Dow AgroSciences Petition (09-233-01p) for Determination of Nonregulated Status of Herbicide-Tolerant DAS-40278-9 Corn, *Zea mays*, Event DAS-40278-9

OECD Unique Identifier:
DAS-40278-9

Draft Environmental Assessment

October 2011

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ACRONYMS

2,4-D	2,4-dichlorophenoxyacetic acid
2,4-DCA	2,4-dichloroanisole
2,4-DCP	2,4-dichlorophenol
ACCase	actetyl coenzyme A carboxylase
ae	acid equivalence
AIA	advanced informed agreement
AMS	Agricultural Marketing Service
ANZFS	Australia and New Zealand Food Standards Agency
AOPP	aryloxyphenoxypropionate
AOSCA	Association of Official Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
BEE	butoxyethyl ester
BRS B	iotechnology Regulatory Service
Bt	Bacillus thuringiensis
CBD	Convention on Biological Diversity
CEQ	Council of Environmental Quality
CFR	Code of Federal Regulations
CHQ	chlorohydroquinone
COC	crop oil concentrate
DAS	Dow AgroScience
DDGs	distillers dried grain with solubles
EA	Environmental Assessment
EFSA	European Food Safety Agency
EIS	Environmental Impact Statement
EPA	Environmental Protection Agency
ERS	Economic Research Service
ESA	Endangered Species Act
ESPP	Endangered Species Protection Program
ESU	evolutionarily significant units
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FFP	food, feed, or processing
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
g	gram(s)
GE	genetically engineered
GHG	greenhouse gases
ha	hectare
HFCS	high-fructose corn syrup
IAA	indole acetic acid
IPCC	Intergovernmental Panel on Climate Change
IPM	Integrated Pest Management

ACRONYMS, CONTINUED

ISHRW	International Survey of Herbicide Resistant Weeds
lb	pound
LMOs	living modified organisms
MOU	Memorandum of Understanding
MSO	methylated seed oil
N_2O	nitrous oxide
NABI	North American Biotechnology Initiative
NAPPO	North American Plant Protection Organization
NASS	National Agricultural Statistics Service
NEPA	National Environmental Policy Act
NHPA	National Historic Presevation Act
NMFS	National Marine Fisheries Service
NOP	National Organic Program
NPS	non-point source
NRC	National Research Council
NRCS	National Resources Conservation Service
OECD	Organization for Economic Cooperation and Development
OSTP	Office of Science and Technology Policy
PPA	Plant Protection Act
PPRA	Plant Pest Risk Assessment
PRA	Pest Risk Analysis
RED	Reregistration Eligibility Document
RSPM	Regional Standards for Phytosanitary Measures
SAV	submerged aquatic vegetation
TES	threatened or endangered species
TSCA	Toxic Substances Control Act
USDA	U.S. Department of Agriculture
USFWS	U.S. Fish and Wildilfe Service
VEC	Value Enhanced Corn
WPS	Worker Protection Standard

1 PURPOSE AND NEED

1.1 REGULATORY AUTHORITY

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

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

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

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

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

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

1.2 REGULATED ORGANISMS

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

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

1.3 PETITION FOR DETERMINATION OF NONREGULATED STATUS: HERBICIDE-TOLERANT DAS-40278-9 CORN, EVENT DAS-40278-9

Dow AgroScience (DAS) has submitted a petition (APHIS Number 09-23301-01p) seeking a determination that DAS-40278-9 corn is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at Part 340.

DAS-40278-9 corn is a genetically engineered (GE) corn line that has been provided increased tolerance to treatment with phenoxy auxin herbicides and resistance to aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase (ACCase) inhibitor ("fop") herbicides (DAS, 2010). The most well-known and widely-used phenoxy auxin herbicide is 2,4-dichlorophenoxyacetic acid (2,4-D) which has been used for many decades as a pre-plant or post-emergent herbicide to control broadleaf (dicot) weeds in cornfields (USDA-APHIS, 2010). AOPP ACCase inhibitors, or "fop" herbicides, are post-emergent graminicides, meaning that the herbicides selectively control emerged grass (Poaceae) weeds. Corn, a plant in the Poaceae family, is sensitive to treatment with “fop” herbicide, and these herbicides have traditionally not been labeled for weed control in cornfields (USDA-APHIS, 2010).

DAS-40278-9 corn is currently regulated under Part 340. Interstate movement, importation, and field testing of DAS-40278-9 corn have been conducted under notifications acknowledged by APHIS. If a determination of nonregulated status is reached, DAS-40278-9 corn will be the first commercially available corn variety with improved tolerance to phenoxy auxin herbicides and resistance to “fop” herbicides.

1.4 PURPOSE OF PRODUCT

DAS has developed the DAS-40278-9 corn as an alternative herbicide-tolerant corn product. The DAS-40278-9 corn (*Zea mays*) incorporates the *aad-1* gene, derived from the common soil bacterium *Sphingobium herbicidovorans* (USDA-APHIS, 2010). In the DAS-40278-9 corn, the *aad-1* gene expresses the AAD-1 protein, which degrades 2,4-D into herbicidally inactive 2,4-dichlorophenol (DAS, 2010). Additionally, this same protein has been demonstrated to degrade certain of the “fop” herbicides to their inactive phenols (DAS, 2010). DAS-40278-9 corn would be the first GE corn variety introduced with tolerance to these herbicides (USDA-APHIS, 2010).

Corn is the primary feed grain in the U.S., accounting for more than 95% of the total feed grain production and use (USDA-ERS, 2011b). In 2011, approximately 23% of corn planted in the U.S. possessed tolerance to an herbicide that was conferred via GE, with up to 88% of all corn planted representing at least one GE variety (USDA-ERS, 2011a). The primary herbicide tolerance trait currently in use has been glyphosate tolerance, and the adoption of this trait in other major crops, such as cotton and soybean, is even higher (USDA-APHIS, 2010). Weed resistance to herbicides is a concern in agricultural production, and the wide-spread adoption of herbicide-tolerant crops, especially GE-derived glyphosate-tolerant crops, has changed the approach that farmers take to avoid yield losses from weeds (Duke and Powles, 2009; Gianessi, 2008).

DAS-40278 corn, either alone or when combined by traditional breeding (i.e., stacked) with other genetically-modified herbicide-tolerant or insect-resistant corn varieties, provides growers with an additional in-crop weed management option to manage broadleaf, glyphosate-resistant (or tolerant) weed species using 2,4-D (DAS, 2010). As the AAD-1 protein also provides tolerance to the “fop” herbicides, DAS-40278-9 corn also would provide the grower with an option to use one of the “fop” herbicides, in this case Quizalofop, to control grasses in corn, some of which have been reported as resistant to glyphosate (DAS, 2010; USDA-APHIS, 2010). DAS indicates that it intends to develop such stacked varieties using the DAS-40278-9 corn as a source for the 2,4-D and “fop” resistance (DAS, 2010, 2011d, 2011e).

1.5 APHIS RESPONSE TO PETITION FOR NONREGULATED STATUS

Under the authority of the plant pest provisions of the PPA and Part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as DAS-40278-9 corn. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) that the GE organism is unlikely to pose a plant pest risk, the GE organism is no longer subject to the plant pest provisions of the PPA and Part 340.

DAS-40278-9 corn has been field tested in the U.S. since 2008, as authorized by APHIS (DAS, 2010). Data were provided in the petition for field trials completed prior to the petition submission. Field test reports can be found in the DAS-40278-9 corn petition at Section VII (DAS, 2010).

DAS has conducted field trials at 27 locations in the U.S. and Canada (DAS, 2010). Field tests conducted under APHIS oversight allow for evaluation in agricultural settings under confinement measures designed to minimize the likelihood of persistence in the environment after completion of the field trial. Under confined field trial conditions, data are gathered on multiple parameters and used by applicants to evaluate agronomic characteristics and product performance. These data are also valuable to APHIS for assessing the potential for a new variety to pose a plant pest risk. The data evaluated by APHIS for DAS-40278-9 corn may be found in the *Plant Pest Risk Assessment for DAS-40278-9 corn* (USDA-APHIS, 2010).

APHIS has prepared this environmental assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality's (CEQ) regulations implementing the National Environmental Policy Act (NEPA) (40 CFR Parts 1500-1508), and the USDA and APHIS NEPA implementing regulations and procedures (7 CFR 1b and 7 CFR Part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from a determination of nonregulated status of DAS-40278-9 corn.

DAS has indicated its intention to develop a "stacked" hybrid through conventional breeding techniques (DAS, 2010, 2011d, 2011e). In this process, the 2,4-D and "fop" resistance from DAS-40278-9 corn will be combined with glyphosate resistance from another corn 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. APHIS does not have jurisdiction under the PPA and Part 340 to review such stacked hybrids developed using nonregulated articles and conventional hybridization techniques where there is no evidence of a plant pest risk. Accordingly, this EA focuses on the cultivation of the DAS-40278-9 corn. Issues associated with potential future stacking, particularly cultivation of a stacked hybrid incorporating glyphosate resistance from a variety previously determined to be nonregulated, are presented and discussed in the cumulative effects analyses where appropriate.

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

1.6 COORDINATED FRAMEWORK REVIEW

Food and Drug Administration

DAS-40278-9 corn (event DAS-40278-9) is within the scope of the 1992 FDA policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (US-FDA, 1992).

DAS has provided the FDA with information on the identity, function, and characterization of the genes for DAS-40278-9 corn, including expression of the gene products. The FDA has completed its review of DAS' submittal and has published a completed consultation (US-FDA, 2011). A copy of this consultation is provided in Appendix A.

APHIS considers the FDA food and feed safety and nutritional assessment determination when assessing potential impacts that may result from a determination of nonregulated status of a GE organism. In the absence of a completed FDA determination, APHIS takes into consideration prior FDA reviews of comparable products to make a preliminary assessment of the potential impacts.

Environmental Protection Agency

The EPA has authority over the use of pesticidal substances and plant-incorporated protectants under the FIFRA as amended (7 USC §136, *et seq.*) and the FFDCA (21 USC §301, *et seq.).* EPA is currently reviewing information submitted by the applicant on the efficacy and potential environmental concerns associated with the use of this product. APHIS considers the EPA's regulatory assessment when assessing potential impacts that may result from a determination of nonregulated status of a GE organism. In the absence of a completed EPA determination, APHIS takes into consideration prior EPA reviews of comparable products to make a preliminary assessment of the potential impacts with the use of this product (DAS, 2011f).

EPA has authority under FIFRA to establish pesticide use restrictions. These use restrictions are presented on pesticide labels which are prepared during the pesticide registration process. DAS-40278-9 corn provides growers with new uses of the herbicides 2,4-D and Quizalofop on corn which will require changes in the EPA approved labels for these herbicides.

The herbicide 2,4-D is one of the most widely-used herbicides in the U.S. This herbicide has been used agronomically and in non-crop situations for broad-spectrum, broadleaf weed control for more than 60 years (DAS, 2010). The current 2,4-D label provides for its use on a wide variety of crops, including broadleaf weeds in cereal grains, corn, sorghum, rice, sugarcane, soybeans (pre-plant only), turf, non-crop areas, and certain aquatic applications (Nufarm, 2009). Currently, for corn without the *aad-1* gene, 2,4-D can be applied pre-emergence up to 1,120 g acid equivalence/hectare[1] (ae/ha), post-emergent on plants 8 inches or less in height (560 g

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[1]Active ingredient (ai) must be distinguished from acid equivalent (ae) for certain herbicide formulations. Herbicides have specific maximum-per-year application rates established through the EPA label process that cannot be exceeded (Hager and Sprague, 2000). Some herbicide products, in this case, 2,4-D, are available in many Footnote continued on next page.

ae/ha), post-emergent on corn >8 inches in height using drop nozzles (560 g ae/ha), and pre-harvest at the dent stage of corn development (1680 g ae/ha) (DAS, 2010). In DAS-40278-9 corn, 2,4-D may be applied pre-emergence (1,120 g ae/ha) followed by one or two post-emergence (560-1,120 g ae/ha) applications at least 12 days apart over-the-top of the corn up to the V8 stage (or 48 inches in height) of development (DAS, 2010). Thus, the maximum seasonal rate of 2,4-D on corn has not been increased; however, DAS-40278-9 corn would allow the grower to apply 2,4-D from pre-emergence up through 48-inch corn (without using drop nozzles) without risk of crop injury (DAS, 2010). DAS has submitted materials to the EPA in support of a new label for over the top applications of 2,4-D to DAS-40278-9 corn. APHIS will use the application rates identified by the petitioner, in conjunction with existing label use restrictions presented on the current 2,4-D label as the basis for its evaluation of the potential impacts associated with the use and exposure to 2,4-D.

The AOPP herbicides such as Quizalofop are graminicides and are not currently used on corn because they would cause severe crop injury (DAS, 2010). However, the *aad-1* gene expressed in DAS-40278-9 corn confers tolerance in corn to this herbicide (DAS, 2010). Quizalofop can be safely applied (up to 92 g/ha) post-emergent on DAS-40278-9 corn through the V6 development stage (or 12 inches in height) without risk of crop injury. The AOPP tolerance of DAS-40278-9 corn also would allow the use of Quizalofop for selection during hybrid corn breeding. This new use of Quizalofop requires a change in the label. The current Quizalofop label provides for its use to control annual and perennial grasses in canola, crambe, corn crops grown for seed, eucalyptus, dry beans, flax, hybrid poplar plantings, lentils, mint, pineapple, ryegrass sown for seed, snap beans, soybeans, sugar beets, sunflowers and noncrop areas (see Assure II® label; DuPont, 2010). Assure II® is also labeled as an herbicide control for volunteer corn in glyphosate-tolerant soybeans, regardless of the corn trait (DuPont, 2010). DuPont is the current registrant of Quizalofop; DAS has committed to work with DuPont to submit appropriate materials to the EPA in support of a new label providing for the use of Quizalofop over DAS-40278-9 corn (DAS, 2010). APHIS will use the application rates provided by the petitioner, in conjunction with the existing label use restrictions presented on the current Quizalofop label as the basis for its evaluation of the potential impacts associated with the use and exposure to Quizalofop.

EPA has issued tolerance exemptions for 2,4-D (40 CFR §180.142; US-EPA, 2011a) and Quizalofop (40 CFR §180.442; US-EPA, 2011c). These previous EPA reviews will be used by

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different formulations. An acid equivalent is that portion of a formulation, such as a 2,4-D ester, which could be converted back to the parent herbicide acid (Hager and Sprague, 2000). In the case of 2,4-D, the ester, salt, and amine formulations are derivatives of the acid parent compound, 2,4-dichlorophenoxyacetic acid (Hager and Sprague, 2000). It is the parent acid which is the herbicidally active portion of the formulation, the salt, ester, or amine formulation has been developed to enhance plant absorption or otherwise facilitate herbicide delivery in the field (Hager and Sprague, 2000). In order to be able to track the application of various formulations against the maximum per year application rate, these formulations are presented as acid equivalents (Hager and Sprague, 2000).

APHIS to analyze the food and safety impacts associated with the use of 2,4-D and Quizalofop in DAS-40278-9 corn.

1.7 PUBLIC INVOLVEMENT

APHIS routinely seeks public comment on draft EAs prepared in response to petitions requesting determination of nonregulated status for GE organisms. APHIS does this through a notice published in the Federal Register. The issues discussed in this EA were developed by considering public concerns, as well as issues raised in public comments submitted for other environmental assessments of GE organisms, concerns raised in lawsuits, as well as those issues that have been raised by various stakeholders. These issues, including those regarding the agricultural production of corn using various production methods, and the environmental and food/feed safety of GE plants, were addressed to analyze the potential environmental impacts of DAS-40278-9 corn.

This EA, the petition submitted by DAS, and APHIS's *Plant Pest Risk Assessment for DAS-40278-9 corn* (USDA-APHIS, 2010) will be available for public comment for a period of 60 days (7 CFR §340.6(d)(2)). Comments received by the end of the 60-day period will be reviewed and used to inform APHIS's determination decision of the regulated status of DAS-40278-9 corn and to assist APHIS in determining whether an Environmental Impact Statement (EIS) is required prior to a determination of the regulatory status of DAS-40278-9 corn.

1.8 ISSUES CONSIDERED

As stated above, the issues considered in this EA were developed based on APHIS's determination of nonregulated status for certain GE organisms; and, for this particular EA, the specific determination for DAS-40278-9 corn. These issues include:

Corn Production:

- Acreage and Areas of Corn Production
- Cropping Practices
- Seed Production
- Organic Farming
- Specialty Corn Production

Environmental Considerations:

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

Public Health Considerations:

- Human Health
- Worker Safety

Animal Feed

Socioeconomic Issues:

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

Other Cumulative Effects

Threatened and Endangered Species

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

2 AFFECTED ENVIRONMENT

The Affected Environment Section provides an overview of the use and biology of corn, followed by a discussion of the current condition of those aspects of the human environment potentially affected by a determination of nonregulated status of DAS-40278-9 corn. For this draft EA, those aspects of the human environment are: agricultural production of corn; the physical environment; animal and plant communities; public health; animal feed; socioeconomic issues; other cumulative effects; threatened and endangered species; consideration of executive orders, standards, and treaties relating to environmental impacts. (The discussion of threatened and endangered species is only presented in Subsection 4.9.)

Conventional farming as defined in this document includes any farming system where synthetic pesticides or fertilizers may be used. This definition of conventional farming also includes the use of GE varieties of corn that have been determined by APHIS to be no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act.

2.1 CORN USE AND BIOLOGY

2.1.1 Corn Taxonomy

Zea mays subsp. *mays* L., corn, or maize, is a member of the Maydeae tribe of the grass family, Poaceae (OECD, 2003). *Z. mays* is a wind-pollinated, monoecious, annual species with imperfect flowers (OECD, 2003; Wozniak, 2002). This means that spatially separate tassels (male flowers) and silks (female flowers) are found on the same plant, a feature which limits inbreeding (Wozniak, 2002). A large variety of corn types are known to exist (e.g., dent, flint, flour, pop, and sweet) and have been selected for specific seed characteristics through standard breeding techniques (OECD, 2003; Wozniak, 2002). *Z. mays* has been domesticated for its current use by selection of key agronomic characters, such as a non-shattering rachis, grain yield, and resistance to pests (Wozniak, 2002). The origin of corn is thought to be in Mexico or Central America, largely based on archaeological evidence of early cob-like maize in indigenous Mesoamerican cultures approximately 7,200 years ago (Wozniak, 2002).

Maize cultivars and landraces are known to contain diploid cells (i.e., two sets of chromosomes) (2n = 20) and can crossbreed to a large degree. However, some evidence for genetic incompatibility exists within the species (e.g., popcorn x dent crosses; Mexican maize landraces x Chalco teosinte) (Wozniak, 2002). The closest wild relatives of *Z. mays* are various *Zea* taxa known as “teosinte” (Ellstrand et al., 2007). More than 40 landraces of maize have been identified in Mexico, and over 250 throughout the Americas (OECD, 2003). Several of the identified subspecies are identified as teosinte, including *Z. mays* subsp. *mexicana*, *Z. mays* subsp. *parviglumis*, *Z. diploperennis*, and *Z. luxurians* (Ellstrand et al., 2007; OECD, 2003).

The closest relative of *Zea* is the gamagrass genus, *Tripsacum* (OECD, 2003). Seventeen species of *Tripsacum* have been identified, with chromosome number varying from 2n = 36 to 2n = 108 (OECD, 2003). All of the *Tripsacum* species are perennial (OECD, 2003). Twelve of the *Tripsacum* species are native to Mexico and Guatemala. *T. dactyloides*, Eastern gamagrass, is known to occur in the eastern half of the U.S.; *T. lanceolatum*, Mexican gamagrass, occurs in the southwest U.S.; and *T. floridanum*, Florida gamagrass, is native to South Florida and Cuba (OECD, 2003; Wozniak, 2002). *T. dactyloides* is the only *Tripsacum* species of widespread occurrence and agricultural importance, and commonly is grown as a forage grass (Wozniak, 2002).

Tripsacum differs from corn in many respects, including chromosome number (*T. dactyloides* n = 18; *Z. mays* n = 10) (Wozniak, 2002). The three *Tripsacum* species in the U.S. exhibit several ploidy types. *T. floridanum* has a diploid chromosome number of 2n = 36 (Wozniak, 2002). *T. dactyloides* includes 2n = 36 forms which are native to the central and western U.S., and 2n = 72 forms which extend along the Eastern seaboard and along the Gulf Coast from Florida to Texas, but which also have been found in Illinois and Kansas (Wozniak, 2002). *T. lanceolatum* has a diploid number 2n = 72 (Wozniak, 2002).

These distinctions in genetic construct between related species are important, as the genetic differences directly affect the ability of cultivated corn to interbreed with wild relatives. The discussion in Subsection 2.4.5, Gene Movement, provides more detail on hybridization between cultivated *Z. mays* varieties and their wild relatives.

2.1.2 Corn Use

Corn is cultivated primarily as animal feed (DAS, 2010). Corn also is processed into a variety of food and industrial products, including starch, sweeteners, corn oil, and alcohols (beverage and industrial, and fuel ethanols) (DAS, 2010). In 2009, it was projected that up to 40% of the total corn production was dedicated to ethanol production for biofuels, resulting in ethanol production being the second-largest use of corn after feed uses (Swoboda, 2009; USDA-ERS, 2010e; Wilson, 2011). More than half of all fuel ethanol is blended into conventional gasoline as an octane enhancer (USDA-ERS, 2010e).

In addition to being cultivated for feed and ethanol production, corn also is cultivated for forage or silage (DAS, 2010). Approximately 6% of the total corn production is harvested for silage (USDA-NASS, 2011b).

The use of corn as feed is enhanced by the ethanol production process. Ethanol wet mills produce corn gluten feed, corn gluten meal, and corn oil as coproducts; whereas, dry mills produce distillers' dried grains (USDA-ERS, 2010e). It has been estimated that each 56-pound bushel of corn that is dry-milled for ethanol production results in 17.5 pounds of distillers' dried grains as a coproduct feed (USDA-ERS, 2010e). Specific products derived from corn include starches and starch products (unmodified and modified starch and dextrin and maltodextrin); corn sugars (glucose, dextrose, fructose, and high-fructose corn syrup); corn oil; corn gluten feed and meal; steepwater; organic acids (including amino acids); polyols; and xanthan gum (CRA, 2011). These products are used throughout the food industry and also have many industrial uses, including constituents in cosmetics, cleaners, pharmaceuticals, industrial chemicals, paper and paper products, adhesives, textiles, and building materials (CRA, 2011).

2.2 AGRICULTURAL PRODUCTION OF CORN

2.2.1 Acreage and Areas of Corn Production

Corn is the world's most widely cultivated cereal, reflecting its ability to adapt to a wide range of production environments (OECD, 2003). Corn is an annual plant typically grown in zones of abundant rainfall and fertile soils (OECD, 2003). In the U.S., moisture levels and number of frost-free days required to reach maturity are ideal for corn to be grown within temperate regions (see, e.g., IPM, 2004, 2007); although corn is reported to have a strong ability to adapt to extreme and variable conditions of humidity, sunlight, altitude, and temperature (OECD, 2003).

In 2009, the U.S. produced 40% of the total world supply of corn (USDA-OCE, 2011b). Corn is cultivated worldwide, including Argentina, South Africa, Brazil, Canada, China, and the former Soviet Union States, including the Ukraine (USDA-OCE, 2011b). Egypt, the EU, Japan, Mexico, Southeast Asia, and South Korea are net importers of corn (USDA-OCE, 2011b). Approximately 15 to 20% of the U.S. corn production is exported (DAS, 2010; USDA-OCE, 2011b).

Corn is the most widely cultivated feed grain, accounting for more than 95% of total value and production of feed grains (USDA-ERS, 2011b). Corn is grown in all 48 of the continental U.S. states with production concentrated in the Corn Belt, loosely defined as the states of Illinois, Iowa, Indiana, the eastern portions of South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri (USDA-ERS, 2011b; USDA-NASS, 2010, 2011a). Iowa and Illinois, the two top corn producing states, typically account for slightly more than one-third of the total U.S. crop (USDA-ERS, 2011b). In the U.S. for the 2011 production year, corn was cultivated on 92.3 million acres, a 5% increase in corn acreage from 2010 (USDA-NASS, 2010, 2011a). Within the 2010 acreage, corn for silage was cultivated on approximately 5.6 million acres, or approximately 6% of the total corn production area (USDA-NASS, 2011b). Corn production in 2010 was estimated at 12.4 billion bushels, valued at an estimated \$5.15 to \$5.65 per bushel (USDA-NASS, 2011b). In early May 2011, corn futures traded on the Chicago Board of Trade at \$7.57 for a July 2011 contract; while in June, corn futures traded at \$6.20 for a December 2011 contract.

Corn acreage in the U.S. increased during the second half of the 2000s. The establishment of a bioethanol industry using corn as a feed stock has been identified as one of the key elements in the increase in acreage devoted to corn, with more than 40% of the corn harvest now dedicated to corn-based biofuel production (Swoboda, 2009; USDA-NASS, 2010, 2011a; Wilson, 2011). Since 2006, many U.S. cotton farmers have converted to corn and soybean because of favorable prices (USDA-ERS, 2009).

Growers can choose from a large number of corn hybrids produced from traditional breeding or GE systems (NCGA, 2009). Like the major commodity crops cotton and soybean, GE varieties of corn have been adopted during the past decade. In 2000, approximately 6% of all corn planted was GE herbicide-tolerant, and 25% of the total crop was GE (Benbrook, 2009). By 2009, 22% of the U.S. corn crop was GE herbicide-tolerant and 17% was insect-resistant (Benbrook, 2009; USDA-ERS, 2010a). As of 2011, it was estimated that approximately 23% of the crop was GE herbicide-tolerant, 16% was GE insect-resistant, 49% was a stacked gene variety, and 88% of the total U.S. corn crop was planted in some GE variety (USDA-NASS, 2011a).

2.2.2 Cropping Practices: Tillage, Crop Rotation, and Agronomic Inputs

Corn planting dates range from late March in Kansas to late May in North Dakota (IPM, 2007). Corn ideally is planted when soil temperature reaches 55°F at 2-inch depth (IPM, 2007).

Growers can choose from several different crop management practices depending upon geographic cultivation area and end-use market (see, e.g., IPM, 2004; IPM, 2007). Common corn cultivation practices include method of tillage, selection of crop rotation system, and agronomic inputs.

2.2.2.1 Tillage

Prior to planting, the soil must be stripped of weeds that would otherwise compete with the crop for space, water, and nutrients. Field preparation is accomplished through a variety of tillage systems, with each system defined by the remaining plant residue on the field. A number of different tillage and planting systems are used in corn production, including primary and/or secondary tillage, or no pre-plant tillage operations (IPM, 2007). Conservation tillage includes reduced till, mulch-till, eco-fallow, strip-till, ridge-till, zero-till, and no-till (IPM, 2007). Conventional tillage is associated with intensive plowing and leaving less than 15% crop residue in the field; reduced tillage is associated with 15 to 30% crop residue; and conservation tillage, including no-till practices requiring herbicide application on the plant residue from the previous season, is associated with at least 30% crop residue and substantially less soil erosion than other tillage practices (US-EPA, 2009a). Increases in total acres dedicated to conservation tillage have been attributed to an increased use of GE crops including corn, reducing the need for mechanical weed control (Towery and Werblow, 2010; USDA-NRCS, 2006b, 2010).

Conservation tillage, although highly valued as a means to enhance soil quality and preserve soil moisture, itself has been identified as a potential challenge for corn disease and pest management. The surface residues have been identified as an inoculum source for certain disease-causing organisms (Robertson et al., 2009). This is especially a problem to growers who cultivate corn-to-corn with minimal tillage (Robertson et al., 2009). Diseases identified as related to corn residues include Anthracnose (caused by the fungus *Colletotrichium graminicola*), Eyespot (caused by the fungus *Kabatiella zea*), Goss's wilt (caused by the bacteria *Corynebactierum nebraskense*), Gray leaf spot (caused by the fungus *Cercospora zeae-maydis*), and Northern corn leaf blight (caused by the fungus *Helminthosporium turcicum*) (Robertson et al., 2009). For each of these diseases, the disease agent overwinters in the cool and moist soil, and inoculum from the corn residue then infects the new year crop (Robertson et al., 2009). Disease control measures includes cultivation of resistant hybrids, crop rotation, and more careful balancing of conservation tillage with residue management (Robertson et al., 2009).

2.2.2.2 Crop Rotation

Crop rotations (successive planting of different crops on the same land) are used to optimize soil nutrition and fertility, reduce pathogen loads, control volunteers (carry over in successive years), and limit the potential for weeds to develop resistance to herbicides (IPM, 2004, 2007; USDA-

ERS, 2010b). Since 1991, 75% of corn planted acreage has been in some form of rotation (USDA-ERS, 2010b). Corn can be grown successfully in conservation tillage system if rotated with other crops such as wheat and soybeans, which will reduce some of the problems encountered with conservation tillage (IPM, 2007).

The benefits of corn rotation with, for example, soybean are many and include (Al-Kaisi et al., 2003):

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

Crops used in rotation with corn vary regionally and include oats, peanut, soybean, wheat, rye, and forage (USDA-APHIS, 2010). Consecutive plantings of corn frequently require at-planting or pre-plant pesticide treatments to control corn pests and pathogens as well as supplemental fertilizer treatments (Erickson and Lowenberg-DeBoer, 2005; IPM, 2004; Sawyer, 2007; Stockton, 2007). Corn-to-corn rotations also may require a change in tillage practices. Corn-to-corn cultivation may produce substantially greater quantities of field residue, requiring additional tillage prior to planting (Erickson and Lowenberg-DeBoer, 2005). The increased adoption of corn-to-corn rotation, mainly in conventional and GE production systems, has been attributed to rising corn demand and prices (Hart, 2006; Stockton, 2007).

Corn has been reported as a volunteer in crops the year after harvest (Beckett and Stoller, 1988 1988; USDA-APHIS, 2010). This issue is discussed in Subsection 2.4.2 Plants: *Corn as a Volunteer* and the corresponding impacts analysis in Subsection 4.4.2 Plants: *Corn as a Volunteer*.

2.2.2.3 Agronomic Inputs

Corn production typically involves the extensive use of agronomic inputs to maximize grain yield (Ritchie et al., 2008). Agronomic inputs include fertilizers to supplement available nutrients in the soil; pesticides to reduce pest plant, insect, and/or microbial populations; and water to ensure normal plant growth and development (Howell et al., 1998; IPM, 2007).

Given the importance of nutrient availability to corn agronomic performance, fertilization with nitrogen, phosphorus, and potassium is practiced widely (Ritchie et al., 2008). In 2005 (the date of the last USDA Agricultural Chemical Usage Summary to include corn), fertilizers were applied to 96% of corn acreage in 19 reported states (USDA-NASS, 2006). Of the reported corn acres, nitrogen was applied to 95% of the corn acreage at an average of 138 pounds per acre (lb/acre); phosphate was applied to 81% of corn acreage at an average rate of 58 lb/acre; and potash was applied to 65% of corn acreage at a rate of 84 lb/acre (USDA-NASS, 2006).

Pesticide use, including both insecticides and herbicides, is common in corn production. Approximately 23% of the corn-planted acreage was treated with insecticides, with the most abundantly applied being tefluthrin for control of corn rootworm (7%), cyfluthrin for corn rootworm and earworms and European corn borer (7%), and tebupirimphos for corn rootworm and seed corn maggot (6%) (USDA-NASS, 2006).

Although it is generally agreed that insecticide use in U.S. crops has decreased since the introduction of GE insect-resistant crops, the trends in herbicide use resulting from the utilization of GE technologies are the subject of much debate (Benbrook, 2009; Brookes and Barfoot, 2010; Fernandez-Cornejo et al., 2009). Benbrook has reported that the adoption of herbicide-tolerant crops has resulted in an increase in the volume of herbicides applied to crops (Benbrook, 2009). Benbrook notes that herbicide use declined between 1996 and 2001 apparently in direct response to the adoption of herbicide-tolerant crops; however, since that time, herbicide use has increased (Benbrook, 2009). Reported increases in herbicide use reflect an increase in glyphosate applications as more glyphosate-tolerant crops are planted and an associated increase in use of other herbicides used to control glyphosate-resistant weeds (Benbrook, 2009).

In 2011, approximately 23% of corn planted in the U.S. possessed tolerance to an herbicide that was conferred through biotechnology (USDA-ERS, 2011a). The primary herbicide tolerance trait in use has been glyphosate tolerance, and the adoption of this trait in other major crops, such as cotton and soybean, is even higher (USDA-APHIS, 2010). Weed resistance to herbicides is a concern in agricultural production and the wide-spread adoption of herbicide-tolerant crops, especially GE-derived glyphosate-tolerant crops, has dramatically changed the approach that farmers take to avoid yield losses from weeds (Duke and Powles, 2009; Gianessi, 2008).

Herbicides were applied to 97% of corn acreage in 2005, with the following four herbicides identified as the most commonly applied: atrazine (66% of the acreage, ~57 million pounds applied), glyphosate (31% of the acreage, ~23 million pounds), s-metolachlor (23% of the acreage, <24 million pounds), and acetochlor (23% of the acreage, <30 million pounds) (USDA-NASS, 2006). The relationship of these herbicide treatments to the adoption of GE varieties is illustrated in Table 2-1 below, which presents the percentage of acres of herbicide-tolerant and insect-resistant corn varieties cultivated in 2010. The data on this table suggest that approximately 23% of the total corn acreage in the U.S. was subjected to an herbicide treatment for which that corn variety was tolerant.

Table 2-1: Percentage of Herbicide-tolerant, Insect-resistant, Stacked Trait, Total GE Corn, and Total Corn Acreage Planted in Select States in 2011

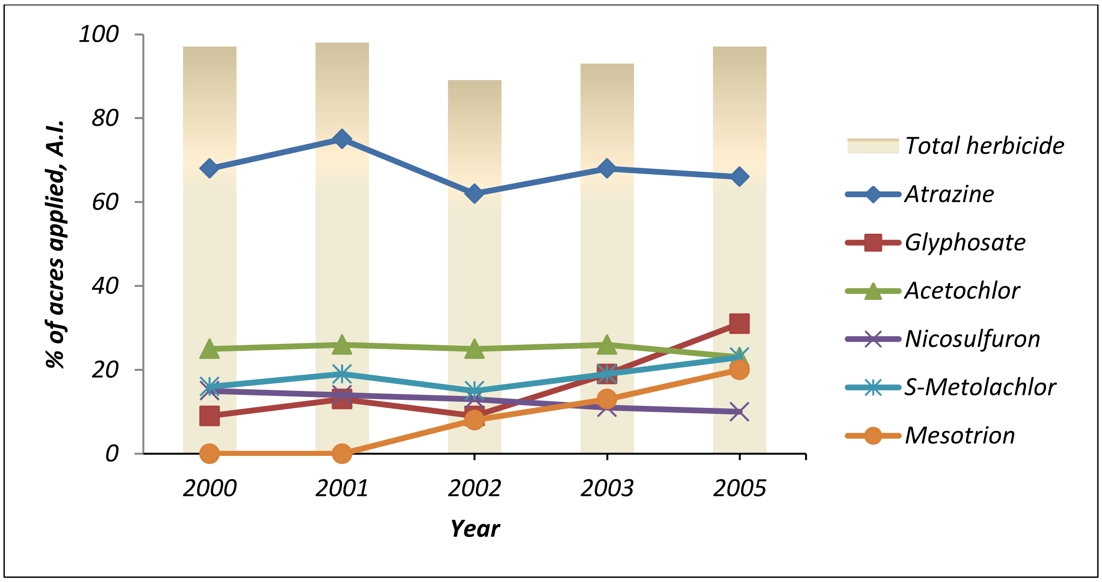
State	Herbicide-tolerant (%)	Insect-resistant (Bt) (%)	Stacked (%)	Total GE (%)	Total Corn Acreage (000 acres)
Indiana	22	7	56	85	5,900
Illinois	17	14	55	86	12,500
Iowa	16	13	61	90	14,200
Kansas	22	28	42	92	5,100
Michigan	24	11	52	87	2,550
Minnesota	29	16	48	93	8,100
Nebraska	26	15	52	93	10,000
North Dakota	32	26	39	97	2,300

State	Herbicide-tolerant (%)	Insect-resistant (Bt) (%)	Stacked (%)	Total GE (%)	Total Corn Acreage (000 acres)
Ohio	13	24	37	74	3,500
South Dakota	25	7	64	96	5,200
Texas	24	22	42	88	1,950
Wisconsin	27	18	41	86	4,150
Total U.S.	23	16	49	88	92,282

Source: (USDA-ERS, 2011a; USDA-NASS, 2011a)

Herbicide application trends are presented in Figure 2-1. Introduction of herbicide-tolerant corn varieties, in particular glyphosate-tolerant corn, has not significantly affected corn acreage managed with total herbicide application (Figure 2-1).

Figure 2-1: Herbicide Application Trends in U.S. Corn Production, 2000-2005



Source: (http://www.nass.usda.gov/: see, e.g., USDA-NASS, 2006)
Note: Trends presented for the six most frequently applied herbicides in corn.

While the applications of atrazine and acetochlor in corn have been relatively stable, application rates for glyphosate have increased. There are several reasons for the success of glyphosate in the market and the corresponding market sector penetration of glyphosate-tolerant crops since their introduction in the mid-late 1990s. Glyphosate: 1) works non-selectively on a wide range of plant species; 2) is a relatively low-cost herbicide; 3) enhances 'no-till' farming practices; and 4) has minimal animal toxicological and environmental impact (USDA-APHIS, 2010). However, increased selection pressure resulting from the wide-spread adoption of glyphosate-tolerant crops, along with the reductions in the use of other herbicides and weed management practices, has resulted in both weed population shifts and increasing glyphosate tolerance among some weed populations (Duke and Powles, 2009; Owen, 2008). To combat this trend and to avoid decreased crop yields resulting from weed competition, growers continually adapt weed management strategies, including the use of herbicides with alternative modes of action (DAS, 2010). Alternative modes of action in this case refer to herbicides which are different with respect to how they act on the plant physiology. Some common modes of herbicide action include auxin growth regulators, amino acid inhibitors, chlorophyll pigment inhibitors, or lipid biosynthesis inhibitors (Ross and Childs, 2011). The practice of using herbicides with alternative modes of action could potentially diminish the populations of glyphosate-tolerant weeds and reduce the likelihood of the development of new herbicide-resistant weed populations (DAS, 2010; Dill et al., 2008; Duke and Powles, 2008, 2009; Owen, 2008).

The emergence of resistance to herbicides is not exclusive to glyphosate-tolerant crops and corresponding weedy species. Tables 2-2 through 2-5 list those weedy species which have been identified as herbicide-resistant in at least some part of their range. The emergence of herbicide resistance presents continued challenges to growers to understand which herbicide-resistant species is present and the best agronomic practice available to manage the weed.

Table 2-2: U.S. Synthetic Auxin-resistant* Weeds through April 2011

Scientific Name	Common Name	Year Identified
Centaurea solstitialis	Yellow Starthistle	1988
Commelina diffusa	Spreading Dayflower	1957
Convolvulus arvensis	Field Bindweed	1964
Daucus carota	Wild Carrot	1952
Digitaria ischaemum	Smooth Crabgrass	2002
Echinochloa crus-galli	Barnyardgrass	1998
Kochia scoparia	Kochia	1995
Lactuca serriola	Prickly Lettuce	2007

Source: (Heap, 2011b)
*2,4-D is a synthetic auxin herbicide.

Table 2-3: U.S. Glyphosate-resistant Weeds through April 2011

System	Species	Year Identified
Weeds identified outside of Roundup Ready® Systems	Rigid Ryegrass (*Lolium rigidum*)	1998
	Hairy Fleabane (*Conyza bonariensis*)	2003
Weeds identified in Roundup Ready® Systems	Annual Bluegrass (*Poa annua*)	2010
	Kochia (*Kochia scoparia*)	2007
	Common Ragweed (*Ambrosia artemisiifolia*)	2004
	Giant Ragweed (*Ambrosia trifida*)	2004
	Horseweed, Marestail (*Conyza canadensis*)	2000
	Palmer Amaranth (*Amaranthus palmeri*)	2005
	Common Waterhemp (*Amaranthus rudis*)	2005
	Italian Ryegrass (*Lolium multiflorum*)	2001
	Johnsongrass (*Sorghum halepense*)	2005

Source: (Heap, 2011b)

Table 2-4: U.S. ACCase Inhibitor-resistant* Weeds through April 2011

Scientific Name	Common Name	Year Identified
Avena fatua	Wild Oat	1985
Digitaria ischaemum	Smooth Crabgrass	1996
Digitaria sanguinalis	Large Crabgrass	1992

Scientific Name	Common Name	Year Identified
Echinochloa crus-galli	Barnyardgrass	2000
Echinochloa phyllopogon	Late Watergrass	1998
Lolium multiflorum	Italian Ryegrass	1987
Lolium persicum	Persian Darnell	1993
Phalaris minor	Little Seed Canary Grass	1993
Rottboellia exalta	Itchgrass	1997
Setaria faberi	Giant Foxtail	1991
Setaria viridis var. robusta-alba Schreiber	Robust White Foxtail	1999
Setaria viridis var. robusta-purpurea	Purple Robust Foxtail	1999
Sorghum halepense	Johnsongrass	1991

Source: (Heap, 2011b)
*Quizalofop is an ACCase inhibitor.

Table 2-5: Photosystem II Inhibitor-resistant* Weeds through April 2011

Scientific Name	Common Name	Year Identified
Abutilon theophrasti	Velvetleaf	1984
Amaranthus hybridus	Smooth Pigweed	1972
Amaranthus palmeri	Palmer Amaranth	1993
Amaranthus powellii	Powell Amaranth	1977
Amaranthus retroflexus	Redroot Pigweed	1980
Amaranthus tuberculatus (syn. rudis)	Common Waterhemp	1994
Ambrosia artemisiifolia	Common Ragweed	1976
Atriplex patula	Spreading Orach	1980
Capsella bursa-pastoris	Shepherd's-purse	1984
Chenopodium album	Lambsquarters	1973
Chenopodium strictum var. glaucophyllum	Late Flowering Goosefoot	1976
Chloris inflata	Swollen Fingergrass	1987
Conyza canadensis	Horseweed	1981
Datura stramonium	Jimsonweed	1992
Echinochloa crus-galli	Barnyardgrass	1978
Eleusine indica	Goosegrass	2003
Kochia scoparia	Kochia	1976
Poa annua	Annual Bluegrass	1978
Polygonum pensylvanicum	Pennsylvania Smartweed	1990
Polygonum persicaria	Ladysthumb	1980
Portulaca oleracea	Common Purslane	1991
Senecio vulgaris	Common Groundsel	1970
Setaria faberi	Giant Foxtail	1984
Setaria glauca	Yellow Foxtail (glauca)	1981
Solanum ptycanthum	Eastern Black Nightshade	2004

Source: (Heap, 2011b)
*Atrazine is a photosystem II inhibitor.

Weed management strategies need to be carefully planned to integrate appropriate technologies into an economic level of control (Shaw et al., 2011). A diverse strategy is essential to reduce selection pressure on the weed population (Powles and Preston, 2009). Such an integrated weed management approach should combine:

- Rotation of crops – to allow a more varied weed control program
- Rotation of cultural practices – to reduce reliance on herbicides
- Rotation of sequences and mixtures of herbicidal modes of action and chemistry – to reduce the pressure on a specific herbicide group (Powles and Preston, 2009).

Monsanto, the developer of glyphosate, includes the following strategies to aid growers in managing the risk of weed resistance (Monsanto, 2011):

- Scout fields before and after herbicide application.
- Start with a clean field, using either a burn-down herbicide application or tillage.
- Control weeds early when they are relatively small.
- Rotate herbicides that have different modes of action.
- Use residual herbicides that have different modes of action.
- Use tank-mixes of herbicides that have different modes of action.
- Incorporate other herbicides and cultural practices as part of glyphosate tolerant cropping systems where appropriate.
- Use the right herbicide product at the right rate and the right time.
- Control weed escapes and prevent weeds from setting seeds.
- Clean equipment before moving from field to field to minimize spread of weed seed.
- Use new commercial seed as free from weed seed as possible.
- Report any incidence of repeated non-performance on a particular weed to the local crop protection chemical company representative, retailer, or county extension agent.

DAS-40278-9 corn was developed to provide growers with alternative herbicides to use in corn, with a specific emphasis on managing weeds which have developed resistance to glyphosate. DAS-40278-9 corn provides tolerance to two herbicides, 2,4-D and the "fop" herbicides (in this case, Quizalofop) (DAS, 2010). The following presents a summary of the current uses and registrations of these two products.

The herbicide 2,4-D is a phenoxy auxin herbicide, introduced more than 60 years ago and registered and used throughout the world for the treatment of broadleaf weeds (Nufarm, 2009; USDA-APHIS, 2010)[1]. The mode of action of 2,4-D is described as an "auxin mimic," meaning that it kills the target weed by mimicking auxin plant growth hormones like indole acetic acid (IAA) (Tu et al., 2001). Auxins and synthetic auxinic herbicides regulate virtually every aspect of plant growth and development; at low doses, auxinic herbicides possess similar hormonal properties to natural auxin (Kelley and Riechers, 2007). However, as rates increase, they can

[1] Reference to the Nufarm Weedar 64 specimen label is for illustration only, and is not intended to infer any recommendation for the use of this product by APHIS or the USDA.

cause various growth abnormalities in sensitive dicots (Tu et al., 2001). Observable plant responses to 2,4-D can include epinasty, root growth inhibition, meristematic proliferation/callusing, leaf cupping/narrowing, stem cracking, adventitious root formation, senescence, and chlorosis. This uncontrolled and disorganized plant growth eventually leads to plant death when applied at effective doses (Tu et al., 2001).

The herbicide 2,4-D is currently available in several formulations, including 2,4-D acid, 2,4-D sodium salt, 2,4-D diethyl amine, 2,4-D dimethylamine salt, 2,4-D isopropyl acid, 2,4-D triisopropyl acid, 2,4-D butoxyethyl ester (BEE), 2,4-D ethylhexyl ester, and 2,4-D isopropyl ester (US-EPA, 2005a). The 2,4-D mode of action as a synthetic auxin is not changed by these formulations, but the chemical and physical properties of each formulation influence the selection of equipment, mitigation measures adopted in the field to minimize off-target impacts, and formulation-specific safety measures. For example, although the 2,4-D ester formulations are not eye irritants, the acid and salt forms are considered severe eye irritants requiring eye protection for workers (US-EPA, 2005a, 2005c). The acid, amine, and ester formulations are each registered for application to water bodies for control of aquatic weeds. The EPA has determined that acute human exposures to the acid and amine formulations in water are not a concern and has further determined that a 24-hour post-application restriction on children swimming in treated water bodies is necessary for the BEE formulation (US-EPA, 2005a, 2005c). In most environmental conditions, the ester and the amine salts have been shown to dissociate rapidly to the acid form (US-EPA, 2005a, 2005c). However, in certain dry soils and sterile acidic aquatic environments, the ester formulation may persist (US-EPA, 2005a, 2005c). The ester formulation also has been identified to readily volatilize, particularly in conditions of high temperature and low humidity (US-EPA, 2005a, 2005c). The EPA label for this herbicide includes use restrictions and safety measures to mitigate against these risks. FIFRA requires that registered herbicides such as 2,4-D be applied in accordance with these label restrictions.

In 2002, 2,4-D was ranked as the third most used herbicide by active ingredient in the U.S. for all purposes (~40 million pounds), behind glyphosate (~102 million pounds) and atrazine (~77 million pounds) (Gianessi and Reigner, 2006). That same report found that the use of 2,4-D remained relatively steady from 1992 to 2002; whereas, glyphosate usage increased more than 5-fold over the same time period. As noted previously, this increase in glyphosate use is attributable to the introduction and wide-spread adoption of GE glyphosate-tolerant crop species (e.g., soybeans, corn, cotton, and canola) and rising adoption of no- or reduced-till farming practices that typically accompanies the use of glyphosate. Overall herbicide use on corn decreased during that same 10-year time frame (from ~213 million pounds in 1992 to ~159 million pounds in 2002), as farmers increasingly favored the use of GE crops which allowed for fewer types and a smaller overall amount of herbicide to be used (Gianessi and Reigner, 2006).

Approximately 46 million pounds of 2,4-D is used in the U.S. annually, with 30 million pounds (66%) used by agriculture and 16 million pounds (34%) used in non-agriculture settings such as pasture/rangeland and lawn/garden (US-EPA, 2005c). 2,4-D is an ingredient in approximately 660 agricultural and home use products as a sole active ingredient or in conjunction with other active ingredients. Agriculturally, it is used on a variety of crops including corn, rice, sorghum, sugar cane, wheat, rangeland, and pasture. In addition, 2,4-D is used to control unwanted vegetative growth on utility corridors, rights-of-way, roadsides, non-crop areas, managed forest, and lawn and turf areas. It is also used to control aquatic and nuisance weeds, e.g., purple loosestrife (Industry Task Force II, 2005). A major use today of 2,4-D is in combination with other herbicides because it economically enhances the weed control spectrum of many other herbicides such as glyphosate, dicamba, mecoprop, and ALS herbicides (US-EPA, 2005c). 2,4-D controls many broadleaf weeds including carpetweed, dandelion, cocklebur, horseweed, morning glory, pigweed sp., lambsquarters, ragweed spp., shepherd's-purse, and velvetleaf. It has little to no effective activity on grasses (Industry Task Force II, 2005).

By comparison with the four commonly applied herbicides (atrazine, glyphosate, s-metalochlor, and acetochlor) noted above, 2,4-D was applied on less than 8% of 2005 corn acreage (~2 million pounds applied) (USDA-NASS, 2006). Although 2,4-D is labeled for use in corn as a broad-leaf weed herbicide, it can produce significant malformations of maize plants when applied at late seedling stages (Wright et al., 2010). The highest recorded use of 2,4-D is its application to 14% of U.S. corn acres in 1994 (USDA-NASS, 2011c).

The "fop" herbicides (AOPP ACCase inhibitors) have been registered for crop use for over 20 years (USDA-APHIS, 2010). The "fop" herbicides traditionally have not been used to control weed species in cornfields because, as a grass (Poaceae family) species, corn is damaged by AOPP ACCase inhibitor activity. The registration and use of "fop" herbicides has been primarily on broadleaf crops, such as soybean, to control grass weed species, although certain cereal plant varieties have a level of tolerance to some "fops" (see DuPont, 2010). According to the USDA National Agricultural Statistics Service (NASS) Agricultural Chemical Use Database, "fop" type herbicides were used for weed control on at least 23 food crop species between 1990 and 2006, totaling over 16 million pounds of active ingredient (USDA-NASS, 2011d).

The AOPP herbicides inhibit chloroplastic ACCase, which catalyzes the first committed step in fatty acid biosynthesis, causing plant death (Burton et al., 1989). The herbicidal activity of Quizalofop-ethyl ester was first reported in 1983 and Quizalofop-ethyl was first approved for use in a registered herbicide product in the U.S. in 1988 (DAS, 2010; DuPont, 2010)[1]. However, all end use product registrations were cancelled prior to 1996 and it was replaced by the more active Quizalofop-P-ethyl (pure R-enatiomer of Quizalofop racemic mixture), which first was approved for use in a registered product in 1990 (DuPont, 2010). Quizalofop-P-ethyl is a systemic herbicide which is absorbed from the leaf surface and translocated throughout the plant (DAS, 2010).

Quizalofop-P-ethyl is used as a selective post-emergent herbicide for the control of annual and perennial grass weeds in potatoes, soybeans, sugar beet, peanuts, oilseed rape, sunflowers, vegetables, cotton, and flax. Most non-graminaceous plants (dicots and sedges) are tolerant to Quizalofop (DAS, 2010; DuPont, 2010).

Dicotyledonous plants contain a prokaryotic form of ACCase which is insensitive to "fop" herbicides. In contrast, monocotyledonous plants contain a sensitive eukaryotic form of ACCase

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[1] Reference to the DuPont Assure® II label is for illustration only, and is not intended to infer any recommendation for the use of this product by APHIS or the USDA.

in the plastid (DAS, 2010). This is the primary reason that the “fop” herbicides are generally good graminicides, with little activity on dicot plants. In addition, some grass species, including some cereal crops and weeds (e.g., annual bluegrass and wild oats), are tolerant of some of these herbicides (i.e., clethodim, Quizalofop, and others) due to their ability to metabolize the herbicides to inactive forms (Devine and Shukla, 2000; Powles and Preston, 2009).

The implications of the potential use of 2,4-D and Quizalofop as part of an herbicide mix in corn cultivation after a determination of nonregulated status of DAS-40278-9 corn are discussed in Section 4.

2.2.3 Seed Production

On an annual basis, certified seed of all varieties of corn combined must be able to plant over 85 million acres in the U.S. alone (USDA-ERS, 2010e). Planting rates are dependent on a wide range of factors, including soil moisture content, soil condition, corn row distance, and final stand density desired (Farnham, 2001). In Iowa, for example, recommended seeding rates range from 24,000 seeds per acre to 44,000 seeds per acre, or between 17 and 34 pounds of seed per acre (Farnham, 2001). Assuming conservative planting rates of between 16 and 24 pounds per acre, this requires between 680,000 and 1,020,000 short tons of planting seed each year.

The Association of Official Seed Certifying Agencies (AOSCA) develops seed certification standards to maintain genetic purity of corn varietal seed and specialty corn crops by precluding gene flow and preventing cross pollination between species and varieties (AOSCA, 2011; Wozniak, 2002).

In a seed certification program, classes of seed are identified to designate the seed generation from the original breeder source (Hartman and Kester, 1975). Foundation seed, Registered seed, and Certified seed production is controlled by public or private seed certification programs (see, e.g., AOSCA, 2010). The original breeder seed stock is controlled by the developer of the variety (Adam, 2005; Hartman and Kester, 1975). The breeder stock is used to produce Foundation seed stock (Adam, 2005). The institution associated with the breeder controls the production of Foundation seed stock. Foundation seed stock, in turn, is used to produce Registered seed for distribution to licensees, such as seed companies (Adam, 2005). Registered seed is used by seed companies to produce large quantities of Certified seed (Adam, 2005; Hartman and Kester, 1975). The Certified (or Select) seed is then sold to growers through commercial channels (Adam, 2005; Hartman and Kester, 1975).

Corn will cross-pollinate readily (Diver et al., 2008). Sweet corn will cross with field corn, producing starchy kernels, for example (Diver et al., 2008). It has been suggested that corn pollen grains mostly fall within the adjacent rows, and that less than 2% of the pollen travels beyond 200 meters from the source (Mallory-Smith and Sanchez-Olguin, 2010). A minimum isolation distance of 250 feet between varieties is recommended; whereas, 700 feet is preferred for complete isolation (Diver et al., 2008). Seed certification cultivation practices commonly include recommendations for minimum isolation distances between various seed lines and planting border or barrier rows to prevent pollen movement (Hartman and Kester, 1975; Wozniak, 2002).

The USDA Agricultural Marketing Service (AMS) provides several approaches for managing seed quality in corn, including isolation distances, border rows, and planting time (to isolate corn tassel from neighboring field pollen) (see 7 CFR §201.76, footnote 14; USDA-AMS, 2010). Isolation distances of 660 feet are established for Foundation and Certified corn, with multiple exceptions provided to take into consideration hand pollination or detasseling, or other mitigating factors such as similarity of the corn variety in color and texture, natural barriers, and different maturation dates (see 7 CFR §201.76, footnotes 12-14; USDA-AMS, 2010). AMS also allows for some flexibility in the number of border rows and distances between fields when the cultivated area is above a certain size (see 7 CFR §201.76, footnote 14; USDA-AMS, 2010).

Gene flow between cultivated corn varieties is likely to occur because of the difficulty in keeping seed segregated in the supply chain (Mallory-Smith and Sanchez-Olguin, 2010). This admixture is especially problematic if the same handling facilities where corn is dried, cleaned, and stored are used to handle different crops or varieties of the same crop (Mallory-Smith and Sanchez-Olguin, 2010). Such admixtures at these facilities has been reported for varieties of GE corn and conventional corn (Mallory-Smith and Sanchez-Olguin, 2010). Identity protection measures are available to provide for the appropriate segregation of seed from planting through harvesting (AOSCA, 2010; Thomison, 2009).

During the growing season, seed certification agencies monitor the fields for off-types, other crops, weeds, and disease (Wozniak, 2002). These certifying agencies also establish seed handling standards to reduce the likelihood of seed source mixing during production stages, including planting, harvesting, transporting, storage, cleaning, and ginning (Wozniak, 2002). Further discussion of cross-pollination, gene transfer, and weediness is presented in Subsection 2.4.5, Gene Movement.

2.2.4 Organic Farming

In the U.S., only products produced using specific methods and certified under the USDA National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (Ronald and Fouche, 2006; USDA-AMS, 2010). The NOP is administered by USDA's AMS. The USDA maintains current information on the domestic organic commodity market at: http://www.nal.usda.gov/afsic/pubs/organicstats.shtml.

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 (Ronald and Fouche, 2006). In accordance with NOP, an accredited organic certifying agent conducts an annual review of the certified operation's organic system plan and makes on-site inspections of the certified operation and its records. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards.

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

> To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or group(s))," the product must be produced and handled without the use of:

> (a) Synthetic substances and ingredients,…
> (e) Excluded methods,…

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

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

The NOP has recognized the feasibility of protecting organically-produced crops from accidental contamination by GE crops by requiring that organic production plans include practical methods to protect organically-produced crops—

> Organic crops must be protected from contamination by prohibited substances used on adjoining lands (for example, drifting pesticides, fertilizer-laden runoff water, and pollen drift from genetically engineered…) (NCAT, 2003).

Organic farming operations, as described by the NOP, require organic production 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. Organic production operations also must develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods. In NOP organic systems, the use of GE crops, such as DAS-40278-9 corn, is excluded (USDA-AMS, 2010).

The organic farming plan used as the basis for organic certification should include a description of practices used to prevent or reduce the likelihood of unwanted substances, like GE pollen or seed, at each step in the farming operation, such as planting, harvesting, storing, and transporting the crop (Krueger, 2007; Kuepper, 2002; Riddle, 2004; Roth, 2011). Organic corn production begins with certified organically grown seed (Diver et al., 2008). Organic farming plans should include how the risk of GE pollen or co-mingling of seed will be monitored (Roth, 2011). Contamination of organic corn crops is a concern because corn naturally cross pollinates (Coulter et al., 2010). Contamination can occur from impure seed; seed admixture; volunteer plants; and residual non-organic seed in the equipment, vehicles, and facilities (Coulter et al., 2010; Mallory-Smith and Sanchez-Olguin, 2010). Farmers using organic methods are requested to let neighboring farmers know that they are using organic production practices and request that the neighbors also help the organic farmer reduce potential contamination events (Krueger, 2007; NCAT, 2003). Delayed planting has been used successfully by some organic corn producers to control weeds and to avoid potential contamination by GE pollen from adjacent fields (Roth, 2011). The late planting allows the grower to conduct a secondary tillage pass before planting to control early emerged weeds, and the late planting results in a later silking in the corn flower; thus avoiding pollen contamination from GE fields which have been planted earlier (Roth, 2011).

Although conventional corn yields tend to be higher than organic yields, net returns from organic acres continues to be greater than net return from conventional acres, with a 16% premium received for organic growers reported in 2008 (Coulter et al., 2010; Kuepper, 2002; Roth, 2011). Certified organic corn acreage is a relatively small percentage of overall corn production in the U.S. The most recently available data show 194,637 acres of certified organic corn production in 2008 (USDA-ERS, 2011e). This is 0.21% of the 90 million acres of corn planted in 2010 (USDA-ERS, 2010e).

2.2.5 Specialty Corn Production

Thomison and Geyer (2009) estimated that approximately 5% of the total corn acreage, or approximately 4 million acres, was devoted to specialty corn varieties. Specialty corn varieties have been developed and marketed as Value Enhanced Corn (VEC) (USDA-FAS, 2004). Varieties cultivated as specialty corn included high oil, white, waxy, blue corn, hard endosperm/food grade, high-amylose, high lysine, high oleic oil, low phytate, nutritionally enhanced, high extractable starch, high total fermentable (for ethanol), popcorn, pharmaceutical and industrial corns, and organic (Thomison and Geyer, 2011). The leading specialty corn states include Illinois, Iowa, Nebraska, and Indiana (Thomison, 2011).

Similar to the production of conventional seed, industry quality standards for specialty crop products have led these seed producers and growers to employ a variety of techniques to ensure that their products are not pollinated by or commingled with conventional or GE crops (Bradford, 2006). Common practices include maintaining isolation distances to prevent pollen movement from other corn sources, planting border or barrier rows to intercept pollen, and employing natural barriers to pollen (NCAT, 2003; Wozniak, 2002). The Federal Seed Act Regulations provide additional details on Certified seed production (see 7 CFR §201, *et seq*). Field monitoring for off-types, other crops, weeds, disease etc. also is carried out by company staff and state crop improvement associations (Bradford, 2006). Seed handling standards are established by AOSCA to reduce the likelihood of seed source mixing during planting, harvesting, transporting, storage, cleaning, and ginning (AOSCA, 2004). In general, the conventional management practices used for conventional seed production are sufficient to meet standards for the production of specialty crop seed (Bradford, 2006).

2.3 PHYSICAL ENVIRONMENT

The use of fertilizers, pesticides, and water may affect segments of the environment including, but not limited to: waterways by increases in nutrients and suspended sediments resulting from erosion and runoff from farm fields; species diversity resulting from the effects of increased pesticide input as well as increases in sedimentation (e.g., mussels, submerged aquatic vegetation (SAV)); the groundwater table resulting from irrigation practices; and cropland productivity resulting from increased salinity as a result of irrigation (USDA-ERS, 2005).

2.3.1 Water Resources

Corn is a water sensitive crop with a low tolerance for drought. The stress response and yield loss depends on the stage of the corn growth (Farahani and Smith, 2011). Corn requires approximately 4,000 gallons through the growing season to produce 1 bushel of grain (NCGA, 2007a). The water demand is variable over the growing season, with the greatest water demand during the silk production stage in mid-season. During this stage, the water requirement is estimated at approximately two inches of water per week (or 0.3 inches per day) (Farahani and Smith, 2011; Heiniger, 2000).

This water demand is met by a combination of natural rainfall, stored soil moisture from precipitation before the growing season, and supplemental irrigation during the growing season (Farahani and Smith, 2011; Heiniger, 2000). Groundwater is the major source of water for irrigation and is used on almost 90% of irrigated corn acreage in the U.S. (Christensen, 2002). Corn for grain has substantially more irrigated area than any other single crop in the U.S. (Christensen, 2002). In 2007, 13.0 million U.S. corn acres were irrigated, representing 15% of all corn acres harvested for grain (USDA-NASS, 2009).

Agricultural non-point source (NPS) pollution is both the primary source of pollutant discharge to rivers and lakes and a major contributor to groundwater contamination. Management practices that contribute to NPS pollution include the type of crop cultivated, plowing and tillage, and the application of pesticides, herbicides, and fertilizers. The primary cause of NPS pollution, however, is increased sedimentation in surface waters following soil erosion. Agricultural pollutants released by soil erosion include sediments, fertilizers, and pesticides that are introduced to area lakes and streams when they are carried off of fields by rain or irrigation waters (US-EPA, 2005b). Increase in sediment loads to surface waters can directly affect fish, aquatic invertebrates, and other wildlife maintenance and survival. It also reduces the amount of light penetration in water which directly affects aquatic plants. Indirectly, soil erosion-mediated sedimentation can increase fertilizer runoff, facilitating higher water turbidity, algal blooms, and oxygen depletion (US-EPA, 2005b).

Conservation tillage and no-till practices have been shown to minimize soil erosion and runoff to surface water. This is discussed more fully in the following section.

2.3.2 Soil

Corn is cultivated in a wide variety of soils across the U.S. (see, e.g., Corn Crop Profiles provided at www.ipmcenters.org/cropfiles/GetCropProfiles.cfm). The timing for corn planting is variable, but generally starts when soil temperatures reach 50°F (IPM, 2004, 2007).

Conventional corn tillage traditionally requires that the producer remove all plant residues and weeds from the soil surface prior to planting, and then continue to cultivate the soil while the crop is growing to control late emerging weeds (NCGA, 2007b). This practice results in soil loss to wind and water erosion (NCGA, 2007b).

Conservation practices, including conservation tillage, have been developed to reduce field tillage and thus reduce the corresponding soil loss (USDA-NRCS, 2006c). By definition, conservation tillage leaves at least 30% of the soil covered by crop residue (Peet, 2001). The new crop is planted into the plant residue or in narrow strips of tilled soil. This is in comparison to conventional tillage where the seedbed is prepared through plowing (to turn the soil surface over), disking (to reduce the size of soil clods created by plowing), and harrowing (to reduce the size of clods left by disking) (Peet, 2001). Benefits of reduced tillage practices include retention of soil organic matter and beneficial insects, increased soil water-holding capacity, less soil and nutrient loss from the field, reduced soil compaction, and less time and labor required to prepare the field for planting (Peet, 2001).

Corn cultivation utilizing conservation tillage practices can result in as much as 50% soil cover as residue following harvest (Werblow, 2007). This land cover aids in maintaining soils (Werblow, 2007). Other conservation measures successfully used on corn acres include contour farming, grass buffered drainageways, terraces, and retention/detention ponds (NCGA, 2007b). Increases in total acres dedicated to conservation tillage have been attributed to an increased use of herbicide-tolerant GE seed which eliminates the need for mechanical weed control (Towery and Werblow, 2010; USDA-NRCS, 2006b).

Corn cultivation residues in a conservation tillage production system have been identified as causing cool, wet soils along with heavy residues which impede cultivation equipment (Werblow, 2007). These concerns can each be addressed through a number of corn cultivation techniques, including corn varieties developed to thrive in cool, wet soils; seed treatments for insect and disease control; selection of appropriate equipment to manage high-residue conditions; and judicious use of appropriate herbicides to control weeds remaining in the conservation tillage fields (NCGA, 2007c; Werblow, 2007). As noted in the discussion of Cropping Practices in Subsection 2.2.2, conservation tillage also has been identified as presenting potential disease management challenges for those growers cultivating corn-to-corn (Robertson et al., 2009).

As reduced tillage practices are adopted, there is a corresponding increase organic matter in soil. This helps bind soil nutrients resulting in significant reductions in the loss of cropland soil from runoff, erosion, and leaching over time (Leep et al., 2003; NCGA, 2007b, 2007c; USDA-NRCS, 2006b, 2006c). Total soil loss on highly erodible croplands and non-highly erodible croplands decreased from 462 million tons per year to 281 million tons per year or by 39.2% from 1982 to 2003 (USDA-NRCS, 2006b). This decrease in soil erosion carries a corresponding decrease in non-point source surface water pollution of fertilizer and pesticides (NCGA, 2007b). The reduction in soil erosion also is attributed to a decrease in the number of acres of highly erodible cropland being cultivated (USDA-NRCS, 2006b).

Depending on the physical setting of the agricultural operation, conservation tillage may be required. Farmers, including corn growers, producing crops on highly erodible land are required by law to maintain a soil conservation plan approved by the USDA National Resources Conservation Service (NRCS) (USDA-ERS, 2010d). These soil conservation plans are prepared by the grower pursuant to the 1985 Food Security Act Conservation Compliance and Sodbuster programs to minimize soil erosion (USDA-ERS, 2010d). Corn farmers also are actively involved in state, local, and national programs that idle environmentally sensitive land from crop production, including the Conservation Reserve Program, the Conservation Reserve Enhancement Program, and the Farmable Wetlands Program (NCGA, 2007c).

The emergence of glyphosate-resistant weeds has resulted in an increase in the number of herbicide treatments in those fields where resistant weeds have emerged (DAS, 2010). Each such herbicide application involves farm equipment for field applications and carries a risk of spills and misapplications. Availability of alternative herbicides for weed control in corn, such as 2,4-D and Quizalofop in the case of DAS-40278-9 corn, may allow for the elimination of some of these extra herbicide treatments currently required in fields where glyphosate-resistant weeds have become established. Herbicide-tolerant corn was cultivated on 23% of the total acres planted in the U.S. in 2011 (USDA-NASS, 2011a). The reduction in herbicide applications may benefit soil quality by reducing the risks associated with environmental spills or misapplications of chemical herbicides to the soil, and reducing the frequency of application will result in less soil compaction when herbicides are applied with ground equipment.

2.3.3 Air Quality

Air emissions from agricultural operations include smoke from agricultural burning, vehicle exhaust associated with equipment used in tillage and harvest, suspended soil particulates associated with tillage, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizer (Aneja et al., 2009; Hoeft et al., 2000; US-EPA, 2011d; USDA-NRCS, 2006a). These agricultural activities individually have the potential to cause negative impacts to air quality.

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

Many of the conservation plans and practices being developed by corn growers to comply with the Conservation Compliance and Sodbuster programs have an air quality focus which target reductions in air emissions from agricultural operations (USDA-NRCS, 2006a). Practices to improve air quality include conservation tillage, residue management, wind breaks, road treatments, burn management, prunings shredding, feed management, manure management, integrated pest management, chemical storage, nutrient management, fertilizer injection, chemigation and fertigation (inclusion in irrigation systems), conservation irrigation, scrubbers, and equipment calibration (USDA-NRCS, 2006a). Conservation tillage practices resulting in improved air quality include: fewer tractor passes across a field, thus decreasing dust generation and tractor emissions; and an increase in surface plant residues and untilled organic matter which physically hold the soil in place and reduce wind erosion (Baker et al., 2005; USDA-NRCS, 2006a). The USDA has estimated that by 2006, the adoption of conservation management plans in the San Joaquin Valley of California had reduced air emissions by 34 tons daily, or more than 20% of the total emissions attributed to agricultural practices (Baker et al., 2005; USDA-NRCS, 2006a).

2.3.4 Climate Change

Agriculture, including land-use changes for farming, is responsible for an estimated 6% of all human-induced greenhouse gases (GHG) in the U.S. (US-EPA, 2011d). Emissions of GHG released from agricultural equipment (e.g., irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, methane (CH_4), reactive organic gases, particulate matter, and sulfur oxides (US-EPA, 2011d). Agricultural soil management practices, including nitrogen-based fertilizer application and cropping practices, represent the largest source of U.S. nitrous oxide (N_2O) emissions; croplands account for 69% of the total N_2O emissions attributable to agricultural land uses (US-EPA, 2011d). Agriculture sources of methane emissions are associated primarily with enteric emissions of gas from cattle and manure management. Carbon dioxide also is a significant GHG gas associated with several agricultural practices, including land uses and energy consumption (US-EPA, 2011d).

Tillage contributes to the release of GHG because of the loss of carbon dioxide (CO_2) to the atmosphere, and the exposure and oxidation of soil organic matter (Baker et al., 2005). The carbon footprint for corn production has been estimated to be approximately 300 pounds of carbon equivalent emission per acre (Nelson et al., 2009). The carbon footprint of corn is directly affected by the associated cultivation practices. Corn cultivation has been estimated to produce higher total CO_2 emissions than wheat or soybean, and lower total emissions than cotton or rice (Nelson et al., 2009). On-site emissions can be reduced by half for some crops when changing from conventional tillage to no-till systems (Nelson et al., 2009).

The contribution of agriculture to climate change largely is dependent on the production practices employed to grow various commodities, the region in which the commodities are grown, and the individual choices made by growers. For example, emissions of nitrous oxide, produced naturally in soils through microbial nitrification and denitrification, can be influenced dramatically by fertilization, introduction of grazing animals, cultivation of nitrogen-fixing crops and forage (e.g., alfalfa), retention of crop residues (i.e., no-till conservation), irrigation, and fallowing of land (US-EPA, 2011d). These same agricultural practices can influence the decomposition of carbon-containing organic matter sequestered in soil, resulting in conversion to carbon dioxide and subsequent loss to the atmosphere (US-EPA, 2011d). Conversion of crop land to pasture results in an increase in carbon and nitrogen sequestration in soils (US-EPA, 2011d).

The EPA has identified regional differences in GHG emissions associated with agricultural practices on different soil types, noting that carbon emission rates differ between mineral soils and organic soils (US-EPA, 2011d). Mineral soils contain from 1 to 6% organic carbon by weight in their natural state; whereas organic soils may contain as much as 20% carbon by weight (US-EPA, 2011d). In mineral soils, up to 50% of the soil organic carbon can be released to the atmosphere on the initial conversion; however, over time, the soil establishes a new equilibrium that reflects a balance between carbon inputs from decaying plant matter and organic amendments and carbon losses from microbial decomposition (US-EPA, 2011d). Organic soils, with their depth and richness in carbon content, continue to release carbon to the atmosphere for a longer period of time (US-EPA, 2011d). The EPA has estimated that mineral soil-based cropland areas sequestered over 45.7 Tg CO_2 Eq[1] in 2008, as compared with carbon emissions from organic soil-based croplands of 27.7 Tg CO_2 Eq (US-EPA, 2011d). The adoption of

[1] The global warming potential of greenhouse gases are measured against the reference gas CO_2, and are reported as teragrams (or million metric tons) of CO_2 Equivalent, expressed as Tg CO_2 Eq.

conservation tillage, particularly in the Midwest regions with mineral soil shows the highest rates of carbon sequestration (US-EPA, 2011d).

Changes in agriculture-related GHG production will not be significant unless large amounts of crop plantings produce changes in measureable concentrations (USDA-APHIS, 2010). For example, the EPA has identified a net reduction in the sequestration of carbon in soil over an 18-year time scale, which it attributes to the declining influence of the Conservation Reserve Program which had encouraged growers to take marginal lands out of production (US-EPA, 2011d). To a certain extent, the EPA also noted that adoption of conservation tillage resulted in increases in carbon sequestration on those croplands (US-EPA, 2011d). The highest rates of carbon sequestration in mineral soils occurred in the Midwest, which is the region with the largest area of cropland managed with conservation tillage (US-EPA, 2011d). This is in contrast to the highest emission rates from organic soils noted in the southeastern coastal region, the areas around the Great Lakes, and the central and northern agricultural areas along the West Coast (US-EPA, 2011d).

Although the adoption of GE herbicide-tolerant crops, such as DAS-40278-9 corn may result in continued adoption of conservation practices by growers, after APHIS has determined that a plant is no longer regulated under the plant pest provisions of the PPA or the regulations of Part 340, APHIS does not maintain control over where the crop is grown, the methods used to produce commodities, or the individual choices that growers make.

One outcome of the potential effects of agriculture on climate change is the potential effect of the climate change on agriculture. In response to climate change, the current range of weeds and pests of agriculture is expected to increase. Current agricultural practices will be required to change in response to these changes in the ranges of weeds and pests of agriculture (Field et al., 2007).

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

2.4 ANIMAL AND PLANT COMMUNITIES

Corn production systems in agriculture are host to a variety of animal species. A number of insects feed on corn plants or prey upon other insects inhabiting cornfields. Although cornfields are generally considered poor habitat for birds and mammals in comparison with uncultivated lands, the use of cornfields by birds and mammals is not uncommon. Although, some birds and mammals use cornfields at various times throughout the corn production cycle for feeding and reproduction, most of the birds and mammals that utilize cornfields are ground foraging omnivores that feed on the corn remaining in the fields following harvest. Conservation practices incorporated in corn cultivation have brought a positive impact to animal and plant communities through reduced tillage, more carefully controlled and targeted chemical placement (fertilizers and pesticides), and better control of irrigation systems. Many GE crop systems provide opportunities to optimize the introduction and implementation of these practices, and have the potential to create more of these benefits. For example, herbicide tolerance in corn and other crops facilitates cultivation with minimal tillage required to control volunteers and weeds (Towery and Werblow, 2010). This subsection provides an overview of the biotic community associated with cornfields and their surrounding landscapes.

2.4.1 Animal Communities

Invertebrate communities in cornfields represent a diverse assemblage of feeding strategies including herbivores, predators, crop-feeders, saprophages, parasites, pollinators, gall formers, and polyphages (Stevenson et al., 2002). Numerous insects and related arthropods perform valuable functions; they pollinate plants, contribute to the decay and processing of organic matter, reduce weed seed populations through predation, cycle soil nutrients, and attack other insects and mites that are considered to be pests. Although many arthropods in agricultural settings are considered pests, such as the European corn borer (*Ostrinia nubilalis*) and the corn rootworm (*Diabrotica* spp.) (Willson and Eisley, 2001), there are many beneficial arthropods which are natural enemies of both weeds and insect pests (Landis et al., 2005). Some of these beneficial species include the convergent lady beetle (*Hippodamia convergens*), carabid beetles, the caterpillar parasitoids (e.g., *Meteorus communis* and *Glyptapanteles militaris*), and the predatory mite (*Phytoseiulus persimilis*) (Shelton, 2011). Earthworms, termites, ants, beetles, and millipedes contribute to the decay of organic matter and the cycling of soil nutrients (Ruiz et al., 2008).

Modern agricultural practices have been noted to simplify the agricultural landscape, with the result that beneficial arthropods may be adversely affected (Landis et al., 2005). The adoption of conservation tillage has been noted to increase resource diversity within agricultural settings, including refuge habitat, which can then support a larger community of beneficial organisms (Landis et al., 2005).

Intensively cultivated lands, such as those used in corn production, provide less suitable habitat for wildlife use than that found in fallow fields or adjacent natural areas. As such, the types and numbers of animal species found in cornfields are less diverse by comparison. Cornfields, however, have been shown to provide both food and cover for wildlife, including a variety of birds as well as large and small mammals (Palmer et al., 2011; Vercauteren and Hygnostrom, 1993).

The types and numbers of birds that inhabit cornfields vary regionally and seasonally but for the most part the numbers are low (Patterson and Best, 1996). Most of the birds that utilize cornfields are ground foraging omnivores that feed on corn seed, sprouting corn, and the corn remaining in the fields following harvest. Bird species commonly observed foraging on corn include red-winged blackbird (*Agelaius phoeniceus*), horned lark (*Eremophila alpestris*), brown-headed cowbird (*Molothrus ater*), vesper sparrow (*Pooecetes gramineus*), ring-necked pheasant (*Phasianus colchicus*), wild turkey (*Meleagris gallopavo),* American crow (*Corvus brachyrhynchos*), and various grouse and quail species (Dolbeer, 1990; Mullen, 2011; Patterson and Best, 1996). Following harvest, it is also common to find large flocks of Canada geese (*Branta canadensis*), Snow geese (*Chen caerulescens*), Sandhill cranes (*Grus canadensis*), and other migratory waterfowl foraging in cornfields (Sherfy et al., 2011; Sparling and Krapu, 1994; Taft and Elphick, 2007).

A variety of mammals forage on corn at various stages of production. For the most part, herbivorous and omnivorous mammals feed on the ear at various stages of growth. Large- to medium-sized mammals that are common foragers of cornfields include: white-tailed deer (*Odocoileus virginianus*), raccoon (*Procyon lotor*), feral pigs (*Sus scrofa*), and woodchuck (*Marmota monax*). The most notable of these is the white-tailed deer which often inhabit woodlots adjacent cornfields and frequent these fields for both food and cover throughout the latter half of the corn growing season (August, September) (Vercauteren and Hygnostrom, 1993). The effects of deer herbivory on cornfields have been well-documented. Cornfields are vulnerable to deer damage from emergence through harvest (Vercauteren and Hygnostrom, 1993), but any damage at the tasseling stage most directly impacts yield (Stewart et al., 2007). White-tailed deer are considered responsible for more corn damage than any other wildlife species (Stewart et al., 2007).

In addition to deer, significant damage to corn by raccoons also has been documented (Beasley and Rhodes, 2008; DeVault et al., 2007). Corn has been shown to constitute up to 65% of the diet of raccoons during the late summer and fall (MacGowan et al., 2006).

As with these larger mammals, small mammal use of cornfields for shelter and forage also varies regionally and includes (Nielsen, 2005):

- Deer mouse (*Peromyscus maniculatus*)
- Meadow vole (*Microtus pennsylvanicus*)
- House mouse (*Mus muscus*)
- Thirteen-lined ground squirrel (*Spermophilus tridecemlineatus*)

Throughout the U.S., the deer mouse is the most common small mammal in almost any agricultural field (Stallman and Best, 1996; Sterner et al., 2003). Deer mice feed on a wide variety of plant and animal matter depending on availability, but primarily feed on seeds and insects. Deer mice have been considered beneficial in agroecosystems because they consume both weed and insect pests (Smith, 2005).

The meadow vole feeds primarily on fresh grass, sedges, and herbs, and also on seeds and grains of field crops. Although the meadow vole may be considered beneficial for its role in the consumption of weeds, this vole can be a significant agricultural pest where abundant when it consumes seeds in the field. Meadow vole populations are kept in check by high intensity agriculture methods, including conventional tillage; this vole is often associated with the field edges where cover is found off the field as well as limited tillage agriculture and strip crops (Smith, 2005).

The lined ground squirrel feeds primarily on seeds of weeds and available crops, such as corn and wheat. This species has the potential to damage agricultural crops, although it also can be considered beneficial when eating pest insects, such as grasshoppers and cutworms (Smith, 2005).

2.4.2 Plant Communities

Surrounding Landscapes and Other Vegetation in Cornfields

Non-crop vegetation in cornfields is limited by the extensive cultivation and weed control programs practiced by corn farmers. Non-crop vegetation in cornfields is generally associated with vegetative communities adjacent to these fields. Cornfields may be bordered by other field crops or by woodlands, hedgerows, rangelands, and/or pasture/grassland areas. These plant communities may occur naturally or they may be managed for the control of soil and wind erosion.

Corn is generally cultivated as a monoculture. Weed control programs are important aspects of corn cultivation to maintain this single crop. Weed control typically involves an integrated approach that includes herbicide use, crop rotation, weed surveillance, and weed monitoring (Farnham, 2001; Hartzler, 2008; IPM, 2004, 2007; University of California, 2009). Intensive use of any single weed management tactic can cause an ecological shift in the weed community as a result of selection pressure on weed populations, with a corresponding greater prevalence of weed species that are not controlled (Shaw et al., 2011). The over-reliance on herbicides for weed management and the lack of herbicide diversity impose intense selection pressure on weed populations, resulting in the evolution of herbicide resistance, including resistance to glyphosate (Wilson et al., 2011b).

When a crop like corn is cultivated year after year in the same fields, using the same cultivation practices, the likelihood is high that weed and pest species will increase in these fields and that agronomic inputs may need additional attention (Erickson and Lowenberg-DeBoer, 2005; Sawyer, 2007; Shaw et al., 2011; Stockton, 2007; University of California, 2009). Crop rotation is an important component of a successful weed management program in corn (Erickson and Lowenberg-DeBoer, 2005; Owen et al., 2011; Ransom et al., 2004; Stockton, 2007; University of California, 2009). As discussed in Subsection 2.2.2.2, Crop Rotation, since 1991, 75% of corn planted acreage has been in some form of rotation (USDA-ERS, 2010b). Corn is commonly grown in rotation with other crops including oats, forage crops, peanut, wheat, rye, cotton, and soybean. The most common rotation system for both corn and soybean is a corn-soybean rotation (USDA-ERS, 2006). Approximately 75% of corn acreage and 80% of soybean acreage in the 10 major corn producing states reported using this crop rotation system in ERS surveys conducted in 2001 (corn) and 2002 (soybeans) (USDA-ERS, 2006).

The types of weeds in and around a cornfield depend on the immediate area in which the corn is planted (IPM, 2004, 2007; Purdue, 2011; University of California, 2009). Data have been collected on weed population densities by species, crop yield and crop production system economics with the intent of providing growers with insights into the sustainability and profitability of diversified weed management programs (Shaw et al., 2011). To assist growers in managing weeds, individual states, typically through their state agricultural extension service, list the prevalent weeds in corn crops in their area and the most effective means for their control (see, e.g., IPM, 2004, 2007; University of California, 2009).

The use of herbicide-tolerant corn provides several weed management advantages to the growers. Broad spectrum post-emergent herbicides such as glyphosate, provide control of weeds early in the cultivation cycle thereby minimizing competition in the fields and providing optimal conditions for corn growth (IPM, 2004, 2007; University of California, 2009). Application of over-the-top post-emergent broad spectrum herbicides to an herbicide-tolerant crop allows the grower to decrease the overall use of herbicides before cultivation, reduce the use of soil-applied herbicides, and streamline field cultivation activities for weed control (Marra et al., 2002; O'Sullivan and Sikkema, 2004; Ransom et al., 2004). Glyphosate-tolerant crops have been widely adopted because glyphosate is highly effective against many economically effective weeds, thus simplifying weed management and facilitating the widespread adoption of no tillage systems (Owen et al., 2011). However, since the introduction of glyphosate-tolerant crops, the use of tank mixtures and sequential applications of herbicides with more than one mode of action has declined, as many growers relied exclusively on glyphosate for weed control (Weirich et al., 2011).

Corn as a Volunteer

Corn periodically occurs as a volunteer when corn seeds remain in the field after harvest and successfully germinates (Beckett and Stoller, 1988; USDA-APHIS, 2010) (see also Bernards et al., 2010; Davis, 2009; Hager, 2009; Johnson et al., 2010; Stewart, 2011; Wilson et al., 2011a; Wilson et al., 2010). Post-harvest seed residues in fields can be a result of harvester inefficiency, bird dispersal or seed drop, with the seed ending up beyond the field margins or remaining as residues in the field after the harvest (Davis, 2009). This can be a particular problem when weather late in the season causes ears to drop or lodging to occur which places the ears on the ground where the seed then germinate the following year. Volunteer corn can be present as single plants or as clumps formed when an ear drops to the ground and is partially buried (Davis, 2009; Wilson et al., 2010). When those seeds survive to the subsequent growing season, volunteer plants may develop within subsequent crops or outside of the cropped area. The potential for GE corn to establish as a volunteer has been the subject of recent research, with a particular emphasis on yield impact and management of herbicide-tolerant corn as a volunteer in subsequent crops modified for tolerance to the same herbicide (Beckett and Stoller, 1988; Beckie and Owen, 2007; Davis, 2009; Wilson et al., 2011a; Wilson et al., 2010).

Corn volunteers are limited by the geography in which they initially are planted. Corn generally does not overwinter in those regions where freezing temperatures are reached in the winter; however, corn seeds which are incorporated in the soil during harvest or in fall tillage may overwinter and grow the following spring (Stewart, 2011). Volunteer corn lacks vigor and competitiveness because the volunteer plant is two generations removed from the cross which produced the hybrid planted (Davis, 2009). For genetically-transformed corn plants that have escaped the cultivated field to produce a viable rogue population, off-field plants would need to inherit and express additional unrelated traits that provide selective advantage to a weedy growth habit. Some of these advantageous traits include having large numbers of easily dispersed seeds, a propensity to grow on disturbed ground, an enhanced vegetative propagation, and increased seed dormancy (US-EPA, 2010). Some literature suggests that these traits do not exist within corn, a species that has been selected for domestication and cultivation under conditions not normally found in natural settings (US-EPA, 2010). However, other literature clearly notes that GE corn is a problematic volunteer the year after harvest in soybean, dry beans, sugar beets and subsequent corn crops (Bernards et al., 2010; Davis, 2009; Hager, 2009; Johnson et al., 2010; Stewart, 2011; Wilson et al., 2011a; Wilson et al., 2010). For example, the presence of volunteer corn in soybeans was identified in 12% of the soybean acreage in Illinois in a 2005 survey of soybean acreage in corn – soybean rotation systems (Davis, 2009), and a 2010 survey of soybean cultivation in Illinois identified a field with up to 500,000 corn plants per acre (Hager, 2010).

Volunteer corn competes with the intended crop for light, soil moisture, and nutrients (Bernards et al., 2010; Soltani et al., 2006; Wilson et al., 2010). The effect of volunteer corn on the yields of the intended crop depends on the density of the volunteer corn (Bernards et al., 2010; Davis, 2009). In controlled agronomic studies, an analysis of yield impacts to soybeans from volunteer corn was evaluated at densities up to 17,800 corn plants per acre of soybean (Alms et al., 2007, 2008). In these controlled studies, volunteer corn densities ranging from zero plants per square meter up to 4.4 plants per square meter were cultivated in soybean, with corresponding soybean yield losses of up to 58% (Alms et al., 2007, 2008). Pre-harvest herbicide treatments of the volunteer corn reduced but did not eliminate the yield impacts. In experimental studies, volunteer corn in soybeans was controlled using different application rates of the herbicide Clethodim in the attempt to better quantify soybean yield loss (Alms et al., 2008). Clethodim treatments of the volunteer corn did reduce the volunteer corn density, although even after a 98% control of the volunteer corn, soybean yield still suffered a 5% reduction in yield (Alms et al., 2008).

Successful control of corn volunteers, including herbicide-tolerant varieties, is accomplished with the use of various combinations of cultivation practices and herbicides (Beckett and Stoller, 1988; Beckie and Owen, 2007; Sandell et al., 2009). Volunteer corn is less of a concern in no-till fields than in fall-tilled fields because of the lower probability that corn seed will survive and germinate in the following growing season (Bernards et al., 2010). In no-till fields, the fallen corn is frequently predated by wildlife and also is subject to winter weather conditions (Bernards et al., 2010). In fall tillage systems, corn seed may be buried in the soil and overwinter, volunteer corn which has emerged from this overwintered seed requires control with spring tillage or with an application of herbicides (Bernards et al., 2010).

The adoption of herbicide-tolerant crops has changed the approaches which growers can use to reduce crop losses from volunteers (Beckie and Owen, 2007). In soybean fields where the volunteer corn is glyphosate- or glufosinate-tolerant, herbicides with alternate modes of action might be employed (e.g., glufosinate in LibertyLink® soybean to control a Roundup Ready® glyphosate-tolerant volunteer corn variety) (Bernards et al., 2010; Minnesota, 2009). Post-emergent grass herbicide ACCase inhibitors also are recommended, including Quizalofop, fluazifop, fenoxaprop, sethoxydim, and clethodim (Bernards et al., 2010; Hager, 2009; Johnson et al., 2010). ALS inhibitors, such as the sulfonylureas, Imadazolinone, and triazoloyrimidine also have been identified for potential control of glyphosate- or glufosinate-tolerant corn (see, Hager, 2009; Wisconsin, 2011). Herbicide tank mix additives are recommended to increase on-plant spray retention and absorption (see Hager and McGlamery, 1997; Johnson et al., 2010; Sandell et al., 2009). Recommended additives include crop oil concentrate (COC), methylated seed oil (MSO), and ammonium sulfate (AMS) (Hager and McGlamery, 1997; Johnson et al., 2010; Monsanto, 2010). Imazethapyr has been identified to control up to 80% of the volunteer corn when the corn is still in early growth stages (Bernards et al., 2010). The ACCase inhibiting herbicides are to be applied prior to the corn reaching the 12 to 24 inch tall stage and the ALS herbicides are effective in controlling smaller (2 to 8 inch corn) (Minnesota, 2009; Monsanto, 2010).

Volunteer corn in cornfields can be controlled using inter-row cultivation and several different herbicides (Minnesota, 2009; Sandell et al., 2009). As noted with volunteer corn in soybean, growers can take advantage of alternate modes of herbicide action if the herbicide tolerance differs between the current crop and the volunteer (e.g., glufosinate in LibertyLink® Corn to control a glyphosate-tolerant variety) (Minnesota, 2009). Pre-emergent controls might include Gramoxone Inteon (paraquat) mixed with Atrazine (Monsanto, 2010; Sandell et al., 2009). When these two herbicides are used together, optimal control is observed if the applications are made before the corn reaches the 6-inch stage (Monsanto, 2010). If the volunteer corn is stacked to express both glyphosate and glufosinate tolerance, inter-row cultivation is the only option for post-emergent control within corn (Sandell et al., 2009).

There are no post-emergent herbicide options to control volunteer corn in sorghum; the only control option is inter-row cultivation (Sandell et al., 2009). Delayed planting of the sorghum is an option that may be used so as to allow the volunteer corn to germinate and then be destroyed with pre-plant tillage (Sandell et al., 2009). Because of the few options for weed management in sorghum, many growers have switched to other crops (Dreiling, 2010). Herbicide-tolerant varieties of sorghum are being developed, including a variety tolerant to ACCase inhibitors (Dreiling, 2010). When such varieties are available, weeds, including volunteer corn, susceptible to the ACCase inhibitor herbicides could be controlled in sorghum (Dreiling, 2010). Control of volunteer corn that is tolerant to the same herbicides, such as the ACCase-tolerant DAS-40278-9 corn in a similar ACCase-tolerant Sorghum, would require other weed management strategies.

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; Jasinski et al., 2003; Young and Ritz, 2000). They also suppress soil-borne plant diseases and promote plant growth (Doran et al., 1996). The main factors affecting microbial population size and diversity include plant type (providers of specific carbon and energy sources into the soil), soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva et al., 2004; Young and Ritz, 2000). Plant roots release a large variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere. Microbial diversity in the rhizosphere is extensive and differs from the microbial community in the bulk soil (Garbeva et al., 2004).

2.4.4 Biological Diversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson, 1988). Agricultural biodiversity has been defined variously to include genetic diversity of the crops through and including the biodiversity of the surrounding ecosystem (see, e.g., Carpenter, 2011). APHIS focuses its analysis of biological diversity at the ecosystem level, that aspect of the environment potentially impacted by a determination of nonregulated status of various GE crops. In this case, biodiversity refers to the ability of a highly managed ecosystem, such as a cornfield, to support species that do not contribute directly to crop production but represent important components of the biological landscape. Such species include species affecting pollination (e.g., bees, butterflies) and control of insect pests, important avian (e.g., songbirds) and mammalian (e.g., small mammals) wildlife, and the plant community.

Among other benefits, biodiversity provides valuable genetic resources for crop improvement (Harlan, 1975) and also provides other functions beyond food, fiber, fuel, and income. These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 2000). Beneficial insects, birds, and mammals are natural predators of many crop pests and play an important role in pest management (USDA-NRCS, 2002). The loss of biodiversity results in a need for costly external inputs in order to provide these functions to the crop (Altieri, 2000).

The degree of biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management; and 4) extent of isolation of the agroecosystem from natural vegetation (Altieri, 1999; USDA-NRCS, 2002). Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest limit habitat diversity resulting in a corresponding decrease in diversity of plants and animals.

Cropland management practices, including a range of practices incorporated in integrated pest management plans can be adopted which increase habitat preservation and plant biodiversity (see, e.g., IPM, 2004; IPM, 2007; Palmer et al., 2011; Sharpe, 2010).

Conservation tillage and no-till practices have a positive impact on wildlife, including the community of beneficial arthropods (Altieri, 1999; Landis et al., 2005; Towery and Werblow, 2010). Benefits include decreased soil erosion and improved water quality in receiving waters, retention of cover, availability of waste grain on the soil surface for feed, and increased populations of predaceous invertebrates as well as invertebrates as a food source (Landis et al., 2005; Sharpe, 2010).

Crop rotations reduce the likelihood of crop disease, insect pests, weed pests, and the need for pesticides (Randall et al., 2002). Reduced pesticide use has a direct positive effect on wildlife by reducing the direct exposure of birds, mammals, and fish to pesticides. Indirect benefits include less alteration of suitable wildlife habitat and an available food supply of insects for insectivores (Palmer et al., 2011; Sharpe, 2010). Crop rotations with legumes and small grains have been shown to provide excellent wildlife nesting cover, food, and brood-rearing habitat (Sharpe, 2010). Polycultures of plants support lower herbivore populations because they provide a more stable and continuous availability of food and habitat for beneficial insects (Altieri, 1999; Altieri and Letourneau, 1982, 1984; Landis et al., 2005).

Field edges can be managed to promote wildlife. These borders are often the least productive areas in a farm field and in some cases, the cost of producing crop areas along field edges exceeds the value of the crop produced (Sharpe, 2010). Allowing field edges to return to volunteer vegetation does contribute to weed seeds in the field, but does not contribute to major pest problems in the crop field itself (Sharpe, 2010). Volunteer border vegetation, such as ragweed, goldenrod, asters, and forbs, quickly develops into nesting and brood habitat for quail and a multitude of songbirds (Sharpe, 2010). Maintaining some weeds harbors and supports beneficial arthropods that suppress herbivore insect pests (Altieri, 1999; Altieri and Letourneau, 1982, 1984). Research conducted at North Carolina State University and the North Carolina Wildlife Resources Commission found that quail populations doubled when field borders were used (Sharpe, 2010). Adjacent wild vegetation provides alternate food and habitat for natural enemies to pest herbivores (Altieri, 1999; Altieri and Letourneau, 1982, 1984).

Contour-strip cropping is another management practice that can be used to promote wildlife habitat. This practice alternates strips of row crops with strips of solid stand crops (i.e., grasses, legumes, or small grains) with the strips following the contour of the land (Sharpe, 2010). The primary purpose of contour-strip cropping is to reduce soil erosion and water runoff, but the solid stand crop also provides nesting and roosting cover for wildlife (Sharpe, 2010). Grass-legume refuge strips have also been used to increase the population density of predaceous carabid beetles in corn (*Zea mays* L.) and soybean fields (Landis et al., 2005).

Drainage ditches, hedgerows, riparian areas, and adjacent woodlands to a cornfield also provide cover, nesting sites, and forage areas, which each contribute to enhancing wildlife populations. Ditch banks, for example, function as narrow wetlands that provide nesting sites and cover, serve as wildlife corridors, and provide areas for the wildlife to occupy when crop fields lack cover (Sharpe, 2010). Ditches have been shown to support birds, rodents, reptiles, furbearers, amphibians, fish, and aquatic organisms (Sharpe, 2010). Minimizing pesticide exposure of ditches, aquatic habitats, border areas, strip-crop areas, and non-crop habitats may help protect fish and wildlife resources (Palmer et al., 2011).

2.4.5 Gene Movement

Gene flow is the movement of genes from one organism to another. Vertical gene flow, or introgression, is the movement of genes to sexually compatible relatives (Ellstrand, 2003; Quist, 2010). Horizontal gene flow is the stable movement of genes from one organism to another without reproduction or human intervention (Keese, 2008; Quist, 2010). This subsection provides a basis for evaluating the potential for movement of genes to other corn varieties and corn relatives, as well as potential for gene movement to unrelated species. A discussion of the movement of genes via pollen to other cultivated corn varieties in the context of seed production is provided in Subsection 2.2.3, Seed Production.

Gene flow between corn varieties is most likely to occur during cultivation as well as the handling and processing of corn (Coulter et al., 2010; Mallory-Smith and Sanchez-Olguin, 2010; Thomison, 2009). Corn is a cross-pollinating crop in which most pollination results from pollen dispersed by wind and gravity (Thomison, 2009).

The possibility of gene movement from the host plant into native or feral populations of *Zea* species or wild or weedy relatives of corn has been evaluated by the EPA and determined to not be a concern in the continental U.S. (US-EPA, 2010). The potential for outcrossing or gene escape is defined as the ability of the gene to escape to wild corn relatives. The closest relative of *Zea* is the genus *Tripsacum* (OECD, 2003). Seventeen species of *Tripsacum* have been identified, with chromosome number varying from 2n = 36 to 2n = 108 (OECD, 2003). All of the *Tripsacum* species are perennial (OECD, 2003). Twelve of the *Tripsacum* species are native to Mexico and Guatemala; *T. dactyloides*, Eastern gamagrass, is known to occur in the eastern half of the U.S., *T. lanceolatum* occurs in the southwest of the U.S., and *T. floridanum* is native to South Florida and Cuba (OECD, 2003; Wozniak, 2002). *T. dactyloides* is the only *Tripsacum* species of widespread occurrence and agricultural importance, and commonly is grown as a forage grass (Wozniak, 2002).

Tripsacum differs from corn in many respects, including chromosome number (*T. dactyloides* n = 18; *Zea mays* n = 10) (Wozniak, 2002). The three *Tripsacum* species in the U.S. exhibit several ploidy types. *T. floridanum* has a diploid chromosome number of 2n = 36 (Wozniak, 2002). *T. dactyloides* includes 2n = 36 forms which are native to the central and western U.S., and 2n = 72 forms which extend along the Eastern seaboard and along the Gulf Coast from Florida to Texas, but which also have been found in Illinois and Kansas (Wozniak, 2002). *T. lanceolatum* has a diploid number 2n = 72 (Wozniak, 2002). The potential for pollen-directed gene flow from maize to Eastern gamagrass is remote (Wozniak, 2002). Although hybridization of *Tripsicum x Zea mays* has been accomplished in the laboratory using special techniques under highly controlled conditions, these hybrids have not been observed in the field. (Wozniak, 2002). Additionally, *Tripsicum* does not represent any species considered a serious or pernicious weed in the U.S. or its territories (Wozniak, 2002). Any introgression of corn genes into this species as a result of cross fertilization is not expected to result in a species that is weedy or difficult to control (Wozniak, 2002).

Distinctions in genetic construct between related species are important to recognize, as the genetic differences directly affect the ability of cultivated corn to interbreed with wild relatives. Hybrids between *Zea mays* and the teosinte subspecies *Zea mays* subsp. *mexicana* are known to occur when the two are sympatric in Mexico (CEC, 2004; Ellstrand et al., 2007). Many species of *Tripsacum* can cross with *Zea*, or at least some accessions of each species can cross, but only with difficulty and the resulting hybrids are primarily male and female sterile (Ellstrand et al., 2007; Wozniak, 2002). The rate at which crop genes enter teosinte populations may be limited by genetic barriers, phenological differences, and subsequently by the relative fitness of the hybrids (CEC, 2004; Ellstrand et al., 2007).

Horizontal gene transfer and consequent expression of DNA from a plant species to bacteria is unlikely to occur (Keese, 2008). Many bacteria (or parts thereof) that are closely associated with plants have been sequenced, including *Agrobacterium* and *Rhizobium* (Kaneko et al., 2000; Kaneko et al., 2002; Wood et al., 2001). There is no evidence that these organisms contain genes derived from plants. In cases where the review of sequence data implied that horizontal gene transfer occurred, these events were inferred to occur on an evolutionary time scale in the order of millions of years (Brown, 2003; Koonin et al., 2001).

2.5 PUBLIC HEALTH

2.5.1 Human Health

In the past 30 years, the public's consumption of corn-based products has more than doubled. Per capita consumption of corn products rose from 12.9 pounds annually per capita in 1980 to 33 pounds in 2008; and corn sweeteners increased from 35.3 pounds annually per capita to 69.2 pounds during that period (USCB, 2011). During the same time period, the share of corn that was GE increased from 0% to 80% (USDA-ERS, 2010a). Public health concerns associated with the use of GE corn, such as DAS-40278-9 corn, and GE corn products focus primarily on human and animal (livestock) consumption of GE food and feed commodities. This subsection provides a summary of the principal human health concerns. Similar issues related to livestock use are presented in Subsection 2.6 – Animal Feed.

There are three principal corn product industries in the U.S.: corn refiners, dry millers, and distillers. Corn refiners produce starches, sweeteners, ethanol, feed ingredients, corn oil, organic acids, amino acids, and polyols (CRA, 2006). Dry millers manufacture flaking grits, snack grits, corn meals, and corn flours and distillers produce beverage and industrial alcohol (CRA, 2006). The production processes in each of these industries frequently involve several sequential mechanical and chemical processes. Depending on the final product, these processes include washing, heating, adjusting pH, steeping in an acid solution, fermentation, mechanical milling and centrifugal separation, extrusions, pressing and solvent extraction, evaporation and filtration, and final refining (CRA, 2006). Each step in the production process reduces residual pesticides in the finished product (CRA, 2000). Manufacturing operations also have been shown to degrade and denature proteins in corn (Hammond and Jez, 2011).

Before a pesticide can be used on a food crop, EPA, pursuant to the FFDCA, must establish a tolerance value establishing the maximum pesticide residue that may remain on the crop or in foods processed from that crop. In addition, the FDA and the USDA monitor foods for pesticide residues and enforce these tolerances (see USDA-AMS, 2011). Foods derived through biotechnology also undergo a comprehensive safety evaluation before entering the market, including reviews under the CODEX, the European Food Safety Agency, and the World Health Organization (FAO, 2009; Hammond and Jez, 2011). Food safety reviews frequently will compare the compositional characteristics of the GE crop with non-transgenic, conventional varieties of that crop (see also Aumaitre et al., 2002; FAO, 2009). Moreover, this comparison also evaluates the composition of the modified crop under actual agronomic conditions, including various agronomic inputs (see, e.g., Herman et al., 2010). 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 (Herman et al., 2010).

Antinutrients represent an important element of this comparison. Antinutrients are compounds produced by a plant which interfere with the absorption and metabolism of the consumed vegetable as well as other foods in the digestive tract (Cordain, 1999). Antinutrients in corn include lectins, which interfere with vitamin absorption and have been associated with cellular level metabolic interference, and trypsin inhibitors, which inhibit protein digestion (Cordain, 1999).

Non-GE corn varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for 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 labeled properly. As a GE product, however, food and feed derived from DAS-40278-9 corn must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far, all applicants who have wished to commercialize a GE variety that would be included in the food supply have completed a consultation with the FDA. In such consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. This process includes: 1) an evaluation of the amino acid sequence introduced into the food crop to confirm whether the protein is related to known toxins and allergens; 2) an assessment of the protein's potential for digestion; and 3) an evaluation of the history of safe use in food (Hammond and Jez, 2011). FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require. Several international agencies also review food safety associated with GE-derived food items, including the European Food Safety Agency (EFSA) and the Australia and New Zealand Food Standards Agency (ANZFS).

As noted by the National Research Council (NRC), unexpected and unintended compositional changes arise with all forms of genetic modification, including both conventional hybridizing and genetic engineering (NRC, 2004). The NRC also noted in its 2004 report that no adverse human health effects attributed to genetic engineering had been documented. More recently, the NRC found that the cultivation of GE crops has resulted in improvements of pesticide application regimens (applications of fewer pesticides or using pesticides with lower environmental toxicity), and that the cultivation of herbicide-tolerant crops were advantageous because of their superior efficacy in pest control and concomitant economic, environmental and presumed personal health advantages (NRC, 2010). Reviews on the nutritional quality of GE foods generally have concluded that there are no biologically meaningful nutritional differences in conventional versus GE plants for food or animal feed (Aumaitre et al., 2002; Faust, 2004; Van Deynze et al., 2004).

DAS has provided the FDA with information on the identity, function, and characterization of the genes for DAS-40278-9 corn, including expression of the gene products. The FDA has completed its review and published its Biotechnology Consultation (US-FDA, 2011). A copy of the FDA's consultation on this product is provided in Appendix A, and is discussed in Subsection 4.5, Public Health. The EPA's role in review of DAS-40278-9 corn is more limited. As DAS-40278-9 corn does not express any pesticidal properties, the EPA has no FIFRA review authority over this corn product. However, as DAS-40278-9 corn provides for a change in use of two registered herbicides, 2,4-D and Quizalofop, the EPA will be reviewing proposed label changes relating to these new herbicide uses. To the extent required, the EPA also will be reviewing the exemption for tolerance for residues of both herbicides on corn pursuant to authority under the FFDCA.

The herbicide 2,4-D currently is registered under various trade names for control of weeds in many crops, including corn (see Nufarm, 2009). In 2002, 2,4-D was ranked as the third most used herbicide by active ingredient in the U.S. for all purposes (~40 million pounds), behind glyphosate (~102 million pounds) and atrazine (~77 million pounds) (Gianessi and Reigner, 2006). In 2005, 2,4-D was applied on less than 8% of corn acreage (~2 million pounds applied) (USDA-NASS, 2006). The highest recorded use of 2,4-D is its application to 14% of the U.S.

corn acres in 1994 (USDA-NASS, 2011d). Tolerance for residues of 2,4-D have been established for a wide variety of commodities (US-EPA, 2011a).

The potential use of Quizalofop on corn is a new use for this herbicide. The “fop” herbicides (AAOP ACCase inhibitors) have been registered for agriculture crop use for over 20 years (USDA-APHIS, 2010). These herbicides traditionally have not been used to control weed species in cornfields because, as a grass (Poaceae family) species, corn is damaged by AOPP ACCase inhibitor activity. The registration and use of “fop” herbicides has been primarily on broadleaf crops, such as soybean, to control grass weed species, although certain cereal plant varieties have a level of tolerance to some “fops” (see DuPont, 2010). According to the USDA NASS Agricultural Chemical Use Database, “fop” type herbicides were used for weed control on at least 23 food crop species between 1990 and 2006, totaling over 16 million pounds of active ingredient (USDA-NASS, 2011d). Tolerance for residues of Quizalofop have been established for a wide variety of commodities (US-EPA, 2011c).

EPA’s core pesticide risk assessment and regulatory processes ensure that protections are in place for all populations of non-target species potentially exposed to pesticides, including humans. These assessments provide EPA with information needed to develop label use restrictions for the pesticide. Growers are required to use pesticides, such as 2,4-D and Quizalofop, consistent with the application instructions provided on the EPA-approved pesticide label (see, e.g., DuPont, 2010; Nufarm, 2009). These label restrictions carry the weight of law and are enforced by EPA and the states (Federal Insecticide, Fungicide, and Rodenticide Act 7 USC 136j (a)(2)(G) Unlawful Acts). Therefore, it is expected that 2,4-D and Quizalofop use on the DAS-40278-9 corn product would be consistent with the EPA-approved label.

The current labels for both 2,4-D and Quizalofop include label use restrictions intended to protect humans, including protective equipment to be worn during mixing, loading, applications and handling, equipment specifications to control pesticide application, and reentry periods establishing a safe duration between pesticide application and exposure to the pesticide in the field (DuPont, 2010; Nufarm, 2009). Used in accordance with the label, these herbicides have been determined to not present a health risk to humans (US-EPA, 2007b). The human health implications of the proposed changes in application rates and use of these two herbicides are discussed in Subsection 4.5.

2.5.2 Worker Safety

Pesticides, including herbicides, are used on most corn acreage in the U.S., and changes in acreage, crops, or farming practices can affect the amounts and types of pesticides used and thus the risks to workers. The EPA pesticide registration process, however, involves the design of use restrictions that if followed have been determined to be protective of worker health.

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

Worker safety precautions and use restrictions are clearly noted on pesticide registration labels. These restrictions provide instructions as to the appropriate levels of personal protection required for agricultural workers to use herbicides. These may include instructions on personal protective equipment, specific handling requirements, and field reentry procedures. (DuPont, 2010; Nufarm, 2009). Used in accordance with the label, these herbicides have been determined to not present a health risk to workers (US-EPA, 2005c, 2007b). The worker safety implications of the proposed changes in application rates and use of these two herbicides are discussed in Subsection 4.5.

2.6 ANIMAL FEED

Corn comprises approximately 95% of the total feed grain production and use, with sorghum, barley, and oats making up the remainder (USDA-ERS, 2011b). The production of corn for feed use is a derived demand, i.e., production of corn for feed will vary depending on the number of animals (cattle, hogs, and poultry) being fed corn (USDA-ERS, 2011b). The amount of corn used for feed also depends on the crop's supply and price (USDA-ERS, 2011b).

Animal feed derived from corn comes not only from the unprocessed grain, but also from the residuals derived from three major corn industries: corn refining, corn dry millers, and distillers (CRA, 2006). Animal feed products from corn refining and wet milling include corn gluten feed, corn gluten meal, corn germ meal, corn steep liquor, and amino acids (CRA, 2006).

Corn gluten feed is the residue remaining after the extraction of starch, gluten, and germ (CRA, 2006). Corn gluten feed is considered a medium protein product and is used widely in complete animal feeds for dairy and beef cattle, poultry, and hogs (CRA, 2006). Corn gluten meal is a high-protein ingredient consisting of corn proteins separated in the milling process, and may contain as much as 60% protein (CRA, 2006). Corn gluten meal has a high xanthophyll content, a yellow plant pigment, making this product highly valued as a pigmenting ingredient in poultry feeds (CRA, 2006). The high protein content also is valued as a cattle feed to protect the cow's rumen (CRA, 2006). Corn germ meal is a residual product obtained from the corn germ after the corn oil has been extracted (CRA, 2006). Corn germ meal is a small fraction of the corn kernel, and has a small market in animal feed as a carrier for liquid nutrients (CRA, 2006). Corn steep liquor is a high protein product comprised of the soluble portions of the corn kernel removed during the corn steep process (CRA, 2006). Corn steep liquor is sometimes combined with other ingredients in corn gluten feed or provided as a liquid protein source (CRA, 2006). Amino acids are produced through the fermentation of corn-derived dextrose (CRA, 2006). Lysine, an essential animal amino acid, is a highly valued corn-derived amino acid for both poultry and swine (CRA, 2006). Threonine and tryptophan amino acid feed supplements also are produced from corn (CRA, 2006).

As discussed in Subsection 2.2.2.3, a determination of nonregulated status of DAS-40278-9 corn is expected to result in an increase in the use of the herbicide 2,4-D in corn, as well as the new use of Quizalofop on corn. Both herbicides currently have established tolerances for residues, including established residue concentrations for 2,4-D in field corn for forage, grain, and stover

(US-EPA, 2011a, 2011c). The EPA establishes tolerances to regulate the amount of pesticide residues that can remain on food or feed commodities as the result of pesticide applications (see, e.g., http://www.epa.gov/pesticides/bluebook/chapter11.html). The tolerance level is the maximum residue level of a pesticide that can legally be present in food or feed, and if pesticide residues are found to exceed the tolerance value, the food is considered adulterated and may be seized.

2.7 SOCIOECONOMIC

Corn is produced for food and feed commodities as well as industrial uses (USDA-ERS, 2011b). Corn is the most widely cultivated feed grain in the U.S., accounting for more than 95% of total value and production of feed grains (DAS, 2010; James, 2009; USDA-ERS, 2011b). Corn is grown in all 48 of the continental U.S. states with production concentrated in the Corn Belt, loosely defined as the states of Illinois, Iowa, Indiana, the eastern portions of South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri (USDA-ERS, 2011b; USDA-NASS, 2010, 2011a). Iowa and Illinois are the two top corn producing states and typically account for more than one-third of the total U.S. crop (USDA-ERS, 2011b).

In the 2011 production year, corn was cultivated on 92.3 million acres, a 5% increase in corn acreage from 2010 (37.4 million hectares) (USDA-NASS, 2010, 2011a). In 2010, corn for silage was cultivated on approximately 5.6 million acres, or approximately 6% of the total corn production area for that year (USDA-NASS, 2011b). GE herbicide-tolerant corn comprised approximately 23% of the total corn acreage in the U.S., insect-resistant varieties comprised 16% of the acreage, and stacked varieties comprising 49% of the total corn acreage (NRC, 2010; USDA-NASS, 2011a). The costs for GE corn seed are higher than that for conventional seed. Growers pay a premium for GE seed, with growers in 2008 paying as much as 50% more for GE corn seed than conventional seed (NRC, 2010). This seed premium includes a technology fee for the cultivation of the seed (NRC, 2010).

Corn production in 2010 was estimated at 12.4 billion bushels, valued at an estimated $5.15 to $5.65 per bushel (USDA-ERS, 2011c; USDA-NASS, 2011b). The value of the corn crop varies over time in response to market conditions. In May 2011, corn futures traded on the Chicago Board of Trade at $7.57 for a July 2011 contract. In June 2011, corn futures traded on the Chicago Board of Trade at $6.20 for a December 2011 contract. U.S. prices for corn, although declining somewhat over the course of the year, are expected to remain high because of the continued demand for corn for ethanol, animal feed, and exports (James, 2009; USDA-NASS, 2011a; USDA-OCE, 2011b).

Corn processed for human consumption and industrial uses accounts for about one-third of domestic corn utilization (USDA-ERS, 2011b). During processing, corn is either wet or dry milled depending on the desired end products: wet millers process corn into high-fructose corn syrup (HFCS), glucose and dextrose, starch, corn oil, beverage alcohol, industrial alcohol, and fuel ethanol. Dry millers process corn into flakes for cereal, corn flour, corn grits, corn meal, and brewers grits for beer production (USDA-ERS, 2011b).

The cultivation of corn for animal feed varies depending upon the demand in the livestock industry (USDA-ERS, 2011b). Direct feeding of corn to livestock has declined in response to declines in meat production since 2007 in the U.S., as well as utilization of certain corn by-products for livestock feeds (USDA-OCE, 2011b). The production of ethanol generates several economically valuable coproducts, including distillers dried grains with solubles (DDGs) (USDA-ERS, 2011b). Each 56 pound bushel of corn used in dry mill ethanol production generates approximately 17.4 pounds of DDGs which are fed to livestock (USDA-ERS, 2011b). Food and industrial use of corn (other than for ethanol production) is projected to increase, although this demand also is related to specific products (USDA-OCE, 2011b). Demand for HFCS, glucose and dextrose is expected to increase, but at lower rates than previous years. Corn starch is considered an industrial product, the production of which is contingent on industrial demand (USDA-OCE, 2011b).

Corn production has increased over time, as higher yields followed improvements in technology (seed varieties, pesticides, and machinery) and in production practices (reduced tillage, irrigation, crop rotations, and pest management systems) (Fernandez-Cornejo et al., 2009; USDA-ERS, 2011b). Corn acreage in the U.S. increased during the second half of the 2000s. The establishment of a bioethanol industry using corn as a feed stock has been identified as one of the key elements in the increase in acreage devoted to corn, with approximately 40% of the corn harvest now dedicated to corn-based biofuel production (Swoboda, 2009; USDA-NASS, 2010, 2011a; USDA-OCE; Wilson, 2011). Corn acreage is expected to increase over the next decade, with two to four million acres of other crops converted to corn cultivation to support both ethanol production and export demand (USDA-OCE, 2011b). Over the past 20 years, the acreage per corn farm has increased, and the number of large corn farms (more than 500 acres) has increased, while the number of small corn farms (less than 500 acres) has declined (USDA-ERS, 2011b).

The adoption of GE corn in U.S. has reduced costs and improved profitability levels on the farm (Brookes and Barfoot, 2010; Carpenter et al., 2002). These cost reductions are a result of reductions in average herbicide and pesticide use per field, and corresponding reductions in tillage and associated field cultivation costs (Brookes and Barfoot, 2010; Carpenter et al., 2002). Other benefits to the grower from adoption of GE crops have included (Brookes and Barfoot, 2010; Carpenter et al., 2002):

- Increased management flexibility and convenience arising from the ease of use of broad-spectrum herbicides like glyphosate;
- A decrease in "knock-back" of the crop associated with post-emergent applications of herbicides on the herbicide-tolerant crop;
- Reduced harvesting costs;
- Higher quality harvested crop;
- An improvement in soil quality as growers reduce quantities of soil-applied herbicides and increase limited tillage; and
- Overall improvements in human health costs associated with use of less toxic products.

The net cost savings from adoption of a GE herbicide-tolerant weed control system were found to range from $32/hectare to $61/hectare per year when compared with the costs of conventional herbicide treatment used to gain the same level of control in a low/reduced till system (Brookes and Barfoot, 2010). Recently, these net cost savings have decreased as a consequence in an increase in the price of glyphosate and other weed control programs (Brookes and Barfoot, 2010).

Continued demands for corn have resulted in some shifts in the corn/soybean rotation in some areas (Hart, 2006). Corn and soybeans frequently were cultivated in two year rotation, but as the demand for corn for ethanol increased, many growers in the upper Midwest converted to a three year rotation schedule, with two consecutive years of corn followed by a year of soybean (Hart, 2006). Although there are certain economic benefits from this change, there also are some costs. Tillage costs may increase in the second year of corn, for example, if the crop residues from the first corn year prevent no-till planting in the second year (Babcock and Hennessy, 2006). Corn after corn rotations also can impact pest and weed pressure as certain corn-specific pests and weeds overwinter in the corn residues remaining in the field (Babcock and Hennessy, 2006). These impacts can be managed through greater crop monitoring, increased applications of pesticides, and selection of appropriate hybrids (Babcock and Hennessy, 2006).

Corn is the dominant feed grain traded internationally (James, 2009; USDA-OCE, 2011a, 2011b). In 2009, the U.S. produced over 40% of the total world supply of corn (USDA-OCE, 2011a, 2011b). Corn is cultivated worldwide, including in the European Union, Argentina, South Africa, Brazil, Canada, China, and the former Soviet Union States, including the Ukraine (USDA-OCE, 2011a, 2011b). GE Corn is cultivated on over 25% of all corn acreage worldwide (James, 2009). Approximately 15 to 20% of the U.S. corn production is exported, with the volume of exports projected to increase over the next decade (DAS, 2010; USDA-OCE, 2011a, 2011b). Egypt, the EU, Japan, Mexico, Southeast Asia, and South Korea are net importers of corn (Brookes and Barfoot, 2010; USDA-OCE, 2011a, 2011b). China is projected to become a net importer of corn to support its expanding livestock and industrial sectors (James, 2009; USDA-OCE, 2011a, 2011b). The increase in China’s imports is expected to account for one-third of the growth in world corn trade (USDA-OCE, 2011a, 2011b).

Value enhanced, specialty corn is an important part of the U.S. export market for corn. High oil corn, for example, is in high export demand as a replacement for animal fats in feed rations (USDA-FAS, 2004). As discussed in Subsection 2.2.5, Specialty Corn Production, the challenges associated with maintaining variety identity in international commodity movement increases the costs, as well as the premiums paid, for these specialty crops (USDA-FAS, 2004).

Trade in feed for livestock has been a driver of this international trade. Corn gluten feed is a major product in international trade in feed ingredients (CRA, 2006). Large volumes of U.S. corn gluten feed are exported to the EU (CRA, 2006).

3 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of DAS-40278-9 corn. To respond favorably to a petition for nonregulated status, APHIS must determine that DAS-40278-9 corn is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2010), APHIS has concluded that DAS-40278-9 corn is unlikely to pose a plant pest risk. Therefore, APHIS must determine that DAS-40278-9 corn is no longer subject to Part 340 or the plant pest provisions of the PPA.

Two alternatives will be evaluated in this EA: 1) no action; and 2) determination of nonregulated status of DAS-40278-9 corn. APHIS has assessed the potential for environmental impacts for each alternative in Section 4 of this EA, Environmental Consequences.

3.1 NO ACTION: CONTINUATION AS A REGULATED ARTICLE

Under the No Action Alternative, APHIS would deny the petition. DAS-40278-9 corn and progeny derived from DAS-40278-9 corn would continue to be regulated articles under the regulations at Part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of DAS-40278-9 corn 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 DAS-40278-9 corn.

This alternative is not the Preferred Alternative because APHIS has concluded through a PPRA (USDA-APHIS, 2010) that DAS-40278-9 corn is unlikely to pose a plant pest risk. Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

3.2 PREFERRED ALTERNATIVE: DETERMINATION THAT DAS-40278-9 CORN IS NO LONGER A REGULATED ARTICLE

Under this alternative, DAS-40278-9 corn and progeny derived from them would no longer be regulated articles under the regulations at Part 340. DAS-40278-9 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2010). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of DAS-40278-9 corn and progeny derived from this event. This alternative best meets the agency's purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in Part 340 and the agency's authority under the plant pest provisions of the PPA. Because the agency has concluded that DAS-40278-9 corn is unlikely to pose a plant pest risk, a determination of nonregulated status of DAS-40278-9 corn is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in Part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Under this alternative, growers may have future access to DAS-40278-9 corn and progeny derived from this event if the developer decides to commercialize DAS-40278-9 corn. Future access to DAS-40278-9 corn includes combining this variety with other corn varieties creating a "stacked" hybrid expressing multiple traits. DAS has indicated its intention to develop a "stacked" hybrid through conventional breeding techniques (DAS, 2010, 2011d, 2011e). In this process, the 2,4-D and "fop" resistance from DAS-40278-9 corn will be combined with glyphosate resistance from another corn 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. APHIS does not have jurisdiction under the PPA and Part 340 to review such stacked hybrids developed using nonregulated articles and conventional hybridization techniques where there is no evidence of a plant pest risk. Accordingly, this EA focuses on the cultivation of the DAS-40278-9 corn. Issues associated with potential future stacking, particularly cultivation of a stacked hybrid incorporating glyphosate resistance from a variety previously determined to be nonregulated, are presented and discussed in the cumulative effects analyses where appropriate.

3.3 ALTERNATIVES CONSIDERED BUT REJECTED FROM FURTHER CONSIDERATION

APHIS assembled a list of alternatives that might be considered for DAS-40278-9 corn. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the PPA and the regulations at Part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for DAS-40278-9 corn. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

3.3.1 Prohibit Any DAS-40278-9 Corn 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 DAS-40278-9 corn, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that DAS-40278-9 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2010).

In enacting the PPA, Congress found that—

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

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

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

Based on our PPRA (USDA-APHIS, 2010) and the scientific data evaluated therein, APHIS has concluded that DAS-40278-9 corn is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of DAS-40278-9 corn.

3.3.2 Approve the Petition in Part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that DAS-40278-9 corn is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the PPA for considering approval of the petition only in part.

3.3.3 Isolation Distance between DAS-40278-9 Corn and Non-GE Corn and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating DAS-40278-9 corn from non-GE corn production. However, because APHIS has concluded that DAS-40278-9 corn is unlikely to pose a plant pest risk (USDA-APHIS, 2010), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the PPA and regulations in Part 340.

APHIS also considered geographically restricting the production of DAS-40278-9 corn based on the location of production of non-GE corn in organic production systems in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' PPRA for DAS-40278-9 corn, there are no geographic differences associated with any identifiable plant pest risks for DAS-40278-9 corn (USDA-APHIS, 2010). This alternative was rejected and not analyzed in detail because APHIS has concluded that DAS-40278-9 corn does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the 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 Part 340 and the agency's authority under the plant pest provisions of the PPA. Nevertheless, APHIS is not expecting significant effects. However, individuals might choose on their own to geographically isolate their non-GE corn productions systems from DAS-40278-9 corn or to use isolation distances and other management practices to minimize gene movement between cornfields. Information to assist growers in making informed management decisions for DAS-40278-9 corn is available from Association of Official Seed Certifying Agencies (AOSCA, 2004).

3.3.4 Requirement of Testing for DAS-40278-9 Corn

During the comment periods for other petitions for a determination of nonregulated status, some commenters requested USDA to require and provide testing to identify 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 DAS-40278-9 corn does not pose a plant pest risk (USDA-APHIS, 2010), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the PPA, the regulations at Part 340, and the biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for DAS-40278-9 corn would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

3.4 COMPARISON OF ALTERNATIVES

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

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

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	**No**	**Yes**
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2010)
Management Practices		
Acreage and Areas of Corn Production	Unchanged	Unchanged
Cropping Practices	Unchanged	Minimal
Seed Production	Unchanged	Unchanged
Organic Farming	Unchanged	Unchanged
Specialty Corn Production	Unchanged	Unchanged
Physical Environment		
Water Resources	Unchanged	Unchanged
Soil	Unchanged	Unchanged
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Animal and Plant Communication		
Animals	Unchanged	Minimal
Plants	Unchanged	Minimal
Soil Microorganisms	Unchanged	Unchanged
Biological Diversity	Unchanged	Minimal
Gene Movement	Unchanged	Unchanged
Public Health		
Human Health	Unchanged	Unchanged
Worker Safety	Unchanged	Unchanged
Animal Feed	Unchanged	Unchanged

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Socioeconomic Issues		
Domestic Economic Environment	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged
Social Environment	Unchanged	Unchanged
Other Cumulative Effects	Unchanged	Minimal
Threatened and Endangered Species	Unchanged	Unchanged
Other U.S Regulatory Approvals	Unchanged for existing nonregulated GE organisms	FDA consultation completed, EPA pesticide residue tolerances, and conditional pesticide registrations being reviewed
Compliance with Other Laws		
CWW, CAA, EOs	Fully compliant	Fully compliant

Notes:

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

4 ENVIRONMENTAL CONSEQUENCES

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, namely taking no action (continuation as a regulated article) and the Preferred Alternative (a determination by the agency that DAS-40278-9 corn does not pose a plant pest risk and therefore should no longer be regulated under 7 CFR 340). Potential environmental impacts from the No Action Alternative and the Preferred Alternative for DAS-40278-9 corn are described in detail throughout this section. A cumulative effects analysis also is included for each environmental issue. In this EA, the cumulative effects analysis is focused on the incremental impacts of the Preferred Alternative taken in consideration with related activities, including past, present, and reasonably foreseeable future actions. Certain aspects of this product and its cultivation would be no different between the alternatives; those instances are described below.

4.1 SCOPE OF THE ENVIRONMENTAL ANALYSIS

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

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

Although the Preferred Alternative would allow for new plantings of DAS-40278-9 corn to occur anywhere in the U.S., APHIS is limiting the environmental analysis to those areas that currently support corn production, as identified by the NASS 2007 Census of Agriculture. The NASS found that corn currently is produced in all 48 continental states (USDA-NASS, 2010, 2011a). However, the majority of the corn produced in the U.S. is cultivated in the states of Illinois, Iowa, Indiana, the eastern portions of South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri (USDA-ERS, 2011b; USDA-NASS, 2010, 2011a). Iowa and Illinois, the two top corn producing states, typically account for slightly more than one-third of the total U.S. corn crop (USDA-ERS, 2011b).

The environmental consequences of the No Action and Preferred Alternatives are analyzed under the assumption that farmers who produce conventional corn, DAS-40278-9 corn, or corn using organic methods are using reasonable, commonly accepted best management practices specific to their agricultural corn production. However, APHIS recognizes that not all farmers follow these best management practices for corn. Thus, the analyses of the environmental effects also will include the assumption that some farmers do not follow these best management practices.

In addition, DAS recently announced the Enlist™ Weed Control System. The Enlist™ Weed Control System is based on a new formulation of 2,4-D created using a choline salt (DAS, 2011a). The new formulation of 2,4-D is chemically identified as 2,4-dichlorophenoxyacetic acid (2-hydroxyethyl) trimethylammonium salt (DAS, 2011a). DAS has submitted applications to the EPA for a label for this new 2,4-D formulation. DAS-40278-9 corn is a GE corn line that has been provided increased tolerance to treatment with phenoxy auxin herbicides and resistance to aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase (ACCase) inhibitor ("fop") herbicides (DAS, 2010). The most well-known and widely-used phenoxy auxin herbicide is 2,4-dichlorophenoxyacetic acid (2,4-D) which has been used for many decades as a pre-plant or post-emergent herbicide to control broadleaf (dicot) weeds in cornfields (USDA-APHIS, 2010). The Enlist™ Weed Control System would be another formulation of 2, 4-D that could be used for weed control pending EPA review and approval. APHIS considers the possible introduction of the Enlist™ Weed Control System and this new 2,4-D formulation as a potential future action and takes this into consideration in the cumulative effects analyses where appropriate.

In a similar regard, the Enlist™ Weed Control System also involves various stacked varieties where the tolerance to 2,4-D and Quizalofop offered by the inclusion of the *aad-1* gene is combined using traditional hybridization techniques with other herbicide-tolerant and insect-resistant corn varieties. The range of potential stacked varieties is quite broad, and includes stacked hybrids incorporating glufosinate tolerance, insect resistance, or other traits. APHIS does not have jurisdiction under the PPA and Part 340 to review such hybrids expressing stacked traits from nonregulated articles developed using conventional hybridization techniques where there is no evidence of a plant pest risk. APHIS considers the future development of these stacked hybrids a speculative event, and, accordingly, evaluates these stacked varieties only in the cumulative effects analyses where appropriate. DAS has indicated its intention to develop a stacked hybrid through conventional breeding techniques combining the 2,4-D and "fop" tolerance from DAS-40278-9 corn with glyphosate tolerance from another nonregulated corn variety (DAS, 2010, 2011d, 2011e). Issues associated with potential future stacking in which glyphosate tolerance is incorporated with the DAS-40278-9 corn are presented and discussed in the cumulative effects analyses where appropriate.

4.2 AGRICULTURAL PRODUCTION OF CORN

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

DAS' studies demonstrate that agronomic characteristics and cultivation practices required for DAS-40278-9 corn are essentially indistinguishable from practices used to grow other corn varieties, including other herbicide-tolerant varieties (DAS, 2010; USDA-APHIS, 2010). Although DAS-40278-9 corn might be expected to replace other varieties of corn currently cultivated, new acreage is not expected to be developed to accommodate the cultivation of DAS-40278-9 corn (DAS, 2010). None of the best management practices currently employed for corn production is expected to change if DAS-40278-9 corn is determined to be no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act. Accordingly, the potential impacts on agricultural production of DAS-40278-9 corn resulting from management practices associated with the No Action and Preferred Alternatives are the same.

4.2.1 Acreage and Areas of Corn Production

GE and non-GE corn varieties are continually under development. In 2011, corn was cultivated on 92.3 million acres (USDA-NASS, 2011a). Although 88% of the U.S. corn acreage is planted in GE corn, only 23% of the 2011 GE crop was herbicide-tolerant (USDA-ERS, 2011a).

Since 2006, U.S. corn planted acreage has increased as market prices have favored the planting of corn over alternative crops, such as cotton (USDA-NASS, 2010, 2011a). The increase in corn acreage has been linked to the increase in demand for corn as a feed stock for ethanol for biofuel (Hart, 2006; USDA-ERS, 2010e). The increase in acreage has involved all varieties of corn and is occurring throughout the corn growing areas (USDA-ERS, 2010e).

The USDA has estimated that over 90 million acres of corn will be required to meet the demands of ethanol, livestock, and export (Hart, 2006). The increased acreage to fulfill the added requirements for ethanol production are expected to come from the upper Midwest and eastern Great Plains areas (Hart, 2006).

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

Based on current acreage trends, conventional corn production practices with GE varieties will likely continue to increase in acreage under the No Action Alternative. Corn currently is produced commercially in 48 states (USDA-NASS, 2010, 2011a) and under the No Action Alternative, the number of states involved in corn cultivation is not expected to change.

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

DAS' studies demonstrate that agronomic characteristics and cultivation practices required for DAS-40278-9 corn are essentially indistinguishable from other corn varieties, including other herbicide-tolerant varieties (DAS, 2010; USDA-APHIS, 2010). DAS-40278-9 corn provides growers with the ability to use broad-spectrum broadleaf herbicides for weed control, particularly where glyphosate-resistant weed species have emerged (DAS, 2010). The tolerance to the AOPP "fop" herbicides provides growers with the ability to control graminaceous weeds as well (DAS, 2010).

Results of the agronomic and morphologic assessments conducted by DAS indicate that the introduced herbicide tolerance trait does not confer any competitive advantage in terms of weediness (USDA-APHIS, 2010). DAS posits that although DAS-40278-9 corn might be expected to replace other varieties of corn currently cultivated, new acreage is not expected to be developed to accommodate the cultivation of DAS-40278-9 corn (DAS, 2010). The herbicide tolerance trait is not expected to extend the range of cultivation for DAS-40278-9 corn outside of existing cultivation areas (DAS, 2010). The Preferred Alternative, i.e., a determination of nonregulated status of DAS-40278-9 corn, is therefore not expected to increase corn production, either by its availability alone or accompanied by other factors, or cause an increase in overall GE corn acreage. Potential impacts would be similar to the No Action Alternative.

Cumulative Effects: Acreage and Areas of Corn Production

Cumulative effects of a determination of nonregulated status of DAS-40278-9 corn are unlikely. Neither the No Action Alternative nor the preferred alternative are expected to directly cause an increase in agricultural acreage devoted to corn production or those corn acres devoted to GE corn cultivation. The availability of DAS-40278-9 corn would not change cultivation areas for corn production in the U.S. and there are no anticipated changes to the availability of GE and non-GE corn varieties on the market under either alternative.

4.2.2 Cropping Practices: Tillage, Crop Rotation, and Agronomic Inputs

As discussed in Subsection 2.2.2, corn cultivation requires significant management considerations regarding tillage, rotation strategy, agricultural inputs, and pesticide inputs. Decisions concerning corn agronomic practice are dependent on grower want and need, and ultimately reflective of external factors including geography, weed and disease pressure, economics of management of yield, and production system (rotation) flexibility (Farnham, 2001; Heiniger, 2000; University of Arkansas, 2008). For example, corn intended for grain is likely to require less tillage and frequency of herbicide/pesticide application relative to seed corn, due to the increased vigor and increased resistance to pests and diseases of hybrid corn varieties relative to inbred corn lines. Consequently, choice of management practice often dictates marketability of a corn product, with certain agricultural consumer sectors stipulating requirements and restrictions regarding corn production methods.

Glyphosate-tolerant crops have become adopted widely since their introduction in the mid-late 1990s for several reasons. Glyphosate works non-selectively on a wide range of plant species, is a relatively low-cost herbicide, enhances ‘no-till’ farming practices, and has minimal animal toxicological and environmental impact (USDA-APHIS, 2010). However, increased selection pressure resulting from the wide-spread adoption of glyphosate-tolerant crops, along with the reductions in the use of other herbicides and weed management practices, has resulted in both weed population shifts and growing numbers of glyphosate-resistant individuals among some weed populations (Duke and Powles, 2009; Owen, 2008). In order to combat this trend, and to avoid decreased crop yields that result from weed competition, growers must continue to adapt their weed management strategies.

The EPA’s assessment of herbicide usage in cornfields showed that the use of glyphosate increased dramatically from 1987 to 2001; whereas 2,4-D usage remained essentially unchanged during that time (Kiely et al., 2004). In 2005, 77 different herbicides were applied to 97% of corn acreage planted in 19 states representing 93% of all corn planted in the U.S. The herbicide most widely used on corn was atrazine (66%, ~57 million pounds applied), glyphosate was second (31%, ~23 million pounds), followed by metolachlor and acetochlor (both at 23%, <24 million pounds and <30 million pounds, respectively) (USDA-NASS, 2006). By comparison, 2,4-D was applied on less than 8% of 2005 corn acreage (~2 million pounds applied) (USDA-NASS, 2006). The highest recorded use of 2,4-D was in 1994 when 14% of U.S. corn acres were treated with 2,4-D (USDA-NASS, 2011c). These data demonstrate that there is a history of successful and effective use of 2,4-D as an herbicide, both generally and specifically on corn crops, to eliminate weed species.

Crop rotation in corn is conducted to optimize soil nutrition and fertility, reduce pathogen loads, and control corn pests (IPM, 2004, 2007). Crop rotation practices have been described previously in Section 2.

No Action: Cropping Practices: Tillage, Crop Rotation, and Agronomic Inputs

Under the No Action Alternative, corn cropping practices are expected to remain as practiced today by the farming community. Growers will continue to have access to existing nonregulated GE corn varieties (both lepidopteran-resistant and herbicide-tolerant), as well as conventional corn varieties. Growers likely will continue to experience the continued emergence of glyphosate-resistant weeds, requiring modifications of crop management practices to address these weeds. These changes may involve all of the techniques identified by Benbrook (2009), including the use of alternative herbicides for weed control as well as mechanical cultivation practices.

Current corn management practices are likely to continue under the No Action Alternative. Growers will continue to choose certain pesticides based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Farnham, 2001; Heiniger, 2000; University of Arkansas, 2008). No-till production of corn will continue to increase under the No Action Alternative, effectively mitigating the negative impacts of conventional tillage and associated soil erosion (Fawcett and Caruana, 2001). Agronomic practices involving the application of external inputs, such as herbicides, pesticides, and moisture, will remain as it is practiced today. As an example of the pesticides used during the production of field corn, the Pesticide Action Network has an online database, including a detailed description of all the pesticides used in corn agriculture in California (Kegley et al., 2011). It lists the top 50 pesticides (e.g., herbicides, insecticides, fungicides) used in California corn production. Any effects due to crop rotation, tillage, and pesticide use in the agricultural production of seed corn and commercial corn will remain the same under the No Action Alternative. Rotation strategies for corn under the No Action Alternative will continue as practiced today, with market demand and available technology strongly influencing corn rotation practices.

Preferred Alternative: Cropping Practices: Tillage, Crop Rotation, and Agronomic Inputs

A determination of nonregulated status of DAS-40278-9 corn is not expected to result in changes in the current corn cropping practices, with the exception of potential changes in the use of certain herbicides. APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to affect changes in crop rotation, tillage, or agronomic inputs. DAS' studies demonstrate DAS-40278-9 corn is essentially indistinguishable from other corn varieties used in terms of agronomic characteristics and cultivation practices (DAS, 2010; USDA-APHIS, 2010).

Although 2,4-D is already used on corn, its use is limited beyond early seedling stages (Wright et al., 2010). Applications of 2,4-D as a post-emergent herbicide at later growth stages in conventional corn can cause significant malformations (Wright et al., 2010). A specimen label for Nufarm's Weedar 64 formulation of the herbicide 2,4-D is provided in Appendix B. DAS-40278-9 corn is tolerant to the application of 2,4-D as a pre-emergent herbicide and for up to two post-emergent applications (DAS, 2011a). The total volume of 2,4-D applied to corn would likely increase in response to the introduction and cultivation of this variety. Table 4-1 compares the current use patterns for 2,4-D on field corn and popcorn with proposed use patterns for 2,4-D on DAS-40278-9 corn (a popcorn and sweet corn use is not being sought by DAS).

Table 4-1: Comparison of Current and Proposed Application Rates for 2,4-D on Corn

Crop Stage	Conventional Field Corn and Popcorn		Proposed New Use on DAS-40278-9 Corn	
	Maximum Application Rate (lb/acre)[1,2]	Directions and Timing	Maximum Application Rate (lb/acre)[1,2]	Directions and Timing
Pre-plant or Pre-emergence	1.0	Apply before corn emerges to control emerged broadleaf weed seedlings or existing cover crops	1.0	Apply before corn emerges to control emerged broadleaf weed seedlings or existing cover crops
Post-emergence	0.5	Apply when weeds are small and corn is less than 8 inches tall (to top of canopy). When corn is over 8 inches tall, use drop nozzles and keep spray off foliage.	0.5 to 1.0	Apply after crop and weed emergence but before corn exceeds growth stage V8 or 48" in height, whichever occurs first. Make 1 to 2 applications with a minimum of 12 days between applications.
Pre-harvest	1.5	Apply after hard dough (or at denting) stage.	---	---
Total Annual Maximum Application	3.0	---	3.0	---

Source: (DAS, 2011e)
Notes:
1. All values expressed as acid equivalents.
2. 1 lb/acre is the equivalent of 1,120 g/hectare.

Although the per acre volume of 2,4-D will not increase over current label rates, the total volume of 2,4-D applied to corn would potentially increase for those DAS-40278-9 corn varieties. Proposed application rates for this new use on this corn variety are up to 1,120 g ae/ha (1 lb/acre) as a pre-emergent herbicide and between 560 and 1,120 g ae/ha (0.5 to 1.0 lbs/acre; up to two applications a minimum of 12-days apart during the first 3-5 weeks before the corn reaches 6-8 inches in height and again up to the V8 (48-inch) stage of corn) as a post-emergent herbicide. These application rates are based on the currently approved rates for field corn and popcorn, which establish a maximum-per-year application rate of 3 lbs/acre, and a maximum single application rate of 1.5 lbs/acre (DAS, 2011e).

DAS-40278-9 corn, if removed from APHIS regulation under Part 340, would be the first nonregulated GE corn variety with tolerance of the "fop" class of herbicides and potentially be marketed as Quizalofop-tolerant. As Quizalofop is not currently registered for use as a post-emergent herbicide on corn, this is a proposed new use[1] (DAS, 2010). The petitioner has indicated that "fop" herbicides could be used to maintain seed purity in DAS-40278-9 corn breeding nurseries, hybrid production fields, and generally for the control of grass weeds in corn. Quizalofop is currently registered for use on canola, crambe, cotton, dry beans, lentils, mint, dry and succulent peas, snap beans, soybeans, and sugar beets (DAS, 2011e). A sample label for a current use of Quizalofop, DuPont's Assure® II, is provided in Appendix C. Table 4-2 provides a summary of the current labeled uses of Quizalofop in comparison with proposed application rates and directions for use in Corn.

Table 4-2: Comparison of Current and Proposed Application Rates for Quizalofop

	Current Use Pattern for Quizalofop on Soybeans and Cotton		Proposed New Use on DAS-40278-9 Corn	
Crop Stage	**Maximum Application Rate (lb/acre)[1,2]**	**Directions and Timing**	**Maximum Application Rate (lb/acre)[1,2]**	**Directions and Timing**
Post-emergence	0.082	Apply 0.034 to 0.082 lb/acre per application. Do not exceed a total of 0.124 lb/acre per season.	0.034 to 0.082	Apply 0.034 to 0.082 lb/acre per application from V2 – V6 Growth stages. Do not make more than 2 applications. Do not exceed a total of 0.082 lb/acre per season. Do not apply later than V6 growth stage.
Total Annual Maximum Application	0.124	---	0.082	---

Source: (DAS, 2011e)
Notes:
1. Active ingredient.
2. 1 lb/acre is the equivalent of 1,120 g/hectare.

In current registered uses, the EPA has approved single application rates ranging from 0.034 to 0.082 pounds ai/acre (38 g ai/ha to 92 g ai/ha), depending on the weed species, with the highest

[1] As required under FIFRA, metabolism and residue data, along with proposed labeling changes, will be submitted to the EPA for the use of "fop"-type herbicides (specifically Quizalofop) in DAS-40278-9 Cornfields (page 18 of the Petition). Under FIFRA, it is unlawful to use an herbicide "in a manner inconsistent with its labeling" without an experimental use permit issued (7 U.S.C. 136j). Quizalofop is currently under registration review (http://www.epa.gov/oppsrrd1/registration_review/) by the EPA with a Final Decision expected sometime in 2013 (EPA-HQ-OPP-2007-1089 at http://www.regulations.gov, accessed 3/2011).

maximum seasonal application rate being 0.206 pounds ai/acre (231 g ai/ha) for weed control in mint (DAS, 2011e). DAS proposes a maximum single application rate of 0.082 lb ai/acre corn (DAS, 2011e). DAS-40278-9 corn has proven tolerant to Quizalofop post-emergent application rates of up to 184 g ai/ha (0.164 lbs ai/acre) in field trials (DAS, 2011a). The proposed maximum application rate is also the seasonal maximum application rate (DAS, 2011e). This maximum application rate is less than that currently approved for use of Quizalofop for control of grassy weeds in soybeans and cotton, where a seasonal maximum application rate of 139 g ai/ha (0.124 lb ai/acre) is approved (DAS, 2011e). A determination of nonregulated status of DAS-40278-9 corn, with the attendant new use of Quizalofop on corn, has the potential to result in an increase in the annual application of Quizalofop.

Although use trends in the six most frequently applied herbicides in 2005 demonstrate relatively stable total herbicide use, the applications of both glyphosate and mesotrion have increased progressively since 2000 (see Figure 2-1 in Subsection 2.2.2.3). The 2,4-D and Quizalofop tolerance in DAS-40278-9 corn would provide the grower with two options to manage glyphosate-resistant weeds. The transition to a 2,4-D- and/or Quizalofop-tolerant corn variety could reduce applications of other herbicides needed to manage glyphosate-resistant weeds — a potentially valuable trait in those corn cultivation areas where herbicide-resistant weeds have emerged. This could allow for improved corn crop yields when grown in the vicinity of glyphosate-resistant weeds, particularly with anticipated labeling changes allowing the expanded application of 2,4-D at a time period critical for controlling weeds that compete with corn in conjunction with labeling changes allowing over-the-top post-emergent use of Quizalofop (see DAS, 2010 at section IX.D.2. page 108 and section IX.E.2., page 113). This practice of using herbicides with alternative modes of action is expected to potentially diminish the populations of glyphosate-resistant weeds (DAS, 2010; Dill et al., 2008; Duke and Powles, 2008, 2009; Owen, 2008). Applications of herbicides with mixed modes of action also are expected to prolong the development of new herbicide-resistant weed populations (Duke and Powles, 2009; Owen, 2008).

Cumulative Effects: Cropping Practices: Tillage, Crop Rotation, and Agronomic Inputs

A determination of nonregulated status of DAS-40278-9 corn is not expected to result in changes in the current corn cropping practices, with the exception of potential changes in the use of certain herbicides. APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to affect changes in tillage, crop rotation, or agronomic inputs. DAS' studies demonstrate DAS-40278-9 corn is essentially indistinguishable from other corn varieties used in terms of agronomic characteristics and cultivation practices (DAS, 2010).

As noted above, the cultivation of DAS-40278-9 corn likely would result in an increase in the use of 2,4-D in corn, as well as the new use of Quizalofop. It is expected that the increase in use of these two herbicides would coincide with the concomitant reduction in the use of other herbicides. This is especially the case in those fields where glyphosate-resistant weeds have emerged and alternative herbicides have been employed to manage those weedy species.

The herbicide 2,4-D is one of the most heavily used herbicides in the U.S. and is currently registered for use by the EPA on corn. The proposed application rates of 2,4-D and total maximum annual application for use on DAS-40278-9 corn are consistent with the current rates. Quizalofop is already used to control annual and perennial grass weeds in potatoes, soybeans, sugar beets, peanuts, oilseed rape, sunflowers, vegetables, cotton, and flax (see DuPont, 2010). A determination of nonregulated status of DAS-40278-9 corn and the attendant new label use would provide growers with the option to use this “fop” herbicide on corn to control grass species which have developed resistance to other herbicides, including glyphosate. The application of Quizalofop to corn is a new use. The proposed application rates are very similar to those currently approved for use on soybeans and cotton, and the total annual maximum application is less than that currently approved for those two crops. When used in accordance with the EPA label restrictions, the use of an EPA registered herbicide is anticipated to present minimal risks to human health and the environment.

DAS has recently announced that the DAS-40278-9 corn would be marketed under the Enlist™ Weed Control System (DAS, 2011e). The Enlist™ Weed Control System involves a new formulation of 2,4-D based on a choline salt (DAS, 2011e). This new formulation is chemically identified as 2,4-dichlorophenoxyacetic acid (2-hydroxyethyl) trimethylammonium salt (DAS, 2011e). This choline salt formulation is reported to present substantially lower volatility, improved stability at low temperatures, and lower odors than the amine and ester formulations (DAS, 2011e). DAS has submitted a new label application to the EPA for the choline salt formulation of 2,4-D (DAS, 2011e). Approved label application rates have not been published for this new formulation. APHIS assumes, for the purposes of this analysis, that if and when this new formulation of 2,4-D becomes available, that this new formulation of the herbicide will be used by growers consistent with the EPA label application rate. Similar to other EPA registered herbicides, when used in accordance with the EPA label restrictions this new formulation of 2,4-D is anticipated to present minimal risks to human health and the environment. DAS has indicated its intention to develop a “stacked” hybrid through conventional breeding techniques (DAS, 2010, 2011d, 2011e). In this process, the 2,4-D and “fop” tolerance from DAS-40278-9 corn will be combined, using conventional breeding techniques, with glyphosate tolerance from another nonregulated corn variety. Nonregulated GE glyphosate-tolerant (e.g., Roundup Ready®) crop varieties have been in the market since 1993, when glyphosate-tolerant cotton was introduced. The first Roundup Ready® corn was introduced in 1996 when Monsanto’s MON 802 Glyphosate-Tolerant and European Corn Borer-Resistant corn was determined to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (see APHIS Petition File 96-317-01p, at http://www.aphis.usda.gov/biotechnology/not_reg.html).

The cultivation of a stacked variety expressing both insect-resistant and other herbicide-tolerant traits is consistent with the current crop cultivation practices (DAS, 2010, 2011a, 2011e). The stacking of beneficial traits represents an increasing proportion of commercially-available corn varieties (see Table 2-1 in Subsection 2.2.2.3). Data presented by the NASS suggests that corn varieties presenting stacked traits are increasing in popularity, with approximately 47% of the total corn acreage in 2010 cultivated in stacked varieties (USDA-ERS, 2010a). Consequently, overall impacts to cropping practices associated with the adoption of stacked varieties and associated current corn pesticide use practices are likely to be minimal.

The choline salt formulation of 2,4-D is also reported to resolve many of the chemical incompatibilities currently associated with the mixing of 2,4-D amine and glyphosate potassium salts in tank mixes (DAS, 2011e). DAS has announced that a premix of the 2,4-D choline salt and glyphosate would be marketed as part of the Enlist™ Weed Control System (DAS, 2011e). Applications for new labels have been submitted to the EPA for this premix (DAS, 2011e). The composition of this premix, and application rates are not yet published. APHIS assumes, for the purposes of this analysis, that if and when the new premix becomes available, that the mixture of herbicides will be used by growers consistent with the EPA label application rate. Similar to other EPA registered herbicides, when used in accordance with the EPA label restrictions this premix is anticipated to present minimal risks to human health and the environment.

The future development and cultivation of a stacked corn variety presenting tolerance to 2,4-D and glyphosate may result in an increase in the acres of corn being treated with glyphosate. Glyphosate use on non-Roundup Ready® corn is limited to pre-emergent stages. On Roundup Ready® varieties, glyphosate is applied in many formulations, in application rates ranging from 0.56 to 1.12 lb ae/acre (Loux et al., 2011). Glyphosate is also commonly used in conjunction with many other herbicides as a tank mix for both pre-plant/pre-emergence weed control up through the 12-leaf stage or until the corn reaches a height of 30 inches (see, e.g., Loux et al., 2011). Tank mixes of glyphosate and 2,4-D are already in use for control of mixed weeds in the pre-plant stage in no-tillage weed control programs (Loux et al., 2011).

The potential effects from the cultivation of glyphosate-tolerant crops, with a corresponding analysis of the implications of the use of glyphosate, have been thoroughly evaluated in other APHIS EAs since the 1993 introduction of the first glyphosate-tolerant crop product. (See: www.APHIS.USDA.gov/biotechnology/not_reg.htm.) Several of these evaluations included crops expressing tolerance to multiple herbicides. Specific crop examples include:

- Sugar Beet, 2011. Monsanto and KWS SAAT AG Glyphosate-tolerant Sugar Beet (Petition No. 03-023-01p).
- Soybean, 2011. Monsanto Improved Fatty Acid Profile Soybean (which includes glyphosate tolerance) (Petition No. 09-201-01p).
- Alfalfa, 2011. Monsanto Glyphosate-tolerant Alfalfa (Petition 04-110-01p).
- Corn, 2009. Pioneer Glyphosate and Imadazolinone-tolerant Corn (Petition 07-152-01p).
- Cotton, 2009. Bayer Crop Science Glyphosate-tolerant Cotton (Petition 06-332-01p).
- Soybean, 2008. Pioneer Glyphosate and Acetolactate Synthase-tolerant Soybean (Petition No. 06-271-01p).
- Soybean, 2007. Monsanto Glyphosate-tolerant Soybean (Petition 06-178-01p).
- Cotton, 2005. Monsanto Glyphosate-tolerant Cotton (Petition 04-086-01p).
- Rapeseed 2001. Monsanto Glyphosate-tolerant Rapeseed (Petition 01-324-01p).
- Corn, 2000. Monsanto Glyphosate-tolerant Corn (Petitions No. 97-099-01p and 00-011-01p).
- Rapeseed 1998. Monsanto Glyphosate-tolerant Rapeseed (Petition 98-216-01p).
- Sugar Beet, 1998. Novartis Seeds and Monsanto Glyphosate-tolerant Sugar Beet (Petition No. 98-173-01p).
- Corn, 1997. Monsanto Glyphosate-tolerant Corn. (Petition No. 97-099-01p).
- Corn, 1996. Monsanto Glyphosate-tolerant and European Corn Borer-resistant Corn. (Petition No. 96-317-01p).

- Cotton, 1995. Monsanto Glyphosate-tolerant Cotton (Petition 95-045-01p).
- Soybean, 1993. Monsanto Glyphosate-tolerant Soybean (petition 93-258-01p).

DAS has submitted an application to the EPA for a new tank mix combination of 2,4-D and glyphosate (DAS, 2010). As with the analysis of the potential impacts of the use of 2,4-D and Quizalofop discussed above, the application of glyphosate and this new tank mix would be subject to similar EPA label use restrictions and best practices. Similar to other EPA registered herbicides, when used in accordance with the EPA label restrictions this new tank mix combination is anticipated to present minimal risks to human health and the environment.

Other stacked varieties might also be developed at a later time which also derive tolerance to 2,4-D and Quizalofop from the DAS-40278-9 corn. Such varieties might express tolerance to other herbicides, resistance to certain insect pests, or a combination of several traits. The development of such stacked hybrids is a business decision, driven by market demand and grower acceptance. Additionally, APHIS lacks the jurisdiction to evaluate stacked hybrids created using conventional hybridization techniques and nonregulated crop varieties. Based on these factors, further analysis of other stacked varieties is outside the scope of this EA.

4.2.3 Seed Production

As discussed in Subsection 2.2.3, corn seed production is managed through the AOSCA standard procedures to preclude gene flow between species and varieties (Wozniak, 2002). Common practices include: 1) maintaining isolation distances to prevent pollen movement from other corn sources; 2) planting border or barrier rows to intercept pollen; 3) employing natural barriers to pollen, including hand pollination and detasseling of the corn; and 4) field monitoring for off-types, other crops, weeds, and disease. Subsection 4.4.5 – Gene Movement, presents an analysis of the potential vertical gene flow from DAS-40278-9 corn to related corn varieties.

<u>No Action: Seed Production</u>

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

<u>Preferred Alternative: Seed Production</u>

The production of corn seed for DAS-40278-9 corn is expected to be conducted consistent with standard seed production practices; no changes to seed production practices are required to cultivate DAS-40278-9 corn. Based on the data provided by DAS for DAS-40278-9 corn (DAS, 2010), as well as previous experience with other herbicide-tolerant corn varieties that have been adopted by growers since their introduction in 1996 (USDA-ERS, 2010e), APHIS has concluded that the availability of DAS-40278-9 corn would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE seed production (USDA-APHIS, 2010). A determination of nonregulated status of DAS-40278-9 corn would not require a change to seed production practices.

Cumulative Effects: Seed Production

Based on current acreage trends, GE corn varieties would likely continue to dominate corn production. To the extent that growers see value in the traits offered by DAS-40278-9 corn, this new variety may replace existing corn varieties, both conventional as well as GE. The availability of DAS-40278-9 corn is not anticipated to change cultivation areas for corn production in the U.S. Because changes in the agronomic practices and locations for corn seed production using DAS-40278-9 corn are not expected, no cumulative effects have been identified for seed production.

4.2.4 Organic Farming

Organic production plans prepared pursuant to the NOP include practical methods to protect organically-produced crops from accidental contamination with GE materials. Contamination of organic corn with GE corn varieties is a concern because corn naturally cross-pollinates (Coulter et al., 2010). Typically, organic growers use more than one method to prevent unwanted material from entering their fields including: isolation of the farm; physical barriers or buffer zones between organic production and non-organic production; planting border or barrier rows to intercept pollen; changing planting schedules to ensure flowering at different times; and formal communications between neighboring farms (Baier, 2008; NCAT, 2003; Roth, 2011). These practices follow the same system utilized for the cultivation of Certified seed under the AOSCA procedures. During the cultivation period, contamination is managed by understanding corn pollen dispersal and maintaining adequate distances between fields (Mallory-Smith and Sanchez-Olguin, 2010; Thomison, 2009). A minimum isolation distance of 250 feet between varieties is recommended; whereas, 700 feet is preferred for complete isolation (Diver et al., 2008).

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

No Action: Organic Farming

Current availability of seed for conventional (both GE and non-GE) corn varieties, and those corn varieties that are developed for organic production, is expected to remain the same under the No Action Alternative. Commercial production of conventional and organic corn is not expected to change and likely will remain the same under the No Action Alternative. Planting and production of GE, non-GE, and organic corn will continue to fluctuate with market demands, as it has over the last 10 years, and these markets are likely to continue to fluctuate under the No Action Alternative (USDA-ERS, 2011d, 2011e).

Preferred Alternative: Organic Farming

Transgenic corn lines including those that are herbicide-tolerant are already in use by farmers. DAS-40278-9 corn should not present any new and different issues and impacts for organic and other specialty corn producers and consumers.

Organic producers employ a variety of measures to manage identity and preserve the integrity of organic production systems (NCAT, 2003). The trend in the cultivation of GE corn, non-GE, and organic corn varieties, and the corresponding production systems to maintain varietal integrity, are likely to remain the same as the No Action Alternative.

According to the petition, agronomic trials conducted in 2008 in a variety of locations in the U.S. demonstrated that DAS-40278-9 corn is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterpart (USDA-APHIS, 2010). No differences were observed in pollen diameter, weight, and viability. Therefore, DAS-40278-9 corn is expected to present a no greater risk of cross-pollination than that of existing corn cultivars. The practices currently employed to preserve and maintain purity of organic production systems would not be required to change to accommodate the production of DAS-40278-9 corn.

Historically, organic corn production represents a small percentage (approximately, 0.2%) of total U.S. corn acreage (USDA-ERS, 2011e). It likely would remain small regardless of whether new varieties of GE or non-GE corn varieties, including DAS-40278-9 corn, become available for commercial corn production.

Accordingly, a determination of nonregulated status of DAS-40278-9 corn is not expected to have a significant impact on organic corn production.

Cumulative Effects: Organic Farming

A determination of nonregulated status of DAS-40278-9 corn is not expected to change the market demands for GE corn or corn produced using organic methods. A determination of nonregulated status to DAS-40278-9 corn would add another GE corn variety to the conventional corn market. Data from USDA's Economic Research service indicates that in 2011, 88 percent of all corn grown in the U.S. was GE varieties (USDA-ERS, 2011a). Based upon recent trend information, adding GE varieties to the market is not related to the ability of organic production systems to maintain their market share. Since 1994, 25 GE corn events or lines have been determined by APHIS to be no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act. Between 2000 and 2008, the total acreage associated with the organic production of corn increased from 78,000 to 194,000 acres (USDA-ERS, 2011e).

4.2.5 Specialty Corn Production

Specialty crop growers employ practices and standards for seed production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with conventional or GE crops (Bradford, 2006). These management practices include maintaining isolation distances to prevent pollen movement from other corn sources, planting border or barrier rows to intercept pollen, changing planting schedules to ensure flowering at different times, and employing natural barriers to pollen (Bradford, 2006; NCAT, 2003; Roth, 2011; Thomison, 2009; Wozniak, 2002). These management practices allow the grower to meet standards for the production of specialty crop seed, maintain genetic purity, and protect the genetic diversity of corn (Bradford, 2006).

No Action: Specialty Systems

Current availability of seed for specialty corn varieties are expected to remain the same under the No Action Alternative.

Preferred Alternative: Specialty Systems

As noted in the discussion of Seed Production, no changes in the production or cultivation of specialty corn are required to accommodate DAS-40278-9 corn.

Specialty system farmers, or other farmers who choose to plant nontransgenic varieties or sell nontransgenic seed, are unlikely to be impacted by the expected commercial use of DAS-40278-9 corn. Transgenic corn lines including those that express herbicide tolerance are already in use by farmers. DAS-40278-9 corn should not present any new and different issues and impacts for specialty corn producers and consumers.

According to the petition, agronomic trials conducted between 2008 in a variety of locations in the U.S. demonstrated that DAS-40278-9 corn is not significantly different in plant growth, yield, and reproductive capacity from its nontransgenic counterpart (USDA-APHIS, 2010). No differences were observed in pollen diameter, weight, and viability. Therefore, DAS-40278-9 corn is expected to present a similar risk of cross-pollination as existing corn cultivars including other GE corn varieties. The practices currently employed to preserve and maintain purity of specialty corn production systems would not be required to change to accommodate the production of DAS-40278-9 corn. A determination of nonregulated status of DAS-40278-9 corn under the Preferred Alternative would not change the availability and genetic purity of seed for specialty corn varieties. Conventional management practices and procedures, as described previously for corn seed production, proper seed handling, protection of wild relatives of corn, and organic corn farming, are in place to maintain the genetic diversity of corn. Corn growers have utilized these methods effectively to meet the standards for the production of specialty crop seed. Impacts would be similar to the No Action Alternative.

Cumulative Effects: Specialty Systems

A determination of nonregulated status of DAS-40278-9 corn is not expected to change the market demands for GE corn or corn produced using specialty systems. A determination of nonregulated status of DAS-40278-9 corn would add another GE corn variety to the corn market. Based on demonstrated agronomic characteristics and cultivation practices, and because the market share of specialty corn varieties is unlikely to change by the introduction of DAS-40278-9 corn, APHIS has determined that there are no past, present, or reasonably foreseeable changes that would impact specialty corn producers and consumers.

4.3 PHYSICAL ENVIRONMENT

4.3.1 Water Resources

Corn is a water sensitive crop with a low tolerance for drought, although the stress response and yield loss depends on the stage of the corn growth (Farahani and Smith, 2011). Corn requires approximately 4,000 gallons through the growing season to produce 1 bushel of grain (NCGA, 2007a). The water demand is variable over the growing season. The greatest water demand occurs during the silk production stage in mid-season and is estimated at approximately two inches of water per week (or 0.3 inches per day) (Farahani and Smith, 2011; Heiniger, 2000).

In 2011, GE corn occupied 88% of the corn acreage; herbicide-tolerant corn was cultivated on 23% of the total acreage (USDA-ERS, 2011a). The introduction of GE herbicide-tolerant corn has resulted in an increase in the adoption of conservation practices such as no-till and low-till, as growers turn to herbicides as part of the initial field cultivation (Towery and Werblow, 2010; USDA-NRCS, 2006b). Intensive monitoring of surface water and groundwater proximate to agricultural fields has demonstrated that conservation tillage practices can reduce runoff from agricultural lands, decreasing non-point source pollution of suspended sediment, fertilizer, and pesticides (University of Tennessee Agricultural Extension Service, 2010). Better nutrient management, including precision farming and variable rate applications, are ensuring inputs are used by the crop and are not entering ground or surface waters (US-EPA, 2005b; USDA-NRCS).

No Action: Water Resources

Under the No Action Alternative, current land acreage and agronomic practices, including irrigation, tillage, and nutrient management associated with corn production would not be expected to change. No expected changes to water use associated with corn production is expected for this alternative.

Preferred Alternative: Water Resources

No differences in morphological characteristics and agronomic requirements were found between DAS-40278-9 corn and hybrid controls (DAS, 2010; USDA-APHIS, 2010). Cultivation of DAS-40278-9 corn would not change cultivation practices for corn production. Also, as previously discussed, the use of DAS-40278-9 corn would not increase the total acres and range of U.S. corn production areas. Therefore, a determination of nonregulated status of DAS-40278-9 corn is unlikely to change the current use of irrigation practices in commercial corn production. Because the DAS-40278-9 corn is expected to simply replace GE and non-GE corn varieties already in use, the consequences of the Preferred Action Alternative on water use are the same as the No Action Alternative with the exception of the potential change in use of 2,4-D and the new use of Quizalofop.

As discussed in Subsection 4.2.2, the herbicide 2,4-D is already approved for use on corn, and the proposed application rates and total maximum annual application for use on DAS-40278-9 corn are consistent with the current rates. The herbicide 2,4-D is approved for aquatic applications to control aquatic weeds in food use areas (i.e., rice and fish farms) as well as industrial areas (i.e., drainage systems) (Nufarm, 2009; US-EPA, 2005c). The half-life (the time it takes for half of the compound to dissipate) of 2,4-D in aerobic aquatic environments is approximately 45 days and the half-life of 2,4-D esters in normal agricultural soil and natural water conditions are less than 3 days (US-EPA, 2005c, 2009b). When used for aquatic treatments (direct application to water for aquatic vegetation control), 2,4-D has a half-life of between 3.2 days and 27.8 days (US-EPA, 2005c). Application requirements as specified on the label have been incorporated to minimize the possibility that drinking water would be impacted by the use of 2,4-D. EPA label application rates also are intended to minimize groundwater contamination by 2,4-D and its metabolites (US-EPA, 2005c). The EPA has stated that the 2,4-D acid and amine salts are practically non-toxic to freshwater or marine fish (US-EPA, 2005c).

The determination of nonregulated status of DAS-40278-9 corn has the potential to result in the application of Quizalofop to corn. This is a new use of this herbicide. Depending upon grower adoption of this herbicide, the total volume of Quizalofop applied has the potential to increase. Quizalofop has been evaluated for its persistence in water and groundwater. Quizalofop has been noted to degrade rapidly in water/sediment systems (from several hours to one or two days, depending upon pH of the receiving water) (US-EPA, 2007b). Quizalofop has not been shown to bioaccumulate in fish. Quizalofop has a limited potential for migration to and persistence in groundwater (EFSA, 2008; US-EPA, 2007b).

The EPA has considered the potential impacts to water resources from the agricultural applications of 2,4-D and Quizalofop, and has included label use restrictions and handling guidance intended to prevent impacts to water. When used in accordance with these EPA label restrictions, the impacts to water resources are expected to be the same as those under the No Action Alternative where these two herbicides are already used.

Cumulative Effects: Water Resources

Except for the potential future changes in herbicide use associated with stacking and new product formulations, no cumulative effects on water use have been identified for a determination of nonregulated status of DAS-40278-9 corn. A determination of nonregulated status of DAS-40278-9 corn is not expected to change the water use and irrigation practices used in commercial corn production.

As noted previously, DAS is developing a new formulation of 2,4-D based on a choline salt. DAS has submitted an application with the EPA for a label for this new formulation. Technical information on the 2,4-D choline salt has not been made publicly available. If EPA approves this new label request, DAS intends to market this 2,4-D choline salt formulation as part of the Enlist™ Weed Control System. For the purposes of this assessment, similar to other EPA label restrictions placed on the use of herbicides, APHIS assumes that the EPA approved label for the new 2,4-D formulation would provide appropriate controls for the use of this product on corn so as to protect water resources.

The Enlist™ Weed Control System also involves the stacking of the DAS-40289-9 Corn with other nonregulated corn varieties, including varieties expressing tolerance to the herbicide glyphosate. Some glyphosate-tolerant crops, also identified as "Roundup Ready®" have been determined by APHIS to have nonregulated status since 1993 when glyphosate-tolerant cotton was introduced. Glyphosate-tolerant corn was introduced in 1996 (see http://www.aphis.usda.gov/biotechnology/not_reg.html). As noted in Subsection 4.2.2, the application and use of glyphosate on Roundup Ready® crops has been well-described and will not be further addressed here. Glyphosate is already used in corn in both conventional and Roundup Ready® varieties. Glyphosate-tolerant crops have been identified as facilitating the adoption of conservation tillage practices (DAS, 2011d). The stacking of DAS-40278-9 corn with a glyphosate-tolerant variety complements the glyphosate-tolerant crop by controlling glyphosate-resistant and inherently hard-to-control weeds without additional tillage (DAS, 2011d; Towery and Werblow, 2010). As glyphosate-resistant weed varieties have emerged, growers have returned to increased tillage as one of the weed management practices. As discussed in Soils, in Subsections 2.3.2 and corresponding Subsection 4.3.2, the adoption of conservation tillage has resulted in substantial improvements to soil health, and correspondingly, water quality, in those areas where the practice has been adopted (Towery and Werblow, 2010). The cultivation of a corn variety stacking multiple modes of action, in this case, tolerance to 2,4-D and Quizalofop, along with glyphosate tolerance, provides growers with an opportunity to stay with their conservation tillage strategies. Maintaining conservation tillage will have a positive impact on water quality.

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

The potential future cultivation of a stacked variety and the associated use of glyphosate in addition to 2,4-D is not expected to result in cumulative effects to water resources.

Based on these findings, and because the amount of corn grown in the U.S. is unlikely to change by the introduction of DAS-40278-9 corn, APHIS has determined that there are no cumulative impacts to water resources.

4.3.2 Soil

This subsection discusses the potential consequences of the No Action and the Preferred Alternatives on soil. Conservation tillage historically has not been the major tillage system in corn production. In 1996, over 60% of the corn acreage was either conventional (30%) or reduced tillage (32%), with the balance split between mulch and no-till systems (Christensen, 2002). Increases in total acres dedicated to conservation tillage have been attributed to an increased use of GE crops, including corn, reducing the need for mechanical weed control (Towery and Werblow, 2010; USDA-NRCS, 2006b, 2010). The USDA NRCS has identified significant reductions in the loss of soil from croplands in the U.S., finding that total soil loss on highly erodible croplands and non-highly erodible cropland decreased by 39.2% from 1982 to 2003 (USDA-NRCS, 2006b).

Additional soil quality benefits from adoption of GE corn may be realized by reducing the risks associated with environmental spills or misapplications of chemical herbicides and insecticides to the soil, and reductions in the frequency with which these products must be applied.

<u>No Action: Soil</u>

Land acreage and agronomic practices associated with traditional and existing nonregulated GE corn production are not expected to change in response to the No Action Alternative.

Current agronomic practices associated with corn production including tillage, cultivation, applications of pesticides and fertilizer, and the use of agricultural equipment are not expected to change under the No Action Alternative. To the extent that currently available GE corn varieties may result in the grower's adoption of conservation tillage, soils would be positively affected.

Preferred Alternative: Soil

With the exception of the potential changes in herbicide use as noted below, no changes to agronomic practices typically applied in the cultivation of corn, including both commercially available GE corn as well as conventional varieties, are required for DAS-40278-9 corn. DAS' field trial and laboratory analyses demonstrated that the agronomic performance of DAS-40278-9 corn was functionally identical to its non-transgenic hybrids used as controls in the tests (DAS, 2010; USDA-APHIS, 2010). Cultivation of DAS-40278-9 corn did not require increases in applications of fertilizers and pesticides or changes in cultivation, planting, harvesting, and volunteer control (DAS, 2010).

DAS-40278-9 corn offers growers the option to apply herbicides with different modes of action to corn for weed control. In this case, it is expected that 2,4-D and Quizalofop would be applied as herbicides of choice on DAS-40278-9 corn. Corn varieties expressing tolerance to several herbicides with multiple modes of action have been designed to provide the growers with options to manage herbicide-resistant weeds (DAS, 2011a, 2011e).

As discussed in Subsection 2.2.2 and corresponding Subsection 4.2.2, the determination of nonregulated status of DAS-40278-9 corn has the potential to result in a change in the application of 2,4-D to corn, and the potential new application of Quizalofop to soil. The herbicide 2,4-D is already labeled for use on corn, and the proposed label changes to provide for the new use slightly modify the application sequence, although the total annual maximum volume applied per field does not change. The application of Quizalofop to corn is a new use. The proposed application rates are very similar to those currently approved for use on soybeans and cotton, and the total annual maximum application is less than that currently approved for those two crops.

The active ingredient 2,4-D has been shown to degrade rapidly in soil across a wide range of soil and climatic conditions, with a soil half-life ranging from 1.6 to 16 days (US-EPA, 2005c). The herbicide 2,4-D is available in many different formulations, including esters, salts, and amine formulations, each of which are derivatives of the herbicidally active acid parent compound, 2,4-dichlorophenoxyacetic acid (Hager and Sprague, 2000). The various salt, ester, or amine formulations have been developed to enhance plant absorption, or otherwise facilitate herbicide delivery in the field (Hager and Sprague, 2000).

When used in accordance with the EPA label, 2,4-D accumulation in soil has not been shown to be significant. The degradation products of 2,4-D are 1,2,4-benzenetriol, 2,4-dichlorophenol (2,4-DCP), 2,4-dichloroanisole (2,4-DCA), 4-chlorophenol, chlorohydroquinone (CHQ), volatile organics, bound residues, and carbon dioxide (US-EPA, 2005c). The EPA has determined that residues other than 2,4-D are not of risk concern due to low occurrence under environmental conditions, comparatively low toxicity, or a combination thereof (US-EPA, 2005c).

The herbicide Quizalofop-P-ethyl (Quizalofop) is the pesticidally active enantiomer of Quizalofop ethyl (DuPont, 2010; US-EPA, 2007b). Quizalofop is anticipated to degrade quickly in soils, with a half-life of one day (US-EPA, 2007b). The degradation products of Quizalofop are Quizalofop acid and phenolic compounds (US-EPA, 2007b). Quizalofop acid was included in EPA's tolerance determinations, and its health effects have been determined to be equivalent to or less than the parent compound (US-EPA, 2007b). When used in accordance with the EPA label, Quizalofop has not been demonstrated to accumulate in soil (US-EPA, 2007b).

Based on this analysis, a determination of nonregulated status of DAS-40278-9 corn and the corresponding change in use of 2,4-D and new use of Quizalofop is not expected to impact soils.

The *aad-1* gene which has been introduced into DAS-40278-9 corn was originally isolated from *Sphingobium herbicidovorans*, a gram negative soil bacterium (DAS, 2010). *Sphingobium* spp. are widespread in the environment, and have been used widely for both biosynthesis and biodegradation (DAS, 2010; Johnsen et al., 2005; Jordan et al., 2009). Representatives of this bacteria group have been utilized successfully to bioremediate environmental contaminants; in soil, *Sphingobium herbicidovorans* has been found to utilize phenoxy auxin and AOPP herbicides as carbon sources for growth (DAS, 2009, 2010; Johnsen et al., 2005). The cultivation of DAS-40278-9 corn and the attendant production of the AAD-1 enzyme would therefore not cause an impact to the physicochemical characteristics of the soil.

Availability of alternative herbicides for weed control in corn, such as 2,4-D and Quizalofop in the case of DAS-40278-9 corn, may allow for the elimination of additional herbicide treatments currently required in fields where glyphosate-resistant weeds have become established. If DAS-40278-9 corn is adopted and replaces non-GE corn varieties, soils currently under non-GE corn production may benefit from the use of DAS-40278-9 corn. A reduction in herbicide applications and treatment acreage currently required to manage herbicide-resistant weeds would be expected. Moreover, soils would benefit from the reduction in soil disturbance as fewer passes by heavy farm equipment would be required.

As explained above, if DAS-40278-9 corn is adopted and cultivated, there may be positive impacts to soil when compared with traditional corn cultivation practices.

Cumulative Effects: Soil

Except for the potential future changes in herbicide use associated with stacking and new product formulations, APHIS has not identified any cumulative effects of the use of DAS-40278-9 corn to soils. DAS has compared phenotypic, agronomic, and cultivation characteristics between DAS-40278-9 corn and control corn hybrids. With the exception of changes in herbicide use associated with this variety, DAS-40278-9 corn requires the same soil, fertilizer, water, and pest management practices as non-GE corn (DAS, 2010). Consequently, the phenotypic, agronomic, and ecological data presented by DAS support the conclusion by APHIS that DAS-40278-9 corn would not result in any significant modification in soil properties that are not already found in conventional corn production practices (DAS, 2010; USDA-APHIS, 2010).

As noted previously, DAS is developing a new formulation of 2,4-D based on a choline salt. DAS has submitted an application with the EPA for a label for this new formulation. Technical information on the 2,4-D choline salt has not been made publicly available. If EPA approves this new label request, DAS intends to market this 2,4-D choline salt formulation as part of the Enlist™ Weed Control System. For the purposes of this assessment, similar to other EPA label restrictions placed on the use of herbicides, APHIS assumes that the EPA approved label for the new 2,4-D formulation would provide appropriate controls for the use of this product on corn so as to protect soils.

The Enlist™ Weed Control System also involves the stacking of the DAS-40289-9 Corn with other nonregulated corn varieties, including varieties expressing tolerance to the herbicide glyphosate. Some glyphosate-tolerant crops, also identified as Roundup Ready® have been determined by APHIS to have nonregulated status since 1993 when glyphosate-tolerant cotton was introduced. Glyphosate-tolerant corn was introduced in 1996 (see http://www.aphis.usda.gov/biotechnology/not_reg.html). As noted in Subsection 4.2.2, the application and use of glyphosate on Roundup Ready® crops has been well-described and will not be further addressed here. Glyphosate is already used in corn in both conventional and Roundup Ready® varieties. Glyphosate-tolerant crops have been identified as facilitating the adoption of conservation tillage practices (DAS, 2011d). The stacking of DAS-40278-9 corn with a glyphosate-tolerant variety complements the glyphosate-tolerant crop by controlling glyphosate-resistant and inherently hard-to-control weeds without additional tillage (DAS, 2011d; Towery and Werblow, 2010). As glyphosate-resistant weed varieties have emerged, growers have returned to increased tillage as one of the weed management practices. As discussed in Soils, in Subsections 2.3.2 and corresponding Subsection 4.3.2, the adoption of conservation tillage has resulted in substantial improvements to soil health (Towery and Werblow, 2010). The cultivation of a corn variety stacking multiple modes of action, in this case, tolerance to 2,4-D and Quizalofop, along with glyphosate tolerance, provides growers with an opportunity to stay with their conservation tillage strategies. Maintaining conservation tillage will have a positive impact on soil quality.

The analysis of the impacts of glyphosate use on soil resources is well documented. Glyphosate has been shown to rapidly dissipate from most agricultural ecosystems across a wide range of soil and climatic conditions, with a median soil half-life (the time it takes for half of the glyphosate to dissipate in the soil) of 13 days (Giesy et al., 2000). A survey reported by Borggaard and Gimsing (2008) noted soil half-lives ranging from 1.2 to 197 days, depending on a wide range of soil chemical and physical parameters.

The potential future cultivation of a stacked variety and the associated use of glyphosate in addition to 2,4-D is not expected to result in cumulative effects to soil.

Based on these findings, and because the amount of corn grown in the U.S. is unlikely to change by the introduction of DAS-40278-9 corn, APHIS has determined that there are no cumulative impacts to soil.

4.3.3 Air Quality

Traditional agricultural practices have the potential to cause negative impacts to air quality. Agricultural emission sources include smoke from agricultural burning, tillage, heavy equipment emissions, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizer (Aneja et al., 2009; USDA-NRCS, 2006a).

The adoption of GE corn has the potential to reduce air emissions from several of these sources. Conservation practices, including conservation tillage associated with GE corn production, require fewer tractor passes across a field, thereby decreasing dust generation and tractor emissions. Surface residues and untilled organic matter physically serve to hold the soil in place, thereby decreasing airborne soils and pesticide drift in wind-eroded soils.

No Action: Air Quality

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

Adoption of GE corn varieties are expected to continue. To the extent that the adoption and cultivation of GE corn varieties allows the grower to implement conservation practices, air quality improvement associated with these practices would be expected to follow. Air quality would continue to be affected by current agronomic practices associated with conventional methods of corn production such as tillage, cultivation, pesticide and fertilizer applications, and the use of agricultural equipment.

Preferred Alternative: Air Quality

DAS-40278-9 corn production does not change land acreage or any cultivation practices for conventional, transgenic, or non-transgenic corn production, with the exception of potential reductions in herbicide use. It is expected that similar agronomic practices that are currently used for commercially available herbicide-tolerant corn also would be used by growers of DAS-40278-9 corn.

If DAS-40278-9 corn is adopted and replaces non-GE corn varieties, air quality associated with pesticide application and use in non-GE corn production may benefit from the use of DAS-40278-9 corn due to a reduction in the herbicide applications required as growers take advantage of the post-emergent herbicides 2,4-D and Quizalofop to manage weeds that have developed resistance to existing herbicides. The collective impact is a reduction in the number of acre-treatments per year requiring the use of heavy farm equipment. A positive impact on air quality would be expected due to the decrease in equipment-related emissions, as well as a decrease in dust and pesticide drift.

Spray drift or volatilization of herbicides and subsequent off-site movement is an air quality concern with direct potential impacts to non-target plants (Jordan et al., 2009; US-EPA, 2005c; Vogel et al., 2008). Spray drift is a concern with all herbicides applied in a liquid form (Jordan et al., 2009; Vogel et al., 2008). The use of 2,4-D, particularly the ester formulation applied in liquid form, has raised a concern for potential off-site impacts to terrestrial plants adjacent to treated fields (Jordan et al., 2009; US-EPA, 2005c). The potential impacts to non-target plants through spray drift are discussed below in Subsection 4.4.2, Plant Communities, and Subsection 4.9, Threatened and Endangered Species.

The EPA has addressed the concerns regarding spray drift through the requirement of spray drift controls when 2,4-D is applied (US-EPA, 2005c). The EPA provides several spray drift risk management procedures, including stipulations on droplet size for liquid sprays, wind speed, ambient temperature, proximity to sensitive plants, and buffer zones of unsprayed or untreated crop (US-EPA, 2005c). The EPA notes that if applied in accordance with these label restrictions, spray drift impacts can be avoided (US-EPA, 2005c).

Based on this information, APHIS concludes that the production of DAS-40278-9 corn is not expected to adversely affect air quality and, in fact, may provide some benefit. Overall impacts are likely to be similar to the No Action Alternative.

Cumulative Effects: Air Quality

Except for the potential future changes in herbicide use associated with stacking and new product formulations, based on the findings described above, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have a negative impact on air quality. The consequences of the Preferred Action Alternative on commercial corn production and the resulting air quality are similar to those expected for the No Action Alternative.

As noted previously, DAS is developing a new formulation of 2,4-D based on a choline salt. DAS has submitted an application with the EPA for a label for this new formulation. DAS has provided some information suggesting that the 2,4-D choline salt formulation has lower volatility and decreased drift than other formulations (DAS, 2011a). The decrease in volatility also results in lower odor associated with this product (DAS, 2011a). Technical information supporting this information has been submitted to the EPA as part of DAS' application for a new pesticide registration, but has not been made publicly available. If EPA approves this new label request, DAS intends to market this 2,4-D choline salt formulation as part of the Enlist™ Weed Control System. For the purposes of this assessment, similar to other EPA label restrictions placed on the use of herbicides, APHIS assumes that the EPA approved label for the new 2,4-D formulation would provide appropriate controls for the use of this product on corn so as to protect air quality.

The Enlist™ Weed Control System also involves the stacking of the DAS-40289-9 Corn with other nonregulated corn varieties, including varieties expressing tolerance to the herbicide glyphosate. Some glyphosate-tolerant crops, also identified as Roundup Ready® have been determined by APHIS to have nonregulated status since 1993 when glyphosate-tolerant cotton was introduced. Glyphosate-tolerant corn was introduced in 1996 (see http://www.aphis.usda.gov/biotechnology/not_reg.html). As noted in Subsection 4.2.2, the application and use of glyphosate on Roundup Ready® crops has been well-described and will not be further addressed here. Glyphosate is already used in corn in both conventional and Roundup Ready® varieties.

The potential future cultivation of a stacked variety and the associated use of glyphosate in addition to 2,4-D is not expected to result in cumulative effects to air quality.

Based on these findings, and because the amount of corn grown in the U.S. is unlikely to change by the introduction of DAS-40278-9 corn, APHIS has determined that there are no cumulative impacts to air quality.

4.3.4 Climate Change

Agriculture, including land-use changes associated with farming, is responsible for an estimated 6% of all human-induced GHG emissions in the U.S. Agriculture-related GHG emissions include carbon dioxide (CO_2), nitrous oxide (N_2O), and methane (CH_4), produced through the combustion of fossil fuels to run farm equipment; the use of fertilizers; or the decomposition of agricultural waste products including crop residues, animal wastes, and enteric emissions from livestock. N_2O emissions from agricultural soil management (primarily nitrogen-based fertilizer use) represent 69% of all U.S. N_2O emissions (US-EPA, 2011d). A comprehensive discussion of the contribution of agricultural practices to GHGs is provided in Subsection 2.3.4, Climate Change.

The adoption of herbicide-tolerant crops, and the attendant increase in conservation tillage has been identified as providing climate change benefits. Conservation tillage, discussed above in cropping practices and soil, in addition to providing benefits to soil health, has the benefit of increasing carbon sequestration in soils. Switching from conventional tillage to a no-till corn-soybean rotation in Iowa, for example, has been estimated to increase carbon sequestration by 550 kg/hectare (485 lb/acre) per year (Brenner et al., 2001; Paustian et al., 2000; Towery and Werblow, 2010). This subsection discusses the potential consequences of the No Action and the Preferred Alternatives on climate change.

<u>No Action: Climate Change</u>

Under the No Action Alternative, environmental releases resulting from the use of DAS 4078-9 Corn would be under APHIS regulation. Current agronomic practices associated with conventional corn production and current GE corn varieties which contribute to GHG emissions, including tillage, cultivation, irrigation, pesticide application, fertilizer applications, and use of agriculture equipment, are not expected to change if DAS-40278-9 corn remains a regulated article. Land acreage and cultivation practices associated with corn production would not be affected. To the extent that the adoption and cultivation of GE corn varieties allows the grower to implement conservation practices, GHG emissions are expected to be reduced commensurate with the air quality improvements anticipated from adoption of conservation tillage practices.

<u>Preferred Alternative: Climate Change</u>

A determination of nonregulated status of DAS-40278-9 corn would not change the cultivation or agronomic practices, or agricultural land acreage associated with growing corn, and thus is expected to have the same effect on climate change as the No Action Alternative.

<u>Cumulative Effects: Climate Change</u>

APHIS has not identified any cumulative effects for this issue. The use of DAS-40278-9 corn in commercial corn production is not expected to cause any cumulative effect on climate change because APHIS does not anticipate any changes in corn production practices or an expansion of corn acreage as a result of DAS-40278-9 corn being no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act. The consequences of the Preferred Action Alternative on commercial corn production and acreage are the same as for the No Action Alternative.

Based on these findings, and because the amount of corn grown in the U.S. is unlikely to change by the introduction of DAS-40278-9 corn, APHIS has determined that there are no cumulative impacts to climate change.

4.4 ANIMAL AND PLANT COMMUNITIES

4.4.1 Animal Communities

Corn production systems in agriculture are host to a variety of animal species. A number of insect pests as well as beneficial insects feed on corn plants or prey upon other insects inhabiting cornfields. Although cornfields are generally considered poor habitat for birds and mammals in comparison with uncultivated lands, the use of cornfields by birds and mammals is not uncommon. This subsection discusses the potential consequences of the No Action and the Preferred Alternatives on animal populations associated with corn production. The cumulative effects analysis for this issue is found below under "Cumulative Effects: Animals, Plants, and Biodiversity" in Subsection 4.4.4.

No Action: Animals

Under the No Action Alternative, conventional and GE transgenic corn production would continue while DAS-40278-9 corn remains a regulated article. Potential impacts of GE and non-GE corn production practices on non-target terrestrial (insect, bird, and mammal) and aquatic (fish, benthic invertebrate, and herptile) species would be unchanged.

Preferred Alternative: Animals

As discussed in Subsection 4.2, a determination of nonregulated status of DAS-40278-9 corn is not expected to impact agronomic practices for the cultivation of corn, with the exception of the changes in the pattern of use of 2,4-D on corn and the new use of Quizalofop. Cultivation of DAS-40278-9 corn would not change land acreage, cultivation practices or agronomic inputs. Regarding the impact of agronomic practices in the cultivation of DAS-40278-9 corn, the potential impacts to animal communities are expected to be the same as those under the No Action Alternative. To the extent that the adoption of DAS-40278-9 corn allows the grower to apply either 2,4-D or Quizalofop to control glyphosate-resistant or inherently more tolerant weeds in areas where those have emerged, the application of these two herbicides provides the grower with the ability to retain conservation tillage practices that would otherwise be adversely impacted from the establishment of glyphosate–resistant weeds. Adopting a diverse weed management strategy which incorporates diverse herbicides allows the grower to retain conservation tillage practices, which would continue to provide benefits to various animal communities (Wilson et al., 2011b).

AAD-1 Protein

The addition of the *aad-1* gene in DAS-40278-9 corn is not expected to impact animals. The *aad-1* gene, which expresses the AAD-1 protein, was derived from the gram negative soil bacterium *Sphingobium herbicidovorans* (DAS, 2010). The *Sphingobium spp.* is a member of the sphingomonads, a widely distributed bacteria group isolated from soil and water as well as plant root systems (DAS, 2009, 2010). The sphingomonads have been used widely in biotechnology applications, including bioremediation of environmental contaminations as well as production of sphingans, bio-based polymers which are used in the food industry (DAS, 2010; Lal et al., 2006; Pollock and Armentrout, 1999). The aryloxyalkanoate dioxygenase proteins, including AAD-1, are a class of enzymes found in these soil bacteria; hence there has been animal exposure to these bacteria and enzymes through normal dietary intake of vegetation and incidental ingestion of soil (ANZFS, 2010b, 2011; DAS, 2009, 2010). DAS has presented evidence of phenotypic and agronomic trials conducted in 27 locations in the U.S. and Canada (DAS, 2010). The trials evaluated incidences of insect and disease damage between the DAS-40278-9 corn variety and other corn hybrids (DAS, 2010). No statistical differences were noted between the varieties (DAS, 2010). Insects, particularly insects which feed on corn, were not impacted by ingesting corn in which the *aad-1* gene was incorporated.

DAS has evaluated the potential allergenicity and toxicity of the AAD-1 protein following the weight-of-evidence approach (DAS, 2010). The AAD-1 protein does not share any meaningful amino acid similarities with known allergens. The AAD-1 protein is degraded rapidly and completely in simulated gastric fluids and the protein is not present in a glycosylated state (DAS, 2010). The protein does not share any amino acid sequence similarities with known toxins (DAS, 2010). The results presented by DAS suggest that the AAD-1 protein is unlikely to be a toxin in animal diets. Based on a review of this information, APHIS has found no evidence that the presence of the *aad-1* gene or the expression of the AAD-1 protein would have any impact on animals, including animals beneficial to agriculture (USDA-APHIS, 2010). Further discussion on the potential impacts from the consumption of DAS-40278-9 corn is presented in Subsection 4.6, Animal Feed.

2,4-D and Quizalofop

To the extent that a determination of nonregulated status of DAS-40278-9 corn would result in a change in the use of 2,4-D on corn, or the new use of Quizalofop on this crop, such pesticide use changes would be regulated by the EPA through the FIFRA labeling process. The potential changes in herbicide applications are discussed in Subsection 4.2.2. Current label application rates and associated use restrictions for both herbicides are designed by the EPA to minimize the potential impacts to non-target organisms. APHIS assumes that both herbicides will be used in accordance with these EPA label restrictions.

As discussed in Subsection 4.2.2, although the per acre volume of 2,4-D will not increase over current label rates, the total volume of 2,4-D applied to corn would potentially increase for those DAS-40278-9 corn varieties, and the sequence timing for the application of 2,4-D will likely change. Proposed application rates provided in the draft revised label for the post-emergence and pre-harvest applications of 2,4-D are different from the currently labeled use. For DAS-40278-9 corn, post-emergence applications earlier in the growing season in conventional corn are lower (0.5 lb ae/acre) compared to that proposed for DAS corn (0.5 to 1.0 lb ae/acre). In the proposed new label, this same application can be repeated within 12 days. Therefore within field and field edges could receive higher doses and more frequent doses during this time frame. These proposed application rates are based on the currently EPA approved rates for field corn and popcorn, which establish a maximum-per-year application rate of 3 lbs/acre, and a maximum single application rate of 1.5 lbs/acre (DAS, 2011e). The EPA currently is reviewing the proposed label changes submitted by DAS.

A potential additional difference between current applications of 2,4-D in corn and proposed new applications involves equipment. The current labeled post-emergent applications require the use of drop nozzles. This drop nozzle allows the grower to protect upper foliage from direct application of the herbicide, and has the added benefit of limiting off-target drift. It is unclear whether EPA will require that same drop nozzle in the new label. If the drop nozzle is not required, animals feeding on corn foliage during that time would receive a higher dose if they forage on the foliage during this post-emergence period. However, current labeled uses provide for a single application of 1.5 lbs. ae/acre at the pre-harvest, later stages when corn is at the hard dough or dent stage. The proposed new label does not seek such an application. Animals feeding on corn foliage treated pre-harvest under the current label would receive a higher dose than under the proposed new label.

The EPA has reviewed the potential impacts to animals associated with the use of 2,4-D in the recent reregistration of the compound (US-EPA, 2005c), as well as analyses of potential impacts to threatened and endangered species (US-EPA, 2009b, 2011e). The EPA considered 2,4-D to be moderately to practically non-toxic to birds from acute oral exposure, and slightly toxic to mammals on an acute oral basis (US-EPA, 2005a, 2005c). The EPA also determined that 2,4-D is practically non-toxic to honey bee (US-EPA, 2005a, 2005c). There are differences identified in the toxicity of various formulations of 2,4-D to fish and aquatic invertebrates. The acid and amine salt formulations were found to be practically non-toxic to fish and aquatic invertebrates; whereas the ester formulation was highly toxic to both (US-EPA, 2005a). Note that 2,4-D is labeled for use in aquatic environments for select weed control, for example, in Minnesota, the amine salt may be applied to control waterplantain in wild rice, as well as aquatic weed control (e.g., water hyacinth (*Eichornia crasipe*) and water milfoil (*Myriophyllum spicatum*)) in other regions (Nufarm, 2009).

In its review of the herbicide, the EPA concluded that the benefits from the use of 2,4-D, considered with its low toxicity to humans, outweigh concerns of toxicity to small mammals (US-EPA, 2005c). The herbicide 2,4-D is noted to cause indirect harm to animals by affecting non-target plants that may serve as forage or cover (US-EPA, 2005c). EPA label use restrictions for 2,4-D are intended to mitigate the potential risks from that exposure, including restrictions on application equipment (use of drop nozzles) and environmental conditions (temperature and wind speed) (Nufarm, 2009 2009). Additional discussion of potential impacts to Threatened and Endangered Species is provided in Subsection 4.9.

As discussed in Subsection 4.2.2, a determination of nonregulated status of DAS-40278-9 corn has the potential to result in the application of Quizalofop to corn. Proposed applications to corn is a new use for Quizalofop. DAS is working with DuPont to present an application to the EPA for a new pesticide label providing for this new use (DAS, 2010). Should growers elect to use Quizalofop as part of their weed management strategy in DAS-40278-9 corn, there would be an attendant increase in the total volume of Quizalofop applied to crops under this alternative.

The Quizalofop application rates proposed for use on DAS-40278-9 corn are less than those evaluated in the EPA's previous assessments. The EPA has evaluated Quizalofop for toxicity to non-target organisms using maximum application rates up to 0.17 lb/acre application to birds, fish, and herptiles (in comparison to the 0.082 lb ai/acre proposed for use on DAS-40278-9 corn), and has found that risks from chronic and acute exposure to Quizalofop do not exceed the EPA's level of concern (US-EPA, 2007b). Quizalofop is currently under registration review by the EPA (see US-EPA, 2007b). Summary documents published by the EPA as part of this registration review suggest that the use of Quizalofop in accordance with the approved label rates has the potential to affect non-target species due to the loss of cover or forage from herbicide drift and/or runoff to aquatic systems. EPA has authorized the continued use of Quizalofop at these application rates while additional data are being gathered (US-EPA, 2007b).

As with the herbicide 2,4-D, the current Quizalofop label includes use restrictions to mitigate the potential risks from off-target spray drift, including restrictions on application equipment (e.g., droplet size) and environmental conditions (temperature and wind speed) (DuPont, 2010). Any change in the EPA approved label providing for the use of Quizalofop on DAS-40278-9 corn would be expected to include similar use limitations to minimize the potential impacts of Quizalofop on non-target species.

In addition to its evaluation of the dietary and environmental exposures associated with the use of 2,4-D and Quizalofop, the EPA has also evaluated indirect exposure impacts for both herbicides (US-EPA, 2005c, 2007b). The EPA has determined that the use of 2,4-D and Quizalofop may result in a loss of habitat adjacent to the field by reducing or eliminating susceptible plants that serve as forage or cover (US-EPA, 2005c, 2007b). EPA label use restrictions are intended to mitigate against that loss.

To the extent that DAS-40278-9 corn displaces other corn varieties, the expression of herbicide tolerance could have an overall positive impact on animal communities. As previously discussed in the analysis of water and soil, in those fields where DAS-40278-9 corn is cultivated, growers would be expected to take advantage of the weed control offered by 2,4-D and Quizalofop and incorporate these herbicides into a diverse weed management strategy. DAS-40278-9 corn, and the associated use of 2,4-D and Quizalofop, provides several potential advantages over conventional weed management programs, including increased flexibility to manage problem weeds, reduced use of soil-applied herbicides, potential reduced total use of herbicides, and more widespread adoption of conservation tillage. The associated adoption of conservation tillage and reduced use of soil-applied herbicides have the potential to positively impact animal communities in fields planted with DAS-40278-9 corn (Eggert et al., 2004).

The EPA has entered into consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service regarding potential impacts of the use of 2,4-D on threatened and endangered species (see NOAA-NMFS, 2011; US-EPA, 2009b). In addition, the EPA is currently completing a comprehensive ecological risk assessment, including an endangered species risk assessment for the labeled uses of Quizalofop (see US-EPA, 2007b). A summary of the EPA's assessments for these two herbicides is presented in Subsection 4.9. The EPA has approved the continued use of both herbicides consistent with current label use restrictions.

Based on these findings, APHIS has determined that the impacts to the animal community from a determination of nonregulated status of DAS-40278-9 corn are the same as those under the No Action Alternative.

4.4.2 Plant Communities

The landscape surrounding a cornfield may be bordered by a number of vegetative communities, including other crop fields, woodland, fencerows, rangelands, and/or pasture/grassland areas. These plant communities represent natural or managed plant buffers for the control of soil and wind erosion and also serve as habitats for a variety of transient and non-transient wildlife species.

Weed control programs are important aspects of corn cultivation. In this context, weeds are those plants which, when growing in the field, compete with the crop for space, water, nutrients, and sunlight; and may thus include native species (IPM, 2004, 2007; University of California, 2009). The types of weeds in and around a cornfield will vary depending on the geographic region where the corn is grown. This subsection discusses the potential consequences of the No Action and the Preferred Alternatives on plants. The cumulative effects analysis for this issue is discussed below under “Cumulative Effects: Animals, Plants, and Biodiversity” in Subsection 4.4.4.

<u>No Action: Plants</u>

Under the No Action Alternative, environmental releases of DAS-40278-9 corn would remain under APHIS regulation. Plant species (i.e., weeds) that typically inhabit GE and non-GE corn production systems would continue to be managed through the use of mechanical and chemical control methods. Multiple herbicides, including the herbicide 2,4-D, will continue to be used on corn. Volunteer corn will continue to be controlled by the recommended ACCase inhibitors and ALS inhibitors (Hager, 2009).

<u>Preferred Alternative: Plants</u>

The potential impacts to plants from a determination of nonregulated status of DAS-40278-9 corn relates to both the potential impacts of the cultivation of DAS-40278-9 corn on other plant communities and the potential for this corn variety to become a weed and thus interfere with other plant cultivation. These are addressed separately.

Surrounding Landscapes and Other Vegetation in Cornfields

The incorporation of tolerance to the herbicides 2,4-D and Quizalofop provides several potential advantages over conventional weed management programs in corn, including increased flexibility to manage weeds, reduced use of soil-applied herbicides, reduced total use of herbicides, and more widespread adoption of conservation tillage (DAS, 2010). The introduction of glyphosate-tolerant crops, including corn, resulted in growers changing historical weed management strategies and relying on a single herbicide, glyphosate, to control weeds in the field (Owen et al., 2011; Weirich et al., 2011). Reliance on a single management technique for weed control resulted in the selection for weeds resistant to that technique (Owen et al., 2011; Weirich et al., 2011). The development of glyphosate-resistant weeds requires that growers diversify their weed management strategies. Many growers, faced with glyphosate-resistant weeds, have returned to tillage and other cultivation techniques to physically control these species when herbicides prove ineffective (DAS, 2011c). A determination of nonregulated status of DAS-40278-9 corn would provide growers with opportunities to introduce a new herbicide to corn cultivation, Quizalofop, and change the use of another, 2,4-D, providing different modes of action to control these glyphosate-resistant weeds. Table 4-3 illustrates the comparative control of glyphosate-resistant and hard to control weeds based on records of glyphosate resistance, ALS resistance, and grower applications of 2,4-D or ACCase "fops" to provide control. Diversifying herbicide weed management strategies is an effective alternative to tillage for mitigating the evolution of weed resistance to glyphosate (Wilson et al., 2011b).

Table 4-3: Comparative Control of Herbicide-resistant Weeds (DAS, 2011a; Heap, 2011b; IPM, 2007)

Weed Species	Hard to Control	Glyphosate-resistant	ALS-resistant	2,4-D Controlled[1]	ACCase Controlled
Ablution theophrasti (Velvetleaf)	X			X	
Amaranthus palmeri (Palmer amaranth)[2]	X	X	X	X	
Amaranthus rudis (Tall or common waterhemp)	X	X	X	X	
Ambrosia artemisifolia (Common ragweed)	X	X	X	X	
Ambrosia trifida (Giant ragweed)	X	X	X	X	
Chenopodium album (common lambsquarters)	X		X	X	
Conyza canadensis (Marestail)	X	X	X	X	
Eleusine indica (Goosegrass)	X	X			X
Ipomoea sp. (Morningglory species)	X			X	
Lolium perenne (Perennial ryegrass)	X	X	X		X
Lolium rigidum (Rigid ryegrass)	X	X	X		X
Poa annua (Annual bluegrass)	X	X			X
Sida spinosa (Prickly sida, Teaweed)	X		X	X	
Solanum ptycanthum (Eastern black nightshade)	X		X	X	
Sorghum halapense (Johnsongrass)	X	X	X	X	X

Notes:
1. 2,4-D application rate of 560 to 1,120 g ae/hectare.
2. Requires a broader management plan.

Although the potential use of 2,4-D and Quizalofop in DAS-40278-9 corn presents changes in herbicide use, the proposed change in use is consistent with current herbicide use practices for these two products. The herbicide 2,4-D is already used on corn, although its use is limited (DAS, 2010). Applications of 2,4-D as a post-emergent herbicide at later growth stages can cause significant malformations in the corn plant (DAS, 2010). DAS-40278-9 corn is tolerant to the application of 2,4-D as a pre-emergent herbicide and for up to two post-emergent applications (DAS, 2011a).

The total volume of the herbicide 2,4-D used on corn had declined in recent years, from a total of approximately 4 million pounds of active ingredient in 1990 to approximately 2 million pounds of active ingredient in 2005 (USDA-NASS, 2006). In 2005, less than 8% of the corn acreage in the U.S. was treated with 2,4-D, and historically 2,4-D has been used on no more than 14% of the corn acreage in 1994 (USDA-NASS, 2006, 2011c). As noted in Table 4-1, in Subsection 4.2.2, per acre applications of 2,4-D are not expected to change. Proposed application rates provided in the draft revised label for this new use of 2,4-D on this corn variety are up to 1,120 g acid equivalent/hectare (ae/ha) (1 lb/acre) as a pre-emergent herbicide and between 560 and 1,120 g ae/ha (0.5 to 1.0 pounds/acre); up to two applications a minimum of 12-days apart during the first 3-5 weeks before the corn reaches 6-8 inches in height and again up to the V8 stage of corn (i.e., a period of rapid plant growth represented by an 8-leaf collar) as a post-emergent herbicide. These proposed application rates are based on the currently approved rates for field corn and popcorn, which establish a maximum-per-year application rate of 3 lbs/acre, and a maximum single application rate of 1.5 lbs/acre (DAS, 2011e). The EPA currently is reviewing the proposed label changes. Based on the proposed label change and this new use procedure, APHIS understands that the total volume of 2,4-D applied to corn could potentially increase in response to the introduction and cultivation of this variety, although the total maximum application on a per-field basis is no different than that already approved by EPA for use in corn.

DAS-40278-9 corn is the first GE corn variety expressing tolerance of the “fop” class of herbicides and would be marketed as Quizalofop-tolerant. Quizalofop currently is not registered for use as a post-emergent herbicide on corn. This is a proposed new use requiring an EPA label change (DAS, 2010). The petitioner has indicated that “fop” herbicides could be used to maintain seed purity in DAS-40278-9 corn breeding nurseries, hybrid production fields, and generally for the control of grass weeds in corn.

Quizalofop currently is registered by EPA for post-emergent control of annual and perennial grasses in canola, crambe, cotton, dry beans, lentils, mint, dry and succulent peas, snap beans, soybeans, and sugar beets (DAS, 2011e; DuPont, 2010). Quizalofop is also registered by EPA for the control of volunteer corn in soybeans (DuPont, 2010). In these uses, EPA has approved single application rates ranging from 0.034 to 0.082 pounds ai/acre, (38 g ai/ha to 92 g ai/ha) depending on the weed species. The highest maximum seasonal application rate of 0.206 pounds ai/acre (231 g ai/ha) is allowed for weed control in mint (DAS, 2011e). As noted in Table 4-2, in Subsection 4.2.2, DAS proposes a maximum single application rate of 0.082 lb ai/acre corn (DAS, 2011e). DAS-40278-9 corn has proven tolerant to Quizalofop post-emergent application rates of up to 184 g ai/ha (0.164 lbs ai/acre) in field trials (DAS, 2011a). The proposed maximum application rate also is the seasonal maximum application rate (DAS, 2011e). This maximum application rate is less than that currently approved by EPA for use of Quizalofop for the control of grassy weeds in soybeans and cotton, where a seasonal maximum application rate of 139 g ai/ha (0.124 lb ai/acre) is approved (DAS, 2011e). The EPA currently is reviewing the proposed label change for Quizalofop. Based on the proposed label change and this new use, APHIS understands that the total volume of Quizalofop applied to crops could increase, and that this application to corn is a new use. APHIS also understands that the total maximum application on a per-field basis in corn is less than that already approved for use in soybeans and cotton.

Spray drift is a concern for non-target susceptible plants growing proximate to fields when herbicides are used in the production of DAS-40278-9 corn. As discussed in Subsection 4.3.3, Air Quality, this potential impact relates to exposure of non-target susceptible plants to the off-target herbicide drift (see, e.g., Jordan et al., 2009). The risk of off-target herbicide drift is recognized by the EPA, which has incorporated both equipment and management restrictions to address drift in the approved herbicide labels. These EPA label restrictions include requirements that the grower manage droplet size, spray boom height above the crop canopy, restricted applications under certain wind speeds and environmental conditions, and using drift control agents (Jordan et al., 2009). EPA addressed spray drift concerns in the 2005 reregistration of 2,4-D by adding label language on required spray droplet size, wind speeds, ambient temperature, avoidance of certain sensitive plants, and specific equipment requirements regarding boom length and height above the canopy (US-EPA, 2005c). These types of label restrictions and application requirements for 2,4-D are not expected to change with the introduction of DAS-40278-9 corn. The EPA label for Quizalofop identifies similar practices to manage spray drift, including controlling droplet size, spray pressure, boom height and length, wind speed, temperature, humidity, and use of specialized shielded sprayers (DuPont, 2010). Spray drift has not been reported as a concern with the application for Quizalofop (US-EPA, 2007b).

Under this alternative, the potential utilization of 2,4-D on Corn would change. The utilization of Quizalofop on corn would be a new use for this herbicide product. APHIS anticipates that the two herbicides would be used consistent with the EPA approved label. Other than the changes in use in 2,4-D and Quizalofop on DAS-40278-9 corn, and in some cases, the reduction in use of the current Quizalofop to control volunteer corn (discussed in the next subsection), overall impacts of a determination of nonregulated status and cultivation of this variety of corn plant are similar to the No Action Alternative.

Although growers may change their weed management strategies due to DAS-40278-9 corn, these changes will not necessitate a major departure from well-established and broadly used agricultural protocols (USDA-APHIS, 2010). DAS intends to incorporate grower education and training on these management strategies and protocols as part of its product stewardship program (DAS, 2011b). These changes would also be consistent with the practices currently employed under the No Action Alternative to control weeds found within cornfields as well as those practices undertaken to protect plants located outside of the cornfield.

The EPA has entered into consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service regarding potential impacts of the use of 2,4-D on threatened and endangered species (see NOAA-NMFS, 2011; US-EPA, 2009b). In addition, the EPA is currently completing a comprehensive ecological risk assessment, including an endangered species risk assessment for the labeled uses of Quizalofop (see US-EPA, 2007b). A summary of the EPA's assessments for these two herbicides is presented in Subsection 4.9. The EPA has approved the continued use of both herbicides consistent with current label use restrictions.

Based on these findings, the potential impacts to other vegetation in corn and the surrounding landscapes from a determination of nonregulated status of DAS-40278-9 corn is not expected to differ from the No Action alternative.

Corn as a Volunteer

Agronomic studies conducted by DAS compared the weediness potential of DAS-40278-9 corn with respect to conventional corn (DAS, 2010). No differences were detected between DAS-40278-9 corn and nontransgenic corn in growth, reproduction, or interactions with pests and diseases, other than the intended effect of tolerance to the herbicides Quizalofop and enhanced tolerance to 2,4-D.

For transformed plants to become weedy escapes as a result of the genetic modification, they would need to inherit and express many other unrelated traits that provide selective advantage to a weedy growth habit (e.g., large numbers of easily dispersed seeds, propensity to grow on disturbed ground, vegetative propagation, and seed dormancy) (US-EPA, 2010). These traits do not exist within corn, a species that has been selected for domestication and cultivation under conditions not normally found in natural settings (US-EPA, 2010). Large cobs or ears that do not shatter severely limit seed dispersal; and it has been theorized that the species as we know it would die out in a few generations due to competition among seedlings germinating from the cob (US-EPA, 2010).

Any corn volunteers expressing only the DAS-40278-9 corn traits easily could be controlled by mechanical cultivation as well as readily available herbicides, including glyphosate, glufosinate, or other graminicides (USDA-APHIS, 2010; Wozniak, 2002), provided that the DAS-40278-9 corn or its progeny does not carry tolerance to these other herbicides (e.g., accidental admixture or intentional or unintentional crossing of resistant varieties). As discussed in Subsection 2.4.2, herbicides recommended for control of volunteer corn in soybeans are the ACCase inhibitors and certain ALS inhibitors. The ACCase inhibitors include two families of herbicides, the AOPP ACCases (e.g., the “fops,” such as Quizalofop, fenoxaprop, and diclofop) and the cyclohexanediones (e.g., the “dims,” such as clethodim and sethoxydim) (Hager, 2009). Although DAS-40278-9 corn is tolerant of the AOPP ACCase herbicides (the “fops”), this variety is still sensitive to the cyclohexanedione family of herbicides (the “dims”) such as clethodim and sethoxydim, and also is sensitive to some of the ALS herbicides such as imazamox (DAS, 2010).

DAS has indicated an intention that if Aphis determines DAS-40278-9 corn variety is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act, it will be combined with other nonregulated corn varieties, including a glyphosate-tolerant variety. Other herbicide-tolerant traits could also be combined in the future. Future control of volunteer corn will require the grower to understand the corn variety which has given rise to the volunteer plants. Grower options for management controls of volunteer corn stacked to express the traits of DAS-40278-9 corn and a glyphosate tolerance, for example, would be limited to the cyclohexadiones (Hager, 2009).

As noted in Subsection 2.4.2, the cultivation of DAS 402878-9 corn does not change the control of volunteer corn in corn or sorghum. Currently there are limited options available to control volunteer corn in corn or sorghum. There are no post-emergent herbicide options to control volunteer corn in sorghum; the only control option is inter-row cultivation (Sandell et al., 2009). If the volunteer corn is tolerant to the same herbicide used in the current corn crop (e.g., two consecutive crops of Roundup Ready® corn), the grower may similarly be limited to inter-row cultivation (Gunsolus and Stachler, 2010; Sandell et al., 2009; Stahl et al., 2008). Alternatively, pre-emergent treatments might be applied using Gramaxone Inteon (paraquat) and atrazine, for example (Monsanto, 2010; Sandell et al., 2009).

Herbicide-tolerant crops are being explored and utilized to control plant parasites, including *Striga* and *Orobanche* spp. using transgenic crops with tolerance to chlorsulfuron, glyphosate, ALS-inhibitors, and/or asulam (Abayo et al., 1998; Joel et al., 1995). Transgenic crops bearing metabolic tolerances (e.g., to glufosinate or 2,4-D) were found to provide limited control to the parasites because the herbicide was degraded before reaching the parasites, although glyphosate-tolerant plants with application of glyphosate were reported to provide good control and normal crop growth (Abayo et al., 1998; Joel, 2000; Joel et al., 1995). However, the ability to use Quizalofop on DAS-40278-9 corn would potentially provide another herbicide option to control alternate grass weed host plants of *Striga* in corn without significant injury to the crop itself.

Based on this analysis, the incorporation of the herbicide tolerance trait is unlikely to appreciably improve seedling establishment or increase the weediness potential of corn. Corn volunteers in soybeans and other broad-leafed crops (e.g., canola) can still be controlled with the “dims”, readily available herbicides (DAS, 2010; Gunsolus and Porter, 2011; Gunsolus and Stachler, 2010). Specific herbicide strategies to control corn volunteers in rotation with various crops should be developed in consultation with local agronomists. For example, Gunsolus and Stachler provide an overview of the various herbicide strategies recommended in North Dakota to control weeds in glyphosate-tolerant corn cultivated in rotation with a wide range of crops, including corn, soybean, sugar beet, wheat, potato and dry bean (Gunsolus and Stachler, 2010). Although growers may have to change their management strategies due to DAS-40278-9 corn, these changes will not necessitate a major departure from well-established and broadly used agricultural protocols and are consistent with the practices currently employed to control volunteer corn under the No Action Alternative.

4.4.3 Soil Microorganisms

Potential impacts to soil microorganisms can arise from the exposure to the introduced gene and expressed protein in the GE crop product, as well as exposure to those elements of agronomic practices which may potentially change in response to the cultivation of the modified crop.

No Action Alternative: Soil Microorganisms

Under the no action alternative, DAS-40278-9 corn remains a regulated article. Corn cultivation practices are expected to remain as currently practiced. Growers will continue to have access to existing nonregulated corn varieties (both lepidopteran-resistant and herbicide-tolerant) as well as conventional corn varieties. Growers will continue to manage their crops, including implementing numerous management strategies to control pests and weeds. As discussed in Subsection 4.2.2, these current practices include the use of 2,4-D for the control of certain weeds. The current cultivation of corn does not include the use of the herbicide Quizalofop. Quizalofop is approved for the control of graminaceous weeds in several dicot crops, including soybeans, a common corn rotation crop.

Preferred Alternative: Soil Microorganisms

A determination of nonregulated status of DAS-40278-9 corn is not expected to result in changes in corn agronomic practices, with the exception of potential changes in the application rates and uses of 2,4-D and Quizalofop in fields cultivating this variety or its progeny.

With regard to the *aad-1* gene and the corresponding AAD-1 protein expressed by the DAS-40278-9 corn, no impacts to soil microorganisms are expected. The *aad-1* gene was derived from the gram negative soil bacterium *Sphingobium herbicidovorans* (DAS, 2010). The *Sphingobium spp*. are common soil bacteria, and the aryloxyalkanoate dioxygenase proteins, including AAD-1, are a class of enzymes naturally found in these soil bacteria. As with other soil dwelling bacteria, *Sphingobium herbicidovorans* has evolved over time and has the ability to use phenoxy auxin and AOPP herbicides as carbon sources for growth; thus affording the bacterium a competitive advantage in soil (Lal et al., 2006; Wright et al., 2010). *Sphingobium spp*. are considered members of the Sphingomonad bacteria group, which are widely distributed in nature and have been isolated from land and water habitats, as well as from plant root systems, clinical specimens, etc. (DAS, 2010). This bacteria group has been used widely in commercial applications for bioremediation of environmental contaminants of soil (DAS, 2010; Lal et al., 2006). Therefore, the subsequent exposure of soil microoganisms to the *aad-1* gene and corresponding AAD-1 protein is not novel. No impacts to microorganisms are anticipated from this exposure.

With regard to the agronomic inputs associated with the cultivation of DAS-40278-9 corn, as discussed in Subsection 4.2.2, growers have the option to change their use of 2,4-D on corn, as well as incorporate Quizalofop in their management strategy. APHIS does not anticipate that the use of 2,4-D and Quizalofop on DAS-40278-9 corn or its progeny will have an adverse impact on soil microorganisms.

The herbicide 2,4-D has a long history of use in American agriculture, and impacts to soil microorganisms have not been raised as a significant issue of concern. In its 2005 RED, the EPA noted that although it did not quantify risks to non-target invertebrates, based on calculations for honey bees, 2-4-D was expected to present minimal risk to non-target insects, including beneficial insects (US-EPA, 2005c). In its assessment of potential impacts to the Red-legged frog, the EPA considered potential impacts to earthworms (US-EPA, 2009b). In this assessment, the EPA noted that the LC_{50} for earthworms was based on a 2,4-D application rate of 5.5 lbs/acre, substantially higher than that proposed for use on DAS-40278-9 corn (see Table 4-1) (US-EPA, 2009b). The World Health Organization has considered impacts to soil microorganisms (WHO, 1989). In this report, the WHO provides summaries of numerous global studies of the impacts of the application of 2,4-D to soil microorganisms. Soil algae were inhibited by applications of 2,4-D, but many soil bacteria, fungi, and microorganisms were unaffected; or, in some instances (e.g., soil amoeba) were stimulated by the herbicide application. The Food and Agriculture Organization (FAO) published a similar evaluation of 2,4-D, and concluded that the risk to soil microorganisms from the use of 2,4-D should be low (FAO, 1998). The FAO also considered potential impacts to other arthropods and earthworms, and reached the same conclusion that potential risks to both were low (FAO, 1998). The National Pesticide Information Center has presented similar findings, noting that effects of 2,4-D on soil microorganisms were species-dependent (Gervais et al., 2008).

In soils, 2,4-D is degraded primarily by microbes (Tu et al., 2001). 2,4-D has been shown to dissipate more rapidly in soils that were previously treated with 2,4-D, presumably because there was an increase in 2,4-D degrading bacteria after the first application (Tu et al., 2001).

The use of Quizalofop on corn, as discussed in Subsection 4.2.2, will be a new use for cornfield management. The EPA has determined that this herbicide is practically non-toxic to non-targeted beneficial terrestrial insects on an acute contact or chronic toxicity basis (US-EPA, 2007b).

Based on these factors, APHIS does not anticipate any impacts to soil microorganisms from the use of 2,4-D or Quizalofop on DAS-40278-9 corn. As both herbicides are currently registered for use on corn (2,4-D) or crops cultivated in rotation with corn (Quizalofop), any potential impacts would be the same as the No Action Alternative.

Cumulative Effects: Soil Microorganisms

A determination of nonregulated status of DAS-40278-9 corn is not expected to result in changes to current corn cropping practices, with the exception of potential changes in use of certain herbicides.

As discussed in Subsection 4.2.2, the cultivation of DAS-40278-9 corn would likely result in an increase in the use of 2,4-D in corn, as well as the new use of Quizalofop. It is further expected that the increase in use of these two herbicides would coincide with the concomitant reduction in use of other herbicides (see Appendix B in DAS, 2011d). To the extent that 2,4-D and Quizalofop present a lower toxicity to soil microorganisms, the aggregated impact of this change is beneficial when compared with the No Action Alternative.

DAS has announced its intention to create stacked hybrids, using conventional breeding techniques to combine the traits of DAS-40278-9 corn with nonregulated glyphosate-tolerant varieties (DAS, 2011e). These hybrids would thus allow the application of glyphosate to DAS-40278-9 corn in addition to 2,4-D and Quizalofop (DAS, 2011e). Additionally, DAS has announced a new formulation of 2,4-D based on a choline salt formulation, and the corresponding development of the new Enlist™ Weed Control System which takes advantage of the stacked hybrid and the choline salt (DAS, 2011e).

Microorganisms produce aromatic amino acids through the Shikimate pathway, similar to plants (USDA-FS, 2003). Because glyphosate inhibits this pathway, it could be expected that glyphosate would be toxic to microorganisms. However, field studies show that glyphosate has little effect on soil microorganisms; and, in some cases, field studies have shown an increase in microbial activity due to the presence of glyphosate (USDA-FS, 2003). Glyphosate use has been identified as potentially causing increases in certain disease-causing microbes (Fernandez et al., 2009; Kremer, 2010). However, reported increases in infections from pathogenic soil fungi have been determined to be more closely related to reduced tillage and continuous cropping using herbicide-tolerant crops, rather than application of glyphosate (Fernandez et al., 2009).

The choline salt formulation of 2,4-D is currently being reviewed by the EPA for a new label registration (DAS, 2011e, 2011f). The proposed tank mixtures combining this new formulation of 2,4-D and glyphosate as part of the Enlist™ Weed Control System are also being reviewed

(DAS, 2011e, 2011f). APHIS understands that the EPA will consider potential non-target impacts when evaluating new pesticides and approving a new pesticide use label, and that the label will provide appropriate precautions and use limitations to protect non-target organisms. APHIS assumes, for the purposes of this analysis, similar to other EPA label restrictions placed on the use of herbicides that if the choline salt and the premix were to become available, that the products will be used consistent with the EPA label application rate.

Based on these factors, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to affect soil microorganisms.

4.4.4 Biological Diversity

Biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management, including selection and use of insecticides and herbicides; and 4) extent of isolation of the agroecosystem from natural vegetation (Altieri, 1999). The introduction of woodlots, fencerows, hedgerows, wetlands, etc. is one way to enhance biodiversity in large scale monocultures. Additional biodiversity enhancement strategies include intercropping (the planting of two or more crops simultaneously to occupy the same field), agroforestry, crop rotations, cover crops, no-tillage, composting, green manuring (growing a crop specifically for the purpose of incorporating it into the soil in order to provide nutrients and organic matter), addition of organic matter (compost, green manure, animal manure, etc.), as well as the introduction of hedgerows and windbreaks. The adoption of GE crops, with the concomitant reduction in pesticide use and enhanced soil conservation practices, has contributed to the increase in biodiversity in agricultural systems (Carpenter, 2011; Jasinski et al., 2003; Young and Ritz, 2000).

No Action: Biological Diversity

Under the No Action Alternative, DAS-40278-9 corn would continue to be a regulated article. Growers and other parties who are involved in production, handling, processing, or consumption of corn would continue to have access to existing nonregulated herbicide-tolerant corn varieties, pest-resistant varieties, stacked varieties presenting both, and conventional corn varieties. The consequences of current agronomic practices associated with corn production whether traditional or GE varieties, on the biodiversity of plant and animal communities, would not be altered.

Preferred Alternative: Biological Diversity

The cultivation of GE corn varieties currently available affects biological diversity by: 1) providing the opportunity to use conservation practices that enhance habitat creation and 2) decreasing the use of pesticides which in turn, limits the impact on the floral and faunal communities that potentially can inhabit the fields and immediate surroundings (Carpenter, 2011; Jasinski et al., 2003; Sanvido et al., 2006). Incorporation of herbicide tolerance in the corn crop will permit the grower to more widely adopt the use of no-till, cover crops, crop rotation, intercropping, and good ditch/border/hedgerow management, each of which contributes to biodiversity in and around cornfields (Palmer et al., 2011; Sharpe, 2010).

DAS has presented results of agronomic field trials comparing DAS-40278-9 corn and a conventional hybrid; the results of which suggest that there are no meaningful differences in agronomic practices (DAS, 2010). Therefore, the introduction of DAS-40278-9 corn is not expected to meaningfully change agronomic practices or plant communities, other than those discussed relative to impacts of the change of herbicide use patterns for 2,4-D and Quizalofop.

As discussed above in Subsection 4.2 – Agricultural Production of Corn, Subsection 4.4.1 – Animal Communities, and Subsection 4.4.2 – Plant Communities, a determination of nonregulated status of DAS-40278-9 corn may result in changes in the use of 2,4-D and Quizalofop in corn, and for the use of Quizalofop for the control of volunteer corn. The potential impact associated with changes in herbicide use in corn cultivation on vegetative biodiversity is an issue of concern. Although cornfields are cultivated as monocultures to optimize yield, areas surrounding a cornfield may harbor a variety of plants as well as the animal communities that depend on those plants for cover and forage. Uncontrolled herbicide drift of these broad spectrum herbicides has the potential to impact off-site plant communities. The EPA has addressed pesticide drift by establishing application protocols on the pesticide label that restrict applications during certain weather conditions and that also provide for specific droplet size to minimize off-target drift (DuPont, 2010; Nufarm, 2009; US-EPA, 2005c) .

The proposed changes in use of 2,4-D and the new use of Quizalofop are not expected to present potential impacts to biodiversity from dietary and environmental exposures. The EPA has evaluated the dietary and environmental exposures associated with the use of 2,4-D and Quizalofop in the course of reregistration of the products (US-EPA, 2005c, 2007b), as well as analyses of potential impacts to threatened and endangered species (US-EPA, 2009b, 2011e). Both herbicides are noted to cause indirect harm by affecting non-target plants that may serve as forage or cover (US-EPA, 2005c, 2007b). EPA label use restrictions for both herbicides are intended to mitigate the potential risks from that exposure; both herbicides are currently approved for use in accordance with the label application restrictions while EPA continues its collection and review of data.

The EPA has entered into consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service regarding potential impacts of the use of 2,4-D on threatened and endangered species (see NOAA-NMFS, 2011; US-EPA, 2009b). In addition, the EPA is currently completing a comprehensive ecological risk assessment, including an endangered species risk assessment for the labeled uses of Quizalofop (US-EPA, 2008). A summary of the EPA's assessments for these two herbicides is presented in Subsection 4.9. The EPA has approved the continued use of both herbicides consistent with current label use restrictions.

The EPA is currently reviewing proposed label changes for both herbicides to provide for the change in application to the DAS-40278-9 corn variety (DAS, 2010). As discussed in Subsections 4.2.2, 4.4.1, and 4.4.2, and based on the information provided by DAS, APHIS understands that the total volume of 2,4-D applied to corn in the U.S. could potentially increase in response to the introduction and cultivation of this variety, although the total maximum application on a per-field basis is no different than that already approved for use in corn. APHIS further understands that the total volume of Quizalofop applied to crops in the U.S. could increase, and that this application to corn is a new use. APHIS also understands that the total maximum application of Quizalofop on a per-field basis in corn is less than that already approved for use in soybeans and cotton. APHIS anticipates that the EPA registration process will address potential biodiversity impacts associated with the change in use, and that the EPA registration labels will include appropriate restrictions on use, if necessary, to provide for the safe application of these products. APHIS further assumes that these products will be used consistent with the EPA approved labels.

A determination of nonregulated status of DAS-40278-9 corn is unlikely to have any direct toxic effects on non-target organisms associated with the exposure to the *aad-1* gene and the AAD-1 protein. Future herbicide use will be conducted consistent with EPA-approved labels. Based on these assumptions, the potential impacts to biodiversity of plant communities from a determination of nonregulated status of DAS-40278-9 corn are similar to those from current corn agronomics.

Based on these findings, the potential impacts to biodiversity from a determination of nonregulated status of DAS-40278-9 corn are not appreciably different from the current conditions experienced in the No Action Alternative. The introduction of alternative modes of action for weed control in DAS-40278-9 corn is anticipated to allow growers to maintain their conservation tillage practices, thus preserving and enhancing soil and water quality, and providing the attendant benefits to biodiversity from those improvements.

Cumulative Effects: Animals, Plants, and Biodiversity

APHIS has determined that there are no impacts from past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to create cumulative impacts or reduce the long-term productivity or sustainability of any of the resources associated with the ecosystem in which DAS-40278-9 corn is planted.

Cultivation of DAS-40278-9 corn, with the attendant expression of the AAD-1 protein providing herbicide tolerance, is unlikely to have direct toxic effects on non-target organisms exposed to the *aad-1* gene and the corresponding AAD-1 protein. Therefore, the likelihood of adverse cumulative effects on non-target organisms and biodiversity as a consequence of direct exposure to the AAD-1 protein following the introduction of DAS-40278-9 corn is minimal.

The cultivation of DAS-40278-9 corn offers the grower the ability to change the use of 2,4-D and Quizalofop relative to the cultivation of corn. The use of Quizalofop on corn is a new use. As presented in Table 4-2, in Subsection 4.2.2 above, to the extent that growers use Quizalofop on DAS-40278-9 corn, there would be a commensurate increase in total volume of Quizalofop applied, although the total annual maximum application per field is less than that already approved by EPA for use in soybeans and cotton. Similarly, although the herbicide 2,4-D is already approved by EPA for use on corn, DAS-40278-9 corn allows the grower to change the application rates during post-emergent use. The proposed 2,4-D application rates are consistent with the currently EPA approved rates for field corn and popcorn (DAS, 2011e). The total per-acre application of 2,4-D will not increase, but the total number of acres of corn treated with 2,4-D may potentially increase. APHIS expects that both herbicides would be used in accordance with proposed EPA labels.

Stacked crop varieties, expressing tolerance to multiple herbicides and different forms of insect resistance, are widespread in the industry. The introduction of DAS-40278-9 corn has the potential to impact the rate of development of such stacked varieties, as the availability of a single gene providing tolerance to two herbicides with different modes of action may result in the inclusion of this gene trait in many such stacked varieties. The notable difference is that the availability of the *aad-1* gene as part of a stacked array would allow growers of these hybrid varieties to incorporate 2,4-D or Quizalofop as part of the weed control program. DAS has announced its intention to combine DAS-40278-9 corn as a stacked hybrid with a nonregulated Roundup Ready® variety (DAS, 2011a). Such a combination would allow growers to continue to use glyphosate for weed control, relying on 2,4-D and/or Quizalofop to control those weeds which have developed resistance to glyphosate or are inherently difficult to control with glyphosate alone. Glyphosate commonly is used in conjunction with many other herbicides as a tank mix for both pre-plant/pre-emergence weed control up through the 12-leaf stage or until the corn reaches a height of 30 inches (see, e.g., Loux et al., 2011). Tank mixes of glyphosate and 2,4-D are already in use for control of mixed weeds in the pre-plant stage in no-tillage weed control programs (Loux et al., 2011).

There are many options available for the development of stacked varieties using traits from GE varieties no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act and non-GE traits. Predicting all potential combinations of stacked varieties that could be created using both nonregulated GE corn varieties and also non-GE corn varieties is hypothetical and purely speculative. Other than the proposed future stacking with other glyphosate-tolerant varieties previously determine to be nonregulated, if APHIS determines that DAS-40278-9 corn, identified by DAS in its petition request, is no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act, there is no guarantee that DAS-40278-9 corn will be stacked with any particular nonregulated GE corn variety. Development and commercialization of stacked varieties is driven by company plans and market demands.

DAS-40278-9 corn would provide growers with the ability to diversify their application of herbicides, employing herbicides with different modes of action, the cumulative impact of which could be beneficial to those growers currently managing weeds that have developed resistance to glyphosate and ALS inhibitor herbicides (Wilson et al., 2011b). Growers generally have three options available to manage glyphosate-resistant weeds: 1) increase the frequency and magnitude of glyphosate applications; 2) use other herbicides in addition to glyphosate; or 3) increase the use of tillage and other mechanical controls (Owen et al., 2011; USDA-NRCS, 2010). By combining herbicides offering alternative modes of action into their agronomic practices, the farmer can reduce the use of other herbicides which have been deployed to manage glyphosate-resistant weeds and continue to adopt conservation tillage systems. The associated adoption of conservation tillage and reduced use of soil-applied herbicides have the potential to positively impact animal communities in fields planted with DAS-40278-9 corn (Eggert et al., 2004). The reduction in herbicide use and increase in conservation tillage both benefit animals, plants, and biodiversity in and around the cornfields.

Control of volunteer corn engineered to express herbicide tolerance is a potential concern. As previously discussed, volunteer corn from a parent strain that expresses glyphosate tolerance might be controlled in a LibertyLink® crop with the use of glufosinate (Minnesota, 2009; Reddy, 2001). As stacked crops are developed expressing multiple herbicide tolerance traits, the options for volunteer control become more limited. However, although DAS-40278-9 corn expresses tolerance to the ACCase inhibitor herbicides, this tolerance is limited to the AOPP family of herbicides (the “fops”) (DAS, 2010). DAS-40278-9 corn is sensitive to the cyclohexanedione family (the “dims”) (DAS, 2010). Based on this selective sensitivity, DAS-40278-9 corn volunteers could be controlled with clethodim or sethoxydim, for example (Bernards et al., 2010; DAS, 2010; Johnson et al., 2010).

DAS has developed a Stewardship Strategy to minimize the development of herbicide-tolerant weeds when the stacked varieties are cultivated (see DAS, 2011b). This strategy incorporates the practices and procedures outlined in Subsections 2.2.2 and 4.2.2, Cropping Practices. Relatively few weeds have developed resistance to synthetic auxins or ACCase inhibitor herbicides when compared with other herbicide classes (USDA-APHIS, 2010). The International Survey of Herbicide Resistant Weeds (ISHRW) provides regularly updated lists of herbicide-resistant weeds (see: http://www.weedscience.org, cited as Heap, 2011b). In the U.S., the ISHRW has identified 8 broadleaf weeds resistant to the synthetic auxins and 15 grasses resistant to ACCase inhibitors (“fops”) (Heap, 2011a; USDA-APHIS, 2010). Within the U.S., none of the broadleaf weeds resistant to synthetic auxins have been found in cornfields to date, and grass weeds resistant to “fops” have not been identified as problems for corn growers (USDA-APHIS, 2010). By comparison, there are 44 weeds in the U.S. identified as resistant to the ALS herbicides (such as atrazine) and 13 species are resistant to glyphosate (Heap, 2011b; USDA-APHIS, 2010). As noted in Table 4-3, many of these weeds are controllable using 2,4-D or ACCase herbicides.

Globally, ISHRW identifies many weeds expressing herbicide resistance to multiple modes of action. Growers implementing weed control strategies incorporating herbicides expressing multiple modes of action will need to adhere closely to the Stewardship Strategy to avoid selecting for such species. For example, Barnyard grass (*Echinochloa crus-galli*) is identified as resistant to synthetic auxins in the U.S., whereas in Brazil, this same species is also identified as resistant to the ALS herbicides (Heap, 2011b). Kochia (*Kochia scoparia*) has been identified as resistant to both synthetic auxins and glyphosate in the U.S. (Heap, 2011b; USDA-APHIS, 2010). This weed, despite being identified as herbicide-resistant in 1994, is not reported to be a major crop management problem (Wright et al., 2011) The ISHRW has identified several instances of weeds in the U.S. which show resistance to ACCase inhibitors and other modes of action (Heap, 2011a; USDA-APHIS, 2010). Adherence to the Stewardship Strategy is expected to minimize the development of weeds with expressing resistance to multiple herbicides (DAS, 2011b; Wright et al., 2011). Although farmers may have to change their management strategies to adopt varieties stacked with the DAS-40278-9 corn traits, these changes will not necessitate a major departure from well-established and broadly used agricultural protocols currently in use.

Based on these findings, APHIS has not identified any cumulative impacts to biological resources (animals, plants and biodiversity) associated with a determination of nonregulated status of DAS-40278-9 corn.

4.4.5 Gene Movement

Vertical Gene Flow – Movement to Other Varieties and Corn Relatives

The possibility of gene movement from the host plant into native or feral populations of *Zea* species or wild or weedy relatives of corn has been evaluated by the EPA and determined not to be a concern in the continental U.S. (US-EPA, 2010).

Gene flow between corn varieties is most likely to occur during cultivation as well as the handling and processing of corn (Coulter et al., 2010; Mallory-Smith and Sanchez-Olguin, 2010; Thomison, 2009). Corn is a cross-pollinating crop in which most pollination results from pollen dispersed by wind and gravity (Thomison, 2009). As discussed above in Subsections 4.2.3 – Seed Production, and 4.2.5, Specialty Corn Production, growers concerned about cross pollination can incorporate standard management methods to control pollen drift in order to manage this form of gene flow.

Gene flow through handling and processing is especially problematic if product handling facilities where corn is dried, cleaned, and stored do not maintain adequate separation between varieties (Mallory-Smith and Sanchez-Olguin, 2010). Such admixtures at these facilities have been reported for varieties of GE corn and conventional corn (Mallory-Smith and Sanchez-Olguin, 2010). As discussed above in Subsection 4.2.5, Specialty Corn Production, procedures for managing identity of specific varieties are already in place to minimize gene flow challenges arising from admixtures during handling. This form of gene flow occurs irrespective of the variety of corn being cultivated, and is not a new concern associated with this variety. Although not a new phenomenon, such gene flow does have the potential to affect management of corn as a volunteer. For example, if the *aad-1* gene from DAS-40278-9 corn should pass to progeny through cross pollination, and the AAD-1 protein is expressed in that cross-pollinated hybrid, and that hybrid becomes a volunteer, that volunteer would not be controlled by Quizalofop. As discussed in Subsection 4.4.2, other alternative methods are available to control corn as a volunteer.

Horizontal Gene Flow – Movement to Unrelated Species

Two soil bacteria species commonly associated with plants, *Agrobacterium* and *Rhizobium*, have been evaluated to determine the probability of horizontal gene transfer between the bacterium and its host plants. *Agrobacterium* moves its genes from its bacterial plasmid to the plant, causing the plant to produce crown gall (abnormal outgrowth) (University of Illinois, 2010). *Rhizobium* aids in nitrogen fixation in legume nodules (Wilkinson and Elevitch, 2011). The genomes of both bacteria have been sequenced, and the sequenced genes evaluated for exogenous genes (Kaneko et al., 2000; Kaneko et al., 2002; Wood et al., 2001). Despite what would appear to be millennia of symbiotic relationships between these bacteria and their host plants, there is no evidence that these organisms contain genes derived from plants; in cases where review of sequence data implied that horizontal gene transfer occurred, these events are inferred to occur on an evolutionary time scale in the order of millions of years (Brown, 2003; Koonin et al., 2001). Transgene DNA promoters and coding sequences are optimized for plant expression, not bacterial expression. Horizontal gene flow, resulting in the relocation of entire transgenes including the regulatory portions of the DNA (those parts of the DNA which code for the production of the specific proteins in that relocated transgene) never has been shown to occur in nature (Clarke, 2007; Stewart, 2008). Thus, even if horizontal gene transfer occurred, proteins associated with these transgenes are not likely to be produced in the new host organism. Based on this information, APHIS considers the horizontal gene flow from DAS-40278-9 corn to unrelated species to be unlikely, and the same as potential horizontal gene flow from existing GE corn varieties.

Horizontal gene flow has been implicated in the incorporation of a specific genetic sequence in the parasitic plant purple witchweed (*Striga hermonthica*), which infests cereal fields including corn and sorghum (*Sorghum bicolor*) (USDA-APHIS, 2010; Yoshida et al., 2010). Yoshida concluded that the incorporation of the specific genetic sequence (with an unknown function) occurred between sorghum and purple witchweed before speciation of purple witchweed (*S. hermonthica*) and related cowpea witchweed (*S. gesnerioides*), a parasitic plant of dicots, from their common ancestor. In other words, horizontal gene transfer between a parasitic plant and its host is an extremely rare event; and furthermore, *S. hermonthica* is not found in the U.S. and *S. asiatica* (another related parasite of cereal crops) is only present in North Carolina and South Carolina (USDA-NRCS, 2011). The *Striga* that occurs in the U.S. is listed as a Federal noxious weed, and is restricted in its distribution - largely due to an APHIS containment, quarantine, and eradication program (Nickrent and Musselman, 2004, Updated 2010 available at http://www.apsnet.org/edcenter/intropp/pathogengroups/pages/parasiticplants.aspx), so the likelihood of this horizontal gene flow occurring is limited by geography. Herbicide-tolerant crops, including transgenic herbicide-tolerant crops, are being explored and utilized to control plant parasites including *Striga* and *Orobanche* spp. (Abayo et al., 1998; Esilaba, 2006) There is no evidence reported to date that herbicide resistance traits have been transferred from herbicide-tolerant crops to *Striga*.

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

<u>No Action: Gene Movement</u>

Under the No Action Alternative, conventional and GE transgenic corn production would continue while DAS-40278-9 corn would remain a regulated article. Gene flow between current commercially available corn cultivars, both GE and non-GE, would remain unchanged from the current condition.

Preferred Alternative: Gene Movement

Under this alternative, DAS-40278-9 corn would be available to growers. The EPA has determined that gene flow associated with the cultivation of DAS-40278-9 corn would not be a concern in the continental U.S. (US-EPA 2010).

APHIS has evaluated the potential for gene flow between cultivated corn and teosinte in Mexico (USDA-APHIS, 2010). Although hybridization is known to occur, these hybrids are difficult to obtain outside of the laboratory, the resulting hybrids are often sterile or have greatly reduced fertility, the hybrids are less fit, do not disseminate seed, have a reduced reproductive capacity, and none can withstand even the mildest winters (OECD, 2003; USDA-APHIS, 2010).

Gene movement between sexually compatible corn varieties and related species is no greater for DAS-40278-9 corn than it is for other non-GE or GE cultivars (USDA-APHIS, 2010). Many factors limit the likelihood of gene movement between corn varieties. These include:

- The *aad-1* gene in DAS-40278-9 corn does not impart an agronomic advantage whereby a greater potential for weediness or invasiveness would result should introgression occur;
- Neither GE or non-GE corn cultivars form self-sustaining populations outside of cultivation because of limitations in seed dispersal, germination, and seasonal limitations (US-EPA, 2010); and
- The corn industry has measures in place as part of seed certification and varietal protection to restrict pollen movement and gene flow between cornfields through the use of isolation distances, border and barrier rows, the staggering of planting dates, detasseling and hand pollination, and various seed handling, transportation and handling procedures (Mallory-Smith and Sanchez-Olguin, 2010; Wozniak, 2002).

If the *aad-1* gene from DAS-40278-9 corn should pass to progeny through uncontrolled cross pollination, and the AAD-1 protein is expressed in that cross-pollinated hybrid, and that hybrid becomes a volunteer, that volunteer corn would not be controlled by Quizalofop. Alternative volunteer weed control methods are available to the grower. Control of volunteer corn is discussed in Subsection 4.4.2.

APHIS has determined that DAS-40278-9 corn is not a plant pest and that gene flow between this product and other plants will not occur in the U.S. (USDA-APHIS, 2010).

Based on the above information, APHIS has concluded that a determination of nonregulated status of DAS-40278-9 corn would have the same effect on gene movement as the No Action Alternative.

Cumulative Effect: Gene Movement

Based on available scientific evidence, APHIS has not identified any cumulative effects on gene movement that would occur from a determination of nonregulated status of DAS-40278-9 corn.

DAS has indicated its intention to develop a “stacked” hybrid through conventional breeding techniques combining the 2,4-D and “fop” tolerance from DAS-40278-9 corn with glyphosate tolerance from another nonregulated corn variety (DAS, 2010, 2011d, 2011e). The possibility of gene movement through cross pollination presents potential cumulative impacts relative to volunteer corn control associated with cultivation of this stacked hybrid. As discussed in Subsection 4.4.2, alternative management strategies are available to growers to manage volunteer corn.

There is no evidence that horizontal gene transfer and expression of DNA occur between corn and soil bacteria or unrelated plant species under natural field conditions. Even if this were to occur, proteins corresponding to the transgenes are not likely to be produced.

Based on these findings, APHIS has not identified any cumulative effects on gene flow from a determination of nonregulated status of DAS-40278-9 corn.

4.5 PUBLIC HEATH

4.5.1 Human Health

Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and labeled properly. Food and feed derived from DAS-40278-9 corn must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market.

With regard to human health effects, the FDA assesses the relative toxicity of the incorporated *aad-1* gene and its expressed AAD-1 protein from the perspectives of food safety as well as direct exposure. DAS has submitted a food and feed safety and nutritional assessment to the FDA. Internationally, organizations such as the EFSA and ANZFS conduct comparable reviews.

Regarding the potential future use of 2,4-D and Quizalofop on corn, the proposed future uses require FIFRA label registration changes from the EPA. Label registration reviews with the EPA are underway for both herbicides.

No Action: Human Health

Under the No Action Alternative, DAS-40278-9 corn would continue as a regulated article. Grower and consumer exposure to this product would be limited to those individuals involved in the cultivation under regulated conditions. Human exposure to existing traditional and GE corn would not change under this alternative.

Preferred Alternative: Human Health

APHIS takes into account the FDA and the EPA regulatory assessments when assessing potential impacts of responding to a petition request for determination of nonregulated status. Two evaluations are conducted for GE agricultural crops such as DAS-40278-9 corn: 1) an analysis of potential impacts associated with incidental consumption of the pesticides applied to the modified crop and 2) an analysis of the food safety associated with the human ingestion of the AAD-1 protein. The FDA has completed its review and published its Biotechnology

Consultation (US-FDA, 2011). A copy of the FDA's consultation is provided in Appendix A. At the time of this writing, EPA is reviewing the information submitted by the applicant for DAS-40278-9 corn.

2,4-D and Quizalofop

DAS-40278-9 corn does not express pesticidal properties, so the EPA has no direct FIFRA jurisdiction over this product. However, as discussed in Subsection 4.2.2, DAS-40278-9 corn provides for a change in how the herbicide 2,4-D might be applied to corn, and further provides for the new use of Quizalofop. These changes in use require changes in the FIFRA labels for both products.

The EPA considers human health effects from the use of pesticides when it conducts its registration evaluation. The pesticide registration label is intended to provide appropriate use guidelines and application restrictions and precautions so as to protect the human health. EPA uses the standard of "no unreasonable adverse effects" in making its registration determinations. FIFRA defines this term as follows—

> UNREASONABLE ADVERSE EFFECTS ON THE ENVIRONMENT — The term ''unreasonable adverse effects on the environment'' means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) …(See; FIFRA, Section 2(bb), 7 U.S.C. §136(bb))

The herbicide 2,4-D is already approved by EPA for use in corn. Proposed label application rates for 2,4-D on DAS-40278-9 corn change the application sequence, eliminating the per-harvest applications currently provided on the label. Although the per acre volume of 2,4-D will not increase over currently approved label rates, the total volume of 2,4-D applied to corn would potentially increase for those growers cultivating this variety.

The human health effects from exposure to 2,4-D have been evaluated by the EPA. The herbicide was introduced in 1946 and registered as a post-emergent broadleaf herbicide in 1948 (US-EPA, 2005a). The herbicide registration was re-evaluated by the EPA, culminating in reregistration by the EPA in 2005 (US-EPA, 2005a). The EPA's Reregistration Eligibility Document (RED) presents the data used by the EPA in reregistering the chemical (see US-EPA, 2005a; US-EPA, 2005c). In the reregistration process, the EPA evaluated the potential impact on human health of the use of the herbicide (US-EPA, 2005a, 2005c). The RED provides EPA's analysis of toxicity, carcinogenicity, and developmental toxicity. The herbicide 2,4-D is considered to have low acute toxicity, although when long-term studies were conducted at high dose levels, the herbicide was identified as toxic to the eye, thyroid, kidney, adrenals, and ovaries/testes, and certain neurotoxicities were observed (US-EPA, 2005a, 2005c). The herbicide has been studied for its carcinogenic potential, and the EPA has concluded that none of the studies definitively link 2,4-D to human cancer cases (US-EPA, 2005a, 2005c). In 2007, the EPA determined that a Special Review of 2,4-D to further evaluate its carcinogenic potential was not warranted by the data presented. The EPA has concluded that when used in accordance with the label, the herbicide 2,4-D does not result in unreasonable adverse effects (US-EPA, 2005a, 2005c). APHIS assumes that any potential future use of 2,4-D on DAS-40278-9 corn or its progeny will be undertaken consistent with the EPA label.

Quizalofop was first registered in 1988, and is currently the subject of a registration review (US-EPA, 2007b). Quizalofop is not currently registered for use on corn, but is registered for use as a graminicide on both soybeans and cotton, among other crops (see DuPont, 2010). As illustrated in Table 4-2, the proposed new use of Quizalofop in DAS-40278-9 corn provides a maximum application rate less than that currently approved for use on soybeans and cotton. In 2006, the EPA completed a human health risk assessment evaluating the consequences of various exposures to Quizalofop (US-EPA, 2007b). The EPA concluded that the risk estimates were below the agency levels of concern for all population subgroups as a result of dietary exposure (US-EPA, 2007b). The EPA also determined that the herbicide did not present a hazard to workers from dermal or inhalation exposures (US-EPA, 2007b). The EPA concluded that Quizalofop presented low acute toxicity for dermal, inhalation, eye and skin irritation; found no evidence of neurotoxicity; and no developmental impacts (US-EPA, 2007b). Quizalofop is also not classified as a human carcinogen (US-EPA, 2007b). The EPA approved label for Quizalofop provides precautions and use limitations to mitigate against no unreasonable adverse effects. APHIS assumes that any potential future use of Quizalofop on DAS-40278-9 corn or its progeny will be undertaken consistent with the EPA label.

Pesticide residue tolerances have been published for 2,4-D (US-EPA, 2011a) and Quizalofop (US-EPA, 2011c) for food consumption for a variety of crop products and animals. The EPA establishes tolerances to regulate the amount of pesticide residues that can remain on food or feed commodities as the result of pesticide applications (see, e.g., http://www.epa.gov/pesticides/bluebook/chapter11.html). The tolerance level is the maximum residue level of a pesticide that can legally be present in food or feed, and if pesticide residues are found to exceed the tolerance value, the food is considered adulterated and may be seized.

Pesticide residue tolerances for 2,4-D in field corn for forage, grain, and stover are already published (US-EPA, 2011a). It is unclear whether the proposed label change for 2,4-D applications on DAS-40278-9 corn would require a corresponding change in the tolerance for 2,4-D on corn. As discussed in Subsection 4.2.2, the changes in application rates and uses for the herbicides 2,4-D and Quizalofop on DAS-40278-9 corn are different from current uses.

The proposed change in use of 2,4-D on corn provides for a change in the post-emergent application of the herbicide to corn, and eliminates the pre-harvest application; the total maximum application rate per field and the total annual maximum application are the same as those already registered for use on corn. Based on the similarity in application rates and total annual applications, the 2,4-D pesticide residue tolerances on DAS-40278-9 corn products are expected to be similar to those already approved by EPA for field corn.

There is currently no pesticide residue tolerance established for Quizalofop on corn. As illustrated in Table 4-2, the proposed total maximum application rate and the total annual maximum application for Quizalofop on corn are equal or less than that already approved for use on soybeans and cotton. APHIS expects that a pesticide residue tolerance for DAS-40278-9 corn derived field corn for grain, forage and stover will be established as part of the new registration for this product.

The processing of corn-based food products has been demonstrated to reduce pesticide residues below the level of detection (CRA, 2000). In 1998, the USDA evaluated pesticide residues in high-fructose corn syrup, milk, vegetables, and fruits (USDA-AMS, 1998). Corn syrup samples were collected from 40 states and analyzed for 109 pesticides; no pesticide residues were detected in any of the corn syrup samples (USDA-AMS, 1998). Corn is an important component of animal feed, and many industrial chemicals, particularly those which are fat-soluble, are known to partition into milk. Part of the AMS study evaluated whether certain pesticides partitioned into milk. In a focused evaluation of 92 whole milk samples for the presence of 2,4-D, no 2,4-D residues were detected in any of the milk (USDA-AMS, 1998).

In the absence of completed agency reviews by the EPA, APHIS takes into consideration prior reviews of comparable products to assist in evaluating potential impacts to human health. In this case, international reviews provide some evidence on pesticide residue concerns for both 2,4-D and Quizalofop. The ANZFS has completed a comprehensive safety assessment of food derived from DAS-40278-9 corn (ANZFS, 2010a, 2010b, 2011). ANZFS concluded that food derived from DAS-40278-9 corn was comparable to non-genetically engineered (non-GE) corn (ANZFS, 2011). The ANXFS analysis included a review of herbicide treatment field trials in which both conventional and DAS-40278-9 corn plots were cultivated, and herbicide treated plots of both were compared with plots which were untreated (ANZFS 2010b; 2011). ANZFS (2011) further concluded that—

> The major residues generated on corn line DAS-40278-9 as a result of spraying with 2,4-D and Quizalofop-P-ethyl are not novel. The residues are the same as those found on conventional crops sprayed with 2,4-D or Quizalofop-P-ethyl. Residue data, derived from supervised trials, indicate that the residue levels for both herbicides are below the limit of quantitation. In the absence of any measurable exposure to either parent herbicide or their metabolites, the risk to public health and safety is likely to be negligible.

Based on existing exemptions from tolerance, the implications of food processing on the residues, and including the conclusions presented by ANZFS, APHIS concludes that the proposed changes in use of 2,4-D and Quizalofop for corn do not present human health concerns.

AAD-1 Protein

The AAD-1 protein in DAS-40278-9 corn is derived from the common gram-negative soil bacterium *Sphingobium herbicidovorans* (DAS, 2010). *Sphingobium* is a member of the sphingomonads, a widely distributed bacteria group isolated from soil and water as well as plant root systems (DAS, 2009, 2010). The sphingomonads have been used widely in biotechnology applications, including bioremediation of environmental contaminations as well as production of sphingans, bio-based polymers which are used in the food industry (DAS, 2010; Lal et al., 2006; Pollock and Armentrout, 1999).

The FDA has concluded its review of DAS' submittal of safety and nutritional data for DAS-40278-9 corn (see Appendix A; US-FDA, 2011). DAS conducted safety evaluations based on Codex Alimentarius Commission procedures to assess any potential adverse effects to humans or animals resulting from environmental releases and consumption of DAS-40278-9 corn (DAS, 2010; FAO, 2009; US-FDA, 2011). These safety studies included evaluating protein structure and function, including homology searches of the amino acid sequences with comparison to all known allergens and toxins, an *in vitro* digestibility assay of the proteins, an acute oral toxicity feeding study in mice, and a feeding study in broiler chickens (DAS, 2010; Herman et al., 2011; Herman et al., 2010; US-FDA, 2011). The DAS-40278-9 corn AAD-1 protein was determined to have no amino acid sequence similar to known allergens, lacked toxic potential to mammals, and was degraded rapidly and completely in gastric fluid (DAS, 2010; US-FDA, 2011). At this time, the FDA considers the consultation on DAS-40278-9 corn to be complete (US-FDA, 2011).

The broiler chicken feeding study supports the human health impacts analysis. In this study, chickens fed diets containing up to 60% DAS-40278-9 corn were compared with chickens fed similar percentages of non-transgenic commercial corn hybrids (Herman et al., 2011). None of the corn used in this feeding study was reported to have been treated with either 2,4-D or Quizalofop (Herman et al., 2011). The results of this study found no difference between any of the feeding cohorts in growth, feed conversion, and carcass weight (Herman et al., 2011). In this study, the birds were exposed through dietary consumption to more than 0.52 ppm of the AAD-1 protein for 42 days, during which time the bird's average weight increased over 60-fold (Herman et al., 2011). No adverse effects or nutritional deficiencies were noted (Herman et al., 2011).

DAS also has evaluated the compositional safety of DAS-40278-9 corn, comparing the composition of the modified corn with conventional products (DAS, 2010; Herman et al., 2010). Compositional elements compared included moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and antinutrients (DAS, 2010; Herman et al., 2010). In these studies, compositional comparisons were made between unsprayed DAS-40278-9 corn, DAS-40278-9 corn sprayed with 2,4-D, DAS-40278-9 corn sprayed with Quizalofop, DAS-40278-9 corn sprayed with both 2,4-D and Quizalofop, and several conventional corn varieties. There were no biologically meaningful differences for any of these compositional characteristics between the DAS-40278-9 corn and the conventional corn varieties (DAS, 2010; Herman et al., 2010).

As discussed in Subsection 2.5, Public Health, human food products manufactured from feed corn are subjected to a variety of mechanical and chemical processes to produce the final product, each step of which tends to disrupt protein integrity (Hammond and Jez, 2011). These processes, in addition to the demonstration by DAS that the protein is rapidly degraded in gastric fluids, suggests that human exposure to the AAD-1 protein in corn will be very limited.

ANZFS has completed a comprehensive safety assessment of food derived from DAS-40278-9 corn (ANZFS, 2010a, 2010b, 2011). ANZFS concluded that food derived from DAS-40278-9 corn was comparable to non-GE corn (ANZFS, 2011).

As with other herbicide-tolerant corn products no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act and commercialized, DAS-40278-9 corn is expected to be used throughout corn producing areas of the country.

Based on these factors, including an analysis of field and laboratory data and scientific literature provided by DAS (DAS, 2010) and safety data available on other GE corn, APHIS has concluded that a determination of nonregulated status of DAS-40278-9 corn would have no adverse impacts on human health. Overall impacts are similar to the No Action Alternative.

Cumulative Effects: Human Health

As discussed in Subsections 4.2.2, DAS has announced its intention to market DAS-40278-9 corn as a stacked variety by combining this trait via conventional hybridization techniques with other nonregulated varieties. The initial stacked variety will combine the DAS-40278-9 corn variety with a glyphosate-tolerant variety, providing the grower with the option to combine several herbicides with different modes of action for control of weeds.

The potential effects from the cultivation of glyphosate-tolerant crops, with a corresponding analysis of the implications of the use of glyphosate, have been thoroughly evaluated in other EAs since the 1993 introduction of the first glyphosate-tolerant crop product. (See: www.APHIS.USDA.gov/biotechnology/not_reg.htm.) A list of APHIS EAs evaluating the potential impacts of the use of glyphosate on the human environment is provided in Subsection 4.2.2. Glyphosate has been widely used on corn since the first glyphosate-tolerant corn variety in 1996 was determined to be no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act (see Petition No. 96-317-01p, Monsanto's Glyphosate-tolerant and European Corn Borer-resistant Corn, at www.APHIS.USDA.gov/biotechnology/not_reg.htm). The use of glyphosate herbicide does not appear to result in adverse effects on development, reproduction, or endocrine systems in humans and other mammals. Under present and expected use conditions, and when used in accordance with the EPA label, glyphosate does not pose a health risk to humans.

DAS has also announced that DAS-40278-9 corn will be marketed under the Enlist™ Weed Control System (DAS, 2011a). The Enlist™ Weed Control System involves a new formulation of 2,4-D based on a choline salt (DAS, 2011a). As discussed in Subsection 4.2.2, DAS has submitted new label registration information on this formulation to the EPA. Approved label application rates, and corresponding precautions and label use restrictions have not yet been published by the EPA. APHIS assumes, for the purposes of this cumulative effects analysis, that the new choline salt formulation of 2,4-D will not be used on DAS-40278-9 corn or its progeny until a new pesticide use registration and corresponding label have been published by the EPA. APHIS also assumes that EPA's label for this new formulation will establish use precautions and restrictions so that when it is used consistent with the label restrictions, no adverse effects to the human environment will be observed.

Based on these factors, no significant impacts to human health related to the No Action Alternative or a determination of nonregulated status of DAS-40278-9 corn are expected, and no cumulative effects have been identified.

4.5.2 Worker Safety

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

No Action: Worker Safety

During agricultural production of corn, agricultural workers and pesticide applicators may be exposed to a variety of EPA registered pesticides. Under the No Action Alternative, agricultural workers and pesticide applicators may be exposed to these agricultural chemicals during corn production, including the herbicide 2,4-D which is labeled for use on corn. Such chemicals would be expected to include those products currently used for management of plant pests and weeds in both GE and non-GE corn cultivation.

Preferred Alternative: Worker Safety

Similar to the No Action Alternative, it is expected that EPA registered pesticides that currently are used for corn production will continue to be used by growers, including the use of 2,4-D. As discussed in Subsection 4.2.2, 2,4-D currently is registered for use on corn, and in 2005, 2,4-D was applied on less than 8% of corn acreage (~2 million pounds applied) (USDA-NASS, 2006). It is conceivable that the cultivation of DAS-40278-9 corn could result in a broader use of 2,4-D on corn. As illustrated in Table 4-1, DAS-40278-9 corn does not change the current application of 2,4-D as a pre-plant or pre-emergent herbicide, but does allow the grower to apply 2,4-D twice during the post-emergent growth period, and eliminates the pre-harvest application (DAS, 2010, 2011a). However, the total per-field application of 2,4-D would not differ from that already approved on the EPA label (see, DAS, 2010). The proposed label changes for 2,4-D provide for annual application rates and maximum total annual applications that are identical to the current corn label (DAS, 2010). In situations where the maximum total annual application is reached, worker exposure to 2,4-D would be similar to that which currently occurs in those farms where 2,4-D currently is applied to corn at the maximum annual rate.

The EPA evaluated occupational risk from exposure to 2,4-D in the product reregistration (US-EPA, 2005c). In that analysis, the EPA concluded that the short-term and intermediate-term exposures to workers, including mixers, loaders, and applicators, were not a human health concern provided that the workers used appropriate personal protective equipment (US-EPA, 2005c). The EPA has reviewed additional information on the potential risks of non-Hodgkins lymphoma, a type of cancer, from 2,4-D exposures (US-EPA, 2007a). Based on the review of epidemiological data and animal studies, the EPA concluded that 2,4-D is not likely to be a human carcinogen (US-EPA, 2007b).

The cultivation of DAS-40278-9 corn does not require use of drop nozzles for post-emergent application. As noted in Table 4-1, the current use of 2,4-D in the post-emergent stage of corn requires the use of drop nozzles to keep the herbicide off of the foliage. As DAS-40278-9 corn is tolerant to 2,4-D, drop nozzles are not required. The current use of drop nozzles has the additional benefit of limiting drift and volatilization of the compound, and by so doing, limiting worker exposure to the product. As 2,4-D is already approved for use on corn as a pre-emergent application without the use of drop nozzles, worker safety precautions are being currently implemented to control this exposure. No changes in management strategies would be required to accommodate this change in application equipment. The application of 2,4-D without drop nozzles is not expected to have a negative impact on worker safety.

As discussed in Subsection 4.2.2, the potential use of Quizalofop on corn is a new use for this herbicide. Although the “fop” herbicides have been registered for crop use for over 20 years these herbicides traditionally have not been used to control weed species in cornfields because, as a grass (Poaceae family) species, corn is damaged by AOPP ACCase inhibitor activity (USDA-APHIS, 2010). The registration and use of “fop” herbicides has been primarily on broadleaf crops, such as soybean, to control grass weed species, although certain cereal plant varieties have a level of tolerance to some “fops” (see DuPont, 2010). Between 1990 and 2006, “fop” type herbicides were used for weed control on at least 23 food crop species, totaling over 16 million pounds of active ingredient (USDA-NASS, 2011d).

The EPA has determined, based on toxicological evidence, that Quizalofop is not toxic through dermal and inhalation routes of exposure (US-EPA, 2007b). Based on this evaluation, occupational risks from exposure are deemed to be well below the EPA’s level of concern (US-EPA, 2007b). DAS is working with DuPont to develop a new EPA label for Quizalofop providing for over-the-top use in DAS-40278-9 corn (DAS, 2010). The proposed application rates and annual maximum total annual applications are equivalent to those rates currently approved for other crops (DAS, 2010).

EPA’s core pesticide risk assessment and regulatory processes ensure that protections are in place for all populations of non-target species, including humans. These assessments provide EPA with information needed to develop label use restrictions for the pesticide. As noted in Subsection 4.5.1, EPA’s baseline criteria for registering a pesticide and providing a label for its use is whether the pesticide use in accordance with the label can be demonstrated to pose “no unreasonable adverse effects” (see FIFRA, 7 U.S.C. §136(bb)). Growers are required to use pesticides, such as 2,4-D and Quizalofop, consistent with the application instructions provided on the EPA-approved pesticide label (see, e.g., DuPont, 2010; Nufarm, 2009). APHIS assumes that worker safety concerns over the proposed changes in 2,4-D application rates will be addressed in any label precautions or use restrictions in the new label for application to DAS-40278-9 corn. These label restrictions carry the weight of law and are enforced by EPA and the states (Federal Insecticide, Fungicide, and Rodenticide Act 7 USC 136j (a)(2)(G) Unlawful Acts). Therefore, it is expected that 2,4-D and Quizalofop use on the DAS-40278-9 corn product would be consistent with the EPA-approved label.

The cultivation of DAS-40278-9 corn may benefit workers by offering access to two herbicides with alternative modes of action in managing fields where glyphosate-resistant weeds have emerged. The emergence of glyphosate-resistant weeds requires changes in weed management tactics, including a return to previous rates of tillage (i.e., increased tillage) as well as increased volume and applications of various pre-emergent and post-emergent herbicides (Owen et al., 2011; Wilson et al., 2011b). As illustrated in Table 4-3, the herbicides 2,4-D and Quizalofop provide alternative means of weed control. In a study of the management of glyphosate-resistant and inherently difficult to control weeds, the adoption of an herbicide program incorporating 2,4-D provided weed control with a lower volume of herbicides per acre than those programs where

2,4-D was not incorporated (DAS, 2011d). A lower volume of herbicides applied would benefit agricultural workers.

Based on the above information, the potential impacts to worker safety from a determination of nonregulated status of DAS-40278-9 corn are the same as those under the No Action Alternative, and to the extent that herbicide application strategies are adopted using 2,4-D to aid in managing resistant weed control resulting in a decrease in herbicide volume applied, worker safety may benefit from the adoption of this product.

Cumulative Effects: Worker Safety

DAS-40278-9 corn is not expected to increase the total acreage of corn production or the cultivation of other varieties of corn. Worker safety issues related to the use of EPA registered pesticides during conventional and GM corn production should remain the same. However, if a grower replaces a non-herbicide-tolerant corn variety with DAS-40278-9 corn, then it would be expected that there would be a change in the use of herbicides associated with corn production, with an increase in use of 2,4-D and Quizalofop.

DAS anticipates that DAS-40278-9 corn will be cultivated as a hybridized stacked variety presenting multiple traits, potentially including other modes of herbicide tolerance as well as insect resistance. Many of the corn varieties with which DAS-40278-9 corn is expected to be hybridized are already commercialized, and the herbicides and insecticidal properties associated with these products have already been evaluated and approved by APHIS, the FDA, and the EPA.

As discussed in Subsections 4.2.2, DAS has announced its intention to market DAS-40278-9 corn as a stacked variety by combining this trait via conventional hybridization techniques with other nonregulated varieties. The initial stacked variety will combine the DAS-40278-9 corn variety with a glyphosate-tolerant variety, providing the grower with the option to combine several herbicides with different modes of action for control of weeds.

The potential effects from the cultivation of glyphosate-tolerant crops, with a corresponding analysis of the implications of the use of glyphosate, have been thoroughly evaluated in other APHIS EAs since the 1993 introduction of the first glyphosate-tolerant crop product. (See: www.APHIS.USDA.gov/biotechnology/not_reg.htm.) A list of APHIS EAs evaluating the potential impacts of the use of glyphosate on the human environment is provided in Subsection 4.2.2. Glyphosate has been widely used on corn since the first glyphosate-tolerant corn variety in 1996 was determined to be no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act (see Petition No. 96-317-01p, Monsanto's Glyphosate-tolerant and European Corn Borer-resistant Corn, at www.APHIS.USDA.gov/biotechnology/not_reg.htm). The use of glyphosate herbicide does not appear to result in adverse effects on development, reproduction, or endocrine systems in humans and other mammals. Under present and expected use conditions, and when used in accordance with the EPA label, glyphosate does not pose a health risk to humans, including workers.

DAS has also announced that DAS-40278-9 corn will be marketed under the Enlist™ Weed Control System (DAS, 2011a). The Enlist™ Weed Control System involves a new formulation of 2,4-D based on a choline salt (DAS, 2011a). As discussed in Subsection 4.2.2, DAS has submitted new label registration information on this formulation to the EPA. Approved label application rates, and corresponding precautions and label use restrictions have not yet been published by the EPA. APHIS assumes, for the purposes of this cumulative effects analysis, that the new choline salt formulation of 2,4-D will not be used on DAS-40278-9 corn or its progeny until a new pesticide use registration and corresponding label have been published by the EPA. APHIS also assumes that EPA's label for this new formulation will establish use precautions and restrictions so that when it is used consistent with the label restrictions, no adverse effects to the human environment will be observed.

DAS has indicated that the new 2,4-D choline salt formulation provides some benefits to the growers, including better management of pesticide drift and volatility, as well as the ability to handle the product as a tank mix with glyphosate (DAS, 2011d). The ability to purchase herbicides as a ready to use premix, in this case combining 2,4-D and glyphosate, would minimize worker exposure to these herbicides during the handling process. To the extent that the new formulation also improves the drift and volatilization characteristics of 2,4-D, this new formulation would also decrease worker exposure through those routes. APHIS assumes that the new pesticide labels being sought by DAS for the choline salt and any premix blends would provide appropriate precautions and use restrictions so as to protect worker health and safety. APHIS further assumes that workers will use these products consistent with these labels.

Based on these factors, no significant impacts to worker safety related to the No Action Alternative or a determination of nonregulated status of DAS-40278-9 corn are expected, and no cumulative effects have been identified.

4.6 ANIMAL FEED

Corn comprises approximately 95% of the total feed grain produced and used in the U.S. (USDA-ERS, 2011b). Animal feed derived from corn comes not only from the unprocessed grain, but also from the residuals derived from three major corn industries: corn refining, corn dry millers, and distillers (CRA, 2006). Animal feed products from corn refining and wet milling include corn gluten feed, corn gluten meal, corn germ meal, corn steep liquor, and amino acids (CRA, 2006).

As with human health, the consumption of the inserted genes and proteins in DAS-40278-9 corn is considered the primary concern relative to animal feed. This subsection also considers the potential impacts of herbicide residues on animal feed.

No Action: Animal Feed

Under the No Action Alternative, DAS-40278-9 corn will remain a regulated product and will not be available as an animal feed.

Corn-based animal feed will still be available from currently cultivated corn crops, both conventional varieties as well as nonregulated GE corn expressing either insect resistance or herbicide tolerance or both. No change in the availability of these crops as animal feed is expected under this alternative.

Preferred Alternative: Animal Feed

APHIS' assessment of the potential impacts of the consumption of the AAD-1 protein by animals considers the source of the gene and the expressed protein as well as safety evaluations conducted by DAS. Our analysis is similar to that presented above in Subsection 4.5.1, Human Health.

Animals are already exposed to the *Sphingobium herbicidovorans* soil bacteria that is the source of the *aad-1* gene and corresponding AAD-1 protein expressed in DAS-40278-9 corn (DAS, 2010). The incorporation of the *aad-1* gene and the expression of the AAD-1 protein is not a novel exposure to animals.

The FDA has concluded its review of DAS' submittal of safety and nutritional data for DAS-40278-9 corn (US-FDA, 2011). DAS conducted safety evaluations based on Codex Alimentarius Commission procedures to assess any potential adverse effects to humans or animals resulting from environmental releases and consumption of DAS-40278-9 corn (DAS, 2010; FAO, 2009; US-FDA, 2011). These safety studies included evaluating protein structure and function, including homology searches of the amino acid sequences with comparison to all known allergens and toxins, an *in vitro* digestibility assay of the proteins, an acute oral toxicity feeding study in mice, and a feeding study in broiler chickens (DAS, 2010; Herman et al., 2011; Herman et al., 2010; US-FDA, 2011). The DAS-40278-9 corn AAD-1 protein was determined to have no amino acid sequence similar to known allergens, lacked toxic potential to mammals, and was degraded rapidly and completely in gastric fluid (DAS, 2010; US-FDA, 2011). At this time, the FDA considers the consultation on DAS-40278-9 corn to be complete (US-FDA, 2011).

The broiler chicken feeding study discussed in Subsection 4.5.1 is also relevant to the animal feed impacts analysis. In this study, chickens fed diets containing up to 60% DAS-40278-9 corn were compared with chickens fed similar percentages of non-transgenic commercial corn hybrids (Herman et al., 2011). In this study, the birds were exposed through dietary consumption to more than 0.52 ppm of the AAD-1 protein for 42 days, during which time the bird's average weight increased over 60-fold (Herman et al., 2011). The results of this study found no difference between any of the feeding cohorts in growth, feed conversion, and carcass weight (Herman et al., 2011).

DAS also has evaluated the compositional safety of DAS-40278-9 corn, comparing the composition of the modified corn with conventional products (DAS, 2010; Herman et al., 2010). Compositional elements compared included moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and antinutrients (DAS, 2010; Herman et al., 2010). In these studies, compositional comparisons were made between unsprayed DAS-40278-9 corn, DAS-40278-9 corn sprayed with 2,4-D, DAS-40278-9 corn sprayed with Quizalofop, DAS-40278-9 corn sprayed with both 2,4-D and Quizalofop, and several conventional corn varieties. There were no biologically meaningful differences for any of these compositional characteristics between the DAS-40278-9 corn and the conventional corn varieties (DAS, 2010; Herman et al., 2010).

As discussed in Subsection 4.5.1, pesticide residue tolerances have been published for 2,4-D (US-EPA, 2011a) and Quizalofop (US-EPA, 2011c) to regulate the amount of pesticide residues that can remain on food or feed commodities as the result of pesticide applications (see, e.g., http://www.epa.gov/pesticides/bluebook/chapter11.html).

Pesticide residue tolerances for 2,4-D in field corn for forage, grain, and stover are already published (US-EPA, 2011a). It is unclear whether the proposed EPA label change for 2,4-D applications on DAS-40278-9 corn would require a corresponding change in the tolerance for 2,4-D on field corn intended for animal feed use as forage, grain, or stover. The proposed change in use of 2,4-D on corn provides for a change in the post-emergent application of the herbicide to corn, and eliminates the pre-harvest application; the total maximum application rate per field and the total annual maximum application are the same as those already registered for use on corn. Based on the similarity in application rates and total annual applications, the 2,4-D pesticide residue tolerances on DAS-40278-9 corn products are expected to be similar to those already approved by EPA for field corn.

There is currently no pesticide residue tolerance established for Quizalofop on corn, although there are pesticide residue tolerances established for Quizalofop for several crops, including crops used as hay and forage (US-EPA, 2011c). As illustrated in Table 4-2, the proposed total maximum application rate and the total annual maximum application for Quizalofop on corn are equal or less than that already approved for use on soybeans and cotton. APHIS expects that a pesticide residue tolerance for DAS-40278-9 corn derived field corn for grain, forage, and stover will be established by EPA as part of the new registration for this product.

The results of studies conducted by DAS confirm that the crops containing this protein can be safely used as animal feed. There are no differences in feed safety between the DAS-40278-9 corn and other varieties currently available under the No Action Alternative.

ANZFS has completed a comprehensive safety assessment of food derived from DAS-40278-9 corn (ANZFS, 2010a, 2010b, 2011). ANZFS concluded that food derived from DAS-40278-9 corn was comparable to non-GE corn (ANZFS, 2011).

Based on the analysis of field and laboratory data and scientific literature provided by DAS (DAS, 2010) and safety data available on other GE corn, APHIS has concluded that a determination of nonregulated status of DAS-40278-9 corn would have no adverse impacts on animal health with regard to animal feed. Overall impacts are similar to the No Action Alternative.

Cumulative Effects: Animal Feed

DAS anticipates that DAS-40278-9 corn will be cultivated as a hybridized stacked variety presenting multiple traits, potentially including other modes of herbicide tolerance as well as insect resistance. Many of the corn varieties with which DAS-40278-9 corn is expected to be hybridized are already commercialized, and the herbicides and insecticidal properties associated with these products have already been evaluated and approved by APHIS, the FDA, and the EPA.

As discussed in Subsections 4.2.2, and in the Human Health analysis in Subsection 4.5.1, DAS has announced its intention to market DAS-40278-9 corn as a stacked variety by combining this trait via conventional hybridization techniques with other nonregulated varieties. The initial stacked variety will combine the DAS-40278-9 corn variety with a glyphosate-tolerant variety, providing the grower with the option to combine several herbicides with different modes of action for control of weeds.

The potential effects from the cultivation of glyphosate-tolerant crops, with a corresponding analysis of the implications of the use of glyphosate, have been thoroughly evaluated in other APHIS EAs since the 1993 introduction of the first glyphosate-tolerant crop product, and are summarized in Subsection 4.2.2 (see: www.APHIS.USDA.gov/biotechnology/not_reg.htm). Glyphosate has been widely used on corn since the first glyphosate-tolerant corn variety in 1996 was determined to be no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act (see Petition No. 96-317-01p, Monsanto's Glyphosate-tolerant and European Corn Borer-resistant Corn, at www.APHIS.USDA.gov/biotechnology/not_reg.htm). The use of glyphosate herbicide does not appear to result in adverse effects on development, reproduction, or endocrine systems in mammals. Under present and expected use conditions, and when used in accordance with the EPA label, glyphosate does not pose a health risk to animals as an animal feed concern. Pesticide residue tolerances for glyphosate include concentration benchmarks for field corn for forage, grain, and stover (US-EPA, 2011b). APHIS assumes that applications of glyphosate to a stacked corn variety incorporating the DAS-40278-9 corn traits will be conducted consistent with the EPA label and consistent with the pesticide residue tolerances.

DAS has also announced that DAS-40278-9 corn will be marketed under the Enlist™ Weed Control System (DAS, 2011a). The Enlist™ Weed Control System involves a new formulation of 2,4-D based on a choline salt (DAS, 2011a). As discussed in Subsection 4.2.2, DAS has submitted new label registration information on this formulation to the EPA. Approved label application rates, and corresponding precautions and label use restrictions have not yet been published by the EPA. APHIS assumes, for the purposes of this cumulative effects analysis, that the new choline salt formulation of 2,4-D will not be used on DAS-40278-9 corn or its progeny until a new pesticide use registration and corresponding label have been published by the EPA. APHIS also assumes that EPA's label for this new formulation will establish use precautions and restrictions so that when it is used consistent with the label restrictions, no adverse effects to the human environment will be observed.

Based on these factors, no significant impacts on animal health related to the No Action Alternative or a determination of nonregulated status of DAS-40278-9 corn, and no cumulative effects have been identified.

4.7 SOCIOECONOMIC ISSUES

4.7.1 Domestic Economic Environment at Risk

Corn has food, feed, and industrial uses (USDA-ERS, 2011b). Corn is the most widely cultivated feed grain in the U.S., accounting for more than 90% of total value and production of feed grains (DAS, 2010). Corn is grown in all 48 of the continental U.S. states with production concentrated in the Corn Belt, loosely defined as the states of Illinois, Iowa, Indiana, the eastern portions of South Dakota and Nebraska, western Kentucky and Ohio, and the northern two-thirds of Missouri (USDA-ERS, 2011b; USDA-NASS, 2010, 2011a). Iowa and Illinois, the two top corn producing states, typically account for slightly more than one-third of the total U.S. crop (USDA-ERS, 2011b).

Domestic economic impacts associated with adoption of a new GE trait are focused on the impact of that trait on the agronomic inputs and associated on-farm costs, as well as the potential market impacts.

No Action: Domestic Economic Environment

Under the No Action Alternative, DAS-40278-9 corn would continue to be a regulated article under the regulations at 7 CFR Part 340. Growers and other parties who are involved in production, handling, processing, or consumption of corn would not have access to DAS-40278-9 corn, but would continue to have access to other nonregulated GE herbicide-tolerant (or stacked) corn varieties as well as other nonregulated GE and conventional corn varieties. Domestic growers would continue to utilize currently available traditional and GE corn varieties based upon availability and market demand.

The continued emergence of glyphosate-resistant weedy species has been identified as an economic concern (NRC, 2010). Glyphosate tolerance has been demonstrated to reduce the effectiveness and economic benefits of glyphosate-tolerant crop systems (DAS, 2011d; Weirich et al., 2011). To manage these tolerant weeds, growers have increased herbicide application rates, increased the number of herbicide applications, and have returned to more traditional tillage practices (DAS, 2011d; NRC, 2010; Sandell et al., 2009). The economic impacts of glyphosate-resistant weeds are a direct result of increased inputs: additional herbicides are required to control the weeds; fuel costs increase as heavy equipment is used more frequently in the field for chemical application; and tillage and labor and management hours increase in association with the application of additional herbicides and machinery use (DAS, 2011c; NRC, 2010; Weirich et al., 2011). There is also an additional cost from the reduction in yield associated with the competition of the crop with the weeds (NRC, 2010; Weirich et al., 2011; Wilson et al., 2011b).

Under the No Action Alternative, the economic trends associated with the increase in costs for agronomic inputs to control herbicide-resistant weedy species would continue.

Preferred Alternative: Domestic Economic Environment

DAS anticipates that DAS-40278-9 corn may replace currently available herbicide-tolerant corn varieties and may be selected by growers of conventional corn varieties making a change to a GE variety; however, availability of DAS-40278-9 corn would not be expected to result in an increase in corn acreage (DAS, 2010). DAS considers the major benefits resulting from the introduction of DAS-40278-9 corn and its progeny to be additional grower choice, with a specific emphasis on providing growers with an option to respond to the emergence of glyphosate-resistant weeds (DAS, 2011c).

DAS presented results of field trials comparing the performance and composition of DAS-

40278-9 corn with other corn varieties when cultivated under different agronomic conditions and using a range of agronomic inputs. No statistically biologically meaningful differences were observed regarding agronomic inputs between DAS-40278-9 corn and any of the other varieties (DAS, 2010). Based on this data, and with the exception of the potential application of new herbicides, the domestic economic impacts associated with the cultivation of DAS-40278-9 corn are no different than those currently observed for other corn varieties under the No Action Alternative.

DAS field trials indicated that DAS-40278-9 corn tolerated the over-the-top application of 2,4-D at later growth stages than is currently possible, and further provides the opportunity to apply Quizalofop to corn, a new use (DAS, 2010). In fields where glyphosate-resistant weeds have emerged, the ability to use these two herbicides, either alone or in conjunction with other herbicides, provides growers with potentially valuable alternatives for weed control in corn, and could be a valuable tool in controlling the escalating costs associated with managing herbicide-resistant weeds.

DAS anticipates that DAS-40278-9 corn would replace or displace existing GE corn varieties currently in the market. Specific economic projections were not provided by DAS. To the extent that the planting of DAS-40278-9 corn results in a decrease in herbicide applications where growers have introduced a variety of herbicides to control glyphosate-resistant weeds, those who have reduced or eliminated these multiple herbicide applications to control glyphosate-resistant weeds might experience an increase in net income over those who follow the strategy currently available under the No Action Alternative. However, net income differentials cannot be projected.

Growers adopting DAS-40278-9 corn would be expected to pay a technology fee to access this variety. These technology fees are imposed by the product developer to cover their research and development costs, and GE seeds are traditionally more expensive than conventional seed (NRC, 2010). Growers cultivating GE crops all pay such technology fees. The NRC suggests that the benefits associated with the adoption of GE crops, including a reduction in agronomic inputs and increases in yield counteract the extra costs of the GE seed (NRC, 2010). With regard to the technology fee to be assessed for the cultivation of DAS-40278-9 corn, APHIS assumes that this fee will be consistent with those charged by developers for other GE crop varieties already in the marketplace. APHIS has no control over the establishment of these technology fees, each grower must make an independent determination as to whether the benefits of the GE variety will offset those technology access costs.

The introduction of DAS-40278-9 corn would provide growers with the option of using Quizalofop to control weedy grasses (if that use is approved by FIFRA) and 2,4-D as a wide-spectrum broadleaf herbicide. Being able to apply a mixture of both herbicides, with two different modes of action, is anticipated to result in control of many of the herbicide-resistant weeds which, in the No Action Alternative, must currently be managed using a variety or agronomic inputs (DAS, 2011c). DAS-40278-9 corn would provide growers with flexibility in herbicide application rates and timing so as to optimize weed control. DAS-40278-9 corn would enable a continuous over-the-top herbicide application window from pre-planting through the post-emergence stage of V8 (vegetative, 8 leaf stage) or 48” tall corn (DAS, 2011d). This application window provides optimal flexibility for growers to manage their weed control program around cultural operations (including other crops) or climatic conditions. This window represents the critical weed control period when weed competition has the greatest detrimental effect on corn growth. Incorporating a diverse herbicide management strategy is expected to result in a reduction in many of the agricultural inputs identified in the No Action Alternative, and a corresponding improvement in grower economics (DAS, 2011d; Weirich et al., 2011).

Based on these factors, a determination of nonregulated status of DAS-40278-9 corn, with the attendant adoption of a diverse herbicide management program, could potentially benefit the domestic economic environment over those conditions currently experienced in the No Action Alternative.

Cumulative Effects: Domestic Economic Environment

Based on the information described above, APHIS concludes that a determination of non-regulated status of DAS-40278-9 corn in itself will have no foreseeable adverse cumulative domestic economic effects.

There are potential implications of the change in herbicide use, particularly with regard to the management of glyphosate-resistant weeds. As discussed in Subsection 4.2.2, DAS intends to develop a stacked hybrid through conventional breeding techniques, combining the DAS-40278-9 corn traits with a glyphosate-tolerant corn variety no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act. This stacked variety has the potential to improve grower management strategies for control of glyphosate-resistant weeds, and also improve grower economics.

By combining 2,4-D with glyphosate, 2,4-D's wide spectrum of broadleaf weed control complements glyphosate because it controls most glyphosate-resistant and hard-to-control broadleaf weed species (DAS, 2011d) 2,4-D will control broadleaf weeds that are resistant to other modes of action such as ALS-enzyme inhibitor and PPO inhibitor herbicides, including weeds with multiple resistance (DAS, 2011d). The traits in DAS-40278-9 corn, when stacked with other herbicide-tolerant varieties, including, in this instance, glyphosate tolerance, will become useful tools to help manage glyphosate-resistant and hard-to-control weeds. This herbicide management strategy is anticipated to sustain the long-term viability of the glyphosate-tolerant cropping system and preserve the benefits it provides to growers, the agricultural industry, and society (DAS, 2011d). The adoption of such a diverse weed management strategy, incorporating several herbicides with alternative modes of action, may initially cost more than the conventional single-herbicide approach, but these costs are offset by an increase in yields in those fields where the weed pressure has been reduced (Weirich et al., 2011).

DAS has compared alternative herbicide application strategies and application rates (DAS, 2011d, 2011f). This analysis evaluated weed control strategies in glyphosate-tolerant corn where glyphosate-resistant and inherently hard to control weeds had emerged. In this 2009 study, DAS compared the current herbicide strategies for weed control in conventional and glyphosate-tolerant corn, and compared them against projected herbicide programs in glyphosate-tolerant corn alone and a glyphosate-tolerant corn stacked with the DAS-40278-9 corn tolerance traits (DAS, 2011d, 2011f). DAS based this analysis on inputs from grower surveys and university agronomists for corn growers in Illinois, Iowa, Minnesota, Ohio, and Georgia (DAS, 2011d, 2011f). Market costs were calculated and normalized to a cost per acre for each strategy (DAS, 2011d, 2011f). DAS found that the projected pounds per acre of herbicides required to control glyphosate-resistant weeds was lower with the Enlist™ Weed Control System than the alternatives (DAS, 2011f). Table 4-4 provides a summary of the results of this research.

Table 4-4: Summary of Projected Application Rates and Corresponding Cost per Acre Comparing Current Corn Weed Management Strategies with Three Potential Future Strategies

	State									
	Illinois		Iowa		Minnesota		Ohio		Georgia	
Strategy	Avg. Rate[1]	Avg. Cost[2,3]	Avg. Rate[1]	Avg. Cost[2,3]	Avg. Rate[1]	Avg. Cost[2,3]	Avg. Rate[1]	Avg. Cost[2,3]	Avg. Rate[1]	Avg. Cost[2,3]
Top Five Herbicide Programs in Glyphosate-Tolerant Corn	2.02	$17.57	1.66	$19.23	1.52	$17.91	2.28	$18.84	2.71	$19.04
Projected Herbicide Programs in Glyphosate-Tolerant Corn Stacked with DAS-40278-9 Corn Traits[4]	2.59	$18.61	2.15	$15.43	2.00	$14.12	2.86	$19.88	3.24	$23.03
Top Five Herbicide Programs in Conventional Corn	2.61	$26.09	2.08	$24.78	1.98	$24.48	2.51	$26.27	NA[5]	NA[5]
Projected Herbicide Programs in Glyphosate-Tolerant Corn without DAS-40278-9 Traits	3.33	$33.40	2.80	$32.10	2.70	$31.80	3.23	$33.58	3.39	$27.98

Source: (DAS, 2011f)
Notes:
1. Average Rate expressed in pounds of active ingredient per acre, combining all herbicide strategies employed.
2. Average costs are based on costs per pound per acre of herbicides, normalized to reflect the % of the acres treated in the survey area.
3. Note that the costs use to make this comparison were based on 2009 pricing for 2,4-D, and do not reflect the retail cost of the new formulation of 2,4-D or associated technology fees.
4. This data was developed assuming an application of 2,4-D at 0.71 lbs ae per acre, which is less than that currently sought in the proposed registration and label use.
5. Data for this strategy in Georgia not reported.

The results of this study would suggest that with the adoption of the Enlist™ Weed Control System, growers would potentially apply fewer pounds of active ingredient per acre to control glyphosate-tolerant weeds, with a corresponding lower cost. The reader is cautioned to note that DAS' analysis was based upon a projected 2,4-D application rate of 0.71 lbs ae per acre, which is less than that currently proposed for use in the Enlist™ Weed Control System, and was also based on 2009 prices for 2,4-D (DAS, 2011d). The projected costs used by DAS in framing the cost comparison also do not consider any change in costs associated with the new 2,4-D formulation or any technology fees associated with this weed control system (DAS, 2011d). A grower adopting this Enlist™ Weed Control System would need to consider the comparative costs in balance with market demands in determining whether to adopt this new weed control strategy.

Based on these factors, no net negative cumulative effects on domestic economics have been identified associated with the cultivation of DAS-40278-9 corn. If growers adopt the stacked variety and take advantage of the weed management strategy incorporating herbicides with different modes of action to control glyphosate-resistant weeds, local farm economics may improve.

4.7.2 Trade Economic Environment at Risk

Corn is the dominant feed grain traded internationally (USDA-OCE, 2011a). In 2009, the U.S. produced over 40% of the total world supply of corn (USDA-OCE, 2011b). Corn is cultivated worldwide, including in Argentina, the European Union (EU), South Africa, Brazil, Canada, China, and the former Soviet Union States, including the Ukraine (USDA-OCE, 2011b). Approximately 15 to 20% of the U.S. corn production is exported, with the volume of exports projected to increase over the next decade (DAS, 2010; USDA-OCE, 2011b). Egypt, the EU, Japan, Mexico, Southeast Asia, and South Korea are net importers of corn (USDA-FAS, 2011; USDA-OCE, 2011b). China is projected to become a net importer of corn to support its expanding livestock and industrial sectors (USDA-OCE, 2011a). The increase in China's imports is expected to account for one-third of the growth in world corn trade (USDA-OCE, 2011a).

Value enhanced, specialty corn is an important part of the U.S. export market for corn. High oil corn, for example, is in high export demand as a replacement for animal fats in feed rations (USDA-FAS, 2004). As discussed in Subsection 2.2.5, Specialty Corn Production, the challenges associated with maintaining variety identity in international commodity movement increases the costs, as well as the premiums paid, for these specialty crops (USDA-FAS, 2004). Trade in feed for livestock has been a driver of this international trade. Corn gluten feed is a major product in international trade in feed ingredients (CRA, 2006). Large volumes of U.S. corn gluten feed are exported to the EU (CRA, 2006).

Potential impacts to the trade economic environment from a determination of nonregulated status of a new GE trait relates to the potential of that trait to impact trade with those countries with which the U.S. engages in corn feed, seed, and food trade.

No Action: Trade Economic Environment

The cropping and marketing decisions made by corn growers are unlikely to be influenced by the selection of this alternative. The acreage planted in GE corn has increased over time, and it is expected that the corn produced will continue to be planted with the currently available GE corn. In 2010, 86% of the corn cultivated in the U.S. in 2010 was GE (USDA-ERS, 2011a). U.S. corn will continue to play a role in global corn market. The U.S. is the largest exported of corn in the world market, exporting 48,500 tons of corn in 2010, against a global export market of 92,875 tons (USDA-FAS, 2011). How and where the corn and corn products will be used will be subject to global market conditions. In 2010, over 25 countries were identified to import corn (USDA-FAS, 2011). These conditions are not expected to change if DAS-40278-9 corn remains a regulated article.

Preferred Alternative: Trade Economic Environment

A determination of nonregulated status of DAS-40278-9 corn is not expected to adversely impact the trade economic environment and may potentially enhance it. The subsequent development and global adoption of the DAS-40278-9 corn could provide another herbicide-tolerant management choice for growers. A reduction in costs for domestic growers associated with the reduction in herbicide use may make U.S. producers more competitive in the global market. As the value and benefits of the product are realized, particularly where glyphosate-resistant weeds have emerged, DAS-40278-9 corn may have potential for export as a seed product.

DAS has submitted applications to several international agencies, including the regulatory authorities in Canada, Japan, Korea, Taiwan, the EU, Australia/New Zealand, South Africa, Brazil, Argentina and Mexico (DAS, 2010). These authorities include U.S. trade partners for import clearance and production approval (see USDA-FAS, 2011), As discussed in Subsection 4.5.1 Human Health, and Subsection 4.6, Animal Feed, ANZFS has completed its review of the application, concluding that food and feed derived from DAS-40278-9 corn is not different from other corn products. As of the time of the preparation of this EA, conclusions of the other international agencies had not been published.

Based on these factors, the trade economic impacts associated with a determination of nonregulated status of DAS-40278-9 corn are anticipated to be very similar to the No Action Alternative.

Cumulative Effects: Trade Economic Environment

Current and historic economic evidence indicates that herbicide-tolerant corn technology has the potential to increase domestic production at lower cost. This trend of lower production costs could enhance international corn trade by making U.S. corn and corn products more competitive in the global market.

Based on the information described above, APHIS has determined that there are no past, present, or reasonable foreseeable actions that in aggregate with effects of the proposed action would negatively impact the trade economic environment.

4.7.3 Social Environment at Risk

According to data from the 2010 Agricultural Income and Finance Outlook, farms growing corn are expected to benefit from increased sales at higher prices. Increases in prices are a function of anticipated increases in domestic uses, including bioethanol, as well as exports for feed (USDA-ERS, 2010c). Prices received for feed grains, including corn, increased 107% from 2003 to 2008 as a direct result of the increase in ethanol production (USDA-ERS, 2010c). During this same time period, production costs have increased also, with the cost of seed rising 67% (USDA-ERS, 2010c). The USDA projected that increases in average income for corn growers over 14% in 2010 as a direct result of an increase in expected cash receipts while expenses remained somewhat stable (USDA-ERS, 2010c).

No Action: Social Environment

Under the No Action Alternative, no direct impact on the social environment surrounding corn farming is expected. The cropping and marketing decisions made by corn growers are unlikely to be influenced by the selection of this alternative.

Preferred Alternative: Social Environment

Most of the corn acreage in the U.S. is planted with GE corn. Of the 88 million acres planted in corn in 2010, 88% of the acres cultivated were GE corn: 16% of that GE corn acreage was GE insect-resistant (Bt) corn; 23% was herbicide-tolerant; and 49% was a stacked variety (USDA-ERS, 2011a).

The introduced herbicide-tolerant trait in DAS-40278-9 corn is not expected to confer any competitive advantage in terms of weediness or to extend the range of cultivation outside of existing cultivation areas. A determination of nonregulated status of DAS-40278-9 corn by the USDA is not expected to significantly expand the number of corn acres and corn acreage is expected to remain relatively stable. Overall impacts are similar to the No Action Alternative.

Cumulative Effects: Social Environment

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

4.8 OTHER CUMULATIVE EFFECTS

Potential cumulative effects regarding specific issues have been analyzed and addressed above. No further potential cumulative effects have been identified. To date, none of the GE corn varieties that have been determined to no longer be regulated articles pursuant to Part 340 and the Plant Protection Act and used for commercial corn production or corn breeding programs subsequently have been found to pose a plant pest risk.

Stacked varieties, i.e., those crop varieties that may contain more than one trait, are currently found in agricultural production and in the marketplace. In the event APHIS reaches a determination of nonregulated status, DAS-40278-9 corn would likely be combined with non-GE and GE corn varieties by traditional breeding techniques. DAS has announced its intention to develop a stacked variety using conventional breeding techniques to combine the herbicide-tolerant gene from DAS-40278-9 corn with genes conferring glyphosate-tolerance from other nonregulated varieties. The implications of such a stack are discussed above, most notably in Subsection 4.4.2 in the analysis of the control of weeds, including corn as a weedy volunteer. The APHIS PPRA also evaluated the implications of stacking glyphosate and glufosinate tolerance traits with the DAS-40278-9 corn (USDA-APHIS, 2010). Although such stacking events may limit the ability to control such a hybrid corn using one of the herbicides for which tolerance has been expressed, other herbicide and management control options exist.

Potential future stacking events might include development of hybrids using other currently available nonregulated corn varieties expressing tolerance to other herbicides, such as glufosinate (stacking the DAS-40278-9 corn with one of the LibertyLink® varieties no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act) or resistance to select insect pests by stacking with one of the biopesticidal genes based on *Bacillus thuringiensis*, for example. APHIS' regulations at Part 340 do not provide for Agency oversight over stacked varieties combining GE varieties previously determined to have nonregulated status unless it can be positively shown that such stacked varieties were likely to pose a plant pest risk. In its evaluation of the consequences of a determination of nonregulated status of DAS-40278-9 corn, APHIS has found no greater incidence of pest or disease in this variety or its progeny (USDA-APHIS, 2010). In the PPRA, APHIS has concluded that there is not likely to be any cumulative plant pest risk from stacking these varieties (USDA-APHIS, 2010).

There is no guarantee that DAS-40278-9 corn will be stacked with any particular nonregulated GE variety, as company plans and market demands play a significant role in those business decisions. Predicting all potential combinations of stacked varieties that could be created using both nonregulated GE corn varieties and also non-GE corn varieties is hypothetical and would be purely speculative.

Based on these findings, no further analysis is required.

4.9 THREATENED AND ENDANGERED SPECIES

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

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

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

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

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

APHIS' regulatory authority over GE organisms under the PPA is limited to those GE organisms for which it has reason to believe might be a plant pest or those for which APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk (7 CFR § 340.1). APHIS does not have authority to regulate the use of any herbicide, including 2,4-D, Quizalofop, or glyphosate. After completing a plant pest risk analysis, if APHIS determines that DAS-40278-9 corn does not pose a plant pest risk, then DAS-40278-9 corn would no longer be subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR Part 340, and therefore, APHIS must reach a determination that the article is no longer regulated. As part of its Environmental Assessment (EA) analysis, APHIS is analyzing the potential effects of DAS-40278-9 corn on the environment including any potential effects to threatened and endangered species and critical habitat. As part of this process, APHIS thoroughly reviews the genetically engineered 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, the following information, APHIS considers the following information, data, and questions:

- A review of the biology and taxonomy of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant); and
- 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.
- 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 DAS-40278-9 corn plants may have, if any, on Federally-listed TES and species proposed for listing, as well as designated critical habitat and habitat proposed for designation. Based upon the scope of the EA and production areas identified in the Affected Environment section of the EA, APHIS obtained and reviewed the

USFWS list of TES species (listed and proposed) for each state where corn is commercially produced from the USFWS Environmental Conservation Online System (ECOS; as accessed 4/15/2011 at http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp). Prior to this review, APHIS considered the potential for DAS-40278-9 corn to extend the range of corn production and also the potential to extend agricultural production into new natural areas. DAS' studies demonstrate that agronomic characteristics and cultivation practices required for DAS-40278-9 corn are essentially indistinguishable from practices used to grow other corn varieties, including other herbicide-tolerant varieties (DAS, 2010; USDA-APHIS, 2010). Although DAS-40278-9 corn might be expected to replace other varieties of corn currently cultivated, new acreage is not expected to be developed to accommodate the cultivation of DAS-40278-9 corn (DAS, 2010). Accordingly, the issues discussed herein focus on the potential environmental consequences of the determination of nonregulated status of DAS-40278-9 corn on TES species in the areas where corn is grown.

APHIS focused its TES review on the implications of exposure to the AAD-1 protein in corn, the interaction between TES and the DAS-40278-9 corn plant including potential for sexual compatibility and ability to serve as a host for a TES (see Subsection 4.9.1); and potential impacts of the use of 2,4-D and Quizalofop herbicides, to non-target organisms and the natural environment (see Subsection 4.9.2).

4.9.1 Potential Effects of DAS-40278-9 Corn on TES

After reviewing the list of threatened and endangered plant species in the States where corn is grown, APHIS determined that DAS-40278-9 corn would not be sexually compatible with any listed threatened or endangered plant species or plant 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 *Zea*.

APHIS considered the possibility that DAS-40278-9 corn could serve as a host plant for a threatened or endangered species. A review of the species list reveals that there are no members of the genus *Zea* that serve as a host plant for any threatened or endangered species.

DAS has presented data evaluating the agronomic and morphological characteristics of DAS-40278-9 corn, including compositional and nutritional characteristics, safety evaluations and toxicity tests, comparing the product to a conventional hybrid corn variety (DAS, 2010). The AAD-1 protein is expressed in DAS-40278-9 corn through the incorporation of the *aad-1* gene which was sourced from the gram-negative soil bacterium *S. herbicidovorans* (DAS, 2010). Bacteria in the Sphingobium group commonly are found in land and water habitats, and have been used widely for both biosynthesis and biodegradation (DAS, 2010; Johnsen et al., 2005). Representatives of this bacteria group have been utilized successfully to bioremediate environmental contaminants; in soil, *S. herbicidovorans* has been found to utilize phenoxy auxin and AOPP herbicides as carbon sources for growth (DAS, 2009, 2010; Johnsen et al., 2005).

DAS has presented information on the food and feed safety of the AAD-1 protein, comparing the DAS-40278-9 corn variety with conventional varieties and evaluating the differences between varieties with and without herbicide applications. (DAS, 2010). The AAD-1 protein does not resemble known allergens or toxins, and the protein is rapidly degraded in simulated gastric fluid (DAS, 2010). Compositionally, DAS-40278-9 corn was determined to be the same as conventional varieties. Compositional elements compared included moisture, protein, fat, carbohydrates, ash, minerals, dietary fiber, essential and non-essential amino acids, fatty acids, vitamins, and antinutrients (DAS, 2010; Herman et al., 2010). The results presented by DAS show that the incorporation of the *aad-1* gene and the attendant expression of the AAD-1 protein in DAS-40278-9 corn does not result in any biologically-meaningful differences between DAS-40278-9 corn and the non-transgenic hybrid. Therefore, the consumption of AAD-1 protein is not expected to affect TES.

The agronomic and morphologic characteristics data provided by DAS were used in the APHIS analysis of the weediness potential for DAS-40278-9 corn, and evaluated for the potential to impact TES. Agronomic studies conducted by DAS tested the hypothesis that the weediness potential of DAS-40278-9 corn is unchanged with respect to conventional corn (DAS, 2010). No differences were detected between DAS-40278-9 corn and nontransgenic corn in growth, reproduction, or interactions with pests and diseases, other than the intended effect of tolerance to the two herbicides (USDA-APHIS, 2010). Corn possesses few of the characteristics of successful weeds, and has been cultivated around the globe without any report that it is a serious weed or that it forms persistent feral populations (USDA-APHIS, 2010). However, corn seed can germinate in undesired locations and would then be considered a weed, such as when corn emerges as a volunteer in a soybean rotation following a corn crop (USDA-APHIS, 2010).

Because the expression of the AAD-1 protein in DAS-40278-9 corn results in greater tolerance to two herbicides, there would be fewer options for controlling volunteer corn. However, as there are multiple options for control of volunteer corn, including the use of other ACCase inhibitor herbicides (e.g., the cyclohexadione “dim” herbicides clethodim or sethoxydim) and acetolactate synthesis inhibitors (ALS; e.g., imazamox, imazequin, and imazethapyr) (Heap, 2011a; WSSA, 2011). The expression of the AAD-1 protein herbicide tolerance trait in DAS-40278-9 corn is unlikely to appreciably improve seedling establishment nor increase weediness potential. Based on the agronomic field data and literature survey on corn weediness potential, DAS-40278-9 corn is unlikely to affect TES as a troublesome or invasive weed (USDA-APHIS, 2010).

In addition to evaluating DAS’ comparisons of DAS-40278-9 corn with the non-transgenic near-isoline hybrid variety for potential differences in agronomic and morphology, APHIS also considers the EPA and FDA regulatory assessment in making its determination of the potential impacts of a determination of nonregulated status of the new agricultural product. As discussed above in Animal and Plant Communities (Subsection 4.4) and Public Health (Subsection 4.5), DAS-40278-9 corn would be the first commercially available food crop expressing the AAD-1 protein. In that regard, DAS has submitted food and feed safety and nutritional assessments for DAS-40278-9 corn to the FDA. DAS also has submitted information to the EPA in support of exemptions from pesticide residue tolerance and registration reviews for the changes in use of 2,4-D and Quizalofop on DAS-40278-9 corn. The EPA review is discussed below in Subsection 4.9.2.

The FDA has concluded its review of DAS’ submittal of safety and nutritional data for DAS-40278-9 corn (US-FDA, 2011). DAS conducted safety evaluations based on Codex Alimentarius Commission procedures to assess any potential adverse effects to humans or animals resulting from environmental releases and consumption of DAS-40278-9 corn (DAS, 2010; FAO, 2009; US-FDA, 2011). These safety studies included evaluating protein structure and function, including homology searches of the amino acid sequences with comparison to all known allergens and toxins, an *in vitro* digestibility assay of the proteins, an acute oral toxicity feeding study in mice, and a feeding study in broiler chickens (DAS, 2010; Herman et al., 2011; Herman et al., 2010; US-FDA, 2011). The DAS-40278-9 corn AAD-1 protein was determined to have no amino acid sequence similar to known allergens, lacked toxic potential to mammals, and was degraded rapidly and completely in gastric fluid (DAS, 2010; US-FDA, 2011). At this time, the FDA considers the consultation on DAS-40278-9 corn to be complete (US-FDA, 2011). A copy of the FDA consultation is provided in Appendix A.

After reviewing the possible effects of allowing the environmental release of DAS-40278-9 corn, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. As a result, a detailed exposure analysis for individual species is not necessary. APHIS also considered the potential effect of a determination of nonregulated status of DAS-40278-9 corn on designated critical habitat or habitat proposed for designation, and could identify no differences from effects that would occur from the production of other corn varieties. Corn is not considered a particularly competitive plant species and has been selected for domestication and cultivation under conditions not normally found in natural settings (US-EPA, 2010). Corn is not sexually compatible with, or serves as a host species for, any listed species or species proposed for listing. Consumption of DAS-40278-9 corn 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 DAS-40278-9 corn, and the corresponding environmental release of this corn 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 concurrence of the USFWS or NMFS are not required.

4.9.2 Potential Effects of the Use of 2,4-D and Quizalofop Herbicides

APHIS met with USFWS officials on June 15, 2011 to discuss whether APHIS has any obligations under the ESA regarding analyzing the impacts of herbicide use associated with all GE crops on TES. As a result of these joint discussions, USFWS and APHIS have agreed that it is not necessary for APHIS to perform an ESA effects analysis on herbicide use associated with GE crops currently planted because EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under FIFRA. APHIS has no statutory authority to authorize or regulate the use of 2,4-D and Quizalofop, or any other herbicide, by corn growers. Under APHIS' current Part 340 regulations, APHIS only has the authority to regulate DAS-40278-9 corn or any GE organism as long as APHIS believes it may pose a plant pest risk. For GE organisms, APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of herbicides or other pesticides on those organisms. Nevertheless, APHIS is aware that there may be potential environmental impacts resulting from the use of 2,4-D and Quizalofop on DAS-40278-9 corn, including potential impacts on TES and critical habitat, based on assessments provided to it by the EPA and as available in the peer reviewed scientific literature. APHIS is providing the available information of potential environmental impacts resulting from 2,4-D and Quizalofop use on DAS-40278-9 corn below.

EPA Endangered Species Protection Program (ESPP)

In 1988, Congress enacted Public Law 100-478 (October 7, 1988) to in part address the relationship between ESA and EPA's pesticide labeling program (Section 1010), which required EPA to conduct a study, and report to Congress, on ways to implement EPA's endangered species pesticide labeling program in a manner that both complies with ESA and allows people to continue production of agricultural food and fiber. This law provided a clear sense that Congress wanted EPA to fulfill its obligation to conserve listed species, while at the same time consider the needs of agriculture and other pesticide users (70 FR 211 2005-11-02).

In 1988 EPA established the ESPP to meet its obligations under the ESA. EPA Endangered Species Protection Program Web site[1] describes the EPA assessment process for endangered species. Some of the elements of that process, reported on the Web site, are summarized below. The goal of EPA's ESPP is to carry out its responsibilities FIFRA in compliance with the ESA, without placing unnecessary burden on agriculture and other pesticide users consistent with Congress' intent. EPA is responsible for reviewing pesticide information and data to determine whether a pesticide product may be registered for a particular use including those uses associated with the approval of biotechnology products. As part of that determination, the Agency assesses whether listed endangered or threatened species or their designated critical habitat may be affected by use of the pesticide product. All pesticide products that EPA determines "may affect" a listed species or its designated critical habitat may be subject to the ESPP. If limitations on pesticide use are necessary to protect listed species in areas where a pesticide may be used, the information is related through Endangered Species Protection Bulletins. Bulletins identify the species of concern and the pesticide active ingredient that may affect the listed species. They also provide a description of the protection measures necessary to protect the species, and contain a county-level map showing the geographic area(s) associated with the protection measures, depending on the susceptibility of the species. Bulletins are enforceable as part of the product label (http://www.epa.gov/oppfead1/endanger/basic-info.htm; last accessed on September 16, 2011 and last updated by EPA on February 25, 2011).

EPA TES Evaluation Process

EPA evaluates listed species and their critical habitat concerns within the context of pesticide registration and registration review so that when a decision is made, it fully addresses issues relative to listed species protection. If a risk assessment determines that use limitations are necessary to ensure that legal use of a pesticide will not harm listed species or their critical habitat, EPA may either change the terms of the pesticide registration or establish geographically specific pesticide use limitations. (http://www.epa.gov/oppfead1/endanger/basic-info.htm).

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

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

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

EPA's core pesticide risk assessment and regulatory processes ensure that protections are in place for all populations of non-target species, not just threatened and endangered species. EPA has developed a comprehensive risk assessment process modeled after, and consistent with, EPA's numerous guidelines for environmental assessments (http://www.epa.gov/oppfead1/endanger/consultation/ecorisk-overview.pdf). The result of an assessment, which may go through several refinements, is to determine whether the potential effects of a pesticide's registration to a listed species will result in either a "no effect" or "may affect" determination. EPA consults on determinations that "may affect" a listed species or adversely modify its critical habitat (http://www.epa.gov/oppfead1/endanger). As a result of either an assessment or consultation, EPA may require changes to the use conditions specified on the label of the product. When such changes are necessary only in specific geographic areas rather than nationwide to ensure protection of the listed species, EPA implements these changes through geographically-specific Endangered Species Protection Bulletins, otherwise, these changes are applied to the label for all uses of the pesticide.

Ecological Risks of 2,4-D and Quizalofop

The herbicide 2,4-D has been used as an herbicide since the mid-1940s (US-EPA, 2005c). Currently over 600 end-use products are registered for use on over 300 distinct agricultural and residential sites, and there are over 100 tolerances for 2,4-D listed in the CFR (US-EPA, 2005c). In 2005, the EPA completed a reregistration analysis for 2,4-D (US-EPA, 2005c). In this pesticide reregistration analysis, EPA considered human health risk and ecological risks associated with potential exposure to 2,4-D through multiple pathways (US-EPA, 2005c). EPA determined that risks could be mitigated by modifying the approved label application rates and spray droplet size (US-EPA, 2005c). Similar concerns and mitigation practices were identified in the EPA's recent Pesticide Effects Determination evaluating the potential impacts of the use of 2,4-D on the Federally Threatened California Red-legged Frog and Alameda Whipsnake (US-EPA, 2009b). Note that the EPA has requested initiation of formal consultation under Section 7 of the Endangered Species Act to address the potential effects of 2,4-D on these two species (US-EPA, 2009b). The EPA's formal consultation request was based on the potential for direct and indirect effects due to decreases in prey items as well as potential habitat effects for all labeled uses except citrus and potato (US-EPA, 2009b).

The EPA is also currently undertaking a separate consultation with the NMFS on potential detrimental effects of 2,4-D on endangered and threatened Pacific salmonids (see http://www.epa.gov/oppfead1/endanger/litstatus/biop4-march2011.pdf). A draft biological opinion was published by the NMFS on March 1, 2011 (NOAA-NMFS, 2011) which concluded that the continued use of 2,4-D is likely to jeopardize the continued existence of 28 ESU and adversely modify or destroy critical habitats for 26 of these ESUs for these endangered and threatened salmonids. The EPA has solicited public comments on the NMFS report as part of the process.

While these consultations are underway, EPA has allowed 2,4-D to remain on the market and is approved for continued use in accordance with all label requirements.

The EPA is currently conducting a reregistration review for Quizalofop (US-EPA, 2007b). The EPA's Final Work Plan for Registration Review (US-EPA, 2008) states that—

> "…there are several Quizalofop ecological data gaps and recently Nissan has submitted several ecological studies that after review may be used to fulfill some of these data gaps. Additionally, a thorough review of fish and aquatic invertebrate toxicity tests has shown that these data are not adequate to support a complete ecological risk assessment. Therefore, some additional aquatic ecotoxicity data along with a Tier II study for non-vascular plants demonstrating NOAEC values will be requested…"

In addition, the EPA is currently completing a comprehensive ecological risk assessment, including an endangered species risk assessment. Submittals to this analysis can be found at www.Regulations.gov under docket designation EPA-HQ-OPP-2007-1089. Labeled uses of Quizalofop are approved pending the outcome of the EPA's ecological risk analysis.

The EPA is currently reviewing the petitioner's applications for label changes for new uses of 2,4-D and Quizalofop on corn to provide for this new variety. The EPA's label reviews would be conducted consistent with the requirements that EPA consider potential impacts to threatened and endangered species associated with these new uses. EPA has approved the continued use of these two herbicides consistent with current label restrictions pending the outcome of the ecological risk analyses being conducted as part of the TES consultations for 2,4-D and the reregistration review of Quizalofop.

There are legal precautions in place to reduce the possibility of exposure and adverse impacts to TES from application of 2,4-D and Quizalofop to DAS-40278-9 corn. These precautions include the EPA pesticide label restrictions and best practice guidance provided by DAS (for 2,4-D and the DAS-40278-9 corn) and DuPont (the manufacturer and label registrant for Quizalofop). EPA will consider potential TES impacts as part of the label changes currently being considered for those changes in use provided by DAS-40278-9 corn. Adherence to these label use restrictions by the pesticide applicator will ensure that the use of either herbicide will not adversely affect TES or critical habitat.

As discussed in Subsections 4.2.2 – Cropping Practices, and 4.4 – Animal and Plant Communities, DAS has announced its intention to market a new formulation of 2,4-D based on a choline salt to be marketed under the new Enlist™ Weed Control System (DAS, 2010, 2011a). (DAS, 2011e). The new formulation of 2,4-D is chemically identified as 2,4-dichlorophenoxyacetic acid (2-hydroxyethyl) trimethylammonium salt (DAS, 2011a). DAS has submitted applications to the EPA for a label for this new 2,4-D formulation. Technical information supporting this pesticide registration package, including chemical and physical characteristics, environmental fate and effect, and toxicity data, are not publicly available. APHIS understands that the EPA will consider each of these characteristics in conducting its registration review, and that appropriate label use restrictions will be included to ensure that the use of this new formulation will not adversely affect TES or critical habitat. Approved label application rates, and corresponding precautions and label use restrictions have not yet been published by the EPA. APHIS assumes, for the purposes of this TES effects analysis, that the new choline salt formulation of 2,4-D will not be used on DAS-40278-9 corn or its progeny until a new pesticide use registration and corresponding label have been published by the EPA. APHIS also assumes that EPA's label for this new formulation will establish use precautions and restrictions so as to avoid adverse effects to listed species or species proposed for listing, designated critical habitat or habitat proposed for listing.

DAS has also announced its intention to market DAS-40278-9 corn as a stacked variety by combining this trait via conventional hybridization techniques with other nonregulated varieties (DAS, 2011e). The initial stacked variety will combine the DAS-40278-9 corn variety with a glyphosate-tolerant variety no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act, providing the grower with the option to combine several herbicides with different modes of action for control of weeds. As noted above for the use of 2,4-D and Quizalofop, the label use restrictions and best practices in place for the use of glyphosate are intended to reduce the possibility of exposure of TES to this herbicide.

Based on the information above, APHIS concludes that the potential future use of a new formulation of 2,4-D and the development and cultivation of a stacked variety expressing tolerance to herbicides with multiple modes of action will not adversely impact listed species or species proposed for listing and would not adversely impact designated critical habitat or habitat proposed for designation.

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

4.10.1 Executive Orders with Domestic Implications

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

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

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

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

Available mammalian toxicity associated with the expression of the AAD-1 protein, establishes the safety of DAS-40278-9 corn and its products to humans, including minorities, low income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken.

Human toxicity has also been thoroughly evaluated by the EPA in its development of pesticide labels for both herbicides (DuPont, 2010; Nufarm, 2009). Pesticide labels include use precautions and restrictions intended to protect workers and their families from exposures. APHIS assumes that growers will closely adhere to these herbicides use precautions and restrictions.

As discussed in Subsections 4.2, 4.3, and 4.4, the cultivation of GE corn varieties with herbicide-tolerant traits no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act has been associated with a decrease and/or shift in pesticide applications for those who adopt these varieties that is either favorable or neutral with respect to environmental and human toxicity. A determination of nonregulated status of DAS-40278-9 corn provides growers with alternative herbicide options with different modes of action. As noted in Table 4-1 in Subsection 4.2.2, the herbicide 2,4-D is already labeled by EPA for use in corn, and although the proposed change in use would change the timing of applications, the proposed change would not increase the annual maximum application. The proposed use of Quizalofop on corn is a new use. As noted in Table 4-2 in Subsection 4.2.2, the proposed application of Quizalofop to corn would be at rates less than those already approved by EPA for use on cotton and soybeans, and the annual maximum application would be less than that approved for those two crops. It is expected that EPA and USDA Economic Research Service (ERS) would monitor the use of this product to determine impacts on agricultural practices, such as chemical use, as they have done previously for other products.

Based on these factors, a determination of nonregulated status of DAS-40278-9 corn is not expected to have a disproportionate adverse effect on minorities, low income populations, or children.

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

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

Non-engineered corn, as well as other herbicide-tolerant corn varieties, is widely grown in the U.S. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by APHIS, DAS-40278-9 corn plants are sufficiently similar in fitness characteristics to other corn varieties currently grown and are not expected to become weedy or invasive (USDA-APHIS, 2010).

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

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

Data submitted by the applicant has shown no difference in compositional and nutritional quality of DAS-40278-9 corn compared with other GE corn or non-GE corn, apart from the presence of the AAD-1 protein. These data included a feeding study in which chickens were fed a diet of DAS-40278-9 corn. The migratory birds that forage in cornfields are unlikely to be adversely affected by ingesting DAS-402-78-9 Corn.

A determination of nonregulated status of DAS-40278-9 corn will also result in a change in the use of 2,4-D on corn, and a potential new use of Quizalofop on corn. The potential impacts of both herbicides on birds have been addressed by the EPA in its label registrations of these products. The EPA considered 2,4-D to be moderately to practically non-toxic to birds resulting from acute oral exposure, and slightly toxic to mammals on an acute oral basis (US-EPA, 2005a, 2005c). The EPA has evaluated Quizalofop for toxicity to non-target organisms using maximum application rates up to 0.17 lb/acre application to birds (in comparison to the 0.082 lb ai/acre proposed for use on DAS-40278-9 corn), and has found that risks from chronic and acute exposure to Quizalofop do not exceed the EPA's level of concern (US-EPA, 2007b).

Based on these factors, it is unlikely that the determination of nonregulated status of DAS-40278-9 corn will have a negative effect on migratory bird populations.

4.10.2 International Implications

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

APHIS has given this EO due consideration and does not expect a significant environmental impact outside the U.S. in the event of a determination of nonregulated status of DAS-40278-9 corn. It should be noted that all the existing national and international regulatory authorities, and phytosanitary regimes that currently apply to introductions of new corn cultivars internationally apply equally to those covered by an APHIS determination of nonregulated status under Part 340.

Any international trade of DAS-40278-9 corn subsequent to a determination of nonregulated status for the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC, 2010). The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC, 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

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

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

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

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the Organization for Economic Cooperation and Development (OECD). NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures (RSPM) No. 14, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO, 2003).

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

4.10.3 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the changes in corn production due to a determination of nonregulated status of DAS-40278-9 corn. Cultivation of DAS-40278-9 corn is not expected to lead to the increased production of corn in U.S. agriculture.

There is no expected change in water use and quality due to the cultivation of DAS-40278-9 corn compared with current corn production. Also, there is no expected change in air quality associated with the cultivation of DAS-40278-9 corn. Potential impacts to air quality are discussed in Subsection 4.3.3.

Based on this review, APHIS concludes that the cultivation of DAS-40278-9 corn would comply with the Clean Water Act and the Clean Air Act.

4.10.4 Impacts on Unique Characteristics of Geographic Areas

A determination of nonregulated status of DAS-40278-9 corn is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

DAS has presented results of agronomic field trials for DAS-40278-9 corn. The results of these field trials demonstrate that there are no differences in agronomic practices between DAS-40278-9 corn and non-GE hybrids. The common agricultural practices that would be carried out in the cultivation of DAS-40278-9 corn are not expected to deviate from current practices. The product is expected to be deployed on agricultural land currently suitable for production of corn and replace existing varieties, and is not expected to increase the acreage of corn production.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to a determination of non-regulated status of DAS-40278-9 corn. This action would not convert land use to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to DAS-40278-9 corn, including the use of EPA registered pesticides. The Applicant's adherence to EPA label use restrictions for all pesticides is expected to mitigate potential impacts to the human environment.

With regard to pesticide use, a determination of nonregulated status of DAS-40278-9 corn is likely to result in changes to the use of 2,4-D and Quizalofop on corn. The potential changes in herbicide use, including application rates and annual maximum allowable applications are discussed in Subsection 4.2.2. DAS has submitted applications to EPA to provide for this change in use for 2,4-D in corn, and is working with DuPont to seek similar label changes to allow the use of Quizalofop in corn. APHIS assumes that any new EPA labels would provide for label use restrictions intended to mitigate potential impacts to the human environment, including potential impacts to unique geographic areas. As noted above, APHIS further assumes that the grower will closely adhere to EPA label use restrictions for all pesticides.

Potential impacts to geographic areas have been considered by the EPA in its evaluation of these two herbicides. In 2005, the EPA completed a reregistration analysis for 2,4-D which considered human health risk and ecological risks associated with potential exposure to 2,4-D in multiple pathways (US-EPA, 2005c). Although some risks were identified, the EPA determined that these risks could be mitigated by modifying the approved label application rates and spray droplet size (US-EPA, 2005c). Similar concerns and mitigation practices were identified in the EPA's recent Pesticide Effects Determination evaluating the potential impacts of the use of 2,4-D on the Federally Threatened California Red-legged Frog and Alameda Whipsnake (US-EPA, 2009b). Note that the EPA has requested initiation of formal consultation under Section 7 of the Endangered Species Act to address the potential effects of 2,4-D on these two species (US-EPA, 2009b). The EPA's formal consultation request was based on the potential for direct and indirect effects due to decreases in prey items as well as potential habitat effects for all labeled uses except citrus and potato (US-EPA, 2009b).

The EPA is also currently undertaking a separate consultation with the NMFS on potential detrimental effects of 2,4-D on endangered and threatened pacific salmonids (see http://www.epa.gov/oppfead1/endanger/litstatus/biop4-march2011.pdf). A draft biological opinion was published by the NMFS on March 1, 2011 (NOAA-NMFS, 2011) which concluded that the continued use of 2,4-D is likely to jeopardize the continued existence of 28 evolutionarily significant units (ESU) and adversely modify or destroy critical habitats for 26 of these ESUs for these endangered and threatened salmonids. The EPA has solicited public comments on the NMFS report as part of the process.

While these consultations are underway, EPA has allowed 2,4-D to remain on the market and is approved for continued use in accordance with all label requirements.

The EPA is currently conducting a reregistration review for Quizalofop (US-EPA, 2007b). The EPA's Final Work Plan for Registration Review (US-EPA, 2008) states that—

> "…there are several Quizalofop ecological data gaps and recently Nissan has submitted several ecological studies that after review may be used to fulfill some of these data gaps. Additionally, a thorough review of fish and aquatic invertebrate toxicity tests has shown that these data are not adequate to support a complete ecological risk assessment. Therefore, some additional aquatic ecotoxicity data along with a Tier II study for non-vascular plants demonstrating NOAEC values will be requested…"

In addition, the EPA is currently completing a comprehensive ecological risk assessment, including an endangered species risk assessment. Submittals to this analysis can be found at the Regulations.gov website under docket designation EPA-HQ-OPP-2007-1089. Labeled uses of Quizalofop are approved pending the outcome of the EPA's ecological risk analysis.

Based on these findings, including the assumption that label use restrictions are in place to protect unique geographic areas and that those label use restrictions are adhered to, a determination of nonregulated status of DAS-40278-9 corn is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

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

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

APHIS' proposed action, a determination of nonregulated status of DAS-40278-9 corn, is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

APHIS' proposed action would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of nonregulated status of DAS-40278-9 corn. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment.

APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the corn production regions. The cultivation of DAS-40278-9 corn is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

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APPENDIX A

FDA BIOTECHNOLOGY CONSULTATION
NOTE TO FILE BNF NO. 000120
SUBJECT: DAS-40278-9, HERBICIDE-TOLERANT CORN

U.S. Food and Drug Administration

Food

Biotechnology Consultation Agency Response Letter BNF No. 000120

See FDA's memo on BNF No. 000120[1] for further details

CFSAN/Office of Food Additive Safety

April 13, 2011

Mr. Craig Blewett
Regulatory Leader
Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268

Dear Mr. Blewett:

This is in regard to Dow AgroSciences LLC's (Dow's) consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on its genetically engineered corn, DAS-40278-9. According to Dow, DAS-40278-9 corn is engineered to confer tolerance to the herbicide 2,4-dichlorophenoxyacetic acid (or "2,4-D") and certain aryloxyphenoxypropionate herbicides (e.g., quizalofop, cyhalofop, haloxyfop). The herbicide tolerance in DAS-40278-9 corn was achieved through expression of the *aad-1* gene, which encodes the aryloxyalkanoate dioxygenase-1 (AAD-1) protein. All materials relevant to this notification have been placed in a file designated BNF 000120. This file wi be maintained in the Office of Food Additive Safety.

As part of bringing this consultation to closure, Dow submitted a summary of its safety and nutritional assessment of the genetically modified corn on September 30, 2009. Dow provide additional information on January 14, March 18, and April 14, 2010. These communications informed FDA of the steps taken by Dow to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Dow has conducted, it is our understanding that Dow has concluded that DAS-40278-9 corn is not materially different in any respect relevant to food or feed safety from corn varieties currently on the market and that the genetically engineered corn does not raise issues that would require premarket review or approval by FDA.

It is Dow's responsibility to obtain all appropriate clearances, including those from the Environmental Protection Agency and the United States Department of Agriculture, before marketing food or feed derived from DAS-40278-9 corn.

Based on the information Dow has provided to FDA, we have no further questions concerning the new corn variety, DAS-40278-9 corn, at this time. However, as you are aware, it is Dow's continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements. A copy of the text of this letter responding to BNF 000120, as well as a copy of the text of FDA's memorandum summarizing the information in BNF 000120, is available for public review and copying via the FDA Completed Consultations on Bioengineered Foods page at www.fda.gov/bioconinventory.

Sincerely,

Mitchell A. Cheeseman, Ph.D.
Acting Director
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition

Links on this page:

1. /Food/Biotechnology/Submissions/ucm254647.htm

Food

Biotechnology Consultation Note to the File BNF No. 000120

Biotechnology Consultation - Note to the File
Biotechnology Notification File BNF No. 000120

DATE

April 8, 2011

Subject

DAS-40278-9, herbicide tolerant corn

Keywords

Corn; maize; *Zea mays*; herbicide tolerance; DAS-40278-9; aryloxyalkanoate dioxygenase-1 protein (AAD-1) from *Sphingobium herbicidovorans*; 2,4-dichlorophenoxyacetic acid (2,4-D); aryloxyphenoxypropionate (AOPP) herbicides; quizalofop; cyhalofop; haloxyfop; Dow AgroSciences LLC

Purpose

This document summarizes our evaluation of Biotechnology Notification File (BNF) No. 000120. In a submission dated September 30, 2009, Dow AgroSciences LLC (Dow) submitted a safety and nutritional assessment of bioengineered herbicide tolerant corn, transformation event DAS-40278-9 (hereafter referred to as DAS-40278-9 corn). Dow provided additional information on January 14, March 18, and April 14, 2010. FDA evaluated the information in Dow's submissions to ensure that regulatory and safety issues regarding human food and animal feed derived from the new plant variety have been resolved prior to commercial distribution.

In our evaluation of BNF No. 000120, we considered all information provided by the notifier as well as publicly available information and information in the agency's files. Here we discuss the outcome of the consultation, but do not intend to restate the information provided in the final consultation in its entirety.

Intended Effect

The intended technical effect of the modification in DAS-40278-9 corn is to confer tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and certain aryloxyphenoxy-propionate (AOPP) herbicides (e.g., quizalofop, cyhalofop, haloxyfop). To accomplish this objective, Dow introduced the *aad-1* gene that encodes the AAD-1 protein, which confers tolerance to 2,4-D and certain AOPP herbicides.[1] The *aad-1* gene used by Dow was obtained from *Sphingobium herbicidovorans* (*S. herbicidovorans*) and has been codon-optimized for expression in plants.

Regulatory Considerations

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

The Environmental Protection Agency (EPA) regulates herbicides under the FFDCA and the Federal Insecticide, Fungicide, and Rodenticide Act. Under EPA's regulations, the herbicide residues and metabolic by-products in DAS-40278-9 corn, resulting from detoxification of the applied herbicide by the expression product, are considered pesticidal substances. In its submission to FDA, Dow indicated that it intended to submit regulatory packages to EPA for the use of 2,4-D and quizalofop on DAS-40278-9 corn.

Genetic Modification and Characterization

Parental Variety

Dow transformed the recipient Hi-II (a publicly available corn line) to obtain DAS-40278-9 corn.

Transformation Plasmid and Methods

Dow described the transformation plasmid. The pDAS1740 plasmid contained the *aad-1* expression cassette within the largest (6236 bp) of the five fragments generated by digestion of the plasmid with the Fsp I restriction enzyme. The larger fragment containing the *aad-1* expression cassette was isolated from the four smaller fragments by column chromatography. The *aad-1* expression cassette contained the coding sequence of the *aad-1* gene under the control of the ZmUbi1 promoter region and the ZmPer5 termination region, both from *Zea mays* (*Z. mays*). The expression cassette was flanked at both ends by matrix attachment regions (MARS) from *Nicotiana tabacum*. According to Dow, the MARs were included to potentially increase consistency of *aad-1* gene expression in transgenic plants. The ampicillin resistance gene AmpR, present in the intact pDAS1740, is not expected to be present in transformed cells because it was outside the isolated larger Fsp1 fragment used for transformation.

To generate DAS-40278-9 corn, Dow used a Whiskers-mediated transformation system. Dow removed immature embryos from the developing caryopsis. The embryos were then callused on semi-solid media, initiated in liquid suspension cultures, cryopreserved, thawed, and re-established as embryogenic suspensions. The *aad-1* expression cassette was introduced into the cells by agitation of the embryogenic suspensions in the presence of silicon carbide whisker fibers and DNA containing the *aad-1* expression cassette, isolated from the pDAS1740 plasmid.

Following transformation, the cells were grown on non-selective medium for three days and transferred to medium containing *R*-haloxyfop to select for those cells expressing the *aad-1* gene. Callus that survived on the herbicide-containing medium were sampled using molecular analysis to confirm the presence of the *aad-1* gene and the absence of the plasmid backbone. Embryogenic tissue from the surviving callus was used to regenerate whole transgenic plants, which were sprayed with quizalofop to confirm herbicide tolerance. Plants surviving treatment with quizalofop were crossed with proprietary inbred corn lines to obtain T1 seed from the initially transformed T0 plants.

Characteristics, Inheritance, and Stability of the Introduced DNA

Dow characterized the insert in DAS-40278-9 corn using restriction enzyme digestion of genomic DNA followed by Southern blot analyses. Dow concluded on the basis of the results of the Southern blot analyses that DAS-40278-9 corn contains a single intact copy of the *aad-1* expression cassette at a single site of insertion. Dow also confirmed that no vector backbone sequences from the pDAS1740 plasmid, including the AmpR gene, were detected in DAS-40278-9 corn.

Dow studied the inheritance of the *aad-1* gene trait in six generations of DAS-40278-9 corn. Each generation was sprayed with quizalofop to identify herbicide-susceptible plants in orde to analyze inheritance of the event on the basis of expected and observed segregation ratios. Based on the results of Chi square analysis of trait inheritance data, Dow concluded that DAS-40278-9 corn displayed the expected inheritance patterns for a single locus across the six generations segregating for the DAS-40278-9 event.

Dow assessed the stability of the DNA insert across five generations of DAS-40278-9 corn through restriction enzyme digestion of genomic DNA followed by Southern blot analysis. In th case of segregating generations, samples were first tested for AAD-1 protein expression (via an AAD-1 specific lateral flow strip test kit) prior to analysis by Southern blot.[2] According tc Dow, the results across all DAS-40278-9 samples were as expected, indicating stable inheritance of an intact, single copy insert across five generations of DAS-40278-9 corn.

Protein Characterization

Identity and Function of Introduced Protein

Dow noted that DAS-40278-9 corn was genetically engineered to express the aryloxyalkanoate dioxygenase protein AAD-1. The AAD-1 protein is an alpha-ketoglutarate-dependent dioxygenase that renders the transgenic plant tolerant to several classes of herbicides, including achiral phenoxy auxins (e.g., 2,4-D), the *R*-enantiomers of chiral phenoxy auxins (e.g., dichlorprop), and certain AOPP herbicides (e.g., quizalofop, cyhalofop, haloxyfop).

The AAD-1 protein is encoded by the *aad-1* gene isolated from the Gram-negative soil bacterium *S. herbicidovorans* MH, which was initially isolated from 2-(2,4-dichloro-phenoxy) propionic acid[3]-enriched soil.[4] Dow stated that there are no reports of *S. herbicidovorans* being implicated as a human pathogen or producing any allergens. The DNA sequence of the *aad-1* gene used by Dow was optimized for expression in plants; the plant-optimized *aad-1* gene encodes a protein sequence identical to the native *S. herbicidovorans* AAD-1 protein, except for one amino acid. The plant-expressed AAD-1 protein contains an additional alanine at position number 2, is 296 amino acids in length, and has an approximate molecular weight of 33 kDa.

Protein Expression Level

Dow conducted field expression studies of the AAD-1 protein in DAS-40278-9 corn. The AAD-1 protein levels were measured and reported for leaf, root, pollen, whole plant, and grain tissue samples collected throughout the growing season from plants from six field locations in North America. DAS-40278-9 corn was subjected to one of four herbicide treatment conditions (unsprayed; sprayed with 2,4-D; sprayed with quizalofop; and sprayed with both 2,4-D and quizalofop) in which the herbicide treatment was designed to replicate maximum label application rate for commercial practices. Three samples per tissue per location were collected for DAS-40278-9 corn and one sample per tissue per location was collected for a non-transgenic, near isoline control corn.[5] The samples were analyzed using enzyme-linked immunosorbent assay (ELISA). Dow reports that the average levels of AAD-1 protein in various plant tissues at various growth stages ranged from 2.87 (R1 stage root) to 127 (pollen) nanograms per milligram of tissue (dry weight). Expression levels were similar among the untreated and herbicide-treated samples. The AAD-1 protein was not detected in the non-transgenic, near isoline control tissues sampled from the six locations.[6]

Safety Assessment of Potential Toxicity and Allergenicity of the Introduced Protein

To obtain sufficient quantities of the AAD-1 protein for conducting safety assessment studies, Dow produced AAD-1 protein using a *Pseudomonas fluorescens* (*P. fluorescens*) protein expression system and an *aad-1* gene optimized for expression in bacteria. The microbe-optimized *aad-1* gene encodes a protein sequence identical to the plant-expressed AAD-1 protein. Through immunoaffinity chromatography, Dow purified small amounts of plant-expressed AAD-1 protein from DAS-40278-9 corn stalk tissue for comparison to the microbially-expressed AAD-1 protein.

To confirm the identity and equivalency of the microbe-derived and plant-derived AAD-1 proteins, Dow used various analytical techniques.[7] Based on the results of these studies, Dow concluded that the DAS-40278-9 corn-expressed AAD-1 and the *P. fluorescens*-expressed AAD-1 proteins were biochemically equivalent. The *P. fluorescens*-expressed AAD-1 protein was subsequently used for *in vitro* and *in vivo* studies.

To assess the potential for toxicity of the AAD-1 protein, Dow conducted an amino acid homology search of the AAD-1 amino acid sequence as well as an acute oral toxicity study in mice. Using a BLASTP sequence similarity search against the GenBank non-redundant protein datasets (posted February 10, 2007 and March 18, 2010), Dow reports that the only significant homologies identified were with other alpha-ketoglutarate-dependent dioxygenases. Dow concluded that the search did not identify any safety concerns that might arise from expression of the AAD-1 protein in plants. In the acute oral toxicity study, a single dose of 2000 milligrams[8] of *P. fluorescens*-produced AAD-1 protein per kilogram of body weight was administered to five male and five female mice. Dow stated that there were no treatment-related gross pathological observations. On the basis of the results of the homology search and the toxicity study, Dow concluded that the AAD-1 protein is unlikely to cause toxic effects in humans or animals.

To assess the potential allergenicity of the AAD-1 protein, Dow used a weight-of-evidence approach, taking into consideration the potential allergenicity of the donor organism as well a AAD-1 protein sequence similarity to known allergens, digestibility in simulated gastric fluid, and heat lability. Dow compared the amino acid sequence of the AAD-1 protein to the amin acid sequences of known allergens in the Food Allergy Research and Resource Program Database (FARRP, version 9.00) and reported that the identified alignments did not exceed the 35 percent identity threshold within 80 amino acid stretches (sliding windows) and no contiguous stretches of eight or greater amino acids are shared between the AAD-1 protein and the proteins in the database.[9] Further, Dow reported that the AAD-1 protein is rapidly (less than 30 seconds) digested in simulated gastric fluid and that AAD-1 enzymatic activity was eliminated (greater than 97 percent) under all heating conditions. Dow concluded that the AAD-1 protein is considered to have a low risk of allergenic potential.

Potential endogenous plant substrates of AAD-1 dioxygenase enzyme activity

Dow screened the AAD-1 protein for the ability to utilize endogenous plant substrates. Dow selected potential substrates based on chemical structure, similarity to known AAD-1 substrates, and abundance within metabolic pathways of plants. The potential substrates were screened using a dioxygenase enzyme-coupled *in vitro* enzyme assay. Dow reported that the compounds tested were not oxidized upon incubation with the AAD-1 protein and, based on these results, concluded that there is no indication that the AAD-1 protein has enzymatic activity on endogenous plant substrates.

Potential Novel Proteins

To assess the potential for novel open reading frames or for disruption of endogenous coding sequences resulting from the insertion of the DNA fragment containing the *aad-1* expression cassette, Dow determined the genomic sequence of the DNA border flanking the transgenic insert in DAS-40278-9 corn. Dow concluded this analysis confirmed that the transgenic DNA insertion neither created novel open reading frames nor interrupted any genomic open reading frames.

Food and Feed Use

Dow stated that DAS-40278-9 corn will be grown for the same commercial uses as current transgenic and non-transgenic commercial corn varieties. Dow provided data from the USDA Economic Research Service's Feed Yearbook (2009) showing that while the primary uses of corn in the United States are for animal feed and fuel alcohol, other major uses of corn include human food (e.g., high-fructose corn syrup, starch, and cereals) and industrial products.

Composition

Scope of Analysis

Dow analyzed the composition of forage and grain from transgenic DAS-40278-9 corn and compared it with a non-transgenic, near isoline control (hereafter referred to as the control), which has the same genetic background as the transgenic line, but does not contain the DAS-40278-9 event.

Study Design - Compositional Analyses

Dow conducted a study to obtain compositional data for forage and grain samples from DAS-40278-9 corn and the control. Plants were grown at six test sites within the corn-producing areas in North America using a randomized complete block design of two row plots with four replicates at each site. DAS-40278-9 corn was subjected to one of four herbicide treatment conditions: (1) unsprayed; (2) sprayed with 2,4-D; (3) sprayed with quizalofop; and (4) sprayed with both 2,4-D and quizalofop. Herbicide treatments were applied according to current agricultural practices. The compositional analysis included key nutrients, secondary metabolites, and antinutrients.[10] Forage samples were collected at the R4 growth stage and grain samples were collected at maturity.

Dow performed statistical analyses on composition data obtained for DAS-40278-9 corn and control samples using values calculated from analytical data obtained from individual sites and data aggregated from all sites. Dow used paired t-tests to compare data from DAS-40278-9 corn and control samples grown under the four herbicide treatment conditions, to identify statistical differences. Dow also used an F-test to identify the presence of any overall treatment effects. Dow reported the composition data analyses by providing mean values, p-values, and p-values adjusted using a False Discovery Rate (FDR) procedure[11] for DAS-40278-9 corn and control samples. A significance level of $p < 0.05$ was chosen for both analyses Dow compared the results of its compositional analyses with values reported in published literature.[12]

Results of analyses - Compositional analysis of corn forage:

Dow reported the results of compositional analysis for crude protein, crude fat, ash, moisture, carbohydrates (by difference), acid detergent fiber (ADF), neutral detergent fiber (NDF), calcium, and phosphorus in forage. No statistically significant differences were observed between DAS-40278-9 corn and the control in the levels of moisture, ADF, NDF, calcium and phosphorus. Statistically significant differences by the paired t-test, in at least one of the four treatment groups, were observed for crude protein, crude fat, ash and carbohydrates. A statistically significant overall treatment effect by F-test was also observed for carbohydrates. However, according to the summary of results across all locations reported by Dow, the mean levels for these components, regardless of treatment group, were within the combined literature range of values for corn forage. Based on the results, Dow concluded that these differences were not biologically meaningful for feed safety and nutrition.

Results of analyses - Compositional analysis of corn grain:

Proximates (Crude Protein, Crude Fat, Ash, Moisture, and Carbohydrates (by difference)) and Fiber (ADF, NDF, and total dietary fiber):

Dow reported the results of compositional analysis for proximates and fiber in grain. No statistically significant differences were observed between DAS-40278-9 corn and the control in the levels of crude fat, ash, NDF and total dietary fiber. Statistically significant differences by the paired t-test, in at least one of the four treatment groups, were observed for crude protein, carbohydrates, and ADF. Statistically significant overall treatment effects by F-test were also observed for crude protein, moisture and carbohydrates. However, based on the summary of results across all locations reported by Dow, the mean levels for these components, regardless of treatment group, were within the combined literature range for corn grain.

Minerals, Amino Acids, Fatty Acids, and Vitamins:

Dow reported the results of compositional analysis of 13 minerals in grain, 4 of which were below the limit of quantitation. No statistically significant differences were observed between DAS-40278-9 corn and the control in the levels of the following minerals: calcium, copper, iron and potassium. Statistically significant differences by the paired t-test, in at least one of the four treatment groups, were observed for magnesium, manganese, molybdenum, phosphorus and zinc. No statistically significant overall treatment effect by F-test was observed for any of the analyzed minerals. Based on the summary of results across all locations reported by Dow, the mean levels for these minerals, regardless of treatment group, were within the combined literature range for corn grain; the only exception being molybdenum for which no literature range was reported.

Dow reported the results of compositional analysis of 18 amino acids in grain. No statistically significant differences were observed between DAS-40278-9 corn and the control in the levels of the following amino acids: arginine, lysine and tyrosine. Statistically significant differences by the paired t-test, in at least one of the four treatment groups, were observed for alanine, aspartic acid, cysteine, glutamic acid, glycine, histidine, isoleucine, leucine, methionine, phenylalanine, proline, serine, threonine, tryptophan and valine. Statistically significant overall treatment effects by F-test were also observed for alanine, aspartic acid, cysteine, glutamic acid, histidine, isoleucine, leucine, methionine, phenylalanine, proline, serine, threonine and valine. However, based on the summary of results across all locations reported by Dow, the mean levels for these amino acids, regardless of treatment group, were within the combined literature range for corn grain.

Dow reported the results of compositional analysis of 22 fatty acids in grain, 14 of which were below the limit of quantitation. No statistically significant differences were observed between DAS-40278-9 corn and the control in the levels of the following fatty acids: palmitic, stearic, linoleic and arachidic acid. Statistically significant differences by the paired t-test, in at least one of the four treatment groups, were observed for oleic acid, eicosenoic acid and behenic acid. A statistically significant overall treatment effect by F-test was also observed for behenic acid. However, based on the summary of results across all locations reported by Dow, the mean levels for these fatty acids, regardless of treatment group, were within the combined literature range for corn grain.

Dow reported the results of compositional analysis of 11 vitamins in grain, 3 of which were below the limit of quantitation. No statistically significant differences were observed between DAS-40278-9 corn and the control in the levels of the following vitamins: vitamin A, vitamin B2, vitamin B5, vitamin B6 and folic acid. Statistically significant differences by the paired t-test, in at least one of the four treatment groups, were observed for vitamin B1, vitamin C and niacin. Statistically significant overall treatment effects by F-test were also observed for vitamin C and niacin. However, based on the summary of results across all locations reported by Dow, the mean levels for these vitamins, regardless of treatment group, were within the combined literature range for corn grain.[13]

Secondary Metabolites and Antinutrients:

Dow reported the results of compositional analysis of 4 secondary metabolites and 3 antinutrients in grain, of which furfural and raffinose were below the limit of quantitation. The secondary metabolites analyzed by Dow included p-coumaric acid, ferulic acid, furfural and inositol; the anti-nutrients included phytic acid, raffinose, and trypsin inhibitor. No statistically significant differences were observed between DAS-40278-9 corn and the control in the levels of inositol and trypsin inhibitor. Statistically significant differences by the paired t-test, in at least one of the four treatment groups, were observed for p-coumaric acid, ferulic acid and phytic acid. A statistically significant overall treatment effect by F-test was also observed for phytic acid. However, based on the summary of results across all locations reported by Dow, the mean levels for p-coumaric acid, ferulic acid and phytic acid, regardless of treatment group, were within the combined literature range for corn grain.

Summary of Compositional Analyses

As noted above, in Dow's analyses, statistically significant differences by paired t-tests were found in the comparisons of DAS-40278-9 corn and the control. Statistically significant overall treatment effects by F-test were also observed for several components. However, the mean levels for each of these components were within the combined range of values compiled by Dow from values for corn in the published literature. Dow concluded that the differences were therefore not biologically meaningful for food and feed safety and nutrition. Based on these data, Dow concluded that DAS-40278-9 corn is compositionally equivalent to its conventional counterpart.

Conclusion

FDA evaluated Dow's submission to determine whether the developer's product raises any safety or regulatory issues with respect to the intended modification or with respect to the food itself. Based on the information provided by the company and other information available to the agency, FDA did not identify any issues under the Federal Food, Drug and Cosmetic Act that would require further evaluation at this time.

Dow has concluded that its herbicide tolerant corn variety, DAS-40278-9 corn, and the food and feed derived from it are as safe as conventional corn varieties and, with the exception of the herbicide tolerance trait, are not materially different in composition or any other relevant parameters from other corn now grown, marketed, and consumed in the United States. At this time, based on Dow's data and information, the agency considers Dow's consultation on DAS-40278-9 corn to be complete.

Carrie McMahon, Ph.D.

[1]Dow submitted its evaluation of the potential for allergenicity and toxicity of the AAD-1 protein, which FDA designated as New Protein Consultation No. NPC 000008 under FDA's Guidance to Industry: "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use." FDA responded that it had no questions regarding Dow's conclusions.

[2]Dow stated that all plants that tested positive for AAD-1 protein expression were also positive for the presence of the *aad-1* gene insert. Conversely, all plants that tested negative for AAD-1 protein expression were also negative for the *aad-1* gene insert.

[3]Also known as "dichlorprop" and "2,4-DP"

[4]Originally classified as a *Flavobacterium* sp., the soil isolate was reclassified as *Sphingobium herbicidovorans* upon further characterization of its herbicide degrading capabilities.

[5]Dow describes the non-transgenic, near isoline control used in the AAD-1 protein expression and compositional analyses as a hybrid of two DAS elite inbred lines, including DAS elite inbred XHH13.

[6]Dow reports that the AAD-1 protein was detected in one root sample from one location. FDA notes that the *aad-1* gene was originally isolated from a soil bacterium, so this result is not wholly unexpected in a root sample.

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

[8]Dose adjusted for purity.

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

[10]Dow notes that the analysis is consistent with OECD guidelines (2002) Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea mays*): Key Food and Feed Nutrients, Anti-nutrients and Secondary Metabolites.

[11]According to Dow, FDR procedures account for multiplicity due to the large number of comparisons made in the compositional analysis. Dow states that "the p-values were adjusted using FDR to improve discrimination of true differences among treatments from random effects (false positives)."

[12]Dow used a combined literature range for its comparison, in which values from several published scientific literature sources (Watson, 1982; Watson, 1987; Codex, 2001; and OECD, 2002;), as well as Version 3.0 of the publicly available International Life Sciences Institute (ILSI) Crop Composition Database (ILSI, 2006), were combined. The database is maintained by ILSI and can be accessed at http://www.cropcomposition.org/.

[13]Dow did not provide published literature values for vitamin C. FDA notes that the vitamin C levels reported by Dow for DAS-40278-9 corn and the control were slightly higher than values obtained for a non-transgenic corn line reported in Naqvi, S., C. Zhu, G. Farre, K. Ramessar, L. Bassie, J. Breitenbach, D. Perez Conesa, G. Ros, G. Sandmann, T. Capell, and P. Christou. 2009. Proc. Natl. Acad. Sci. 106(19):7762-7767.

Links on this page:

APPENDIX B

NUFARM WEEDAR® 64
BROADLEAF HERBICIDE
PRODUCT LABEL

SPECIMEN LABEL

This information is for promotional purposes only. Space considerations may require information to be omitted. Always refer to the actual package for complete label verbiage. This product may not yet be available or approved for sale or use in your area.

Nufarm

Weedar® 64

Broadleaf Herbicide

THE 2,4-D AMINE WEED KILLER

TO CONTROL SUSCEPTIBLE BROADLEAF WEEDS IN CEREAL GRAINS, CORN, SORGHUM, RICE, SUGARCANE, SOYBEANS (Preplant only), TURF, NON-CROP AREAS, AND CERTAIN AQUATIC APPLICATIONS.

ACTIVE INGREDIENT:	
2,4-Dichlorophenoxyacetic acid, dimethylamine salt*	46.8%
OTHER INGREDIENTS:	53.2%
TOTAL:	100.0%

*2,4-Dichlorophenoxyacetic acid equivalent 38.9% by weight or 3.8 pounds per gallon. Isomer specific by AOAC method No. 978.05

KEEP OUT OF REACH OF CHILDREN

DANGER / PELIGRO

PRECAUCION AL USUARIO: Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

SEE INSIDE BOOKLET FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300
For Medical Emergencies Only, Call (877) 325-1840

EPA Reg. No. 71368-1

Manufactured for
Nufarm, Inc.
150 Harvester Drive
Burr Ridge, IL 60527

Nufarm

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER / PELIGRO

Corrosive. Causes irreversible eye damage. Harmful if swallowed. Avoid breathing vapors or spray mist. Do not get in eyes, on skin or on clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE):
Some of the materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category A on an EPA chemical-resistance category selection chart.

All mixers, loaders, applicators, and other handlers must wear:
- long-sleeved shirt and long pants,
- shoes and socks, plus
- chemical-resistant gloves (except for applicators using ground boom equipment),
- chemical-resistant apron when mixing or loading, cleaning up spills or equipment, or otherwise exposed to the concentrate, and
- protective eyewear (goggles or face shield).

See engineering controls for additional requirements.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROLS STATEMENTS:
When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d) (4-6)], the handler PPE (personal protective equipment) may be reduced or modified as specified in the WPS. Pilots must use an enclosed cockpit that meets the requirements listed in the WPS for agricultural pesticides [40 CFR 170.240(d)(6)].

USER SAFETY RECOMMENDATIONS

Users Should:
- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. If pesticide gets on skin, wash immediately with soap and water.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

FIRST AID

IF IN EYES	• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
You may also contact 1-877-325-1840 for emergency medical treatment information.

NOTE TO PHYSICIANS

This product contains a phenoxy herbicidal chemical. There is no specific antidote. All treatments should be based on observed signs and symptoms of distress in the patient. Probable mucosal damage may contraindicate the use of gastric lavage. Overexposure to materials other than this product may have occurred.

ENVIRONMENTAL HAZARDS

This product may be toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark except as noted on appropriate labels. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment washwater or rinsate.

This product contains a chemical with properties and characteristics associated with chemicals detected in groundwater. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination. Application around a cistern or well may result in contamination of drinking water or groundwater.

For Aquatic Uses: Fish breathe dissolved oxygen in the water and decaying weeds also use oxygen. When treating continuous, dense weed masses, it may be appropriate to treat only part of the infestation at a time. For example, apply the product in lanes separated by untreated strips that can be treated after vegetation in treated lanes has disintegrated. During the growing season, weeds decompose in a 2 to 3 week period following treatment. Begin treatment along the shore and proceed outwards in bands to allow fish to move into untreated areas. Waters having limited and less dense weed infestations may not require partial treatments.

Do not contaminate water used for irrigation or domestic purposes (except as specifically recommended on this label) especially in areas where grapes, cotton, tomatoes or other susceptible plants are grown.

Do not treat irrigation ditches in areas where water will be used to overhead (sprinkler) irrigate susceptible crops especially grapes, tomatoes, tobacco, and cotton.

Do not apply this product directly to, or permit to drift onto cotton, okra, grapes, tomatoes, fruit trees, vegetables, flowers or other desirable crop or ornamental plants which are susceptible to 2,4-D herbicide. Do not apply near susceptible plants since very small quantities of the 2,4-D will cause severe injury during the growing or dormant periods. Crops contacted by this product sprays or spray drift may be killed or suffer significant stand loss with extensive quality and yield reduction.

MIXING AND LOADING: Most cases of ground water contamination involving phenoxy herbicides such as 2,4-D have been associated with mixing/loading and disposal sites. Caution should be exercised when handling 2,4-D pesticides at such sites to prevent contamination of ground water supplies. Use of closed systems for mixing or transferring this pesticide will reduce the probability of spills. Placement of the mixing/loading equipment on an impervious pad to contain spills will help prevent ground water contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read entire label before using this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 48 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is: coveralls, chemical-resistant gloves made of any water-proof material, shoes plus socks, protective eyewear.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Do not enter or allow people (or pets) to enter the treated area until sprays have dried.

GENERAL PRECAUTIONS AND RESTRICTIONS

Do not apply this product through any type of irrigation system. Do not use in or near a greenhouse. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

GENERAL INFORMATION

INJURY TO CROPS FROM THIS HERBICIDE MAY OCCUR. IF YOU ARE NOT PREPARED TO ACCEPT SOME DEGREE OF CROP INJURY DO NOT USE THIS PRODUCT.

Crop varieties vary in response to 2,4-D and some are easily injured. Apply this product only to varieties known to be tolerant to 2,4-D. If you are uncertain concerning tolerant varieties or local use situations that may affect crop tolerance to 2,4-D, consult your seed company, State Agricultural Extension Service or qualified crop consultant for advice.

Be sure that use of this product conforms to all applicable laws, rules and regulations. Certain states have restrictions pertaining to application distances from susceptible crops. The applicator should become familiar with these laws, rules or regulations and follow them exactly.

MIXING INSTRUCTIONS

Add about one-half the water to the mixing tank, then add this product with agitation and finally the rest of water with continuing agitation.

NOTE: Adding oil, wetting agent, or other surfactants to the spray may increase effectiveness on weeds but also may reduce selectivity to crops, resulting in crop damage.

COMPATIBILITY

If this product is to be tank mixed with fertilizers or with other pesticides, compatibility should be tested prior to mixing. To test for compatibility, use a small container and mix a small amount (0.5 to 1 quart) of spray, combining all ingredients in the same ratio as the anticipated use. If any indications of physical incompatibility develop, do not use this mixture for spraying. Indications of incompatibility usually will appear within 5 to 15 minutes after mixing.

Read and follow all directions and precautions on this label and on the labels of any products for which a tank mixture is being considered.

APPLICATION PROCEDURES

Apply by air or ground equipment in sufficient gallonage to obtain adequate coverage, except as otherwise directed on this label.
Use 2 or more gallons of water per acre for aerial application and 10 or more gallons of water per acre for ground application.

SPRAY DRIFT MANAGEMENT

A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application (e.g., ground, aerial, airblast, chemigation) can influence pesticide drift. The applicator must evaluate all factors and make appropriate adjustments when applying this product.

Droplet Size

When applying sprays that contain 2,4-D as the sole active ingredient, or when applying sprays that contain 2,4-D mixed with active ingredients that require a Coarse or coarser spray, apply only as a Coarse or coarser spray (ASAE standard 572) or a volume mean diameter of 385 microns or greater for spinning atomizer nozzles.

When applying sprays that contain 2,4-D mixed with other active ingredients that require a Medium or more fine spray, apply only as a Medium or coarser spray (ASAE standard 572) or a volume mean diameter of 300 microns or greater for spinning atomizer nozzles.

Wind Speed
Do not apply at wind speeds greater than 15 mph. Only apply this product if the wind direction favors on-target deposition and there are not sensitive areas (including, but not limited to, residential areas, bodies of water, known habitat for nontarget species, nontarget crops) within 250 feet downwind. If applying a Medium spray, leave one swath unsprayed at the downwind edge of the treated field.

Temperature Inversions
If applying at wind speeds less than 3 mph, the applicator must determine if: a) conditions of temperature inversion exist, or b) stable atmospheric conditions exist at or below nozzle height. Do not make applications into areas of temperature inversions or stable atmospheric conditions.

Susceptible Plants
Do not apply under circumstances where spray drift may occur to food, forage, or other plantings that might be damaged or crops thereof rendered unfit for sale, use or consumption. Susceptible crops include, but are not limited to, cotton, okra, flowers, grapes (in growing stage), fruit trees (foliage), soybeans (vegetative stage), ornamentals, sunflowers, tomatoes, beans, and other vegetables, or tobacco. Small amounts of spray drift that might not be visible may injure susceptible broadleaf plants.

Other State and Local Requirements
Applicators must follow all state and local pesticide drift requirements regarding application of 2,4-D herbicides. Where states have more stringent regulations, they must be observed.

Equipment
All aerial and ground application equipment must be properly maintained and calibrated using appropriate carriers or surrogates.

Additional requirements for aerial applications:
The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter.

Release spray at the lowest height consistent with efficacy and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety. This requirement does not apply to forestry or rights-of-way applications.

When applications are made with a crosswind, the swath will be displaced downwind. The applicator must compensate for this by adjusting the path of the aircraft upwind.

Additional requirements for ground boom application:
Do not apply with a nozzle height greater than 4 feet above the crop canopy.

SMALL QUANTITY DILUTION TABLE

To spray small areas use the following dilution table.

If Dosage on Label Shows Following Rate Per Acre	Use this Amount for each Gallon of Water Per 1,000 Square Feet
2 pints (1 quart)	0.72 ounces (4.3 teaspoons)
3 pints (1-1/2 quarts)	1.1 ounces (2 tablespoons)
4 pints (2 quarts)	1.4 ounces (2.8 tablespoons)
6 pints (3 quarts)	2.2 ounces (4.4 tablespoons)

GENERAL WEED LIST

Annual and Biennial Weeds

Beggarticks*
Bullthistle
Coffeeweed
Common cocklebur
Common burdock
Common evening primrose
Common lambsquarters
Hairy galinsoga
Jimsonweed
Knotweed*
Mallow* (venice or little)
MarshelderMorningglory
(common, ivy, woolly)
Musk thistle* (***)
Mustards (except blue mustard)
Pepper weeds (except perennial)
Pigweeds** (Amaranthus spp.)
Prickly lettuce
Ragweed (common or giant)
Rough fleabane
Russian thistle*
Salsify (western or common)
Smartweeds* (annual species)
Sowthistles (annual or spiny
Sunflower
Vervains*
Vetches
Wild carrot
Wild lettuce
Wild parsnips

Perennial Weeds

Bindweed* (hedge, field, European)
Blue lettuce
Canada thistle*
Catnip
Chicory
Dandelion
Docks*
Dogbane*
Goldenrod*
Healall
Ground ivy*
Hoary cress*
Ironweed*
Jerusalem artichoke
Many flowered aster
Nettles* (including stinging)
Orange hawkweed*
Plantains
Sowthistle (perennial)
Vervains*
Wild garlic*
Wild onion*

*These species may require repeated applications and/or use of the higher rate recommended on this product label even under ideal conditions for application.

**Control of pigweeds in the High Plains area of Texas and Oklahoma may not be satisfactory with this product.

***Not registered for control of musk thistle in California.

SPECIFIC USE DIRECTIONS

APPLES, PEARS, STONE FRUIT AND NUT ORCHARDS

WEEDS IN CROPS	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Annual broadleaf weeds	3 pints	For control of weeds on the orchard floor, apply using coarse sprays and low pressure in sufficient volume of water to obtain thorough wetting of weeds. Treat when weeds are small and actively growing. For filberts, apply a maximum of 2.1 pints (1.0 lb. ae) per 100 gallons of spray solution per application. Do not use on light sandy soil. **DO NOT USE IN CALIFORNIA.**

RESTRICTIONS AND LIMITATIONS FOR USE IN APPLES, PEARS, STONE FRUIT AND NUT ORCHARDS

- Do not apply to bare ground as injury may result.
- Do not apply immediately before irrigation and withhold irrigation for 2 days before and for 3 days after treatment.
- Do not allow spray to drift onto or contact foliage, fruit, stems, trunks of trees or exposed roots as injury may result.
- Do not apply to newly established or young orchards. Trees must be at least 1 year old and in vigorous condition.
- Do not apply during bloom.
- Do not graze or feed cover crops from treated orchards.
- Do not make more than 2 applications per crop cycle. Maximum of 4.2 pints (2.0 lbs. ae) per acre per application.
- Do not harvest apples and pears within 14 days of application, stone fruit within 40 days of application and nuts within 60 days of application.
- For apples, pears and stone fruits, allow at least 75 days between applications.
- For tree nuts, allow at least 30 days between applications.
- Do not cut orchard floor forage for hay within 7 days of application.

CEREAL GRAINS

Barley, Oats, Rye, Triticale, Wheat

WEEDS IN CROP	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Not underseeded with legumes **Postemergence** Annual and biennial broadleaf weeds Perennial broadleaf weeds	 1/2 to 2 pints* 1 to 2 pints*	Apply after grain is well tillered (usually about 4 to 8 inches high). **Do not spray grain in the boot to dough stage.**
Underseeded with legumes	1/4 to 1/2 pint*	Apply after grain is 8 inches tall. **Do not spray grain in boot to dough stage.** Do not spray alfalfa or sweet clover unless the infestation is severe and injury to these legumes can be tolerated.
Emergency weed control in Triticale, Wheat Perennial broadleaf weeds	2.6 pints	Apply when weeds are approaching bud stage, after the grain dough stage. **Do not spray during the boot to dough stage.** The 2.6 pints per acre application can produce injury to wheat. Balance the severity of your weed problem against the possibility of crop damage. Where perennial weeds are scattered, spot treatment is suggested to minimize the extent of crop injury.

*Use the lower rate if small annual and biennial weeds are the major problem. Use the higher rate if perennial weeds or annual and biennial weeds are present which are in the hard-to-kill categories as determined by local experience. The higher rates increase the risk of grain injury and should be used only where the weed control problem justifies the grain damage risk. Do not apply this product to grain in the seedling stage.

RESTRICTIONS AND LIMITATIONS FOR USE ON CEREAL GRAINS

- For aerial application on grain, apply this product in 3 to 10 gallons of water per acre.
- For ground application a minimum of 10 to 15 gallons of water per acre is recommended for proper spray coverage.
- Do not permit dairy animals or meat animals being finished for slaughter to forage treated grain fields within 2 weeks after treatment.
- Do not feed treated straw to livestock if an emergency treatment as described above is applied.
- Do not harvest within 14 days of application.
- Limit to one postemergence application per crop cycle.
- Limit to one preharvest application per crop cycle.
- **Postemergence:** Maximum of 2.6 pints (1.25 lbs. ae) per acre per application.
- **Preharvest:** Maximum of 1 pint (0.5 lb. ae) per acre per application.
- Limit to 3.6 pints product (1.75 lbs. ae) per acre per crop cycle.

CORN AND SORGHUM

WEEDS IN CROP	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
CORN (Field and Sweet) **Preplant**	1 to 2 pints	To control emerged broadleaf weed seedlings or existing cover crops prior to planting corn, apply 7 to 14 days before planting. Do not use on light, sandy soil, or where soil moisture is inadequate for normal weed growth. Use high rate for less susceptible weeds or cover crops such as alfalfa.
Preemergence	2 pints	Apply 3 to 5 days after planting but before corn emerges. Do not use on light, sandy soils or where soil moisture is low.
Postemergence Annual broadleaf weeds Perennial broadleaf weeds	1/2 to 1 pint 1 pint	Apply when weeds are small and corn is less than 8 inches tall (to top of canopy). When corn is over 8 inches tall, use drop nozzles and keep spray off foliage. Treat perennial weeds when they are in the bud to bloom stage. **Do not spray corn in the tassel to dough stage.** Corn treated with 2,4-D may become temporarily brittle. Winds or cultivation may cause stalk breakage during the period of time when the corn is brittle.
Grain Sorghum (Milo) Postemergence	1 pint	Apply when sorghum is 6 to 15 inches tall. If sorghum is taller than 8 inches to top of the canopy, use drop nozzles and keep spray off the foliage. **Do not treat during the boot, flowering or dough stage.**

RESTRICTIONS AND LIMITATIONS FOR USE ON CORN AND SORGHUM
- Do not forage or feed fodder for 7 days following application.
- Do not harvest within 7 days of application.
- Limit to one preplant, postemergence or preharvest application per crop cycle.
- **Preplant or Preemergence:** Maximum of 2 pints (1.0 lb. ae) per acre per application.
- **Postemergence:** Maximum of 1 pint (0.5 lb. ae) per acre per application.
- **Preharvest:** Maximum of 3 pints (1.5 lbs. ae) per acre per application.
- Maximum of 6 pints (3.0 lbs. ae) per acre per crop cycle.
- Do not permit meat or dairy animals to consume treated crop as fodder or forage for 30 days following application.
- The preharvest interval (PHI) for sorghum is 30 days.

HOPS (Except CA)

WEEDS IN CROPS	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Annual broadleaf weeds	1 pint	Make directed applications to the row middles. Make up to 3 applications at 30-day intervals with the last application before harvest.

RESTRICTIONS AND LIMITATIONS FOR HOPS
- Limited to 3 applications per crop cycle.
- Maximum of 1 pint (0.5 lb. ae) per acre per application.
- Maximum of 3 pints (1.5 lbs. ae) per acre per crop cycle.
- Minimum of 30 days between applications.
- Observe the preharvest interval (PHI) of 28 days.

RICE

WEEDS IN CROP	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Preplant	1 to 2 pints	Apply four or more weeks prior to planting rice. **DO NOT USE IN CALIFORNIA.**
Postemergence	1 to 2-1/2 pints	Apply when rice is in the late tillering stage of development at the time of first joint development. Do not apply after panicle initiation, after rice internodes exceed one-half inch, at early seedling, early panicle, boot or heading stages. Consult local university or Agricultural Extension Service specialists for more specific information on rates and timing of application. **DO NOT USE IN CALIFORNIA.**

RESTRICTIONS AND LIMITATIONS FOR USE IN RICE
- Do not apply more than a total of 2-1/2 pints per acre of this product to rice per growing season.
- Do not use on rice in California without an approved Supplemental Label allowing the use.
- Observe the preharvest interval (PHI) of 60 days.
- **Preplant:** Limited to 1 preplant application per crop cycle. Maximum of 2 pints (1.0 lb. ae) per acre per preplant application.
- **Postemergence:** Limited to 1 postemergence application per crop cycle. Maximum of 3 pints (1.5 lbs. ae) per acre per postemergence application.

WILD RICE (For Use In Minnesota Only)

WEEDS IN CROP	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Common waterplantain	1/2 pint	Broadcast in 4 to 10 gallons total spray volume. Apply after waterplantain has emerged from the water and when wild rice is in the 1 to 2 aerial leaf to early tillering stage. Do not spray after wild rice has reached the boot stage.

RESTRICTIONS AND LIMITATIONS FOR USE IN WILD RICE
- For use only on wild rice grown in commercial paddies.
- Do not apply to wild rice growing in lakes, rivers or streams.
- Water that is drained out of wild rice paddies is not to be used to irrigate other crops. In order to protect federally listed endangered or threatened species, the Minnesota Department of Agriculture has a program to pre-notify landowners where pesticide applications may affect federally listed endangered or threatened species.
- Limited to 1 application per crop cycle.
- Do not apply more than 1/2 pint per acre of 2,4-D Amine 4 (0.25 lb. ae/A) per use season.
- Observe the preharvest interval (PHI) of 60 days.

SOYBEANS* (Preplant Only)

WEEDS IN CROP	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Postemergence	3/4 to 1 pint	Apply not less than 15 days prior to planting soybeans, when weeds are small and actively growing. Use the higher rate on larger weeds and when perennials are present.
	>1 to 2 pints	Apply not less than 30 days prior to planting soybeans, when weeds are actively growing.
In addition to those weeds found on the GENERAL WEED LIST, this product will suppress or control the following broadleaf weeds frequently encountered in reduced tillage soybean production systems: alfalfa*, bullnettle, smallflowered bittercress, Carolina geranium, smallflowered buttercup, common and rough cinquefoil, red clover*, horseweed or marestail, mousetail, wild mustard, field pennycress, cutleaf evening primrose, common purslane, speedwell, velvetleaf, and Virginia copperleaf. * These weeds are only partially controlled. Apply no more than 2.0 pints of this product in one season prior to planting soybeans. After applying, plant soybean seed as deep as practical or at least 1-1/2 to 2 inches deep. Adjust the planter press wheel, if necessary, to ensure that planted seed is completely covered. If desired, this product may be applied pre-plant to soybeans in tank mixtures with other herbicides such as Poast®, Poast Plus®, Roundup®, Roundup D-Pak®, Honcho®, Gramoxone Extra®, Prowl®, Pursuit Plus®, Scepter®, Scepter 70 DG, Squadron® and others that are registered for pre-plant soybean use. **NOTE**: Unacceptable injury to soybeans planted in fields previously treated with this product may occur and the extent of injury will depend on weather and agronomic factors such as the amount of weed vegetation and previous crop residue present that may be in effect between the time of application and the emergence of the soybean plant.		

RESTRICTIONS AND LIMITATIONS FOR USE IN SOYBEANS (PREPLANT)
- Do not apply this product when weather conditions such as temperature, air inversions, or wind favor drift from treated areas to susceptible plants.
- Apply no more than 2.0 pints of this product per acre in one season prior to planting soybeans.
- Only one application per growing season, regardless of the application rate used, is allowed.
- Do not apply this product prior to planting soybeans if you are not prepared to accept the results of soybean injury including possible loss of stand and yield.
- Do not replant fields treated with this product in the same growing season with crops other than those labeled for 2,4-D pre-plant use.
- Do not mow or cultivate weeds prior to treating with this product as poor control may result.
- Do not cut for feed treated hay, forage, or fodder or graze treated soybeans to livestock.
- Do not apply this product pre-plant to soybeans in fields having a coarse-textured soil where the percent organic matter is <1.0%.
- Only one application of this product may be made prior to planting soybeans per growing season.
- Do not feed treated hay, forage, or fodder. Livestock should be restricted from feeding/grazing of treated cover crops.

***Not currently registered for use in California.**

SUGARCANE

WEEDS IN CROP	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Preemergence	4 pints	Apply before canes appear for control of emerged broadleaf weeds. **DO NOT USE IN CALIFORNIA.**
Postemergence	1-1/2 to 4 pints	Apply after cane emerges and through lay-by. **DO NOT USE IN CALIFORNIA.**

RESTRICTIONS AND LIMITATIONS FOR USE IN SUGARCANE
- Do not apply more than a total of 8 pints of this product to sugarcane per acre per growing season.
- Do not harvest cane prior to crop maturity.
- **Preemergence:** Limited to 1 application per crop cycle. Maximum of 4 pints (2.0 lb. ae) per acre per application.
- **Postemergence:** Limited to 1 application per crop cycle. Maximum of 4 pints (2.0 lb. ae) per acre per application.

CONSERVATION RESERVE PROGRAM AREAS

WEEDS	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Annual broadleaf weeds In young grasses In established grasses	 1/2 to 1 pint 1/2 to 2 pints	Apply to actively growing annual broadleaf weeds. Use 1/2 to 1 pint when weeds are small; use higher rates on older weeds. Do not apply to young grasses with fewer than 6 leaves or prior to tillering, as excessive injury may result. Do not apply more than 1 pint until grasses are well established as excessive injury may result.
Biennial and perennial broadleaf weeds In established grasses	2 to 4 pints	Treat when biennial weeds are in the seedling to rosette stage and before flower stalks become apparent. Treat perennial weeds in the bud to bloom stage. Apply to actively growing weeds.

RESTRICTIONS AND LIMITATIONS FOR USE ON CONSERVATION RESERVE PROGRAM AREAS

- Use at least 2 gallons of water per acre by air and 5 gallons of water per acre by ground.
- Do not harvest or graze treated Conservation Reserve Program areas.
- Do not apply to grasses in the boot to dough stage if grass seed production is desired.
- Do not cut forage for hay within 7 days of application.
- **Postemergence:**
  - For susceptible annual and biennial broadleaf weeds, do not exceed 2 pints (1.0 lb. ae) per acre per application.
  - For moderately susceptible biennial and perennial broadleaf weeds and for difficult to control weeds and woody plants, do not exceed 4 pints (2.0 lbs. ae) per acre per application.
  - Spot treatments do not exceed 4 pints (2.0 lbs. ae) per acre.
  - Maximum of 2 applications per year.
  - Maximum of 8 pints (4.0 lbs. ae) per acre per year.
  - Minimum of 30 days between applications.
- If grass is to be cut for hay, Agricultural Use Requirements for the Worker Protection Standard are applicable.
- For program lands, such as Conservation Reserve Program, consult program rules to determine whether grass or hay may be used. The more restrictive requirements of the program rules or this label must be followed.

ESTABLISHED GRASS PASTURES, RANGELAND AND CONSERVATION RESERVE PROGRAM AREAS

WEEDS	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Annual broadleaf weeds **Biennial and perennial broadleaf weeds**	2 pints 2 to 4 pints	Apply when weeds are small and actively growing and prior to bud stage. Spray while musk thistles or other biennial species are in the seedling to rosette stage and before flower stalks become apparent. The lower rate can be used in the spring during rosette stage. Use the highest rate in the fall or after flower stalks have developed. Do not apply to newly seeded areas until grass is well established. Do not apply to grass in the early boot through milk stage if grass seed production is desired. Bentgrass and legumes may be injured by this treatment.

RESTRICTIONS AND LIMITATIONS FOR USE ON ESTABLISHED GRASS PASTURES, RANGELAND AND CONSERVATION RESERVE PROGRAM AREAS

- Do not cut forage for hay within 7 days of application.
- **Postemergence:**
  - For susceptible annual and biennial broadleaf weeds, do not exceed 2 pints (1.0 lb. ae) per acre per application.
  - For moderately susceptible biennial and perennial broadleaf weeds and for difficult to control weeds and woody plants, do not exceed 4 pints (2.0 lbs. ae) per acre per application.
  - Spot treatments do not exceed 4 pints (2.0 lbs. ae) per acre.
  - Maximum of 2 applications per year.
  - Maximum of 8 pints (4.0 lbs. ae) per acre per year.
  - Minimum of 30 days between applications.
- If grass is to be cut for hay, Agricultural Use Requirements for the Worker Protection Standard are applicable.
- For program lands, such as Conservation Reserve Program, consult program rules to determine whether grass or hay may be used. The more restrictive requirements of the program rules or this label must be followed.

GRASS CUT FOR HAY

WEEDS	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Annual broadleaf weeds **Biennial and perennial broadleaf weeds**	2 pints 2 to 4 pints	Apply when weeds are small and actively growing and prior to bud stage. Spray while musk thistles or other biennial species are in the seedling to rosette stage and before flower stalks become apparent. The lower rate can be used in the spring during rosette stage. Use the highest rate in the fall or after flower stalks have developed. Do not apply to newly seeded areas until grass is well established. Do not apply to grass in the early boot through milk stage if grass seed production is desired. Bentgrass and legumes may be injured by this treatment.

RESTRICTIONS AND LIMITATIONS FOR USE IN PASTURES, RANGELANDS AND GRASS CUT FOR HAY

- Do not graze (dairy) cattle in treated areas for 7 days after application.
- Do not cut forage for hay within 30 days of application.
- Do not permit dairy animals or meat animals being finished for slaughter to forage treated fields within 3 days of slaughter.
- **Postemergence:**
  - For susceptible annual and biennial broadleaf weeds: Use 2 pints (1.0 lb. ae) per acre per application.
  - For moderately susceptible biennial and perennial broadleaf weeds: Use 2 to 4 pints (1.0 to 2.0 lbs. ae) per acre per application.
  - For difficult to control weeds and woody plants: Use 4 pints (2.0 lbs. ae) per acre per application.
  - Spot treatment: Use 4 pints (2.0 lbs. ae) per acre.
  - Maximum of 2 applications per year.
  - Maximum of 8 pints (4.0 lbs. ae) per acre per year.
  - Minimum of 30 days between applications.
- If grass is to be cut for hay, Agricultural Use Requirements for the Worker Protection Standard are applicable.

FALLOWLAND AND CROP STUBBLE

WEEDS	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Annual broadleaf weeds	1 to 2 pints	Use the lower rate when weeds are small (2 to 3 inches tall) and actively growing. Use the higher rate on older and drought-stressed plants.
Biennial broadleaf weeds	2 to 4 pints	Spray when musk thistles or other biennial species are in the seedling to rosette stage and before flower stalks become apparent. The lower rate can be used in the spring during rosette stage. Use the highest rate in the fall or after flower stalks have developed.
Perennial broadleaf weeds	2 to 4 pints	Spray weed in the bud to bloom stage or while in good vegetative growth. Do not disturb treated areas for at least 2 weeks after treatment, or until tops are dead.
Wild garlic and onion in crop stubble	4 pints	Apply to new regrowth of wild garlic or onion which occurs in the fall following harvest of small grains, corn or grain sorghum.

RESTRICTIONS AND LIMITATIONS FOR USE IN FALLOWLAND AND CROP STUBBLE

- Limit to two applications per year.
- Maximum of 4 pints (2.0 lbs. ae) per acre per application.
- Plant only labeled crops within 29 days following application.
- Minimum of 30 days between applications.

GRASSES FOR SEED PRODUCTION

WEEDS IN CROP	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Annual and perennial broadleaf weeds	2 to 4 pints	Apply to established stands in spring from tiller to early boot stage. **Do not spray in boot stage.** New spring seedings may be treated with the lower rate after grass seedlings have at least 5 leaves. Perennial weed regrowth may be treated in the fall.

RESTRICTIONS AND LIMITATIONS FOR USE ON GRASSES FOR SEED PRODUCTION

- Do not graze dairy animals or cut forage for hay within 7 days of application.
- Maximum of 4 pints (2.0 lbs. ae) per acre per application.
- Limited to 2 applications per year.
- Minimum of 21 days between applications.

NON-CROPLAND

Such as Fencerows, Hedgerows, Roadsides, Drainage Ditches, Rights-of-Way, Utility Power Lines, Railroads and Other Non-Crop Areas

WEEDS	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Annual broadleaf weeds	2 to 4 pints	Treat when weeds are young and actively growing. Perennial weeds should be near the bud stage, but not flowering at application. Do not use on susceptible southern grasses such as St. Augustine. Do not apply to newly seeded areas until grass is well established. Bentgrass, clover, legumes and dichondra may be injured by this treatment.
Biennial and perennial broadleaf weeds	4 pints	

RESTRICTIONS AND LIMITATIONS FOR USE ON NON-CROPLAND
- Maximum of 4 pints (2.0 lbs. ae) per acre per application.
- Applications to non-cropland areas are not applicable to treatment of commercial timber or other plants being grown for sale or other commercial use, or for commercial seed production, or for research purposes.
- Limit 2 applications per year.
- Minimum 30 days between applications.

SPOT TREATMENT IN NON-CROP AREAS

Mix 2 to 3 fluid ounces of this product in 3 gallons of water. Wet all weeds and stems thoroughly. For best results, treat when weeds are actively growing.

ORNAMENTAL TURF AREAS

Golf Courses, Cemeteries, Parks, Turfgrass, and Other Grass Areas

WEEDS	AMOUNT OF WEEDAR® 64 PER ACRE	DIRECTIONS
Annual broadleaf weeds	2 to 3 pints	Treat when weeds are young and actively growing. Perennial weeds should be near the bud stage, but not flowering at application. Do not use on susceptible southern grasses such as St. Augustine. Do not apply to newly seeded area until grass is well established. Bentgrass, clover, legumes and dichondra may be injured by this treatment.
Biennial and perennial broadleaf weeds	3 pints	

RESTRICTIONS AND LIMITATIONS FOR USE ON ORNAMENTAL TURF AREAS
- Use sufficient gallonage for thorough and uniform coverage.
- Do not apply more than 2 broadcast applications per year per treatment site. This does not exclude spot treatments.
- Do not allow people (other than applicator) or pets on treatment area during application.
- Do not enter treatment areas until sprays have dried.
- Maximum of 3 pints (1.5 lbs. ae) per acre per application.
- Maximum of 6 pints (3.0 lbs. ae) per acre per year, excluding spot treatments.

POPLAR/COTTONWOOD TREES GROWN FOR PULP BROADLEAF WEED CONTROL

This product may be applied through wick applicators or conventional ground sprayers. (Excluding irrigation systems) Do not allow this product to contact leaves or green bark of the tree. Use 1/2 pint to 3 pints per acre in enough water to provide uniform coverage prior to or after planting of Poplar/Cottonwood trees. Application during warm weather is preferred. Apply when weeds are actively growing, preferably before bud stage. Repeat treatment may be necessary for less susceptible weeds; re-apply as needed. Accord® may be mixed with this product to increase weed control. Follow both labels to determine correct rates. Two quarts or more of a spreader - activator per 100 gallons of spray solution may be added to improve herbicide performance.

RESTRICTIONS AND LIMITATIONS FOR USE ON POPLAR/COTTONWOOD TREES GROWN FOR PULP BROADLEAF WEED CONTROL
- Limited to 1 broadcast application per year. Maximum of 8 pints (4.0 lbs. ae) per acre per broadcast application.

FORESTRY - TREE INJECTION

For Controlling Species Such as Alder, Aspen, Birch, Blackgum, Cherry, Oak, Sweetgum, and Tulip Poplar

Make injections as near to the root collar as possible, using one injection per inch of trunk dbh (4-1/2 feet). For resistant species such as hickory, injections should overlap. For best results, injections should be made during the growing season, May 15th through October 15th.

For Dilute Injection

Mix 1 gallon of product in 19 gallons of water for dilute injections.

For Concentrate Injections

Use 1 to 2 ml of concentrate WEEDAR® 64 per injection. The injection bit must penetrate the inner bark.

RESTRICTIONS AND LIMITATIONS FOR USE ON FORESTRY - TREE INJECTION
- Limited to 1 injection application per year. Maximum of 2 ml of 4.0 lbs. ae formulation per injection site.

WEEDS AND BRUSH ON IRRIGATION CANAL DITCHBANKS

(Seventeen Western States: Arizona, California, Colorado, Idaho, Kansas, Montana, Nebraska, New Mexico, Nevada, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, and Wyoming)

For Control of Annual and Perennial Broadleaf Weeds

Apply 1 to 2 quarts of this product per acre in approximately 20 to 100 gallons per acre. Treat when weeds are young and actively growing before the bud or early bloom stage. For harder-to-control weeds, a repeat spray after 3 to 4 weeks using the same rates may be needed for maximum results. Apply no more than two treatments per season.

For Woody Brush and Patches of Perennial Broadleaf Weeds

Mix 1/2 gallon of product in 150 gallons of water. Wet foliage thoroughly using about 1 gallon of solution per square rod.

Spraying Instructions

Apply with low pressure (10 to 40 psi) power spray equipment mounted on a truck, tractor, or boat. Apply while traveling upstream to avoid accidental concentration of chemical into water. Spray when the air is fairly calm, 5 mph or less. Do not use on small canals (less than 10 cfs) where water will be used for drinking purposes.

Boom spraying onto water surface must be held to a minimum and no cross-stream spraying to opposite banks should be permitted. When spraying shoreline weeds, allow no more than 2 foot overspray onto water with an average of less than 1 foot overspray to prevent introduction of greater than negligible amounts of chemical into the water.

RESTRICTIONS AND LIMITATIONS FOR USE ON IRRIGATION CANAL DITCHBANKS

- Do not allow dairy animals to graze on treated areas for at least 7 days after spraying.
- Water within treated banks should not be fished.
- **Postemergence:** Limited to 2 applications per season. Maximum of 4 pints (2.0 lbs. ae) per acre per application. Minimum of 30 days between applications. Spot treatment permitted.

Do not use on small canals with a flow rate less than 10 cubic feet per second (CFS) where water will be used for drinking purposes. CFS may be estimated by using the formula below. The approximate velocity needed for the calculation can be determined by observing the length of time that it takes a floating object to travel a defined distance.

Divide the distance (ft.) by the time (sec.) to estimate velocity (ft. per sec.). Repeat 3 times and use the average to calculate CFS.

Average Width (ft.) x Average Depth (ft.) x Average Velocity (ft. per sec.) = CFS

For ditchbank weeds:

- Do not allow boom spray to be directed onto water surface.
- Do not spray across stream to opposite bank.

For shoreline weeds:

- Allow no more than 2 foot overspray onto water.

AQUATIC WEED CONTROL

For Use in Ponds, Lakes, Reservoirs, Marshes, Bayous, Drainage Ditches, Non-Irrigation Canals, Rivers and Streams that are Quiescent or Slow Moving.

NOTICE TO APPLICATORS

State and Local Coordination

Before application, coordination and approval of local and state authorities may be required, either by letter of agreement or issuance of special permits for such use.

Wind Velocity - Ground or Surface Application: Do not apply when wind speeds are at or above 10 mph. **Air Application:** Do not apply when wind speeds are at or above 5 mph. The restrictions do not apply to subsurface applications used in weed control programs.

WATER HYACINTH (*Eichornia crasipe*) - Directions For Use

This product will control water hyacinth with surface and air applications.

Amounts to Use: 2 to 4 quarts (4 lb. acid equivalent per gallon) per acre. **Spray the weed mass only.** Use 4 quarts when plants are matured or when the weed mass is dense.

When To Apply: Spray when water hyacinth plants are actively growing. Repeat as necessary to kill regrowth and hyacinth plants missed in the previous operation.

How To Use - Surface Application: Use power sprayers operated with a boom or spray gun mounted on a boat, tractor or truck. Thorough wetting of foliage is essential for maximum control. Use 100 to 400 gal. per acre of spray mixture. Special precautions such as the use of low pressure, large nozzles and thickening agents should be taken to avoid spray drift in areas of sensitive crops. For DIRECTA-SPRA™ operation use this product with 1 pint of drift control agent in 50 to 100 gallons of water. For other applications, follow the drift control agent label for mixing directions.

Air Application: Use drift control spray equipment or thickening agents mixed into the spray solution. Apply 1.0 gallon per acre of this product through standard boom systems with a minimum of 5 gallons of spray mix per acre. For MICROFOIL® drift control spray systems, apply this product in 12 to 15 gallons spray mix per acre.

2,4-D Acid Equivalent	1/2 pound	1 pound	2 pounds	3 pounds	4 pounds
WEEDAR® 64	1 pint	2 pints	2 quarts	3 quarts	4 quarts

RESTRICTIONS

FLOATING AND EMERGENT WEEDS:

- Maximum of 8 pints per surface acre per application.
- Limited to 2 applications per season.
- Minimum of 21 days between applications.
- Spot treatments are permitted.

Apply to emergent aquatic weeds in ponds, lakes, reservoirs, marshes, bayous, drainage ditches, non-irrigation canals, rivers, and streams that are quiescent or slow moving. Coordination and approval of local and state authorities may be required, either by letter of agreement or issuance of special permits for aquatic applications.

WATER USE

1. Water for irrigation or sprays:
   A. If treated water is intended to be used only for crops or non-crop areas that are labeled for direct treatment with 2,4-D such as pastures, turf, or cereal grains, the treated water may be used to irrigate and/or mix sprays for these sites at anytime after the 2,4-D aquatic application.
   B. Due to potential phytotoxicity considerations, the following restrictions are applicable:
   If treated water is intended to be used to irrigate or mix sprays for plants grown in commercial nurseries and greenhouses; and other plants or crops that are not labeled for direct treatment with 2,4-D, the water must not be used unless one of the following restrictions has been observed:
      i. A setback distance from functional water intake(s) of greater than or equal to 600 ft. was used for the application, or,
      ii. A waiting period of 7 days from the time of application has elapsed, or,
      iii. An approved assay indicates that the 2,4-D concentration is 100 ppb (0.1 ppm) or less at the water intake. Wait at least 3 days after application before initial sampling at water intake.
2. Drinking water (potable water):
   A. Consult with appropriate state or local water authorities before applying this product to public waters. State or local agencies may require permits. The potable water use restrictions on this label are to ensure that consumption of water by the public is allowed only when the concentration of 2,4-D in the water is less than the MCL (Maximum Contaminant Level) of 70 ppb. Applicators should consider the unique characteristics of the treated waters to assure that 2,4-D concentrations in potable water do not exceed 70 ppb at the time of consumption.
   B. For floating and emergent weed applications, the drinking water setback distance from functioning potable water intakes is greater than or equal to 600 ft.
   C. If no setback distance of greater than or equal to 600 ft. is used for application, applicators or the authorizing organization must provide a drinking water notification prior to a 2,4-D application to the party responsible for public water supply or to individual private water uses. Notification to the party responsible for a public water supply or to individual private water users must be done in a manner to assure that the party is aware of the water use restrictions when this product is applied to potable water. The following is an example of a notification via posting, but other methods of notification which convey the above restrictions may be used and may be required in some cases under State or local law or as a condition of a permit.
   Example: Posting notification should be located every 250 feet including the shoreline of the treated area and up to 250 feet of shoreline past the application site to include immediate public access points. Posting must include the day and time of application. Posting may be removed if analysis of a sample collected at the intake 3 or more days following application shows that the concentration in the water is less than 70 ppb (100 ppb for irrigation or sprays), or after 7 days following application, whichever occurs first.
   Text of notification: Wait 7 days before diverting functioning surface water intakes from the treated aquatic site to use as drinking water, irrigation, or sprays, unless water at functioning drinking water intakes is tested at least 3 days after application and is demonstrated by assay to contain not more than 70 ppb 2,4-D (100 ppb for irrigation or sprays).
   Application Date: _____ Time: _____ .
   D. Following each application of this product, treated water must not be used for drinking water unless one of the following restrictions has been observed:
      i. A setback distance from functional water intake(s) of greater than or equal to 600 ft. was used for the application, or
      ii. A waiting period of 7 days from the time of application has elapsed, or,
      iii. An approved assay indicates that the 2,4-D concentration is 70 ppb (0.07 ppm) or less at the water intake. Sampling for drinking water analysis should occur no sooner than 3 days after 2,4-D application. Analysis of samples must be completed by a laboratory that is certified under the Safe Drinking Water Act to perform drinking water analysis using a currently approved version of analytical Method Number 515, 555, other methods for 2,4-D as may be listed in Title 40 CFR, Part 141.24, or Method Number 4015 (immunoassay of 2,4-D) from U.S. EPA Test Methods for Evaluating Solid Waste SW-846.
   E. Note: Existing potable water intakes that are no longer in use, such as those replaced by a connection to a municipal water system or a potable water well, are not considered to be functioning potable water intakes.
   F. Drinking water setback distances do not apply to terrestrial applications of 2,4-D adjacent to water bodies with potable water intakes.
3. Except as stated above, there are no restrictions on using water from treated areas for swimming, fishing, watering livestock or domestic purposes.

WATER MILFOIL (*Myriophyllum spicatum*) - Directions For Use

This product will control water milfoil with surface, subsurface and air applications.

How To Use: To control water milfoil when less than 5 gallons of concentrate per acre is recommended, dilute the concentrate with water to apply a minimum of 5 gallons of spray mix per acre. Do not treat within 1/2 mile of potable water intakes. Shoreline areas should be treated by sub-surface injection applied by boat to avoid aerial drift. Do not apply when weather conditions favor drift from target area. Do not contaminate water by cleaning of equipment washwaters.

Open Water Areas: To reduce contamination and prevent undue exposure to fish and other aquatic organisms, do not treat water areas that are not infested with aquatic weeds.

Amounts To Use: Apply 2.5 to 2.75 gallons of this product per acre. The higher rate is used in areas of greater water exchange. These areas may require a repeat application.

When To Apply: For best results, apply in spring or early summer when milfoil starts to grow. This timing can be checked by sampling the lake bottom in areas heavily infested with weeds the year before.

Subsurface Application: Apply 2.5 to 2.75 gallons of this product per acre as a concentrate directly into the water through boat mounted distribution systems.

Surface Application: Apply 2.5 to 2.75 gallons of this product per acre in a minimum spray volume of 5 gallons mix per acre.

Air Application: Use drift control spray equipment or thickening agents mixed into the spray solution. Apply 2.5 to 2.75 gallons per acre of this product through standard boom systems with a minimum of 5 gallons of spray mix per acre. For MICROFOIL® drift control spray systems apply this product in 12 to 15 gallons spray mix per acre.

Do not apply within 21 days of previous application.

When treating moving bodies of water, applications must be made while traveling upstream to prevent concentration of 2,4-D downstream from the application.

RESTRICTIONS

SUBMERSED AQUATIC WEEDS:

- Maximum of 22.7 pints (10.8 lbs. ae) per acre-foot per per application.
- Limited to 2 applications per season.

Apply to aquatic weeds in ponds, lakes, reservoirs, marshes, bayous, drainage ditches, non-irrigation canals, rivers, and streams that are quiescent or slow moving. Do not apply within 21 days of previous application. When treating moving bodies of water, applications must be made while traveling upstream to prevent concentration of 2,4-D downstream from the application. Coordination and approval of local and State authorities may be required, either by letter of agreement or issuance of special permits for such use.

TABLE 1. AMOUNT OF 2,4-D TO APPLY FOR A TARGET SUBSURFACE CONCENTRATION

SURFACE AREA	Average Depth	For Typical Conditions 2 ppm 2,4-D ae/acre-foot	For Difficult Conditions* 4 ppm 2,4-D ae/acre-foot
1 Acre	1 ft.	5.4 lbs. (11.3 pts. product)	10.8 lbs. (22.7 pts. product)
	2 ft.	10.8 lbs. (22.7 pts. product)	21.6 lbs. (45.4 pts. product)
	3 ft.	16.2 lbs. (34.1 pts. product)	32.4 lbs. (68.2 pts. product)
	4 ft.	21.6 lbs. (45.4 pts. product)	43.2 lbs. (90.9 pts. product)
	5 ft.	27.0 lbs. (56.8 pts. product)	54.0 lbs. (113.6 pts. product)

* Examples include spot treatment of pioneer colonies of Eurasian Water Milfoil and certain difficult to control aquatic species.

WATER USE

1. Water for irrigation or sprays:
   A. If treated water is intended to be used only for crops or non-crop areas that are labeled for direct treatment with 2,4-D such as pastures, turf, or cereal grains, the treated water may be used to irrigate and/or mix sprays for these sites at anytime after the 2,4-D aquatic application.

   B. Due to potential phytotoxicity and/or residue considerations, the following restrictions are applicable:

   If treated water is intended to be used to irrigate or mix sprays for unlabeled crops, noncrop areas or other plants not labeled for direct treatment with 2,4-D, the water must not be used unless one of the following restrictions has been observed:

   i. A setback distance described in the Drinking Water Setback Table was used for the application, or,

   ii. A waiting period of 21 days from the time of application has elapsed, or,

   iii. An approved assay indicates that the 2,4-D concentration is 100 ppb (0.1 ppm) or less at the water intake. See Table 3 for the waiting period after application but before taking the initial sampling at water intake.

2. Drinking water (potable water):
   A. Consult with appropriate state or local water authorities before applying this product to public waters. State or local agencies may require permits. The potable water use restrictions on this label are to ensure that consumption of water by the public is allowed only when the concentration of 2,4-D in the water is less than the MCL (Maximum Contaminant Level) of 70 ppb. Applicators should consider the unique characteristics of the treated waters to assure that 2,4-D concentrations in potable water do not exceed 70 ppb at the time of consumption.

   B. For submersed weed applications, the drinking water setback distances from functioning potable water intakes are provided in Table 2. Drinking Water Setback Distance (below).

   C. If no setback distance from the Drinking Water Setback Distance Table (Table 2) is to be used for the application, applicators or the authorizing organization must provide a drinking water notification and an advisory to shut off all potable water intakes prior to a 2,4-D application. Notification to the party responsible for a public water supply or to individual private water users must be done in a manner to assure that the party is aware of the water use restrictions when this product is applied to potable water. The following is an example of a notification via posting, but other methods of notification which convey the above restrictions may be used and may be required in some cases under State or local law or as a condition of a permit.

   Example: Posting notification should be located every 250 feet including the shoreline of the treated area and up to 250 feet of shoreline past the application site to include immediate public access points. Posting should include the day and time of application. Posting may be removed if analysis of a sample collected at the intake no sooner than stated in Table 3 (below) shows that the concentration in the water is less than 70 ppb (100 ppb for irrigation or sprays), or after 21 days following application, whichever occurs first.

   Text of notification: Wait 21 days before diverting functioning surface water intakes from the treated aquatic site to use as drinking water, irrigation, or sprays, unless water at functioning drinking water intakes is tested no sooner than (insert days from Table 3) and is demonstrated by assay to contain not more than 70 ppb 2,4-D (100 ppb for irrigation or sprays).

   Application Date: ______ Time: _____ .

   D. Following each application of this product, treated water must not be used for drinking water unless one of the following restrictions has been observed:

   i. A setback distance described in the Drinking Water Setback Distance Table was used for the application, or

   ii. A waiting period of at least 21 days from the time of application has elapsed, or,

   iii. An approved assay indicates that the 2,4-D concentration is 70 ppb (0.07 ppm) or less at the water intake. Sampling for drinking water analysis should occur no sooner than stated in Table 3. Analysis of samples must be completed by a laboratory that is certified under the Safe Drinking Water Act to perform drinking water analysis using a currently approved version of analytical Method Number 515, 555, other methods for 2,4-D as may be listed in Title 40 CFR, Part 141.24, or Method Number 4015 (immunoassay of 2,4-D) from U.S. EPA Test Methods for Evaluating Solid Waste SW-846.

   E. Note: Existing potable water intakes that are no longer in use, such as those replaced by a connection to a municipal water system or a potable water well, are not considered to be functioning potable water intakes.

   F. Drinking water setback distances do not apply to terrestrial applications of 2,4-D adjacent to water bodies with potable water intakes.

3. Except as stated above, there are no restrictions on using water from treated areas for swimming, fishing, watering livestock or domestic purposes.

Table 2. Drinking Water Setback Distance for Submersed Weed Applications			
APPLICATION RATE AND MINIMUM SETBACK DISTANCE (FEET) FROM FUNCTIONING POTABLE WATER INTAKE			
1 ppm*	2 ppm*	3 ppm*	4 ppm*
600	1200	1800	2400
* ppm acid equivalent target water concentration			

Table 3. Sampling for Drinking Water Analysis After 2,4-D Application for Submerged Weed Applications			
MINIMUM DAYS AFTER APPLICATION BEFORE INITIAL WATER SAMPLING AT THE FUNCTIONING POTABLE WATER INTAKE			
1 ppm*	2 ppm*	3 ppm*	4 ppm*
5	10	10	14
* ppm acid equivalent target water concentration			

Use of this product in certain portions of California, Oregon, and Washington is subject to the January 22, 2004 Order for injunctive relief in Washington Toxics Coalition, et al. v. EPA, C0132C, (W.D. WA). For further information, please refer to EPA Web Site: http://www.epa.gov/espp.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container in a dry, secured storage area. Keep container tightly closed when not in use. Store at temperature above 32°F. If allowed to freeze, warm to at least 40°F and remix before using. Freezing does not alter this product.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law and may contaminate ground water. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

Nonrefillable Containers 5 Gallons or Less: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. **Triple rinse as follows:** Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers are also disposable by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Nonrefillable Containers Larger than 5 Gallons: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. **Triple rinse as follows:** Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. **Pressure rinse as follows:** Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 psi for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Refillable Container Larger than 5 Gallons: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10% full with water and, if possible, spray all sides while adding water. Agitate vigorously or recirculate water with the pump for two minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

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If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(RV031109)

NOTICE TO BUYER

Purchase of this material does not confer any rights under patents governing this product or the use thereof in countries outside of the United States.

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All other trademarks are the property of their respective owners.

APPENDIX C

DUPONT™ ASSURE® II HERBICIDE PRODUCT LABEL

DUPONT®

DuPont™ Assure® II

herbicide

DuPont™ ASSURE® II Highlights

- Provides postemergence control of both annual and perennial grasses in canola, crambe, cotton, crops grown for seed, eucalyptus, dry beans, including Chickpea, dry and succulent peas, flax, hybrid poplar plantings, lentils, mint (spearmint and peppermint), pineapple, ryegrass grown for seed, snap beans, soybeans, sugarbeets, sunflowers and noncrop areas.
- ASSURE® II herbicide controls volunteer corn in glyphosate-tolerant soybeans, regardless of the corn trait.
- ASSURE® II has a flexible rate range and tank mix options.
- For Soybeans, ASSURE® II may be tank mixed with DuPont™ CLASSIC®, DuPont™ HARMONY® GT and DuPont™ SYNCHRONY® XP herbicides. See "Applications with Broadleaf Herbicides" and "Soybeans - Tank Mixes".
- For Dry Beans, ASSURE® II may be tank mixed with "Basagran". See "Applications with Broadleaf Herbicides."
- Include crop oil concentrate or nonionic surfactant as recommended in this label. See "Spray Adjuvants."
- May be applied by ground (broadcast, band, or spot spray) or by air.
- For ground application, use a minimum of 10 to 15 gallons water per acre. Use flat fan or hollow cone nozzles at 25-60 psi. See "Application Equipment."
- Apply to actively growing grasses at the recommended sizes. See "Application Timing" and "Environmental Conditions and Biological Activity."
- Consult label text for complete instructions. Always read and follow label directions for use.

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DuPont™ Assure® II

herbicide

Emulsifiable Concentrate

Active Ingredients	*By Weight*
Quizalofop P-Ethyl Ethyl(R)-2-[4-(6-chloroquinoxalin-2-yl oxy)- phenoxy]propionate	10.3%*
Other Ingredients	89.7%
TOTAL	100.0%

Contains petroleum-based distillates.

* Equivalent to 0.88 lb ai per gal

EPA Reg. No. 352-541 EPA Est. No. ___________

Nonrefillable Container

Net: _____________

OR

Refillable Container

Net: _____________

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Do not give any liquid to this person. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Contains petroleum distillate. Vomiting may cause aspiration pneumonia.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-441-3637 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER! Causes irreversible eye damage. Harmful if swallowed, inhaled, or absorbed through the skin. Avoid contact with eyes, skin, or clothing. Avoid breathing vapor or spray mist.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category G on an EPA chemical-resistance category selection chart.

Applicators and other handlers must wear:

Long-sleeved shirt and long pants.
Chemical-resistant gloves, such as barrier laminate or Viton.
Shoes plus socks.
Protective eyewear.

Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROL STATEMENTS

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR part 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

USERS SHOULD: Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing .

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and invertebrates. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate.

This product may contaminate water through drift of spray in wind. This product has a potential for runoff for several months or more after application. Poorly drained soils and soils with shallow water tables are more prone to produce runoff that contains this product. A level, well maintained vegetative buffer strip between areas to which the product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours. Sound erosion practices will reduce this product's contribution to surface water contamination.

PHYSICAL AND CHEMICAL HAZARDS

Combustible. Keep away from heat, sparks, and open flames. Keep container closed.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. DuPont™ ASSURE® II must be used only in accordance with instructions on this label or in separate published DuPont instructions.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment(PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls.
Chemical-resistant gloves, such as barrier laminate or Viton.
Shoes plus socks.
Protective eyewear.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Weed control in "Non-Agricultural Uses" is not within the scope of WPS. Keep unprotected persons out of treated areas until sprays have dried.

ENVIRONMENTAL CONDITIONS AND BIOLOGICAL ACTIVITY

ASSURE® II is a systemic herbicide that is rapidly absorbed by treated foliage and translocated to the roots and other growing points of the plant. When affected, younger plant tissues become chlorotic/necrotic and eventually die, leaving treated plants stunted and noncompetitive. In general, these symptoms are first observed within 7 to 14 days after application depending on the grass species treated and the environmental conditions.

The degree of control and duration of the effect of ASSURE® II depend upon the rate used, weed spectrum, weed size and variability, growing conditions at and following treatment, soil moisture, precipitation, tank mixtures, and spray adjuvant used.

Conditions conducive to healthy, actively growing plants optimize the performance of ASSURE® II. Unacceptable control may occur if ASSURE® II is applied to grasses stressed from :

- abnormal weather (excessive heat or cold, or widely fluctuating temperatures),
- hail damage,
- drought,
- water saturated soils,
- mechanical injury, or
- prior herbicide injury.

Grasses under these conditions are often less sensitive to herbicide activity. Delay application until the stress passes and weeds and crop resume growth.

Before making applications of ASSURE® II to crops previously under stress, or injured from other pesticide applications, the crop needs to be fully recovered and growing vigorously.

ASSURE® II is rainfast 1 hour after application.

APPLICATION INFORMATION

Agricultural Uses

ASSURE® II herbicide is a selective that controls annual and perennial grasses in canola, crambe, cotton, crops grown for seed, eucalyptus, dry beans, including Chickpea, dry and succulent peas, flax, hybrid poplar plantings, lentils, mint (spearmint and peppermint), pineapple, ryegrass grown for seed, snap beans, soybeans, sugarbeets, sunflowers and noncrop areas. ASSURE® II does not control sedges or broadleaf weeds. Applied at specified rates and timings, ASSURE® II controls the grasses listed in the "Weeds Controlled and Rate Selection" chart on page 4. See Seasonal Use Limits and Harvest intervals on page 10 for the specific crop.

ASSURE® II herbicide is a selective postemergence herbicide registered for control of annual and perennial grasses in alfalfa, onion, carrot, garlic, Swiss chard, spinach, radish, Chinese cabbage, and red beets grown specifically under contract as non food/non feed crops for seed production only. See "Restrictions" portion of label before using. Applied at specified rates and timings, ASSURE® II herbicide will control emerged grasses. Subsequent flushes of grasses require additional treatment.

Non-Agricultural Uses

Non-Crop Areas

DuPont™ ASSURE® II is registered for postemergence control of certain grasses on noncrop sites such as fence rows, roadsides, equipment storage areas, and other similar areas.

Make a single application of ASSURE® II at a rate of 12 to 16 fluid ounces per acre to actively growing grasses.

Non-Crop Areas - to aid in establishment of Wildflowers

- Since ASSURE® II controls many grasses but not most broadleaf plants, it may be used to enhance establishment and growth of certain broadleaf plants on non-crop sites (that is, plants identified as "wildflowers" such as indian blanket, cone flowers, bachelor button, dwarf cornflower, coreopsis, white yarrow, oxeye daisy, dames-rocket, blue flax, eveningprimrose, blackeyed-susan, marigolds, impatiens, bluebonnet, indian paintbrush, verbena, gaillardia, chrysanthemum, catchfly and scarlet pimpernel).
- For this use refer to use rates in the Weeds Controlled area of this label, and not the rates in the NON-CROP Section above.

Application Timing

Crop and Non-Crop Uses

Apply ASSURE® II to young, actively growing grasses according to the rate chart that follows. If a field is to be irrigated, apply ASSURE® II after the irrigation. Applications made to grasses that are larger than the sizes listed in the rate charts or to grasses under stress may result in unsatisfactory control.

Sequential Applications

Do not exceed the maximum use rate per acre per year, as specified for the specific crop (see section: Seasonal use limits and Harvest Intervals, page 11).

Annual Grasses

In the event of a subsequent flush of grass, or regrowth of previously treated grass occurs, a second application of ASSURE® II may be applied. Select the appropriate rate for the grassy weed from the "Weeds Controlled - Rate selection" chart.

Perennial Grasses

If perennial grasses regrow, reapply ASSURE® II at 6-7 fluid ounces of product per acre. Application timing should be as follows: bermudagrass (3" tall or up to 6" runners), rhizome johnsongrass (6"-10"), quackgrass (4"-8"), wirestem muhly (4"-8").

Spray Adjuvants

Applications of ASSURE® II must include either a crop oil concentrate or a nonionic surfactant. Consult local DuPont fact sheets, technical bulletins, and service policies prior to using other adjuvant systems. If another herbicide is tank mixed with ASSURE® II to increase the weed spectrum, select adjuvants authorized for use with both products. Products must contain only EPA-exempt ingredients (40 CFR 1001).

Petroleum Crop Oil Concentrate (COC)

- Petroleum-based crop oil concentrates are the preferred adjuvant system in arid areas.
- Apply petroleum-based crop oil concentrate at 1% v/v (1 gallon per 100 gallons spray solution) or 2% under arid conditions. Note – In soybeans and sunflowers, up to 2% v/v may be used based on local recommendations.
- Oil adjuvants must contain at least 80% high quality, petroleum (mineral) or modified vegetable seed oil with at least 15% surfactant emulsifiers.
- For aerial applications apply 0.5% v/v (2 quarts product per 100 gallons spray solution).

Nonionic Surfactant (NIS)

- Apply at 0.25 % v/v (1 quart of product per 100 gallons spray solution).
- Surfactant products must contain at least 60% nonionic surfactant with a hydrophilic/lipophilic balance (HLB) greater than 12.

Ammonium Nitrogen Fertilizer

- An ammonium nitrogen fertilizer may be added to the spray mixture, in addition to crop oil concentrate or nonionic surfactant, but is not required to optimize performance of this product.
- Use 2 quart/acre of a high-quality urea ammonium nitrate (UAN), such as 28%N or 32%N, or 2 lb/acre of a spray-grade ammonium sulfate (AMS). Use 4 quart/acre UAN or 4 pound/acre AMS under arid conditions.
- Do not use liquid nitrogen fertilizer as the total carrier solution.

Special Adjuvant Types

- Combination adjuvant products may be used at doses that provide the required amount of NIS, COC, MSO and/or ammonium nitrogen fertilizer. Consult product literature for use rates and restrictions.
- In addition to the adjuvants specified above, other adjuvant types may be used if they provide the same functionality and have been evaluated and approved by DuPont Product Management.

WEEDS CONTROLLED AND RATE SELECTION

	Size at Application (in)	ASSURE® II Applied Alone (fluid ounces product/A)	DuPont™ ASSURE® II* Tank Mixed with Broadleaf Herbicide (fluid ounces product/A)
Annual Grasses**			
Volunteer Corn *(Zea mays)****	6-30		4 - 8
Foxtail, Giant *(Setaria faberi)*	2-4 (pretiller)		
Johnsongrass, Seedling *(Sorghum halepense)*	2-8	5 - 8	5
Shattercane *(Sorghum bicolor)*	6-12		
Wild Proso Millet *(Panicum miliaceum)*	2-6		7
Crowfootgrass *(Dactyloctenium aegyptium)*	2-6		
Fall Panicum *(Panicum dichtomiflorum)*	2-6		
Field Sandbur *(Cenchrus incertus)*	2-6		8
Foxtail, Bristly *(Setaria verticillata)*	2-4		
Foxtail, Giant *(Setaria faberi)*	2-8		7
Foxtail, Green *(Setaria viridis)*	2-4		8
Foxtail, Yellow *(Setaria lutescens)*	2-4		Split†
Goosegrass *(Eleucine indica)*	2-6‡	7 - 8	
Itchgrass *(Rottboellia exaltata)*	2-8		
Sprangletop *(Leptochloa filiformis)*	2-6		
Volunteer Barley *(Hordeum vulgare)*	2-6		8
Volunteer Oats *(Avena sativa)*	2-6		
Volunteer Rye *(Secale cereale)*	2-6		
Volunteer Wheat *(Triticum aestivum)*	2-6		
Wild Oat *(Avena fatua)*	2-6		
Witchgrass *(Panicum capillare)*	2-6		
Barnyardgrass *(Echinochloa crus-galli)*	2-6		
Crabgrass, Large *(Digitaria sanguinalis)*	2-6‡	8 - 10	Split†
Crabgrass, Smooth *(Digitaria ischaemum)*	2-6‡		
Junglerice *(Echinochloa colonum)*	2-6		10
Texas Panicum *(Panicum texanum)*††	2-4		Split†
Red Rice *(Oryza sativa)*	1-4	9 - 10	Split†
Woolly Cupgrass *(Eriochloa villosa)*	2-4§		
Broadleaf Signalgrass *(Brachiaria platyphylla)*	2-6	10	Split
Downy brome (Bromus tectorum) Italian ryegrass (*Lolium multiflorum*) Jointed goatgrass (*Aegilops cylindrica*) Windgrass (*Bromus mollis*)	2-6 2-6 2-6 2-6	10-12	12
Perennial Grasses**			
Wirestem Muhly *(Muhlenbergia frondosa)*	4-8	8 - 10	Split†
Bermudagrass *(Cynodon dactylon)*	3" tall (or up to 6" runners)	10 - 12	Split†
Johnsongrass, Rhizome *(Sorghum halepense)*	10-24		10
Quackgrass *(Agropyron repens)*	6-10		Split†

* See "Applications With Broadleaf Herbicides".

** For annual and perennial grasses, up to 12 fluid ounces per acre may be applied, based on local recommendations. **Under arid conditions the higher use rate is recommended.**

*** Control includes "Roundup" Ready (glyphosate resistant), Liberty Link, and IMI-Corn. Apply 4 fluid ounces/acre ASSURE® II for up to 12 inch tall corn. Apply 5 fluid ounces/acre ASSURE® II for 12-18 inch volunteer corn; use 8 oz ASSURE® II for 18-30 inch volunteer corn.

† Split = Split Application. May not be controlled adequately using a tank mix with broadleaf herbicides. For best results, alternate applications of ASSURE® II with a broadleaf herbicide, ensuring that ASSURE® II is applied either 24 hours before or 7 days after the broadleaf herbicide.

‡ Length of lateral growth.

§ Size in height or diameter, whichever is more restrictive. Applications to plants with more than three tillers may result in unsatisfactory control.

†† **In Texas and other areas of the arid west, 10 fluid ounces is the recommended use rate for control of Texas panicum, use of lower rates may result in unsatisfactory control.**

Specific Weed Problems

Volunteer Glyphosate-Resistant Corn

For control of volunteer glyphosate resistant corn in other glyphosate resistant crops, DuPont™ ASSURE® II may be used in a tank mix with glyphosate as follows:

- Apply ASSURE® II at a rate of 4 fluid ounces/acre for up to 12 inch volunteer corn, 5 fluid ounces for 12-18 inch volunteer corn and 8 fluid ounces ASSURE® II for 18-30 inch volunteer corn, tank mixed with a labeled rate of glyphosate.

ASSURE® II may be used in a tank mix with glyphosate as follows:

1. If the glyphosate formulation does not include a built-in adjuvant system, a nonionic surfactant or petroleum based crop oil concentrate must be included, per directions on this label.
2. If the glyphosate formulation contains a built-in adjuvant system (ie "Roundup WeatherMax"), additional adjuvant is still required. Add nonionic surfactant at a rate of 0.125% v/v (1 pt per 100 gal spray solution). Under arid conditions consider adding a petroleum based crop oil concentrate at 1% v/v (1 gallon per 100 gallons spray solution) instead of a nonionic surfactant.

Rhizome Johnsongrass - South East States

For control of rhizome johnsongrass in the states of Alabama, Arkansas, Florida, Georgia, Louisiana, Maryland, Mississippi, Tennessee, Virginia, and West Virginia, a reduced rate of ASSURE® II may be used if applied in a sequential application program as follows:

1. Apply ASSURE® II at 5 fluid ounces per acre when johnsongrass is 10"-24" tall.
2. Apply ASSURE® II a second time at 5 fluid ounces per acre when johnsongrass regrowth is 6"-10" tall.

Do not apply ASSURE® II in a tank mix with postemergence broadleaf herbicides when using this reduced rate, sequential application program. Do not exceed the maximum specified rate/acre/season for the crop that is going to be planted when additional applications are made to control Rhizome Johnsongrass.

Rhizome Johnsongrass

ASSURE® II herbicide will provide control of weeds in Fallow, including emerged Rhizome and Seedling Johnsongrass. Note that, when applied at specified rates and timings to control grass weeds, ASSURE® II herbicide will provide control of emerged grasses only. Subsequent flushes of grasses require additional treatment.

Apply ASSURE® II herbicide for control of Seedling and Rhizome Johnsongrass at the range indicated.

1. Apply ASSURE® II at 8 ounces per acre when seedling johnsongrass is 2" - 6" tall.
2. Apply ASSURE® II at 12 ounces per acre when rhizome johnsongrass is 12"-16" tall.
3. If rhizome Johnsongrass regrows, reapply ASSURE® II at 8 ounces per acre. Application timing should be when Johnsongrass regrowth is 6"-10" in height.

Tank mixes of ASSURE® II with postemergence broadleaf herbicides may result in reduced grass control. If grass control is reduced, an additional application of ASSURE® II may be required after grass plants begin to develop new leaves.

Specific Crop Uses

For Use On Non Food/Non Feed Crops Grown Under Contract For Seed Production

ASSURE® II herbicide is registered for control of annual and perennial grasses in alfalfa, onion, carrot, garlic, Swiss chard, spinach, radish, Chinese cabbage, and red beets grown specifically under contract as non food/non feed crops for seed production only in the sates Idaho, Montana, Oregon, Washington and Wyoming. See "Restrictions" portion of this label before using. Applied at specified rates and timings, ASSURE® II herbicide will control emerged grasses. Subsequent flushes of grasses require additional treatment.

Spray Additives

Always include a nonphytotoxic petroleum based crop oil concentrate at 1% v/v (4 quarts/100 gallons) or a nonionic surfactant at 0.25% v/v (1 quart/100 gallons). Crop oil concentrate is the preferred adjuvant in arid areas.

Tank Mix Applications

Tank mixtures of ASSURE® II with any pesticide or spray adjuvant is not recommended except as directed on this label or on other supplemental labels.

For Use In Eucalyptus Plantations

How To Use

ASSURE® II herbicide is registered for control of annual and perennial grasses in Eucalyptus plantations in the state of Hawaii. Use a tractor sprayer properly calibrated to a constant speed and rate of delivery.

Apply ASSURE® II as a broadcast spray at a rate of 15 to 30 fluid ounces of product per acre per application in Eucalyptus fields. A maximum of 4 applications may be made per year.

Weeds Controlled

Para grass (*Panicum muticum*)
Crab grass (*Digitaria spp.*)

Weeds Partially Controlled

Torpedo grass (*Panicum repens*)

For Establishment Of Hybrid Poplar Plantings

ASSURE® II herbicide is registered for the control of grasses to aid in the establishment of hybrid poplar plantings in the states of Maine and Minnesota.

ASSURE® II may be applied over hybrid poplar following planting. Apply at the rate of 5 to 10 fluid ounces of product per acre to be sprayed. Refer to the table for the appropriate size or growth stage of the grasses to be controlled. Follow recommendations regarding the use of surfactants, spray additives and tank mix partners.

For Use In Pineapple

DuPont™ ASSURE® II herbicide is registered for control of annual and perennial grasses in pineapple in Hawaii and Puerto Rico. Apply at specified rates and timing, ASSURE® II herbicide will control emerged grasses. Subsequent flushes of grasses require additional treatment.

How To Use

Use a sprayer properly calibrated to a constant speed and rate of delivery. Mix the proper amount of ASSURE® II in water.

- Foliar applications - Apply ASSURE® II at 15-30 fluid ounces of product per acre per application. A maximum of 4 applications may be made per harvest.
- Directed spot treatments for perennial grasses - Spray perrenial grasses postemergence to wet (50-100 gallons per acre depending on size) with 15 to 30 fluid ounces product per 100 gallons of water as a spot treatment. A maximum of 4 applications may be made per harvest.

Weeds Controlled

Sour Grass (*Tricachne insularis*)
Crabgrass (*Digitaria* spp.)
Natal Red Top (*Agrostis alba*)

Weeds Partially Controlled

Guineagrass (*Panicum maximum*)

Wiregrass (*Eleusine Indica*)

Molasses Grass (*Melinis Minutiflora*)

For Use In Grass Control In Non-Food/Non-Feed ASSURE® II Tolerant Perennial Ryegrass Crops Grown Only For Seed Production

ASSURE® II herbicide is registered for control of annual and perennial grasses in non food/non feed ASSURE® II tolerant perennial ryegrass crops grown specifically for seed production in the state of Minnesota. See "Restrictions" portion of this label before using. ASSURE® II herbicide will control emerged grasses when applied at specified rates and timings. Subsequent flushes of grasses require additional treatment.

How To Use

Apply ASSURE® II at 10 fluid ounces/acre prior to the boot stage in the spring of the second year of ASSURE® II tolerant perennial ryegrass growth. Application at this stage is for vegetative suppression of quackgrass growth and preventing quackgrass seed contamination during ryegrass harvest.

- Application of ASSURE® II at 10 fluid ounces/acre may be made in the first season of ASSURE® II tolerant perennial ryegrass growth for control of heavier quackgrass infestations. Such applications can be made anytime from planting until the end of August.
- Fall application of ASSURE® II should be avoided on ASSURE® II tolerant perennial ryegrass because seed production may be reduced.

TANK MIXES

Refer to the labels of all tank mix products for information regarding use information (such as rates, timing, application information, and sprayer cleanup) and product precautions and restrictions (especially adjuvants - ASSURE® II requires the use of an adjuvant). The most restrictive provisions apply. If those instructions conflict with this label, do not tank mix the herbicide with ASSURE® II.

DuPont also recommends that you first consult your state experiment station, university, or extension agent, Agricultural dealer, or DuPont representative as to the potential for any adverse interactions (resulting in unacceptable grass control and/or crop injury) before using new herbicide, insecticide and fungicide mixtures. If no information is available, limit the initial use of ASSURE® II and the new herbicide, insecticide or fungicide product to a small area.

Always conduct a jar test to evaluate physical compatibility before applying a particular mixture to crops for the first time.

Application With Insecticides and Fungicides

ASSURE® II may be tank mixed with postemergence insecticides registered for use in the specific crop (such as DuPont™ ASANA® XL insecticide, DuPont™ LANNATE® insecticide, LANNATE® LV insecticide, DuPont™ VYDATE® C-LV insecticide, and VYDATE® L insecticide).

ASSURE® II may be tank mixed with postemergence fungicides and bactericides registered for use in the specific crop.

Application With Broadleaf Herbicides

For best results, apply ASSURE® II alone or in sequence with a broadleaf herbicide(s). Tank mixtures of ASSURE® II with chlorimuron-ethyl (e.g. DuPont™ CLASSIC® or DuPont™ SYNCHRONY® XP) or with cloransulam-methyl (e.g. "FirstRate") containing herbicides may fail to control certain grass species normally controlled by ASSURE® II alone. Under arid or stressful environmental conditions, tank mixtures with other broadleaf herbicides may show a small reduction in control of some grass species. Activity of the postemergence broadleaf herbicide in the tank mixture is not affected.

Split Applications with Postemergence Broadleaf Herbicides

Applying ASSURE® II immediately prior to or following an application of a postemergence broadleaf herbicide may reduce control of some grasses. For best results, follow these recommendations when making split applications:

- Apply postemergence broadleaf herbicides at least 24 hours after applying ASSURE® II.
- Apply ASSURE® II when grass begins to develop new leaves (generally 7 days after the postemergence broadleaf herbicide application) in fields treated with a postemergence broadleaf herbicide.

Dry Beans, Dry and Succulent Peas in ID, MT, OR and WA

DuPont™ ASSURE® II herbicide can be tank mixed with "Basagran" herbicide for selective post emergence weed control of annual and perennial grasses and broadleaf weeds in dry beans, dry peas and succulent peas.

When tank mixing ASSURE® II with "Basagran", annual grass antagonism can be minimized by increasing the specified use rate of ASSURE® II by 2 ounces per acre. Refer to the "Seasonal Use Rates and Harvest Intervals" section of this label for seasonal maximum use rates.

ASSURE® II requires the use of a spray adjuvant (surfactant, crop oils, ect.) Refer to the "Basagran" label for application information and restrictions regarding rates, weeds controlled, crop size, use of adjuvants (adjuvant type, temperature and geography), rotational crop intervals, sprayer cleanup, use precautions and other information. The most restrictive provisions on either label will apply. Do not use the tank mix if any restrictions on the "Basagran" label conflict with instructions on the ASSURE® II label. Do not tank mix ASSURE® II and adjuvants with "Basagran" when temperatures exceed 80 degree F, as excessive leaf burn may occur.

Soybeans - Tank Mixes with Postemergence Broadleaf Herbicides

ASSURE® II can be tank mixed with postemergent soybean broadleaf herbicides such as CLASSIC®, DuPont™ HARMONY® GT XP and SYNCHRONY® XP herbicide, "Flexstar", or "Basagran" for use on soybeans to control broadleaf weeds and selected grasses.

Include ammonium nitrogen fertilizer if specified on the tankmix partner label. Include either a crop oil concentrate or a nonionic surfactant as specified in the following table:

(Pints per 100 gallons of spray solution)

DuPont™ ASSURE® II Tank mix partner	Ground COC	or NIS	Aerial COC	or NIS
CLASSIC®	8	2	4	2
HARMONY® GT	–*	1-2†	–*	1-2†
SYNCHRONY® XP	–*	1-2†	–*	1-2†
"Basagran"	8	–	4	–
"Flexstar"	8	–	4	–

* Do not use "Dash" or crop oil concentrate when tank mixing ASSURE® II with HARMONY® GT, CLASSIC® + HARMONY®GT or SYNCHRONY® XP unless specified on other DuPont supplemental labeling.

† Using the higher rate of nonionic surfactant, particularly under hot, humid conditions, may increase temporary crop injury.

SPOT/SMALL AREA SPRAY INSTRUCTIONS

To spot treat small areas of annuals (i.e., volunteer corn) or perennials (i.e., rhizome johnsongrass)

- use a 0.375% v/v solution of ASSURE® II and water.

SPRAY VOLUMES FOR SMALL AREAS

Spray Volume (gallon)	ASSURE® II (fluid ounces product)	+	Crop Oil Concentrate (fluid ounces)	OR	Nonionic Surfactant (fluid ounces)
1	0.5 (1 tbsp)		1.25 (2.5 tbsp)		0.3 (2 tsp)
25	12 (3/4 pt)		32 (1 qt)		8 (1 cup)
50	24 (1.5 pt)		64 (2 qt)		16 (1 pt)
100	48 (3 pt)		128 (1 gal)		32 (1 qt)

Do not spot treat grasses using a tank mix of ASSURE® II and broadleaf herbicides.

- include a nonphytotoxic crop oil concentrate at 1 gallon per 100 gallons of spray solution (1% v/v) or a nonionic surfactant at 1 qt per 100 gallons of spray solution (0.25% v/v).
- treat plants on a spray-to-wet basis to ensure good coverage.
- Do not treat >10% of the total treated area as spot/small area treatment. Do not exceed the maximum specified rate/acre/season for the crop that is going to be planted when additional applications are made as spot treatment or small area treatment.

CULTIVATION

A timely cultivation may be necessary to control suppressed weeds, weeds that were beyond the maximum size at application, or weeds that emerge after an application of ASSURE® II.

Cultivation up to 7 days before the postemergence application of ASSURE® II may decrease weed control by pruning weed roots, placing the weeds under stress, or covering the weeds with soil and preventing coverage by ASSURE® II .

To allow ASSURE® II to fully control treated weeds, cultivation is not recommended for 7 days after application.

Optimum timing for cultivation is 7 - 14 days after a postemergence application of ASSURE® II.

CROP ROTATION

Do not rotate to crops other than Canola, Cotton, Crambe, Dry Beans (including Chickpea), Flax, Lentils, Mint (Spearmint and Peppermint), Peas (Dry and Succulent Peas), Snap Beans, Soybeans, Sunflowers or Sugarbeets within 120 days after application.

GRAZING

Do not graze livestock in treated areas. In addition, do not feed forage, hay, or straw from treated areas to livestock.

APPLICATION EQUIPMENT

- See SPRAY DRIFT MANAGEMENT section for additional information and precautions.

Ground Application

Broadcast Application

- Use flat fan or hollow cone nozzles at 25-60 psi.

- Do not use flood, rain drop, whirl chamber, or any other nozzle types that produce coarse, large spray droplets. In addition, do not use controlled droplet applicator (CDA) type nozzles as poor weed control or excessive spray drift may result.
- Use a minimum of 10 gal of water per acre in nonarid areas.
- Use a minimum of 15 gal of water per acre in arid areas.
- Do not exceed 40 gal of water per acre.
- Increase spray volume and pressure as weed or crop density and size increase.

Band Application

- Because band application equipment sprays a narrower area than broadcast application equipment, calibrate equipment to use proportionately less spray solution.
- To avoid crop injury, carefully calibrate the band applicator not to exceed the labeled rate.
- Carefully follow the manufacturer's instructions for nozzle type, nozzle orientation, distance of the nozzles from the crop and weeds, spray volumes, calibration, and spray pressure.
- For additional information on row banders see DuPont bulletin, "Application Accuracy - Row Banders".

Aerial Application

- Use nozzle types and arrangements that provide optimum spray distribution and maximum coverage.
- Use a minimum of 3 gal of water per acre in nonarid areas.
- Use a minimum of 5 gal of water per acre in arid areas.

MIXING INSTRUCTIONS

1. Fill the tank 1/4 to 1/3 full of water.
2. While agitating, add the required amount of DuPont™ ASSURE® II. If ASSURE® II and a tank mix partner are to be applied together, consult the tank mix partner label for information on which should be added first (normally granules and powders are added first).
3. Continue agitation until the ASSURE® II is fully dispersed, at least 5 minutes.
4. Once the ASSURE® II is fully dispersed, maintain agitation and continue filling tank with water.
5. As the tank is filling, add the required volume of spray additives, always add these to the spray tank last.
6. Apply ASSURE® II spray mixture within a reasonable period of time of mixing to avoid product degradation (24 to 48 hrs). If the spray mixture stands for any period of time, thoroughly re-agitate before using.

SPRAYER CLEANUP

The spray equipment must be cleaned before ASSURE® II is sprayed. Follow the cleanup procedures specified on the labels of the previously applied products. If no directions are provided, follow the six steps outlined in After Spraying ASSURE® II. It is very important that any buildup of dried pesticide deposits which have accumulated in the application equipment be removed prior to spraying ASSURE® II. Steam-cleaning spray tanks to facilitate the removal of any caked deposits of previously applied products will help prevent accidental crop injury.

At the End of the Day

It is recommended that during periods when multiple loads of ASSURE® II herbicide are applied, at the end of each day of spraying the interior of the tank be rinsed with fresh water and then partially filled, and the boom and hoses flushed. This will prevent the buildup of dried pesticide deposits which can accumulate in the application equipment.

After Spraying ASSURE® II and Before Spraying Crops Other Than Those Listed in the Crop Rotation Section

To avoid subsequent injury to desirable crops, thoroughly clean all mixing and spray equipment immediately following applications of ASSURE® II as follows:

1. Drain tank; thoroughly rinse spray tanks, boom, and hoses with clean water. Loosen and physically remove any visible deposits.
2. Fill the tank with clean water and 1 gal of household ammonia* (contains 3% active) for every 100 gal of water. Flush the hoses, boom, and nozzles with the cleaning solution. Then add more water to completely fill the tank. Circulate the cleaning solution through the tank and hoses for at least 15 min. Flush the hoses, boom, and nozzles again with the cleaning solution, and then drain the tank.
3. Remove the nozzles and screens and clean separately in a bucket containing cleaning agent and water.
4. Repeat step 2.
5. Rinse the tank, boom, and hoses with clean water.
6. If only Ammonia is used as a cleaner, the rinsate solution may be applied back to the crop(s) recommended on this label. Do not exceed the maximum labeled use rate. If other cleaners are used, consult the cleaner label for rinsate disposal instructions. If no instructions are given, dispose of the rinsate on site or at an approved waste disposal facility.

   *Equivalent amounts of an alternate-strength ammonia solution or a DuPont-approved cleaner can be used in the cleanout procedure. Carefully read and follow the individual cleaner instructions. Consult your Ag dealer, applicator, or DuPont representative for a listing of approved cleaners.

Notes:

1. CAUTION: Do not use chlorine bleach with ammonia as dangerous gases will form. Do not clean equipment in an enclosed area.
2. Steam-cleaning spray tanks is recommended prior to performing the above cleanout procedure to facilitate the removal of any caked deposits.

3. When DuPont™ ASSURE® II is tank mixed with other pesticides, all cleanout procedures should be examined and the most rigorous procedure should be followed.
4. In addition to this cleanout procedure, all precleanout guidelines on subsequently applied products should be followed as per the individual labels.
5. Where routine spraying practices include shared equipment frequently being switched between applications of ASSURE® II and applications of other pesticides to ASSURE® II-sensitive crops during the same spray season, it is recommended that a sprayer be dedicated to ASSURE® II to further reduce the chance of crop injury.

SPRAY DRIFT MANAGEMENT

The interaction of many equipment and weather-related factors determines the potential for spray drift. The applicator is responsible for considering all these factors when making application decisions.

AVOIDING SPRAY DRIFT IS THE RESPONSIBILITY OF THE APPLICATOR.

Importance of Droplet Size

The most effective way to reduce drift potential is to apply large droplets (>150 - 200 microns). The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. The presence of sensitive species nearby, the environmental conditions, and pest pressure may affect how an applicator balances drift control and coverage. APPLYING LARGER DROPLETS REDUCES DRIFT POTENTIAL, BUT WILL NOT PREVENT DRIFT IF APPLICATIONS ARE MADE IMPROPERLY OR UNDER UNFAVORABLE ENVIRONMENTAL CONDITIONS! See **Wind**, **Temperature and Humidity**, and **Temperature Inversions** sections of this label.

Controlling Droplet Size - General Techniques

Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

Pressure - Use the lower spray pressures recommended for the nozzle. Higher pressure reduces droplet size and does not improve canopy penetration. WHEN HIGHER FLOW RATES ARE NEEDED, USE A HIGHER-CAPACITY NOZZLE INSTEAD OF INCREASING PRESSURE.

Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles.

Controlling Droplet Size - Aircraft

Number of Nozzles - Use the minimum number of nozzles with the highest flow rate that provide uniform coverage.

Nozzle Orientation - Orienting nozzles so that the spray is emitted backwards, parallel to the airstream will produce larger droplets than other orientations.

Nozzle Type - Solid stream nozzles (such as disc and core with swirl plate removed) oriented straight back produce larger droplets than other nozzle types.

Boom Length - The boom length should not exceed 3/4 of the wing or rotor length - longer booms increase drift potential.

Application Height - Application more than 10 ft above the canopy increases the potential for spray drift.

Boom Height

Setting the boom at the lowest labeled height (if specified) which provides uniform coverage reduces the exposure of droplets to evaporation and wind. For ground equipment, the boom should remain level with the crop and have minimal bounce.

Wind

Drift potential increases at wind speeds of less than 3 mph (due to inversion potential) or more than 10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given wind speed. AVOID GUSTY OR WINDLESS CONDITIONS.

Note: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

Temperature and Humidity

When making applications in hot and dry conditions, set up equipment to produce larger droplets to reduce effects of evaporation.

Temperature Inversions

Drift potential is high during a temperature inversion. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain close to the ground and move laterally in a concentrated cloud. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

Shielded Sprayers

Shielding the boom or individual nozzles can reduce the effects of wind. However, it is the responsibility of the applicator to verify that the shields are preventing drift and not interfering with uniform deposition of the product.

Air Assisted (Air Blast) Field Crop Sprayers

Air assisted field crop sprayers carry droplets to the target via a downward directed air stream. Some may reduce the potential for drift, but if a sprayer is unsuitable for the application and/or set up improperly, high drift potential can result. It is the responsibility of the applicator to determine that a sprayer is suitable for the intended application, is configured properly, and that drift is not occurring.
Note: Air assisted field sprayers can affect product

performance by affecting spray coverage and canopy penetration. Consult the application equipment section of this label to determine if use of an air assisted sprayer is recommended.

RESISTANCE

When herbicides that affect the same biological site of action are used repeatedly over several years to control the same weed species in the same field, naturally-occurring resistant biotypes may survive a correctly applied herbicide treatment, propagate, and become dominant in that field. Adequate control of these resistant weed biotypes cannot be expected. If weed control is unsatisfactory, it may be necessary to retreat the problem area using a product affecting a different site of action.

To better manage herbicide resistance through delaying the proliferation and possible dominance of herbicide resistant weed biotypes, it may be necessary to change cultural practices within and between crop seasons such as using a combination of tillage, retreatment, tank-mix partners and/or sequential herbicide applications that have a different site of action. Weed escapes that are allowed to go to seed will promote the spread of resistant biotypes.

It is advisable to keep accurate records of pesticides applied to individual fields to help obtain information on the spread and dispersal of resistant biotypes. Consult your agricultural dealer, consultant, applicator, and/or appropriate state agricultural extension service representative for specific alternative cultural practices or herbicide recommendations available in your area.

INTEGRATED PEST MANAGEMENT

This product may be used as part of an Integrated Pest Management (IPM) program that can include biological, cultural, and genetic practices aimed at preventing economic pest damage. IPM principles and practices include field scouting or other detection methods, correct target pest identification, population monitoring, and treating when target pest populations reach locally determined action thresholds. Consult your state cooperative extension service, professional consultants or other qualified authorities to determine appropriate action treatment threshold levels for treating specific pest/crop systems in your area.

USE RESTRICITIONS AND PRECAUTIONS

Injury to or loss of desirable trees, vegetation, or adjacent sensitive crops may result from failure to observe the following:

- Do not use on lawns, walks, driveways, tennis courts, or similar areas.
- Prevent drift of spray to desirable plants.
- Take all necessary precautions to avoid all direct or indirect contact (such as spray drift) with non-target plants or areas. Most grass crops, including wheat, barley, rye, oats, sorghum, rice, and corn are highly sensitive to DuPont™ ASSURE® II.
- Carefully observe all sprayer cleanup instructions both prior to and after using this product, as spray tank residue may damage crops other than those included in the crop rotation section.
- Do not contaminate any body of water.
- Do not apply this product through any type of irrigation system.

DuPont will not be responsible for losses or damages resulting from the use of this product in any manner not specifically recommended by DuPont.

SEASONAL USE LIMITS AND HARVEST INTERVALS

Canola and Crambe

- Do not apply ASSURE® II within 60 days of harvest.
- The maximum use rate of ASSURE® II is 18 fluid ounces per acre per season.
- Application intervals should be greater than 7 days apart to allow regrowth to occur.

Cotton

- Do not apply ASSURE® II within 80 days of harvest.
- The maximum use rate of ASSURE® II is 18 fluid ounces per acre per season.
- Application intervals should be greater than 7 days apart to allow regrowth to occur.

Crops Grown for Seed

- Do not apply ASSURE® II within 14 days of anticipated bloom.
- The maximum use rate of ASSURE® II is 25 fluid ounces per acre per season.
- After using ASSURE® II, do not divert any portion of crop (seed, sprouts, screenings, forage, hay, etc.) to use for human or animal consumption.
- Grazing of treated crop is prohibited.
- Do not make more than 2 applications per acre per season. Application intervals should be greater than 7 days apart to allow regrowth to occur.
- Do not apply ASSURE® II through any type of irrigation system.
- Most grass crops, including wheat, barley, rye, oats, sorghum, rice, and corn are highly sensitive to ASSURE® II herbicide and all direct or indirect contact (such as spray drift) should be avoided.
- All seed crops treated with ASSURE® II herbicide are to be tagged at the processing facility, "Not for Human or Animal Consumption". It shall be the growers' responsibility to notify the processing facility of any seed crop that has been treated with ASSURE® II.

Dry and Succulent Peas

- Do not apply ASSURE® II on dry peas within 60 days of harvest.
- Do not apply ASSURE® II on succulent peas within 30 days of harvest.
- The maximum use rate of ASSURE® II on dry and succulent peas is 14 fluid ounces per acre per season.
- Application intervals should be greater than 7 days apart to allow regrowth to occur.

Dry Beans, including Chickpea

- Do not apply DuPont™ ASSURE® II within 30 days of harvest.
- The maximum use rate of ASSURE® II is 24 fluid ounces per acre per season.
- Application intervals should be greater than 7 days apart to allow regrowth to occur.

Eucalyptus

- Do not apply more than 60 fluid ounces of ASSURE® II herbicide per acre per year in Eucalyptus.
- Application intervals should be greater than 7 days apart to allow regrowth to occur.

Flax

- Do not apply ASSURE® II within 70 days of harvest.
- The maximum use rate of ASSURE® II is 24 fluid ounces per acre per season.
- Application intervals should be greater than 7 days apart to allow regrowth to occur.

Lentils

- Do not apply ASSURE® II within 60 days of harvest.
- The maximum use rate of ASSURE® II is 14 fluid ounces per acre per season.
- Application intervals should be greater than 7 days apart to allow regrowth to occur.

Mint (Spearmint and Peppermint)

- Do not apply ASSURE® II within 30 days of harvest.
- The maximum use rate of ASSURE® II is 24 fluid ounces per acre per season.
- Do not apply more than 2 applications per acre per season.
- Application intervals should be greater than 7 days apart to allow regrowth to occur.

Pineapple

- Do not apply more than 60 fluid ounces of ASSURE® II herbicide per acre per harvest.
- Do not harvest within 160 days of last application.
- Do not graze treated fields or harvest for forage or hay.
- Application intervals should be greater than 7 days apart to allow regrowth to occur.

Perennial Ryegrass Grown for Seed

- Do not apply ASSURE® II after boot stage of growth of ASSURE® II tolerant perennial ryegrass.
- The maximum use rate of ASSURE® II is 20 fluid ounces per acre per season.
- Do not make more than 2 applications per acre per season. Application intervals should be greater than 7 days apart to allow regrowth to occur.
- After using ASSURE® II, do not divert any portion of crop (seed, sprouts, screenings, forage, hay, stover, etc.) to use for human or animal consumption. Grazing of treated crop is prohibited.
- Do not apply ASSURE® II through any type of irrigation system.

Snap Beans

- Do not apply ASSURE® II within 15 days of harvest.
- The maximum use rate of ASSURE® II is 14 fluid ounces per acre per season.
- Application intervals should be greater than 7 days apart to allow regrowth to occur.

Soybeans

- Do not apply ASSURE® II within 80 days of harvest. Do not apply to soybeans after pod set.
- The maximum use rate of ASSURE® II is 18 fluid ounces per acre per season.
- Application intervals should be greater than 7 days apart to allow regrowth to occur.

Sugarbeets

- Do not apply ASSURE® II within 45 days of beet harvest.
- The maximum use rate of ASSURE® II is 25 fluid ounces per acre per season.
- Do not feed beet tops within 60 days of last application.
- Do not apply more than 4 applications per acre per season. Application intervals should be greater than 7 days apart to allow regrowth to occur.

Sunflowers

- Do not apply ASSURE® II within 60 days of harvest.
- The maximum use rate of ASSURE® II is 18 oz per acre per season.
- Application intervals should be greater than 7 days apart to allow regrowth to occur.

STORAGE AND DISPOSAL

Pesticide Storage: Store product in original container only. Do not contaminate water, other pesticides, fertilizer, food or feed in storage. Store in a cool, dry place.

Product Disposal: Do not contaminate water, food, or feed by disposal. Waste resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Refer to the Net Contents section of this product's labeling for the applicable "Nonrefillable Container" or "Refillable Container" designation.

Nonrefillable Rigid Plastic and Metal Containers (Capacity Equal to or Less Than 5 Gallons): Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then, for Plastic Containers, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. For Metal Containers, offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Nonrefillable Rigid Plastic and Metal Containers (Capacity Greater Than 5 Gallons): Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then, for Plastic Containers, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. For Metal Containers, offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Nonrefillable Rigid Plastic and Metal Containers, e.g., Intermediate Bulk Containers [IBC] (Size or Shape Too Large to be Tipped, Rolled or Turned Upside Down): Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying the contents from this container into application equipment or mix tank and before final disposal using the following pressure rinsing procedure. Insert a lance fitted with a suitable tank cleaning nozzle into the container and ensure that the water spray thoroughly covers the top, bottom and all sides inside the container. The nozzle manufacturer generally provides instructions for the appropriate spray pressure, spray duration and/or spray volume. If the manufacturer's instructions are not available, pressure rinse the container for at least 60 seconds using a minimum pressure of 30 PSI with a minimum rinse volume of 10% of the container volume. Drain, pour or pump rinsate into application equipment or rinsate collection system. Repeat this pressure rinsing procedure two more times. Then, for Plastic Containers, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. For Metal Containers, offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

All Refillable Containers: Refillable container. *Refilling Container:* Refill this container with DuPont™ ASSURE® II containing quizalofop p-ethyl only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller. Prior to refilling, inspect carefully for damage such as cracks, punctures, abrasions, worn out threads and closure devices. If damage is found, do not use container, contact DuPont at the number below for instructions. Check for leaks after refilling and before transporting. If leaks are found, do not reuse or transport container, contact DuPont at the number below for instructions. *Disposing of Container:* Do not reuse this container for any other purpose other than refilling (see preceding). Cleaning the container before final disposal is the responsibility of the person disposing of the container. To clean the container before final disposal, use the following pressure rinsing procedure. Insert a lance fitted with a suitable tank cleaning nozzle into the container and ensure that the water spray thoroughly covers the top, bottom and all sides inside the container. The nozzle manufacturer generally provides instructions for the appropriate spray pressure, spray duration and/or spray volume. If the manufacturer's instructions are not available, pressure rinse the container for at least 60 seconds using a minimum pressure of 30 PSI with a minimum rinse volume of 10% of the container volume. Drain, pour or pump rinsate into application equipment or rinsate collection system. Repeat this pressure rinsing procedure two more times. Then, for Plastic Containers, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. For Metal Containers, offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Do not transport if container is damaged or leaking. If the container is damaged, leaking or obsolete, or in the event of a major spill, fire or other emergency, contact DuPont at 1-800-441-3637, day or night.

Notice to Buyer: Purchase of this material does not confer any rights under patents of countries outside of the United States.

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It is impossible to eliminate all risks associated with the use of this product. Such risks arise from weather conditions, soil factors, off target movement, unconventional farming techniques, presence of other materials, the manner of use or application, or other unknown factors, all of which are beyond the control of DuPont. These risks can cause: ineffectiveness of the product, crop injury, or injury to non-target crops or plants. WHEN YOU BUY OR USE THIS PRODUCT, YOU AGREE TO ACCEPT THESE RISKS.

DuPont warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for the purpose stated in the Directions for Use, subject to the inherent risks described above, when used in accordance with the Directions for Use under normal conditions.

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For product information call: 1-888-6-DUPONT

Internet address: http://cropprotection.dupont.com/

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APPENDIX D

APHIS THREATENED AND ENDANGERED SPECIES DECISION TREE FOR FWS CONSULTATIONS

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APHIS THREATENED AND ENDANGERED SPECIES DECISION TREE FOR FWS CONSULTATIONS

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

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

BACKGROUND

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

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

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

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

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

Is the transgenic plant sexually compatible with a TE plant[1] without human intervention?

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

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

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

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

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

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

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

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

For the biotechnologist:

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

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

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

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