peas, dry beans, snap beans, cucurbits, red clover, and all other rotational crops may be replanted 18 months after application of Callisto. Planting unspecified rotational crops, or those rotational crops that are specified at shorter than recommended intervals, may result in injury to the rotational crop.

Table 1 lists the currently established tolerances for residues of mesotrione and its metabolites or degradates, as published in 40 CFR part 180.571.

3.5.5 Application method

Mesotrione can be applied preemergence by ground equipment with a 14-day application interval (USEPA, 2001b). The current Callisto label indicates that aerial application is not allowed. Postemergence applications should be made when annual broadleaf weeds are less than 5 inches tall but before corn reaches 30 inches in height. Adjuvants (nonionic surfactants or crop oil concentrate) and added nitrogen (ammonium sulfate or urea ammonium nitrate) are required for postemergence use.

Table 1 Established Tolerances for Residues of Mesotrione (and degradates or metabolites) in or on Raw Agricultural Commodities

Commodity	Tolerance Limit (ppm)
Asparagus	0.01
Berry, group 13	0.01
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Corn, pop, grain	0.01
Corn, pop, stover	0.01
Corn, sweet, forage	0.50
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	1.50
Cranberry	0.02
Flax, seed	0.01
Grass, forage	0.01
Grass, hay	0.01
Grass, seed screenings	0.10
Grass, straw	0.10
Lingonberry	0.01
Millet, forage	0.01
Millet, grain	0.01
Millet, hay	0.02
Millet, straw	0.02
Oat, forage	0.01
Oat, grain	0.01
Oat, hay	0.01
Oat, straw	0.01
Okra	0.01
Rhubarb	0.01
Sorghum, grain, forage	0.01
Sorghum, grain, grain	0.01
Sorghum, grain, stover	0.01
Sorghum, sweet	0.01
Soybean, seed	0.01
Sugarcane, cane	0.01

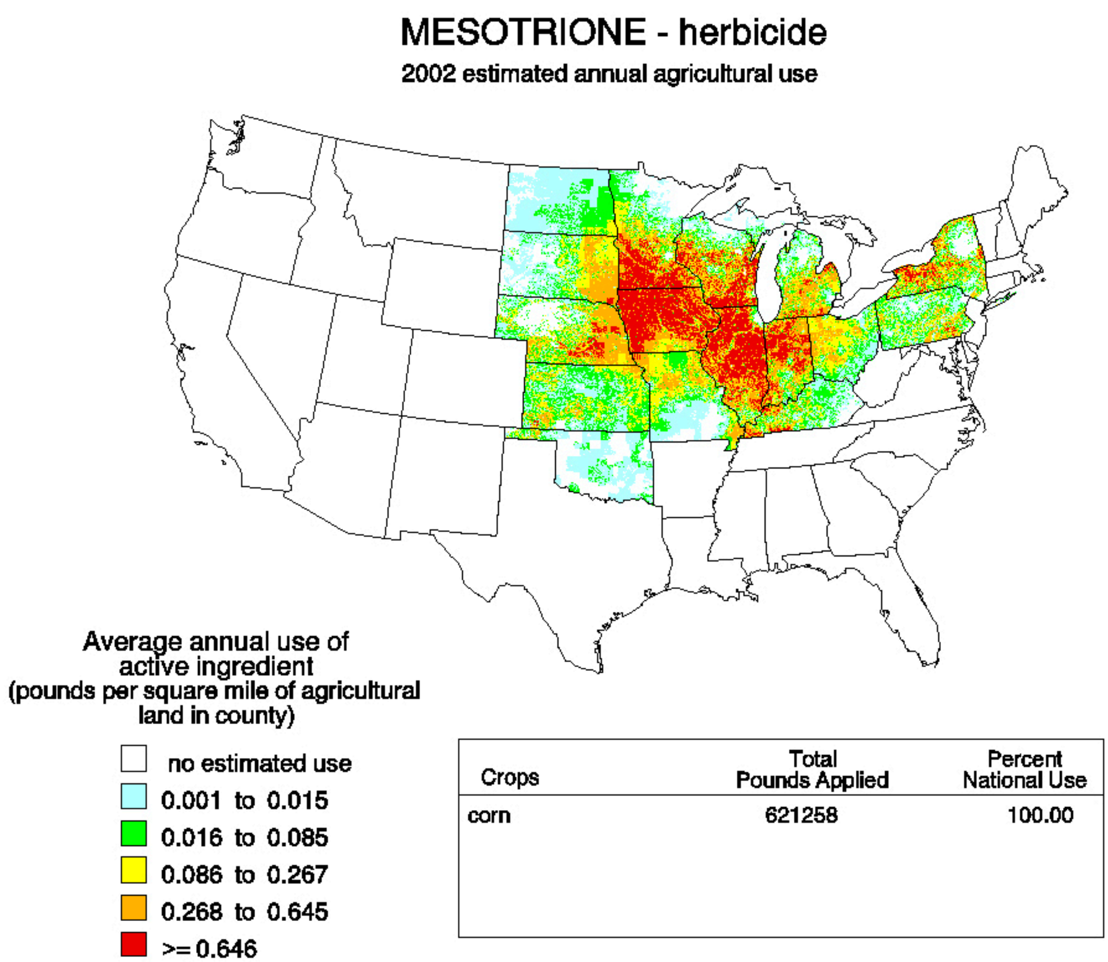
Source: (USEPA, 2013)

3.5.6 Usage Rates

The current maximum single application rates for registered uses were established in 2008 and range from 0.094 to 0.25 lb ai/A; the annual total (twice per season) application rates range from 0.188 to 0.5 lb ai/A (USEPA, 2008c). In 2009, Syngenta was granted a 3-year Experimental Use Permit by EPA (100-EUP-114) for testing mesotrione on HPPD-inhibitor-tolerant soybeans. The Experimental Use Permit, extended through 2014, has an annual application rate of 1.5 lb ai/A (Syngenta, 2011b), three times the highest previously registered seasonal application rate. However, these rates are for crop tolerance testing purposes only. The approved new (in 2009) use of mesotrione on soybeans has a registered application rate of 0.188 lb ai/A per season, at the low end of the approved application rates for other crops. The proposed seasonal maximum for Callisto on HPPD-inhibitor-tolerant soybeans will be 0.31 lb ai/A, within the range of the annual total application rates for registered uses.

The US Geological Survey (USGS) estimated average annual agricultural use for numerous pesticides, including mesotrione, based on a 4-year period from 1999 to 2002 (USGS, 2002). USGS estimated that 621,658 pounds of mesotrione (as the active ingredient in various herbicide mixtures) would be applied to US corn fields in 2002. Although the data are over 10 years old, Figure 3, showing annual mesotrione usage in 2002, provides a visual image of the intensity and extent of its application in that time period.

Figure 3 Estimated Agricultural Use of Mesotrione in 2002



3.5.7 Target Weeds

Mesotrione provides control or partial control for a range of broadleaf weeds in postemergence or preemergence applications, as listed below. In postemergence applications, mesotrione may be used alone when weeds are less than 5 inches tall, or in combination with other herbicides (such as *S*-metolachlor and atrazine) for corn and sugarcane when weeds are less than 5 inches or between 5 and 10 inches tall. In preemergence applications, it may be used alone or in combination with other herbicides on corn, sorghum, and sugarcane.

Weeds Controlled with Postemergence Applications of Callisto

Amaranth, Palmer	Hemp	Pigweed, tumble
Amaranth, Powell	Horse nettle	Pokeweed, common
Amaranth, spiny	Jimsonweed	Potatoes, volunteer
Atriplex	Knotweed, prostrate	Pusley, Florida
Broadleaf signalgrass	Kochia	Ragweed, common
Buckwheat, wild	Lambsquarters, common	Ragweed, giant
Buffalobur	Mallow, Venice	Sesbania, hemp
Burcucumber	Morningglory, entireleaf; ivyleaf	Sida, prickly (teaweed)
Carpetweed	Morningglory, pitted	Smartweed, ladysthumb
Carrot, wild	Mustard, wild	Smartweed, pale
Chickweed, common	Nightshade, black	Smartweed, Pennsylvania
Cocklebur, common	Nightshade, eastern black	Sunflower, common
Crabgrass, large	Nightshade, hairy	Thistle, Canada
Dandelion	Nutsedge, yellow	Velvetleaf
Dock, curly	Pigweed, redroot	Waterhemp, common
Galinsoga	Pigweed, smooth	Waterhemp, tall

Weeds Controlled with Preemergence Applications of Callisto

Amaranth, Palmer	Nightshade, eastern black
Amaranth, Powell	Nightshade, hairy
Amaranth, spiny	Pigweed, redroot
Broadleaf signalgrass	Pigweed, smooth
Buffalobur	Pigweed, tumble
Carpetweed	Ragweed, common
Chickweed, common	Ragweed, giant
Cocklebur, common	Smartweed, ladysthumb
Crabgrass, large	Smartweed, pale
Galinsoga	Smartweed, Pennsylvania
Jimsonweed	Sunflower, common
Kochia	Velvetleaf
Lambsquarters, common	Waterhemp, common
Morningglory, entireleaf; ivyleaf	Waterhemp, tall
Morningglory, pitted	

3.5.8 Tolerant Weeds

According to the *International Survey of Herbicide Resistant Weeds*, certain biotypes of common waterhemp (*Amaranthus tuberculatus* (syn. *rudis*)) and Palmer amaranth (*Amaranthus palmeri*) are the only weeds currently known to have developed tolerance to post-emergence applied HPPD-inhibitor herbicides, including mesotrione (Heap, 2013b). Common waterhemp and Palmer amaranth are dicot weeds in the Amaranthaceae family. HPPD-inhibitor resistant biotypes of common waterhemp have been identified in limited areas of Illinois, Iowa, and Nebraska, and HPPD-inhibitor resistant biotypes of Palmer amaranth have been identified in limited areas of Kansas and Nebraska. Certain biotypes of these weeds are also known to have resistance to other herbicide modes of action.

4. Environmental Fate and Ecological Effects

This section describes the environmental fate and ecological effects of mesotrione. Section 4.1 describes the toxicological effects of mesotrione and its metabolites on plants and animals (including humans), based principally on EPA review documents. Sections 4.2 and 4.3 describe mesotrione's persistence in soil and water, and Section 4.4 discusses its effects on soil microbes. Sections 4.5 and 4.6 explain the risk to plants and animals, respectively, from application of mesotrione as an herbicide on agricultural fields. Human health effects are described in Section 5.

The ecological effects of mesotrione are driven, in part, by its chemical properties and environmental fate parameters, as listed in Table 2.

Table 2 General Chemical Properties and Environmental Fate Parameters for Mesotrione

Parameter	Value
Selected Physical and Chemical Parameters	
Molecular mass	339.3 g/mol
Vapor pressure (20^{o}C)	4.3 x10^{-8} torr
Water solubility(20^{o}C)	1.5g/100ml at pH 6.9
Partition coefficient (octanol-water)	Log P_{ow} = 0.11 in unbuffered water
Bioconcentration	Not expected
Persistence	
Hydrolysis half-life	Stable
Aqueous photolysis half-life	84 days
Soil photolysis half-life	30 days
Aerobic soil metabolism half-life	5 to 32 days
Anaerobic aqueous metabolism half-life	4 days
Aerobic aqueous metabolism half-life	3 to 6 days
Mobility	
Organic carbon distribution coefficient (KOC)	16 to 390 mL/g_{oc}
Field Dissipation	

Terrestrial field dissipation half-life range	2 to 14 days

Sources: (USEPA, 2001b; USEPA, 2008c)

4.4 Toxicology of Mesotrione and Metabolites

As mentioned in Section 3.1, *Chemical Name and Structure*, mesotrione is a triketone and metabolism of mesotrione leads to two major degradates: MNBA, formed through aerobic metabolism, and AMBA, formed through anaerobic metabolism (USEPA, 2008c). Carbon dioxide is a final degradate of the metabolites.

EPA's chemical review (USEPA, 2001b) for mesotrione's toxicological effects on plants and animals is summarized in tables appended to this paper. In regard to plants, EPA concluded that adverse effects were seen in both nontarget monocots and dicots. Specifically:

For crop seedling emergence, lettuce is the most sensitive dicot and onion is the most sensitive monocot;

For crop vegetative vigor, tomato is the most sensitive dicot and onion is the most sensitive monocot; and

Kirchneria subcapitata (a green algae) is the most sensitive nonvascular aquatic plant.

In regard to animals, EPA concluded that mesotrione is:

Practically nontoxic to avian species on a subacute dietary basis;

Practically nontoxic to the bobwhite on an acute oral basis;

Practically nontoxic to small mammals on an acute and chronic oral basis;

Practically nontoxic to bees on an acute contact basis;

Practically nontoxic to freshwater fish on an acute basis;

Practically nontoxic to aquatic invertebrates on an acute basis;

Practically nontoxic to estuarine/marine fish on an acute basis; and

Moderately toxic to slightly toxic to estuarine/marine invertebrates on an acute basis.

EPA's most recent hazard assessment of mesotrione (USEPA, 2009a) states that mesotrione has low acute toxicity via oral, dermal adsorption, and inhalation routes. It is a mild eye irritant, but is not a dermal irritant or dermal sensitizer. In subchronic and chronic oral studies, ocular lesions, liver and kidney effects, and /or body-weight decrements were the major adverse effects seen in the rat, mouse, and dog at high doses. Plasma tyrosine levels were increased in the rat, mouse, and dog in the chronic and reproductive studies in which they were measured. The ocular, liver and kidney effects are believed to be mediated by the high tyrosine levels in the blood caused by inhibition of the enzyme HPPD. Even though the rat is the most sensitive species to this effect compared to the dog and the mouse, EPA's Health Effects Division (HED) Mechanism of Toxicity Science Advisor Review Committee (MTSARC) concluded that the mouse is a more appropriate model for assessing human risk than is the rat. There was no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies and no concerns for mutagenicity. No evidence of neurotoxicity or neuropathology was seen in the acute and subchronic neurotoxicity studies. In the multi-generation mouse reproduction study, one F_1 male and one F_1 female had retinal detachment with marked cataractous changes at the highest dose tested (greater than 1,000 mg/kg/day). In the subchronic toxicity dog study, the high-dose females had decreased absolute and relative brain weights; however, no microscopic abnormalities were noted in any brain tissue from the high-dose group and the effect was not observed in the chronic toxicity dog study.

Based on the overall weight of evidence, HED concluded that the requirement of a developmental neurotoxicity study is waived, and the *Food Quality Protection Act* (FQPA) safety factor for the incomplete database is set at 1X. In a toxicology evaluation (USEPA, 2001d), MNBA and AMBA were determined to have low acute oral toxicity; MNBA has low dermal toxicity. MNBA caused an increase in motor activity in adult female rats. MNBA and AMBA are very weak to weak inhibitors of HPPD *in vitro* and it appears they will not perturb tyrosine catabolism *in vivo*.

An independent study (Elskus et al., 2008) of certain stressors[62] to Atlantic salmon determined that Callisto (as well as other pesticides) had no significant effect on innate immunity, development rate or behavior (spontaneous swimming, prey capture) in zebrafish (as a toxicological model for early life stage Atlantic salmon).

4.5 Persistence in Soil

Mesotrione is approximately 40 times more acidic than acetic acid, which influences its behavior in environmental media at different pHs (USEPA, 2001b). There is a high correlation between pH and sorption to soil organic matter, and a moderate correlation between pH and soil "half-life." Mesotrione, MNBA, and AMBA have low to very low sorption to tested soils/sediments at the more neutral pHs, indicating potential for leaching and runoff (USEPA, 2001b).

Mesotrione has low sorption to soils/sediments at all pHs tested (K_{oc}: 16 to 390 mL/g) and is moderately mobile to mobile (USEPA, 2008c). Mesotrione is relatively short-lived in soil, tending to offset the opportunity for leaching and runoff (USEPA, 2001b). Photolysis, aerobic and anaerobic soil metabolism, and terrestrial field dissipation studies indicate that mesotrione is not persistent in soil (USEPA, 2001g). Mesotrione dissipates through aerobic soil metabolism with rates dependent on ambient conditions (half life of 5 to 32 days) (USEPA, 2008c).

Volatilization of mesotrione and its transformation products (except for carbon dioxide) is not indicated (USEPA, 2001b). As shown in Table 3, the vapor pressure of mesotrione is relatively low (compared to other herbicides such as dicamba and 2,4-D). Mesotrione vapors are not transported by wind for deposition on soil away from application sites.

4.6 Persistence in Water

Mesotrione may reach surface water through spray drift and/or runoff. In aquatic environments, mesotrione is stable to hydrolysis and has limited photolysis but dissipates rapidly through aerobic (half life of 3 to 6 days) and anaerobic (half life of 4 days) metabolism (USEPA, 2008c). Mesotrione is not persistent in water but its degradates MNBA and AMBA may be persistent

62 Pesticides used on blueberries, acidity, and aluminum concentrations in water.

under suboxic (groundwater) conditions (USEPA, 2001g). Under suboxic or anoxic conditions, as would be associated with groundwater, MNBA would be reduced to AMBA (USEPA, 2001b).

Field dissipation and prospective groundwater (PGW) studies to evaluate the potential for mesotrione, MNBA, and AMBA to reach groundwater were reviewed by EPA. The 2002 Drinking Water Assessment (USEPA, 2002) concludes that:

> Laboratory results are supported by results from field studies. Terrestrial field dissipation studies showed dissipation half-lives of 2 to 14 days and did not find any residues below 6 inches, although review of these studies found they did not adequately account for dissipation. A prospective groundwater study (PGW) was conducted in Michigan and found no leaching, but the study was determined not to represent conditions of upper bound vulnerability. Another PGW is ongoing in North Carolina.

The review (USEPA, 2008b) of the PGW study conducted in North Carolina states that:

> Mesotrione and its degradates were detected above the limit of quantification only in soil-pore water at the 3-foot depth. Detections were found at four of the eight 3-ft lysimeters with breakthrough of parent and/or degradates occurring at 0.5 to 1.5 MAT and no detections after 3.5 MAT. Peak parent concentrations at one lysimeter reached 11 ppb and at the others were less than or equal to 2 ppb with degradate concentrations all at less than or equal to 0.48 ppb mesotrione equivalents. The AMBA results may under represent actual concentrations due to the poor storage stability, but this is not expected to affect study conclusions. Throughout the 38 months of the study, no detections of parent or degradates were made at any deeper lysimeters or in ground water. The clear pattern of increase and decline at the 3-ft lysimeters suggests that the compound reached this depth and dissipated through regular sorption and degradation processes rather than through preferential flow or a rapid initial pulse following a precipitation event. The lack of detection at deeper locations, then, can be interpreted as evidence that leaching is not expected, rather than of insufficient sampling time.

4.7 Effect on Soil Microbes

EPA does not evaluate risk to microbial communities as part of its pesticide review process. EPA did conclude that bioconcentration of mesotrione, MNBA, and AMBA in soils is not expected (USEPA, 2001b).

4.8 Risk to Plants

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. EPA conducted a screening level risk characterization by the risk quotient (RQ) method. RQs are calculated by dividing estimated environmental concentrations (EECs) by acute and chronic ecotoxicity values. RQs are then compared to EPA's levels of concern (LOCs) defined by the EPA for acute and chronic exposures where an RQ greater than the LOC value indicates a potential screening-level risk. For screening level findings with an RQ greater than the LOC, EPA performs a more refined risk assessment using multiple lines of evidence to more specifically characterize exposure and ecotoxicity.

The risk to plants was assessed for different application rates for Callisto on corn and other listed crops. For all application scenarios for mesotrione in the Callisto formulation (see Section 3.3.4), EPA's acute LOCs are exceeded for monocots and dicots in dry and semi-aquatic areas (USEPA, 2001b). An exception is for monocots in a dry area for either single applications (aerial or ground) or for two ground applications using monocot seedling emergence data.

The application rate of 0.188 lb ai/A proposed by Syngenta in 2008 for the preemergence use on soybean varieties with some natural mesotrione tolerance is approximately equal to the lowest previously registered rate. EPA concluded that potential adverse environmental effects to aquatic plants were minimal from the proposed new use (USEPA, 2008c). The Experimental Use Permit application rate slightly exceeded EPA's LOCs for aquatic vascular plants but the new use application rate did not; no exceedances were noted for non-vascular plants. Table 3 shows the RQs associated with the aquatic vascular plants for soybean and sugarcane mesotrione use (bold values).

Table 3 Acute RQ Values for Aquatic Vascular Plants Exposed to Mesotrione

Use	Peak EEC (ppb)	Vascular Plant RQs (EEC/EC_{50})
Soybean Preemergence Use	5.1	0.5
Soybean Experimental Use	25.1	**2.6**
Sugarcane	12.5	**1.3**

Source: (USEPA, 2008c)

4.9 Risk to Animals

EPA has concluded that mesotrione is unlikely to present a risk to aquatic and terrestrial animals on an acute or chronic basis (USEPA, 2001b). EPA indicated that loss of habitat and food items may indirectly affect terrestrial and aquatic organisms as a result of damage to non-target plants from off-target transport (e.g., spray drift or run-off).

The new use of mesotrione on soybeans approved in 2009 was for a preemergence application rate of 0.188 lb/ai/A per year, equivalent to the lowest previously registered rate. Even at the increased application rate of 1.5 lb/ai/A of the Experimental Use Permit for soybeans (three times the maximum registered rate), all categories of risk to aquatic animals resulted in RQs of less than 0.01 (USEPA, 2008c). Additional risks to terrestrial animals from the Experimental Use Permit application rate were considered by the EPA. Risk to mammals and invertebrates remained minimal, but some LOCs for birds were slightly exceeded. Chronic exposure RQs for birds that feed on short grass (RQ = 2.6), tall grass (RQ = 1.2), or broadleaf plants and small insects (RQ = 1.5), exceeded the LOC of 1. For all other classes of birds, acute and chronic exposure RQs are below LOCs. A summary of the environmental risk to animals from soybean application rates is provided in Table 4.

Table 4 Summary of Environmental Risks for Use of Mesotrione on Soybeans

Assessment Endpoint	Risk to Animals (0.188 lb ai/A/yr)
Acute and Chronic Risk to Freshwater and Marine/ Estuarine Fish and Amphibians	None
Acute and Chronic Risk to Freshwater and Marine/ Estuarine Invertebrates	None
Acute and Chronic Risk to Mammals	None
Acute and Chronic Risk to Birds and Reptiles	None
Risk to Terrestrial Invertebrates	None likely, based on honeybee toxicity data

Source: (USEPA, 2008c)

5. Human Health Effects

5.4 Human Health Risks

EPA evaluates available animal toxicity data to determine human health risk. In the most recent hazard assessment for mesotrione (USEPA, 2009a), EPA states that the chronic reference dose (cRFD), short- and intermediate-term incidental exposure and dermal endpoints are based on the lowest-observed adverse-effect level (LOAEL) of 2.1 mg/kg/day based on tyrosinemia in F1 and F2 offspring and ocular discharge in F1 pups seen in a reproduction study in mice. The HED mesotrione risk assessment team concluded that the FQPA safety factor of 3X for use of LOAEL (instead of a no observed adverse effect level (NOAEL)) is adequate for addressing any uncertainties associated.

No appropriate endpoint was identified to quantify risk to the general US population or to females 13 to 50 years old from a single-dose administration of mesotrione. Therefore, there is no acute reference dose (aRFD). The short- and intermediate-term endpoints for all routes of exposure (dermal, inhalation, and oral) are based on tyrosinemia in adults and pups and ocular discharge in pups observed in a mouse reproduction study. The cRFD is 0.007 mg/kg/day. Mesotrione is classified as “not likely to be carcinogenic to humans” based upon lack of evidence of carcinogenicity in rats and mice. Therefore, a cancer risk assessment is not required. Since an oral study was selected for all durations of inhalation exposure, an unrealistically high 100 percent inhalation-absorption factor (relative to oral absorption) was used in the route-to-route extrapolation. Based on the results of an *in vivo* dermal-absorption study, a dermal-absorption factor of 1 percent was used for dermal exposure assessment.

The FQPA safety factor is 3X; consequently, the chronic population-adjusted dose (cPAD) value is 0.007 mg/kg/day. In the dietary exposure and risk assessment, food and water exposure estimates are not of concern (less than 100 percent of the cPAD).

5.5 Occupational Health Risks

Risks to agricultural workers were also considered by EPA in the Occupational and Residential Exposure Risk Assessment for mesotrione under the Callisto formulation (USEPA, 2001e). In the most recent hazard assessment for mesotrione (USEPA, 2009a), EPA concluded that residential handler exposure is not of concern. Short-term aggregate margins of exposure (MOEs) for the adult, youth, and toddler population subgroups and the intermediate-term aggregate MOE for the toddler population subgroup were assessed, and are not of concern to HED (MOEs greater than 300).

Short- and intermediate-term estimated risks for handlers are not of concern provided handlers of liquid formulations wear protective gloves. Since the proposed label for the liquid formulation included gloves as required PPE, HED concluded that handler risk is not of concern. There are no short-term occupational post-application dermal risks of concern on day 0 for all post-application activities.

Mesotrione is classified in Toxicity Category III for acute dermal and Category IV for acute oral, acute inhalation, and primary eye and skin irritation. It is not a dermal sensitizer. Therefore, the Worker Protection Standard (WPS) interim restricted-entry interval (REI) of 12 hours is adequate to protect agricultural workers from post-application exposures to mesotrione. The labels currently have REIs of 12 hours or more.

Syngenta has prepared Material Safety Data Sheets (MSDSs) for Callisto (Syngenta, 2012a) with mesotrione as the active ingredient at 40 percent concentration, and for Mesotrione Technical (Syngenta, 2011c) at 79 percent concentration. The MSDSs are similar because they focus on active ingredient rather than other ingredients, and provide toxicological and ecological information summarized from EPA reviews (Section 4.1). The toxicological information for mesotrione provided in Section 11 of the MSDS is based on animal toxicological studies. The toxicity data from the Callisto MSDS are consistent with the toxicological data compiled by EPA (as summarized in Section 4.6 and appended to this paper) and are provided in Table 5.

Table 5 Callisto MSDS Acute and Chronic Toxicity Data

Parameter	Test Animal	Exposure Limit
Acute ingestion toxicity	Rabbit, rat	LD_{50}: >5,000 mg/kg body weight
Acute dermal toxicity	Rabbit, rat	LD_{50}: >5,000 mg/kg body weight
Acute inhalation toxicity	Rat	LC_{50}: >5.19 mg/L – 4 hours
Eye contact	Rabbit	Mildly irritating
Skin contact	Rabbit	Slightly irritating
Sensitization	Guinea pig	Not a sensitizer
Reproductive & developmental toxicity	Not specified	Not a reproductive or developmental hazard.
Chronic/subchronic toxicity	Not specified	Animal studies showed evidence of reduced bodyweight

		gain, increased liver and kidney weights, blood effects (polycythemia, reduced white blood cell count) and eye effects (cataract formation, keratitis). No known neurotoxic effect based on animal studies.
Carcinogenicity	Not specified	Not carcinogenic in animal studies; not mutagenic.

Source: (Syngenta, 2010a; Syngenta, 2012a)

Appendix C: Sample Management Plans for SYHT0H2 Soybean

Mesotrione

Burndown with POST Emergent Application

Burndown	Alternate 1	Glufosinate and Broadleaf residual	-or- Paraquat or- glyphosate or mesotrione or IFT
Burndown	Alternate 2	Residual grass herbicide and/or- broadleaf herbicide (such as s-metolachlor or metribuzin)	-or- Paraquat or- glyphosate
Preplant		N/A	
POST (Early)		N/A	
POST		Glufosinate	-with or without- mesotrione or IFT or soybean selective herbicide

Preplant with POST Emergent Application

Burndown	N/A	
Preplant	Mesotrione or IFT	-and- Residual grass herbicide- with or without- broadleaf herbicide (s-metolachlor or metribuzin)
POST (Early)	N/A	

Mesotrione

POST	Alternate 1	Glufosinate (1x-2x)	
POST	Alternate 2	Glufosinate (1x-2x)	-and- Soybean selective herbicide (s-metolachlor or fomesafen)

Burndown with Early POST Application

Burndown	Glufosinate	-or- Paraquat or-glyphosate
Preplant	N/A	
POST (Early)	Mesotrione or IFT	-and- Soybean selective residuals (as recommended on label, such as s-metolochlor or fomesafen)
POST	N/A	

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Appendix C: Sample Management Plans for SYHT0H2 Soybean

Mesotrione

Burndown with POST Emergent Application

Burndown	Alternate 1	Glufosinate and Broadleaf residual	-or- Paraquat or-glyphosate or mesotrione or IFT
Burndown	Alternate 2	Residual grass herbicide and/or- broadleaf herbicide (such as s-metolachlor or metribuzin)	-or- Paraquat or-glyphosate
Preplant		N/A	
POST (Early)		N/A	
POST		Glufosinate	-with or without-mesotrione or IFT or soybean selective herbicide

Preplant with POST Emergent Application

Burndown		N/A	
Preplant		Mesotrione or IFT	-and- Residual grass herbicide-with or without-broadleaf herbicide (s-metolachlor or metribuzin)
POST (Early)		N/A	

Mesotrione

POST	Alternate 1	Glufosinate (1x-2x)	
POST	Alternate 2	Glufosinate (1x-2x)	-and- Soybean selective herbicide (s-metolachlor or fomesafen)

Burndown with Early POST Application

Burndown	Glufosinate	-or- Paraquat or-glyphosate
Preplant	N/A	
POST (Early)	Mesotrione or IFT	-and- Soybean selective residuals (as recommended on label, such as s-metolochlor or fomesafen)
POST	N/A	