

J.R. Simplot Company Petition (13-022-01p) for Determination of Non-Regulated Status for Innate™ Potatoes with Low Acrylamide Potential and Reduced Black Spot Bruise: Events E12 and E24 (Russet Burbank); F10 and F37 (Ranger Russet); J3, J55, and J78 (Atlantic); G11 (G); H37 and H50 (H)

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Draft Environmental Assessment

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ACRONYMS AND ABBREVIATIONS

AMS	Agricultural Marketing Service (within USDA)
AOSCA	American Organization of Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service (within USDA AMS)
BRS	Biotechnology Regulatory Services (within USDA–APHIS)
CAA	Clean Air Act
CBD	Convention on Biological Diversity
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (United States)
CH₄	Methane
CO	carbon monoxide
CO₂	carbon dioxide
DNA	deoxyribonucleic acid
EA	environmental assessment
EIS	environmental impact statement
EO	Executive Order
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act of 1973
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FFP	food, feed, or processing
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FONSI	Finding of No Significant Impact
FQPA	Food Quality Protection Act
FR	Federal Register
FWS	Fish and Wildlife Service (of the U.S)
GE	genetically engineered
GHG	greenhouse gas

ACRONYMS AND ABBREVIATIONS

IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measures
LMO	living modified organism
M	Million
NGO	non-government organization
NO₂	nitrogen dioxide
N₂O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NABI	North American Biotechnology Initiative
NAPPO	North American Plant Protection Organization
NEPA	National Environmental Policy Act (of 1969 and subsequent amendments)
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NOP	National Organic Program (of USDA AMS)
NPS	non-point source
NRC	National Research Council
PIP	Plant-incorporated protectants
PM	Particulate matter
PPA	Plant Protection Act
PPM	parts per million
PPRA	Plant Pest Risk Assessment
RNA	ribonucleic acid
SSA	sole source aquifer
TES	threatened and endangered species
U.S.	United States
USDA	U.S. Department of Agriculture
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-FAS	U.S. Department of Agriculture-Foreign Agricultural Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service

ACRONYMS AND ABBREVIATIONS

USDA-NOP	U.S. Department of Agriculture-National Organic Program
WPS	Worker Protection Standard (for agricultural pesticides)

1 PURPOSE AND NEED

1.1 Background

J.R. Simplot of Boise, Idaho, submitted petition 13-022-01p to the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) in March 2013, seeking a determination of nonregulated status for Simplot Innate™ Potato with low acrylamide potential and reduced black spot bruise (events E12 and E24 (Russet Burbank); F10 and F37 (Ranger Russet); J3, J55, and J78 (Atlantic); G11 (G); and H37 and H50 (H)). The petition was deemed complete by APHIS on March 22, 2013. Simplot Innate™ Potato is currently regulated under 7 CFR part 340. Interstate movements and field trials of Simplot Innate™ Potato have been conducted under permits issued or notifications acknowledged by APHIS since 2009. These field trials were conducted in Florida, Indiana, Idaho, Michigan, Nebraska, North Dakota, Washington, and Wisconsin. Data resulting from these field trials are described in Simplot's Innate™ Potato petition (Simplot, 2013a) and analyzed for plant pest risk in the APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2013a).

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

1.1 The APHIS Regulatory Authority

As noted in 1.1.1, the PPA authorizes and mandates APHIS to regulate, manage and control plant pests. This directive includes regulatory authority over the introduction (i.e., importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340, when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under 7 CFR 340, when APHIS has reason to believe that the GE organism may be a plant pest, or APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

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

1.1.1 Purpose of this Product

Simplot Innate™ Potato is genetically engineered to silence genes that lead to acrylamide formation in cooked potatoes, and genes that cause browning in damaged potatoes. Acrylamide is a human neurotoxicant and potential carcinogen that may form in potatoes and other starchy foods under high-temperature cooking conditions. Black spot bruise is a post-harvest physiological disorder primarily resulting from the handling of potato tubers during harvest, transport and processing, and refers to the black or grayish color which may form in the interior of damaged potatoes.

The 10 Simplot Innate™ Potato events were produced by using *Agrobacterium*-mediated transformation of potato internode explants of 5 different varieties: Ranger Russet, Russet Burbank, Atlantic, variety G and variety H (Simplot, 2013a). The binary plasmid vector pSIM1278 (Simplot, 2013a), consisting of the vector backbone (Simplot, 2013a) and the DNA insert (Simplot, 2013a) was used to create all 10 events; only the DNA insert portion was intended to be transferred to the recipient plants. The DNA insert in plasmid pS2IM1278 is designed to silence four different genes in the potato: asparagine synthetase-1 (*Asn1*), polyphenol oxidase-5 (*Ppo5*), potato phosphorylase L (*PhL*) and the starch-associated R1 gene (*R1*). The suppression of *Asn1* should result in potatoes with reduced free asparagine, and the suppression of *PhL* and *R1* should result in potatoes with a lower content of reducing sugars. Collectively, the silencing of these 3 genes should result in potato tubers with a reduced acrylamide potential. The suppression of *Ppo5* confers the Simplot Innate™ potatoes with a non-browning phenotype resulting in tubers with reduced black spot bruising. Black spot bruise can lead to economic losses as high as 20 % (Partington *et al.*, 1999); the potato industry therefore has a vested interest in minimizing these losses. Bachem *et al.* 1994 (Bachem *et al.*, 1994) demonstrated that black spot bruise can be reduced by silencing *Ppo* genes in potatoes, and Simplot has further developed this concept in the design of Simplot Innate™ potatoes (Simplot, 2013a).

The intended purpose of the 10 Simplot Innate™ potato lines is to provide the potato processing industry with new varieties with low acrylamide potential and reduced black spot bruise. Both of these changes are intended to benefit potato consumers, producers, and processors. The low acrylamide potential is intended to benefit consumers because of concerns about the health effects of ingesting acrylamide (FDA, 2013b). Simplot Innate™ potatoes offer an efficient method to reduce acrylamide in the diet. The reduced black spot bruise trait is intended to benefit consumers by providing a higher quality product, to benefit producers by reducing culls at delivery, and to benefit processors by reducing wastage.

Simplot Innate™ potato tubers are nutritionally and compositionally similar to their respective parental varieties and/or other commercial potato varieties, with the exception of the intentional changes conferred by the introduced genes. These intentional changes fall into three broad categories: (1) reduction of PPO enzyme levels in tubers; (2) alteration of the levels of asparagine and glutamine in the pool of free amino acids in tubers; and (3) reduction in the levels of the reducing sugars glucose and fructose in tubers (USDA-APHIS, 2013a).

1.2 Coordinated Regulatory Framework for Genetically-Engineered Organisms

The U.S. government has regulated genetically engineered (GE) organisms since 1986 under Federal regulations published in the *Federal Register* (51 FR 23302; 57 FR 22984) entitled “The Coordinated Framework for the Regulation of Biotechnology” (henceforth referred to here as the Coordinated Framework). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products. It also explains how Federal agencies will use existing Federal statutes 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 was created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk. The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA APHIS, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). A summary of each role follows.

1.2.1 USDA-APHIS

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

1.2.1 Environmental Protection Agency

The EPA is responsible for regulating the sale, distribution, and use of pesticides, including those that are expressed by an organism modified using techniques of modern biotechnology. Such pesticides are regulated by EPA as plant-incorporated protectants (PIPs) under the Federal

Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). EPA also regulates certain biological control organisms under the Toxic Substances Control Act (15 U.S.C. 53 *et seq.*). Before planting a crop containing a PIP, a company must seek an experimental use permit from EPA. Commercial production of crops containing PIPs for purposes of seed increase and sale requires a FIFRA Section 3 registration with EPA.

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

EPA also sets tolerances (maximum residue levels) or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA). A tolerance is the amount of pesticide residue that can remain on or in food for human consumption or animal feed. Before establishing a pesticide tolerance, EPA is required to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the FQPA. FDA enforces the pesticide tolerances set by EPA. The ten Simplot Innate™ Potato events are not engineered to express substances to protect the potatoes against plant pests, and are therefore not subject to EPA review.

1.2.2 Food and Drug Administration

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

In June 2006, FDA published recommendations in “Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use” (US-FDA, 2006). This establishes voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including GE plants. Early food safety evaluations help make sure that potential food

safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with FDA, but the information may be used later in the biotechnology consultation.

1.3 Purpose and Need for This APHIS Action

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

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

1.3.1 Public Involvement

APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. APHIS does this through a notice published in the *Federal Register*. Through a March 6, 2012, notice published¹ in the *Federal Register*, APHIS implemented changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for GE organisms. The purpose of this change was to allow early public involvement in the process. As identified in this notice, APHIS publishes two separate notices in the *Federal Register* for petitions for which APHIS prepares an EA. The first notice announces the availability of the petition; the second announces the availability of the APHIS decision-making documents. The new process allows for public involvement by establishing a comment period after each of the two notices published in the *Federal Register*.

First Opportunity for Public Involvement:

Once APHIS judges a petition complete, a 60-day comment period is established for the public to submit comments to assist the Agency in the development of it EA and PPRA. The availability of the petition for public comment is announced in a *Federal Register* notice.

¹This notice can be accessed at: <http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf>

Second Opportunity for Public Involvement

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

Approach 1. For GE organisms that do not involve substantive new issues.

This is used when APHIS determines, based on a review of the petition and its evaluation and analysis of public submissions received during the 60-day comment period for the petition, that the GE organism does not involve new biological, cultural, or ecological issues. Agency criteria for this decision include a determination that the nature of the modification is not novel or that the Agency has a high degree of familiarity with the organism through previous regulatory actions, or both. After this determination is made, APHIS conducts the necessary analysis and prepares its PPRA, EA, and finding of no significant impact (FONSI). Once completed, APHIS publishes a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the EA, FONSI, and PPRA for a 30-day public review and comment period.

Unless information received in public comments warrants substantially changing the PPRA or EA analysis and determination, the Agency's preliminary regulatory determination becomes effective. No further *Federal Register* notices are published announcing the final regulatory determination. The Agency posts this public notification in an announcement on the APHIS website.

Approach 2. For GE organisms involving substantive new issues not previously analyzed. This protocol is used when a petition is for nonregulated status for a novel GE organism. A novel organism is one that is not identical with or sufficiently similar to organisms determined previously by APHIS to have nonregulated status. Examples include organisms with new gene modifications that could have substantial biological, cultural, or ecological effects not previously analyzed. For this process, APHIS prepares drafts of a PPRA and an EA, and then solicits further comments during a 30-day period that is announced in a *Federal Register* notice. APHIS reviews and evaluates comments and other relevant information, then revises the PPRA as necessary and prepares a final EA. Following preparation of these documents, APHIS approves or denies the petition, then announces its decision in the *Federal Register*, and provides notice of the availability of the final EA, PPRA, NEPA decision document, and regulatory determination. More details about this expansion of opportunities for stakeholder review and comment are available in the [Federal Register](#) notice² published on March 6, 2012.

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

1.3.2 Public Involvement Approach for This EA

APHIS has determined that the protocol for preparation of this EA will follow Approach 2. The issues considered in this EA were developed by reviewing the public concerns, including public comments received in response to the *Federal Register* notice on May 3, 2013 (78FR 25942-25943) announcing the availability of the petition (i.e., the first opportunity for public involvement previously described in this document). The Agency also considered public comments submitted for other EAs of GE organisms, and concerns described in lawsuits or expressed by various stakeholders. These issues, including those regarding the agricultural production of Simplot Innate™ Potato using various production methods and the environmental and food/feed safety of GE plants, were addressed to analyze the potential environmental impacts of Simplot Innate™ Potato.

The public comment period for the review of this petition for nonregulatory status of Simplot Innate™ Potato closed on July 2, 2013. At its closing, the docket file contained a total of 308 public comments. These were screened and sorted into categories according to the subject matter addressed (e.g., air, water, soil impacts), and classified as either non-substantive or substantive. Most of the comments that expressed a general dislike of the use of GE organisms were non-substantive. One comment from a non-governmental organization (NGO) had 41,475 signatures appended to it.

Eighty-five of the comments supported the petition, citing potential improved health benefits to consumers and decreased wastage of potato as economically beneficial to the potato industry. The majority of the negative comments expressed a general dislike of the use of GE organisms. This issue is outside the scope of this EA.

The issues that were raised in the public comments which were related to the Simplot Innate™ Potato petition included:

- Contamination of conventional potato production.
- Concerns that more research should be done prior to approval of the petition.
- Concerns that plant fitness will be negatively affected.
- Impact that petition approval may have on export markets.

APHIS has analyzed and evaluated the issues described in these comments, and has included a discussion of these issues in this EA with citations where appropriate.

1.4 Issues Considered

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

Agricultural Production Considerations:

- Land Use of Potato Production
- Agronomic/Cropping Practices
- Potato Seed Production
- Organic Potato Production

Environmental Considerations:

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

Human Health Considerations:

- Public Health
- Worker Safety

Livestock Health Considerations:

- Livestock Health/Animal Feed

Socioeconomic Considerations:

- Domestic Economic Environment
- Trade Economic Environment

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

2 AFFECTED ENVIRONMENT

This section includes a review of the prevailing conditions of the human environment that might be impacted by Simplot Innate™ Potato production. Relevant environmental components include agricultural production area of Simplot Innate™ Potato, the physical environmental, biological resources, human health, animal feed, and socioeconomic resources.

2.1 Agricultural Production and Agronomic Practices of Potato

Potato is the fourth most important crop in the world in terms of human consumption, following rice, wheat, and maize (corn) (Arvanitoyannis *et al.*, 2008) (Llorente *et al.*, 2011). Potato is grown in over 100 countries, with world potato production exceeding 300 million metric tons (Center, 2010).

2.2.1 Land Use

Potatoes are grown across most of the continental U.S., with seven States (Colorado, Idaho, Minnesota, North Dakota, Oregon, Washington and Wisconsin) accounting for approximately 77% of annual production (USDA-APHIS, 2013a) (Figure 1). Within recent years, land devoted to potato production has shifted from the East and Midwest to the Pacific Northwest. This shift has resulted from a number of factors, including improvements in the U.S. transportation system, the relative decline in consumption of fresh potatoes coupled with advantages associated with processing potatoes in the Northwest such as lower taxes, and lower power and labor costs, more favorable weather, and available land for acreage. The largest potato-growing region by far in the U.S. is the Snake River Plain of southern Idaho, a major agricultural area where water is available for irrigation, where nearly all the Idaho crop is grown (Bechinski *et al.*, 2001), (USDA-NASS, 2012c). The second-largest growing region is the Columbia Basin in Washington and Oregon, where approximately 137,000 acres were harvested in 2010 (USDA-NASS, 2012c). Other important areas (with 2010 harvested acreage in parentheses) are the Red River Valley, which lies between the northern borders of North Dakota and Minnesota (63,000); San Luis Valley in south central Colorado (55,200), Aroostook County in Maine (50,400), and the Central Sands region of Wisconsin (36,700) (USDA-NASS, 2012c). Simplot Innate™ Potato events may be grown in any of the U.S. potato-growing regions.

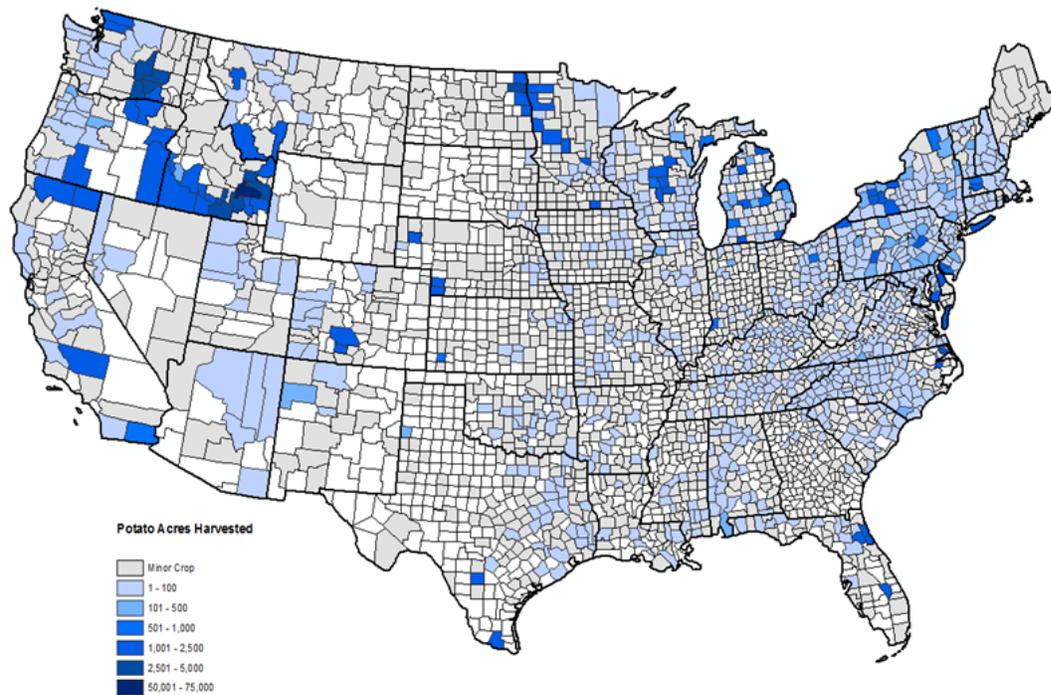


Figure 1. Potato Growing Regions of the U.S. (USDA-NASS, 2007)

Potato acres harvested in the U.S. have ranged between 1.0 and 1.5 million acres since 1951, with highs of 1.5 million in 1953, 1966 and 1967, and lows of 1.0 million in 2008, 2009 and 2010 (USDA-NASS, 2012c). In most years from 1900 to 1937, more than 3 million acres were harvested, with a high of 3.9 million in 1922 (USDA-NASS, 2012c). While acreage has declined over the years, total production has increased (Guenther, 2010a). For example, in the 1930s, from about 3.5 million acres of potatoes were harvested, whereas by 1985, production had nearly doubled on less than half the acreage of the 1930s, and by 2005, acreage had declined to about 1 million acres, less than 1/3 the 1930s acreage (Guenther, 2010a). Total annual U.S. production has been over 400 million CWT (one CWT = 100 pounds) every year since 1990, with a peak of 513,544,000 CWT in 2000 (USDA-NASS, 2012c). Per-acre yields, which averaged approximately 336 CWT per acre in 2012, have increased seven-fold since the early 1900s and have doubled since the early 1960s. For example, in 1901 approximately 2.95 million acres of potatoes were harvested, producing roughly 125 million CWT, or 46.6 CWT per acre (USDA-NASS, 2012c; 2013).

The top ten potato producing states shown in Table 1 account for almost 83% of the United States potato crop (USDA-NASS, 2013

). Highest yields are in regions where daytime temperatures exceed 100° F during the hottest part of growing season, and where nights are cool (about 65° F), such as in Washington’s Columbia Basin, eastern Oregon, California, and Nevada (Rosen, 2010d).

Table 1. Major Potato Production States

State	Production (1,000 CWT)	Percent of Total U.S. Production
Idaho	141,820	30.6
Washington	95,940	20.7
Wisconsin	29,440	6.4
North Dakota	25,200	5.4
Colorado	23,365	4.8
Minnesota	18,800	4.1
Michigan	15,925	3.4
Maine	15,675	3.4
California	15,501	3.3
Oregon	2,236	0.4

Source: (USDA-NASS, 2013)

Most potatoes are harvested in July through October. Fall crops have increased because of demand for processing (Guenther, 2010a). Harvested potatoes are either used for food (~93%), feed (<1%), industrial purposes (<1%) or as “seed” for planting (5%) (NPC, 2012b; USDA-NASS, 2013). Usage is partially dependent on a variety of characteristics related to tuber quality. Only about one quarter of U.S. potatoes are consumed fresh (USDA-NASS, 2013), while approximately 60% of annual output is processed into frozen products (such as frozen fries and wedges), chips, dehydrated potato and starch (11%), canned potatoes (0.4%), and 6% is replanted as seed potato. Americans eat, on average, approximately 112 lb (51 kg) of potatoes per person per year (NPC, 2012b).

Raw potato waste products (peels, out of specification raw potatoes, or other non-processed raw potato products) and processed discards (French fries, hash brown, etc.) are routinely incorporated into feed rations at livestock feedlot operations (Simplot, 2013a). U.S. 2012 potato harvests by state are summarized in Table 2 (in acres).

Table 2.U.S. 2012 Potato Harvest by State

State	Acres Of Potato Harvested
Idaho	344,000
Washington	164,000
North Dakota	84,000
Wisconsin	64,000
Colorado	59,300
Maine	57,000
Minnesota	47,000
Michigan	45,500
Oregon	41,700
California	37,300
Florida	36,600
Nebraska	23,300
Texas	20,100
New York	16,500
North Carolina	16,000
Montana	11,700
Missouri	8,900
Pennsylvania	8,700
Illinois	7,400
Kansas	5,200
Virginia	4,800
Massachusetts	3,900
Arizona	3,700
Total	1,134,550

Source: (USDA-NASS, 2013)

2.2.2 General Agronomic Practices

USDA classifies potato production by season, according to the period when the largest supplies are harvested. Winter, spring and summer potatoes are harvested while the vines are still green and the tubers comparatively immature. These potatoes go directly from the field to fresh markets or into processing.

Fall potatoes are usually harvested when the vines and tubers are mature. Mature potatoes are usually higher in dry matter, which makes them better for most processing, and also have tougher skins, which makes them easier to handle (Johnson, 2010). A large percentage of the fall crop is stored for processing and fresh market through the winter, spring and summer

months. Many modern storage facilities are equipped with temperature, humidity, and forced-air ventilation control. Capacity can range from 500 tons to over 20,000 tons (Olsen, 2010). Proper water management is integral to obtaining optimum quality and yield since potatoes are more sensitive to water stress than some other crops. Potatoes have a relatively shallow root-zone depth, and are frequently grown on soils with only fair water-holding capacities (King and Stark, No Date).

The easternmost regions of the U.S. generally receive enough rainfall in order to produce good quality and yield of potatoes, whereas the western part of the country typically relies on some form of irrigation. Specific guidelines for irrigation depend on geographic region and factors typical of that region such as temperature, relative humidity, and daylength. Water requirements also vary to some degree with cultivar. Most potato-growing regions require between 18 and 36 in. of water to produce an optimum crop. Enough moisture to keep plant stomata open during the hottest part of the day is critical (Shock, 2010).

In regions where rainfall is the primary source of water, growers may increase water use efficiency by avoiding steeply sloping fields for planting, and by preparing the soil so that infiltration of water is increased, and by also making ridges in the furrows to mitigate the amount of water running off the field (Shock, 2010).

Timing of water application and amount of water delivered are important to potato production. Some physical defects, such as growth cracks, hollow heart, black spot, and knobby tubers, are directly related to amount and distribution of water during the growing season. Excessive water may result in yield reduction and diseases such as *Rhizoctonia* stem canker, scab, and tuber late blight (DEFRA, 2006; Shock, 2010; King and Stark, No Date). Too little water at the time of tuber initiation can lead to a reduced number of tubers (DEFRA, 2006). Daily water needs increase from emergence of plants to approximately two weeks after row closure, but then decline rapidly after onset of vine maturation (DEFRA, 2006; Shock, 2010). Potatoes need more water during tuber initiation and early tuber development. At harvest, soil water content is also important to reduce mechanical damage to tubers which are frequently associated with dehydration such as blackspot bruise, and excess water such as shatter bruise and thumbnail cracking (DEFRA, 2006; King and Stark, No Date).

Potato Breeding

The tetraploid nature of commercial potato varieties is a significant impediment to potato breeding, as well as biological factors such as inbreeding depression, and cytoplasmic and nuclear sterility (Hoopes and Plaisted, 1987; Arvanitoyannis *et al.*, 2008). Due to complex chromosome segregation ratios, polyploid crops are inherently more difficult to breed. Furthermore, vegetatively propagated crops like potato are often poor seed producers due to partial or full sterility. For seed propagated crops, like corn or soybean, trait developers often create a single elite event and then backcross that elite event into a wide range of elite germplasm. This is not possible in potato. Each parent variety must be independently transformed to achieve the desired phenotype in that variety (USDA-APHIS, 2013a). If a single

variety was transformed, it could take decades to move these new traits into the other commercial varieties by conventional breeding, and even then, it would be difficult to reconstitute the desirable characteristics of the original variety (Llorente *et al.*, 2011; USDA-APHIS, 2013a).

Because maintenance of a vegetatively propagated, disease- and insect-free genetic stock is difficult, much of the genetic base is kept as true seed populations (Spooner, 2010).

Cultivation

Potatoes typically require high levels of soil cultivation (Hopkins *et al.*, 2004), which helps with weed control, aeration, shaping beds, maintaining proper seed depth and establishing irrigation furrows (Bechinski *et al.*, 2001; Sieczka, 2010). Potato production is generally not conducive to maintaining healthy soil conditions, because of intensive tillage, minimal crop residues left on the field, heavy field traffic and long periods of soil being left bare (Hopkins, 2010). In the Northwest, potato fields are typically tilled both before and after the season (Hopkins *et al.*, 2004). In the Red River Valley, between North Dakota and Minnesota, a common practice just before planting is to plow once in the fall, till two or more times during the winter, and disc the field in the spring (USDA, 2000).

Cover Crops

In potato production, a fall cover crop is frequently planted in order to reduce erosion from fields (Sexton, 2010). Subsequent to mowing the cover crop, the residues may be left on the field to minimize wind erosion (Rosen, 2010b). Another method of reducing erosion as well as mitigated disease pressure is to till green manure crops into the soil prior to planting (Hopkins *et al.*, 2004). Growers in Florida use Sudan grass as a cover crop to provide nitrogen prior to potato planting (Mossler and Hutchinson, 2011).

Growing cover crops can also increase yield of the subsequent cash crop (University, 2013).

Crop Rotation

One of the challenges that growers face is the high short-term economic demand for potatoes to be grown continuously, partly because of the investment that is put into the specialized equipment used in potato growing, and because potatoes represent the highest potential gross return per acre (Hopkins *et al.*, 2004). Continuous cropping, and short rotations of this crop along with others, causes potato crops to become more susceptible to complications and increases the risk of insect, disease, and nematode pressure, decrease in soil nutrient levels, and an increase in erosion potential (Hopkins *et al.*, 2004) (Delahaut, 2000; Hall *et al.*, 2000) (Bennett and O'Rourke, 2002; Larkin, 2003). Lower microbial biomass occurs in fields where continuous cropping is practiced, compared to fields where crops are rotated (Larkin, 2003). Therefore, frequent rotation of other crops with potatoes is recommended (Hopkins, 2010) (University, 2013) in order to increase yield and to reduce insect and disease pressure, as well as to reduce the population density of weeds. Farmers are also advised to avoid planting potatoes near fields where potatoes were planted the previous year. Rotation crops vary with geographical region:

for example, in Idaho, potatoes are rotated with small grains, sugar beets, alfalfa, dry beans and corn (Hopkins *et al.*, 2004); with grains in the Red River Valley in North Dakota and Minnesota (USDA, 2000); with malting barley in the San Luis Valley in Colorado (McDonald *et al.*, 2003); and corn, small grains, legumes and green manure crops in Wisconsin (Delahaut, 2000).

Insect Control

The potato crop is intensively managed with integrated pest management (IPM) to control a variety of insect and disease (Johnson, 2007b). More than 150 species of insects may damage potatoes, most of which cause only minor economic injury. However, several species cause economic injury through feeding on foliage, tubers, or roots, or by transmitting disease pathogens to the plant. While major insect pests vary within production regions, the most serious overall is the Colorado potato beetle. In the eastern U.S., leafhoppers can also cause yield loss to plants before plants present any visual symptoms of feeding damage; several leafhopper species are serious problems because they vector phytoplasmas (Radcliffe, 2010). Aphid-transmitted diseases cause greater economic losses than all other insect damage combined together. At least 9 potato viruses are transmitted via aphids, the most important of which is potato leaf roll virus (PLRV), vectored primarily by green peach aphid, and potato Y virus (PVY), vectored by potato aphid, pea aphid, melon aphid, buckthorn-potato aphid, soybean aphid, and bird cherry-oat aphid (Radcliffe, 2010; Rondon, 2012). Occasional pests include armyworm, loopers, cutworms and spider mites(Rondon, 2012).

Some soil insects can cause a decrease in quality of tubers, but generally cause little decrease in yield. The most important of these are wireworms, the larval stage of elaterid beetles (Bechinski *et al.*, 2001), particularly if fields are laden with sod sometime before planting (Roberts and Cartwright, No Date-a).

Growers may also mitigate insect pressure by avoiding planting on fields nearby cornfields since European corn borer may also infest potato (University, 2013).

Insect pests in stored corn include potato tuber moth, *Phthorimaea operculella*, and seed corn maggot, *Delia platura* (Rondon, 2012).

Table 3. Major Insect Pests of Potato

Common Name	Scientific Name
Colorado potato beetle	<i>Leptinotarsa decemlineata</i>
Green peach aphid	<i>Myzus persicae</i>
Wireworms	<i>Limonius californicus</i> , <i>L. canu</i> , <i>Ctenicera pruinera</i>
Potato leafhopper	<i>Empoasca fabae</i>
Pea aphid	<i>Acyrtosiphon pisum</i>
Soybean aphid	<i>Aphis glycine</i>
Thrips	<i>Franklinella spp.</i> , <i>Thrips spp.</i>
Flea beetle	<i>Epitrix spp.</i>
European cornborer	<i>Ostrinia nubilalis</i>

Potato psyllid	<i>Bactericera (Paratrioza) cockerelli</i>
Potato Tuberworm or Tuber Moth	<i>Phthorimaea operculella</i>

Sources: (Radcliffe, 2010; Rondon, 2012; Roberts and Cartwright, No Date-a)

Disease Control

Potato diseases can be caused by viruses, viroids, phytoplasmas, and most importantly, by bacteria and fungi. Infection can occur when cutting potatoes into seed pieces prior to planting, in which a disease organism present in the seed potato is transmitted to the resulting potato plant. The cut surfaces of the seed pieces, until they are suberized, are open wounds that provide a route of entry for pathogens (Davidson, 2010).

Potatoes can become infected with a number of viruses (e.g. potato leafroll virus, and potato viruses A, M, X and Y); however, IPM options for virus pests are limited to insecticidal control of their insect vectors and planting of resistant varieties, including some GE varieties (Arif *et al.*, 2012; Arif *et al.*, 2012; USDA-APHIS, 2013a).

There are several factors to consider in controlling potato diseases, including part of the plant being attacked, pathogen transmission mechanism, and environmental conditions. Table 4 lists the major diseases of potato. Some of these are more common while plants are in the field, while others only emerge during storage (Bechinski *et al.*, 2001). Growers may plant disease-resistant cultivars, use certified seed, spray fungicides, and rotate potato with other crops in order to mitigate disease pressure (Johnson *et al.*, 2010) (Hollingsworth, No Date).

Table 4. Major Diseases of Potato

Common Name	Scientific Name
Bacteria	
Aster Yellows MLO	Member of Acholeplasmataceae
Bacterial ringrot	<i>Corynebacterium sepedonicum</i>
Bacterial brown rot	<i>Ralstonia solanacearum</i>
Bacterial soft rot	<i>Pectobacterium carotovorum</i>
Blackleg	<i>Erwinia carotovora</i>
Golden nematodes	<i>Globodera rostochiensis</i>
Potato tuber rot	<i>Ditylenchus destructor</i>
Root knot	<i>Meloidogyne</i> spp.
Columbia root knot	<i>Meloidogyne chitwoodi</i>
Root lesion	<i>Pratylenchus penetrans</i>
Viruses	
Potato Leafroll Virus	<i>Luteovirus</i>

Potato Spindle Tuber Viroid	Member of Pospiviridae
Potato Virus A, M, X, Y	Members of Potyviridae, <i>Carlavirus</i> ,
Tobacco Rattle Virus	<i>Tobravirus</i>
Fungi	
Late blight	<i>Phytophthora infestans</i>
Pink rot	<i>Phytophthora erythroseptica</i>
Early dying	<i>Verticillium</i> spp.
Sclerotinia stalk rot or white mold	<i>Sclerotinia sclerotiorum</i>
Canker or black scurf	<i>Rhizoctonia solani</i>
Scab	<i>Streptomyces scabies</i>
Dry rot	<i>Fusarium</i> spp.
Fusarium wilt	<i>Fusarium solani</i> var <i>eumartii</i> , <i>Fusarium oxysporum</i>
Water or shell rot	<i>Pythium ultimum</i>
Early blight	<i>Alternaria solani</i>
Gray mold	<i>Botrytis cinerea</i>
Black dot	<i>Colletotrichum coccodes</i>
Ring rot	<i>Clavibacter michiganensis</i> subsp. <i>Sepedonicus</i>
Powdery scab	<i>Spongospora subterranea</i>
Silver scurf	<i>Helminthosporium solani</i>
Wart	<i>Synchytrium endobioticum</i>
Nematodes	
Golden nematodes	<i>Globodera rostochiensis</i>
Potato tuber rot	<i>Ditylenchus destructor</i>
Root knot	<i>Meloidogyne</i> spp.
Columbia root knot	<i>Meloidogyne chitwoodi</i>
Root lesion	<i>Pratylenchus penetrans</i>

Sources: (Johnson *et al.*, 2010; Roberts and Cartwright, No Date-a)

Weed Management

Weeds pose a management issue for growers, potentially causing a significant loss in yield by outcompeting potatoes for nutrients, water and sunlight. Tillage and herbicide usage can help control weeds (Delahaut, 2000); (Hutchinson, 2010), although tillage can also damage potato plants and reduce yields. Common weeds in potato fields fall into three main classes: annual broadleaf plants, which are the easiest to control, with the exception of nightshade; annual grasses, which may germinate later than most broadleaf annuals; and perennials, which are the most difficult to control (Hutchinson, 2010; University, 2013). Major weed species in potato

fields are noted in Table 5. In addition to competition with potato plants for resources, weeds are detrimental to the crop due to potential penetration of potato tubers by weed roots, causing a severe reduction in crop quality (Hutchinson, 2010).

Table 5. Major Weeds of Potato

Broadleaf Annuals	Annual Grasses	Perennials
Hairy nightshade (<i>Solanum sarrachoides</i>)	Barnyardgrass (<i>Echinochloa crus-galli</i>)	Nutsedges (<i>Cyperus</i> spp.)
Common lambsquarters (<i>Chenopodium album</i>)	Foxtail (<i>Setaria</i> spp.)	Quackgrass (<i>Elytrigia repens</i>)
Redroot pigweed (<i>Amaranthus retroflexus</i>)	Wild oat (<i>Avena fatua</i>)	Canada thistle (<i>Cirsium arvense</i>)
Ragweed (<i>Ambrosia artemisiifolia</i>)	Fall panicum (<i>Panicum dichotomiflorum</i>)	
Kochia (<i>Kochia scoparia</i>)		
Pennsylvania smartweed (<i>Polygonum pennsylvanicum</i>)		

Source: (Hutchinson, 2010)

In order to mitigate weed problems, growers should avoid planting potatoes on fields with heavy infestations of weeds. Most growers also scout their fields to assess the need for herbicides, and choose rotational crops that compete successfully with weeds (Bechinski *et al.*, 2001).

Commonly used herbicides are metribuzin, EPTC, and metolochlor (Bechinski *et al.*, 2001), (USDA, 2000) (McDonald *et al.*, 2003). Growers may also rotate herbicide use according to chemical class in order to avoid or delay the development of weed resistance (Bechinski *et al.*, 2001).

Volunteer Potatoes

Volunteer potatoes are tubers that are left in fields after a harvest, which compete with rotational crops for sunlight, water, and essential nutrients, and then compete with a subsequent potato crop. In addition to becoming weeds, volunteer potatoes can also be hosts for disease such as late blight, potato leaf roll, and virus Y (Eberlein *et al.*, 1998; Boydston and Williams, 2005). Several herbicides can be used for the control of volunteer potato plants ((Boydston and Williams, 2005); (Everman and Long, 2010). Other control measures may include post-harvest grazing and rotation to crops competitive with the volunteers (Eberlein *et al.*, 1998).

In general, potato is a poor colonizer in wild ecosystems. Outside agricultural fields, volunteer potato seedlings cannot compete well with other plants, and, therefore, are unlikely to establish themselves. During transportation and processing, there is a possibility of tubers being released, but again, there is little probability of successful establishment (OECD, 1997b).

Organic Potatoes

To bear a certified organic label, farms grossing more than \$5,000/year in revenues must be certified by a USDA National Organic Program (NOP) accredited certifying agency.

Certifying agencies also have specific cultural requirements with regard to field selection (e.g., fields cannot have been treated with prohibited chemicals for 3 years before harvest of a certified organic crop, and there must be sufficient buffer zones between certified organic crops and conventionally grown crops in order to reduce potential contamination between the two such as via pollination) (University, 2013). There are other requirements and recommended practices for organic potato production see, e.g., (Moore and Olsen, No Date) for organic potato production in Idaho, and (Hollingsworth, No Date) for organic potato production in California.

In terms of US organic potato production, measured in cwt/year, the leading states are Washington (>600,000), Colorado (>500,000), California (>400,000), Oregon (>300,000), Idaho (>200,000), and much lesser amounts from Maine (>25,000), Wisconsin (>23,000), Ohio (>17,000), and Vermont (>7,000) (reference from Omar). In terms of sales/year, the leading states are California (>\$10 million), Colorado (>\$6 million), Washington (>\$4 million), Oregon (>\$3 million), and Idaho and Maine (each state, >\$1 million) (USDA-NASS, 2008). As discussed in Section 2.3.1, Domestic Economic Environment, organic potatoes command a premium price compared to conventionally grown potatoes.

Potato Seed Production

Potatoes are vegetatively propagated by planting tubers or seed pieces (Davidson, 2010) (NSF, 2011). In 2012, approximately 6 percent of the 2012 annual potato crop was used as seed (NPC, 2012a) in the form of seed potatoes. Certified seed potatoes are produced to ensure genetic purity and to reduce disease introduction (NPC, 2012a). Most seed that is sold is labeled certified seed (USDA, 2000), which means that certification agency requirements must be met. These requirements include inspections of fields, storage facilities, and shipping points in order to evaluate whether disease incidence exceeds established thresholds (Moore and Olsen, No Date). There are 16 potato seed certification agencies in the U.S., including one in each major production state (NPC, 2012a). Typically, seed potatoes are grown in the same areas where potatoes for commercial production are grown, although the areas of maximum seed production sometimes differ from the areas of maximum tuber production. Major seed production states in 2012 in order of decreasing production were Idaho (>35,000 acres harvested), North Dakota, Colorado, Maine, Wisconsin and Minnesota (>7,000 acres harvested)(USDA-NASS, 2013).

The use of good quality seed potatoes is important to successful potato culture. It is recommended that seed size be ideally about two to four ounces, about the size of a golf ball (Hollingsworth, No Date).

Potato Processing and Storage

About 60% of potatoes are processed into frozen commodities such as French fries and shoestring potatoes and dehydrated. Typically, frozen and dehydration industries are concentrated in the Northeast, upper Midwest, and Pacific Northwest. Potato chip processors tend to be more evenly distributed throughout the country because chips are fragile, and long-distance shipping is expensive. Therefore, chipping plants tend to be located near heavily populated areas (Guenther, 2010b).

Long-term storage is needed for processing operations. Capacities of storage facilities typically range from 500 to >20,000 tons. Most of the tubers are kept in bulk piles, but some facilities use box storage. In northern production areas, a large percentage of the potato crop is stored for processing and fresh market uses during the winter, spring, and summer months. Storage facilities are frequently equipped with ventilation systems and systems to monitor temperature, relative humidity and carbon dioxide levels. Some storage facilities are refrigerated to cool stored potatoes during warmer spring and summer months(Olsen, 2010). Potatoes kept stored for > 130 days have a tendency to sprout, and are therefore chemically treated to prevent sprout formation (Kleinkopf, 2010). Prolonged storage can also lead to lowered tuber quality from moisture loss, which can cause tuber surface wrinkling (Arvanitoyannis *et al.*, 2008).

2.3 Physical Environment

2.3.1 Water Resources

The principal law governing pollution of the nation's water resources is the Federal Water Pollution Control Act of 1972, better known as the Clean Water Act (CWA). The Act utilizes water quality standards, permitting requirements, and monitoring to protect water quality. The EPA sets the standards for water pollution abatement for all waters of the U.S. under the programs contained in the CWA, but, in most cases, gives qualified states the authority to issue and enforce permits. Drinking water is protected under the Safe Drinking Water Act of 1974 (Public Law 93-523, 42 U.S.C. 300 *et seq.*).

Surface water in rivers, streams, creeks, lakes, and reservoirs supports everyday life through the provision of water for drinking and other public uses, irrigation, and industry. Surface runoff from rain, snowmelt, or irrigation water can affect surface water quality by depositing sediment, minerals, or contaminants into surface water bodies. Surface runoff is influenced by meteorological factors such as rainfall intensity and duration, and physical factors such as vegetation, soil type, and topography. Agricultural production, including potatoes, can adversely impact surface water quality, primarily through sedimentation from erosion and nutrient loading from fertilizers ((US-EPA, 2005b) (US-EPA, 2009a). Nitrogen loss in the form of ammonium and nitrates to surface water can occur as a result of direct runoff, or by infiltration through the root zone, and discharge to surface water by drainage or seepage (Zebarth *et al.*, 1999).

Groundwater is the water that flows underground and is stored in natural geologic formations called aquifers. It sustains ecosystems by releasing a constant supply of water into wetlands and contributes a sizeable amount of flow to permanent streams and rivers. Based on 2005 data, the largest use of groundwater in the U.S. is irrigation, representing approximately 67.2% of all the groundwater pumped each day (McCray, 2009a; McCray, 2009b). In the U.S., approximately 47% of the population depends on groundwater for its drinking water supply. The EPA defines a sole source aquifer (SSA) as an aquifer that supplies at least 50% of the drinking water consumed in the area overlying the aquifer. An SSA designation is one tool to protect drinking water supplies in areas where there are few or no alternative sources to the groundwater resource. There are 77 designated SSAs in the U.S. and its territories (US-EPA, 2011e). Crop production has the potential to impact groundwater in areas with shallow (less than approximately 15 feet deep) water tables through leaching of the nitrates from fertilizers (Nolan *et al.*, 2002; DEFRA,

2006). Agricultural production leads to nitrate contamination of groundwater through leaching associated with high applications of manure or fertilizers or excessive irrigation (Zebarth *et al.*, 1999) (DEFRA, 2006)

Unlike a point source which is a “discernible, confined and discrete conveyance”, nonpoint source (NPS) pollution comes from many diffuse sources. Rainfall or snowmelt moving over the ground, also known as runoff, picks up and carries away natural and human-made pollutants, creating NPS. The pollutants may eventually be transported by runoff into lakes, rivers, wetlands, coastal waters and ground waters. Agricultural NPS pollution includes animal wastes, fertilizers, and pesticides. Surface water may be contaminated by agricultural sediments transported by erosion that may also include pesticides, fertilizers, and sometimes fuel and pathogens. Agricultural practices that introduce contaminants into the groundwater include fertilizer and pesticide application, spilled oil and gasoline from farm equipment, nitrates, and pathogens from animal manure.

NPS pollution is the leading source of water quality impacts on rivers and lakes, the second largest source of impairments to wetlands, and a major contributor to groundwater contamination (US-EPA, 2005a; 2005b). 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 is increased sedimentation in surface waters following soil erosion (US-EPA, 2005a; 2005b). The major contribution to groundwater contamination derives from agricultural areas (nitrogen inputs from fertilizer and manure drainage and leaching from root-zone areas due to over-irrigation; and salts in the form of carbonates, sulfates, and chlorides, from drainage) and is influenced by regional environmental factors such as precipitation and soil characteristics (Skaggs *et al.*, 1993; US-EPA, 2003; King and Stark, No Date). Nutrients applied in excess of recommended application rates are listed as the second cause of impairment in lakes, reservoirs, and ponds, with agriculture listed as the third most probable source of the impairment (US-EPA, 2012b).

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, 2005a; 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, thereby increasing nutrient loading and facilitating higher water turbidity, algal blooms, and oxygen depletion (Skaggs *et al.*, 1993; US-EPA, 2005a; 2005b). Over-fertilization should be avoided to prevent nutrient leaching into groundwater, risk of ground water pollution with nitrates, and risk of estuary pollution from nitrates and phosphates (Carroll and Robinson, 2006). Preservation and conservation of water and soil resources must be maximized and non-point-source pollution must be minimized (Carroll and Robinson, 2006).

Most of the potatoes produced in the U.S. are grown under irrigation, including potatoes grown in Idaho, Washington, Oregon, California, and Wisconsin, whereas rainfall provides adequate moisture for potato crops in the eastern U.S. (Shock, 2010) (King and Stark, No Date). Potato yield can be reduced by both under- and over-irrigating (King and Stark, No Date). Potato processing can contribute to eutrophication of water (DEFRA, 2006).

2.3.2 Soil Quality

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

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

There are a multitude of organisms associated with soils, ranging from microorganisms to larger organisms, such as worms and insects. The microbial populations of the soil encompass an enormous diversity of bacteria, algae, fungi, protozoa, viruses, and actinomycetes (filamentous bacteria) (Doran *et al.*, 1996a; Doran *et al.*, 1996b). The extent of the diversity of microorganisms in soil is seen to be critical to the maintenance of soil health and quality. Microorganisms in soil are critical to the maintenance of soil function in both natural and managed agricultural soils because of their involvement in such key processes as soil structure formation; decomposition of organic matter; toxin removal; and the cycling of carbon, nitrogen, phosphorus, and sulfur (Bruinsma *et al.*, 2003). In addition, certain microbial organisms may contribute to the protection of the root system against soil pathogens (Garbeva *et al.*, 2004a; Garbeva *et al.*, 2004b).

Potatoes grow well in a wide range of soils. Optimum soils are deep, loose, and drain well (Rosen, 2010c). Poorly drained soils tend to yield poorly shaped tubers and tubers which are

susceptible to diseases like tuber rot (Johnson and Sideman, 2006) (Plissey and Erhardt, 2000). Sandy soils can also produce high-quality potatoes, but these soils are more susceptible to wind erosion (Rosen, 2010b). The ability of soils to retain water is important because the drier soil becomes, the more difficult it is for the crop to pull water from it, and is dependent on soil texture and structure (DEFRA, 2006). Maintaining organic matter in soil is advisable because it keeps the soil loose and well-aerated, which in turn, leads to better penetration of root structures, and development of tubers, but is a problem in almost all regions where potatoes are grown except for those areas where soils contain muck and peat (Rosen, 2010a). The recommended pH for soils is slightly acidic, which helps reduce incidence of diseases such as scab (Plissey and Erhardt, 2000) (Johnson and Sideman, 2006).

Maintaining adequate soil conditions in potato fields may be difficult due to crop tillage, low crop residues on soil surfaces, and foot traffic from agricultural workers, which can lead to higher erosion rates. Erosion mitigation strategies include growing a cover crop and utilizing the subsequent crop plant residues (Hopkins *et al.*, 2004). Where potatoes are grown in fields with stones such as in Maine, removal of stones may ease movement of mechanical harvesters, but may also negatively affect tuber yield (Saini and Grant, 1980). Soil compaction can occur with excessive tillage (Roberts and Cartwright, No Date-b), continuous cropping, and the use of large agricultural machines and increased pesticide spraying operations. As the number of machinery passes through the fields increases, soil compaction increases, and oxygen diffusion rate to roots decreases, which in turn may lead to a reduction in tuber size and increased soil erosion (Saini and Grant, 1980). Compacted soil also reduces the ability of roots to find water in soil (DEFRA, 2006).

2.3.3 Air Quality

The Clean Air Act (CAA) requires the maintenance of National Ambient Air Quality Standards (NAAQS). The NAAQS, developed by the EPA to protect public health, establish limits for six criteria pollutants: ozone (O₃), nitrogen dioxide (NO₂), carbon monoxide (CO), sulfur dioxide (SO₂), lead (Pb), and inhalable particulates (coarse particulate matter [PM] greater than 2.5 micrometers and less than 10 micrometers in diameter [PM₁₀] and fine particles less than 2.5 micrometers in diameter [PM_{2.5}]). The CAA requires states to achieve and maintain the NAAQS within their jurisdiction. Each state may adopt requirements stricter than those of the national standard and each is also required by EPA to prepare a State Implementation Plan (SIP) containing strategies to achieve and maintain the national standard of air quality within the state. Areas that violate air quality standards are designated as non-attainment areas for the criteria pollutant(s), whereas areas that comply with air quality standards are designated as attainment areas. Non-attainment areas are typically associated with large metropolitan areas with many mobile (e.g., vehicle) and stationary (e.g., power plants and factories) sources. Other than emissions from mobile sources, crop farming emission sources are not specifically regulated nationwide under the CAA. The degree to which emissions from farming practices (such as prescribed burning) are allowed are location-specific within each State Implementation Plan (US-EPA, 2011f). Regulation of agricultural sources within a State Implementation Plan does not appear to be typical. For example, based on a review of the available plans in Idaho,

achievement of air quality standards is focused on managing residential wood burning, vehicle emissions, and facilities such as factories and processing plants (US-EPA, 2011a).

Agricultural production may produce air emissions such as fugitive dust from the disturbance of bare soil from farming activities or wind, vehicle emissions, and emissions associated with fertilizer and pesticide applications. In some agricultural areas, prescribed burning is practiced and results in higher air emissions levels (US-EPA, 2011f). Ammonia may be lost to the atmosphere via inorganic nitrogenous fertilizers, but occurs mostly from livestock production processes such as manure storage and application. Atmospheric ammonia can then contribute to the eutrophication of surface water and acidification of soil and water (Zebarth *et al.*, 1999). The US EPA regulates mobile source emissions by reformulated gasoline and automobile pollution control devices (US-EPA, 2011f). Stricter requirements, such as vapor recovery nozzles on gas pumps, may apply in non-attainment areas.

2.3.4 Climate Change

Climate change represents a statistical change in global climate conditions, including shifts in the frequency of extreme weather. Agriculture is recognized as a direct (e.g., exhaust from equipment) and indirect (e.g., agricultural-related soil disturbance) source of greenhouse gas (GHG) emissions. The EPA has identified carbon dioxide (CO₂), methane (CH₄), and nitrous oxide (N₂O) as the most important GHGs contributing to climate change. While each of these gases occurs naturally in the atmosphere, human activity has significantly increased the concentration of these gases since the beginning of the industrial revolution. The level of human produced gases accelerated even more so after the end of the Second World War, when industrial and consumer consumption expanded greatly. With the advent of the industrial age, there has been a 36% increase in the concentration of CO₂, 148 % in CH₄, and 18 % in N₂O (US-EPA, 2012a)

Greenhouse gases vary in their global warming potential (GWP), and the US EPA converts all gases to carbon dioxide (CO₂) equivalents. For the three greenhouse gases most associated with agriculture, GWPs are as follows: CO₂ = 1, methane (CH₄) = 21, and nitrous oxide (N₂O) = 310 (US-EPA, 2012a). The US EPA classifies different sources by sector, with the energy sector being the largest contributor of greenhouse gas emissions (US-EPA, 2012a). The agriculture sector, as defined by US EPA, represented 6.3 percent of total greenhouse gas emissions for the U.S. in 2010 (US-EPA, 2012a). However, this does not include CO₂ emissions and removals from agricultural-related land use activities such as liming of agricultural soils (which are included in the land use sector) and it does not include emissions of CO₂ and N₂O from diesel or gasoline-powered agricultural equipment (which are included in the energy sector). The primary greenhouse gases contributed by the agriculture sector as defined by US EPA are N₂O and CH₄. The relative percent contribution to total CO₂ equivalent emissions of the various agricultural sources in 2010 was as follows: agricultural soil management (fertilizer application and other cropping practices that contribute N₂O), 49 percent; enteric fermentation (primarily methane emissions from cattle), 33 percent; manure management, 16 percent; and rice cultivation, two percent. Most of the climate change potential from potato production is derived from transportation, packing and processing of potatoes. Emissions from field burning of agricultural residues, the remaining category, were less than 0.1 percent of the total (DEFRA, 2006; US-EPA, 2012a).

2.4 Biological Resources

This section provides a summary of the biological environment and includes an overview of animals, plants, microorganisms, and biodiversity associated with potato production. This summary provides the foundation to assess the potential impact to plant and animal communities.

2.4.1 Animal Communities

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

A wide array of wildlife species occur within the major potato-producing U.S. states and could possibly be found in potato fields at least intermittently. There are reports of wildlife feeding on foliage of potato, but reports of damage resulting in economic loss are uncommon. This is not surprising considering that the foliage and stems of potato contain toxic glycoalkaloids known to cause illness when consumed (Sinden, 1987a). In 1992, APHIS Wildlife Services conducted formal appraisals of wildlife damage on 490 acres of potatoes in Wisconsin and did not report any damage or economic loss (USDA-APHIS, 2013d). However, white tailed deer have been reported to damage potatoes in some areas (Marinette County, 2014) and it is well known that wild boar and voles will feed on tubers (O'Brien, 2005; Taylor, 2014) (Taylor, 2014). USDA-APHIS Wildlife Services has also received complaints for damage caused by sandhill cranes (USDA-APHIS, 2013d).

There are numerous insects found in and around potato fields. Some insects and other invertebrates can be beneficial to potato production, providing services such as nutrient cycling and preying on plant pests. As discussed in Section 2.2.6, Insect Control, many insects and invertebrates are detrimental to potato crops, including: Colorado potato beetle (*Leptinotarsa decemlineata*), various aphid species including the green peach aphid (*Myzus persicae*), wireworms (*Limonius californicus*, *L. canus*, *Ctenicera pruina*), flea beetles (*Epitrix* sp.), European corn borer (*Ostrinia nubilalis*), potato psyllid (*Bactericera (Paratrioza) cockerelli*), tuberworm (*Phthorimaea operculella*), and the potato leafhopper (*Empoasca fabae*) (Johnson, 2007a; Simplot, 2013a). Nematodes can also be found in potatoes such as the root knot nematodes (*Meloidogyne* spp.), and cyst nematodes (*Globodera pallida*) and (*G. rostochiensis*) (Hardy, 1996). The potato crop is intensively managed with integrated pest management (IPM) practices to control these insects, nematodes, and several disease pathogens that include fungi, bacteria and viruses (Johnson, 2007b) and to enhance potato yield. As a result, pesticides, including insecticides, nematicides, and fungicides, are generally part of an IPM strategy to keep losses below economic thresholds (US-EPA, 2000), (Senseman, 2007). Conventional broad-spectrum insecticides are potentially toxic to invertebrates and vertebrates. The US-EPA requires application control measures for certain Restricted Use insecticides to limit human and environmental exposure. These impacts can affect animal communities, with those communities

within and in close proximity to potato fields experiencing the greatest impact (US-EPA, 2000),(US-EPA, 2009b).

2.4.2 Plant Communities

The landscape surrounding a potato field may be bordered by other potato fields, other crops, or may be surrounded by forest, grassland, bodies of water, or built-up areas. As discussed in Section 2.2, most commercial potatoes are grown in large agricultural areas, such as the Snake River Valley in Idaho. Thus, other crops would most frequently make up the surrounding vegetation, although some fields would be bordered by non-crop vegetation. Growers may provide buffer zones to reduce or prevent impact to adjacent vegetation. Because potatoes are grown throughout much of the U.S., a wide variety of plants may be found adjacent to the agricultural fields. These plants have the potential to be impacted by agricultural practices, including the use of pesticides, which are regulated by US EPA. Aquatic plant communities near agricultural fields may be affected by sedimentation resulting from erosion, or by nutrients leached from fertilizers.

Plants which compete with potato in crop fields are generally regarded as weeds, and are discussed in Section 2.2.8, Weed Management. Native or wild plant species related to cultivated potatoes are of interest because of the potential for interbreeding through gene flow. By definition, interbreeding between species that result in viable offspring is not common, otherwise the two plants would not be classified as different species. Interbreeding can occur to a limited extent between some species under some circumstances. Among the many factors that must be present for hybridization to occur between two species are: 1) the species must occur in the same area and habitat, 2) the flowering periods of the species involved must overlap, and 3) appropriate pollinators must be present (OECD, 1997b). Section 2.4.3, Gene Flow and Weediness discusses this subject.

Threatened and Endangered Species

There are currently three plants in the genus *Solanum* on the U.S. Fish and Wildlife Service (US FWS) list of threatened or endangered plant species: Erubia (*S. drymophilum*), found only in Puerto Rico; and popolo ku mai (*S. incompletum*) and Aiakeakua popolo (*S. sandwicense*), both found only in Hawaii (FWS, 2011) p. 47). Based on the evaluation of wild potatoes presented above, these species would not interbreed with cultivated potatoes; additionally, potatoes are not commercially grown in these areas.

2.4.3 Gene Flow and Weediness

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

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

Volunteer potatoes arise from overwintered tubers, and can be a weed problem in the following crop. Potatoes have a fairly low frost tolerance, and tubers planted too shallowly are subject to loss by frost. In temperate climates up to 20% of tubers left in the soil show no dormancy and will sprout the next season (Andersson and de Vicente, 2010). However, volunteer potatoes can be easily controlled with cultivation and herbicides and do not persist as weeds for more than one or a few years (Andersson and de Vicente, 2010). In general, potato has a low propensity for weediness or persistence and is incapable of survival outside of agricultural production (OECD, 1997b) (Holm and Pancho, 1979) (Muenscher, 1980a) (Love, 1994b).

Gene flow by hybridization is not possible for some potato cultivars such as the Russet Burbank, the most commonly grown potato, because they are sterile (NSF, 2011), (PAA, 2009a) (Simplot, 2013a). Pollination of potato is mostly by insects such as such as bumblebees (*Bombus impatiens*) (OECD, 1997b), which have a relatively short flight range, and, therefore, pollen dispersal is limited. Because potato flowers have little nectar, the honey bee (*Apis mellifera*) is not attracted to them, and wind plays an insignificant role in pollination (OECD, 1997b). Empirical field testing of outcrossing distances in potato show that separations of 20 meters or more are sufficient to prevent outcrossing (Conner and Dale, 1996).

Of the fertile varieties, which include Ranger Russet, Atlantic and “G”, about 80 to 100 percent of true seed produced is derived from self-pollination (Hoopes and Plaisted, 1987). A potential source of volunteers is true potato seed (TPS). TPS is seed produced via pollination, which develops inside small fruiting bodies formed on the potato vine. Its major disadvantage is that it segregates for numerous traits because potato is highly heterozygous, and plants arising from TPS typically take longer to establish and set tubers, resulting in lower yield than from seed potatoes (Simplot, 2013a) (Pallais, 1987). Of the five parent varieties used to develop the 10 Simplot Innate™ Potato events, Russet Burbank and “H” are fully sterile, precluding any possibility of TPS production. However, the Simplot Innate™ Potato events derived from Ranger Russet, Atlantic and “G” are fertile and may produce TPS. But plants produced from TPS are no weedier than volunteer plants produced from over-wintered tubers and are relatively easy to control in rotational crops.

Potato (*Solanum tuberosum*) belongs to the Solanaceae plant family, along with other cultivated crop plants such as tomato (*Solanum lycopersicon*), eggplant (*Solanum melogena*), tobacco (*Nicotiana tabacum*), and pepper (*Capsicum annuum*) (OECD, 1997b). *S. tuberosum* is divided into two subspecies: *tuberosum* and *andigena*. The subspecies *Solanum andigena* is also a cultivated species, but its cultivation is restricted to Central and South America (OECD, 1997b). While there appears to be minimal, if any, overlap geographically between cultivated and wild potatoes in the U.S., there is a possibility that a few wild potato plants may be growing near

potato fields (Love, 1994b). However, the potential for hybridization between wild and domesticated potatoes is extremely unlikely. Approximately 200 species of wild potatoes have been identified (Hijmans and Spooner, 2001), but only two species grow within US borders, the tetraploid species *Solanum fendleri* (recently reclassified as *Solanum stoloniferum*) and the diploid species *Solanum jamesii* (Bamberg *et al.*, 2003); (Bamberg and del Rio, 2011). In addition to geographic separation (US-EPA, 2011c), there are several biological barriers to gene transfer such as multiple ploidy levels and endosperm imbalances (Love, 1994b). Hybridization between native and cultivated potatoes has never been reported in the US, although gene transfer has been accomplished using special laboratory techniques (Love, 1994b) (US-EPA, 2011c).

2.4.4 Microorganisms

Soil microorganisms play a critical role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, most biochemical soil processes (Garbeva *et al.*, 2004a) and maintenance of soil structure and composition (Rosen, 2010b). Compared to soil supporting crops, fallow soil has the lowest microbial mass and diversity (Larkin, 2003). Microorganisms suppress soil-borne plant diseases and promote plant growth (Doran *et al.*, 1996a) (Inceoglu *et al.*, 2013). The main factors affecting microbial population size and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, irrigation and herbicide and fertilizer application) (Garbeva *et al.*, 2004a; Garbeva *et al.*, 2004b) (Rosen, 2010b). Crop type also may play an important role in the type of soil microorganisms in soils (Larkin, 2003). Plant roots, including those of potato, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere, whereby microorganisms may be attracted to and stimulated by the roots (Inceoglu *et al.*, 2013). Microbial diversity in the rhizosphere may be extensive and differs from the microbial community in the bulk soil (Garbeva *et al.*, 2004a).

Larkin (Larkin and Honeycutt, 2006) investigated the effect of potato production on soil microbial communities over a period of three years. A two-year rotation period appears to control soilborne disease. Potato soil microbial populations were lower than for several other crops, including canola, barley, and corn. Use of rotations also appeared to reduce the incidence and severity of black scurf, as well as reduced the number of misshapen tubers. Larkin (Larkin and Honeycutt, 2006) suggested that activity and diversity of microbial populations were negatively correlated with the percentage of misshapen tubers.

In a study examining the abundance and structure of bacterial communities in a potato-barley-potato rotation, it was determined that the roots of all potato cultivars had positive effects on bacterial numbers in the soil, diversity and community structure of bacterial communities varied with time and season, and the composition of bacterial communities is linked to the specific requirements of different cultivars. Bacterial composition was potentially related to tuber starch content, as well as specific fertilizers (Inceoglu *et al.*, 2013).

Pathogenic microorganisms which are associated with diseases of potatoes, is discussed in section 2.2.7, General Agronomic Practices, Disease Control.

2.1.1 2.2.5 Biodiversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem. Biodiversity provides valuable genetic resources for crop improvement (Wilson, 1988a; Wilson, 1988b); (Harlan, 1975b; Harlan, 1975a), and also provides other functions beyond food, fiber, fuel, and income. These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 1999). The loss of biodiversity results in a need for costly management practices in order to provide these functions to the crop (Altieri, 1999). The degree of biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem; 2) permanence of various crops within the system; 3) intensity of management; 4) extent of isolation of the agroecosystem from natural vegetation (Southwood and Way, 1970).

Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas (Altieri, 1999). Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvesting limits the diversity of plants and animals (Lovett *et al.*, 2003).

Biodiversity can be maintained or reintroduced into agroecosystems through the use of woodlots, fencerows, hedgerows, and wetlands. Agronomic practices 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 (e.g., compost, green manure, animal manure), hedgerows and windbreaks (Altieri, 1999).

Because potatoes are grown throughout regions of the U.S., there is a large diversity of plants and animals that inhabit the areas surrounding the potato fields. These include the weeds discussed in Section 2.2, Agronomic Practices, Weed Control, and animals in Section 2.4.2, Animal Communities.

2.2

2.2.1 2.2.6 Human Health

Humans interact with potatoes either as consumers of potato and products derived from it, as workers who produce potato crops. Under the FFDCFA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from GE potato 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 wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food (insert reference to

FDA letter). FDA evaluates the submission and responds to the developer by letter. Simplot submitted a letter of consultation on February 12, 2013, which FDA is still reviewing (BNF No. 141).

As noted by the National Research Council (NRC), unexpected and unintended compositional changes arise with all forms of genetic modification, including both conventional hybridizing and genetic engineering (NRC, 2004). The NRC also noted that at the time, no adverse health effects attributed to genetic engineering had been documented in the human population. Reviews on the nutritional quality of GE foods have generally concluded that there are no significant nutritional differences in conventional versus GE plants for food or animal feed (Faust, 2002; Flachowsky *et al.*, 2005).

Consumer Health

The potato is the world’s number one non-grain food commodity (FAO, 2008). Potatoes are high in nutrients and at least twelve essential vitamins, especially vitamins B and C, and minerals such as iron, potassium, and zinc (Arvanitoyannis *et al.*, 2008) (Bushway, 2010) (FAO, 2008). They have the highest protein content (around 2.1 percent on a fresh weight basis) in the family of root and tuber crops. As a low-fat source of carbohydrates, potatoes can be instrumental in providing a solution to long-term problems of world hunger (Bushway, 2010).

Because of their high sugar and starch content and resulting high glycemic index, consumption of potatoes by persons with diabetes or similar conditions may need to eat potatoes sparingly. U.S. per capita potato consumption is summarized in Table 6 (NPC, 2012b).

Table 6. U.S. Per Capita Potato Consumption in 2012

	Fresh Market	Processing				Total Processing	All Potatoes
		Canned	Frozen	Chips	Dehydrated		
	35	1	50	15	12	78	112

Source: (NPC, 2012b); totals may not add due to rounding.

Toxins and Allergens in Potato

Potatoes contain two classes of toxins and/or allergens: glycoalkaloids and patatins. Acrylamide is a toxic compound formed in cooking potatoes at high temperatures, such as roasting or baking and frying.

Glycoalkaloids are well-known naturally-occurring compounds that are present in all potatoes, which likely serve a defense mechanism against predator attack. These compounds are concentrated in foliage, flowers and sprouts, although glycoalkaloids are present in lower concentrations in other parts of the plant, including tubers. For food safety purposes, an upper limit for glycoalkaloid content of 20 milligrams per 100 grams of potato is generally accepted.

Concentrations exceeding this are potentially poisonous to humans and livestock. Light exposure to harvested tubers can increase glycoalkaloid content in potatoes, and may result in green areas of coloration on potato skins (Sinden, 1987a) (Center, 2010).

Patatins are a family of proteins that makes up 30 to 40 percent of the soluble protein in potatoes (Mignery *et al.*, 1988). Allergic reactions to cooked potatoes are considered to be very uncommon and have been reported for children only (De Swert *et al.*, 2002), with patatin identified as the major allergen involved in this reaction (De Swert *et al.*, 2007). Because potato protein naturally contains a relatively large proportion of patatin, those who are allergic to patatin would need to avoid eating potatoes.

Of greatest significance to human health is the toxic compound acrylamide, which is a known carcinogen of rodents and a probable human carcinogen (WHO-IARC, 1994) (NTP, 2011) (Chawla *et al.*, 2012) (Halford *et al.*, 2012a). In particular, risk of endometrial and ovarian cancer appears to increase with increased acrylamide intake (Pedreschi, 2009). Acrylamide is also regarded as a mammalian cell mutagen, wherein very low dosages of the compound can damage chromosomes (Chawla *et al.*, 2012). Acrylamide has also been reported to be a cumulative neurotoxin (Friedman, 2003).

Acrylamide is formed in potatoes which are cooked at high temperatures, such as baking or frying. In 2002, Swedish researchers demonstrated that acrylamide forms when starchy foods, such as potatoes and breads, are heated at high temperatures, such as in baking, roasting, and frying, but not in unheated or boiled foods (Tareke *et al.*, 2002; Halford *et al.*, 2012a). Therefore, even though dietary exposure to acrylamide is measurable, it is not a natural compositional component of unheated foods derived from plants. Acrylamide forms during the Maillard reaction (Martins *et al.*, 2000) which is a reaction at high temperatures (such as frying French fries) between certain sugars such as glucose and fructose (reducing sugars) and asparagine (an amino acid) that are naturally present in the food (FDA, 2009). In addition, prolonged heating time increases acrylamide content, whereas higher moisture content reduces acrylamide content (Kotsiou *et al.*, 2013). Maillard reaction products, which affect the flavor and texture of the cooked food, are formed by a chemical reaction between an amino acid and a reducing sugar (Halford *et al.*, 2012b). Oxidation of the free amino acid asparagine, a major amino acid in potatoes and cereals (Mottram *et al.*, 2002; Chawla *et al.*, 2012), is the main source of acrylamide when starchy foods are baked or fried (Stadler *et al.*, 2002; Friedman, 2003; Halford *et al.*, 2012a; Kotsiou *et al.*, 2013). Color of cooked potato products such as potato chips has been found to correlate well with acrylamide formation: the darker the color, the higher the greater the acrylamide concentration (Halford *et al.*, 2012a) (Kotsiou *et al.*, 2013) (Pedreschi, 2009) (Arvanityannis *et al.*, 2008).

Important variables leading to acrylamide formation and affecting acrylamide concentration in cooked potatoes include reducing sugar content, processing/cooking temperature and method, cooking/processing time, moisture content, and additives (Kotsiou *et al.*, 2013) (Halford *et al.*, 2012a). In turn, concentrations of sugars and amino acids are influenced by cultivar, fertilizers, climate, and storage conditions (Pedreschi, 2009).

It is estimated that potato chips and fried potato products such as French fries are responsible for about 1/3 of the human dietary exposure to acrylamide (Chawla *et al.*, 2012). Acrylamide is also present in other foods such as coffee, some breads, biscuits, gingerbread, and processed onion mix and dip mixes. Smoking may contribute to human exposure to acrylamide (Chawla *et al.*, 2012) (Kotsiou *et al.*, 2013) (Friedman, 2003).

For all of these reasons, the discovery of acrylamide in cooked potato products has raised concerns throughout the potato processing industry, as well as among consumers. The FAO/WHO Expert Committee on Food Additives has recommended that dietary exposure to acrylamide should be reduced (FAO/WHO, 2011). Perhaps because children consume more acrylamide-laden products such as French fries and potato chips, their exposure to the chemical is greater than for adults (Friedman, 2003) (Halford *et al.*, 2012b). The State of California listed acrylamide as a potential carcinogen under Proposition 65 in 1990 and established a No Significant Risk Level (NSRL) of 0.2 µg/day (CEPA-OEHHA, 2005). Subsequent to the discovery of acrylamide in cooked foods, this NSRL was revised to 1.0 µg/day (CEPA-OEHHA, 2005). FDA has recently released draft guidance for the food industry to reduce acrylamide in foods (FDA, 2013a).

Proposition 65 requires that food manufacturers warn consumers about the dangers of acrylamide in their products. In 2005, the State of California sued Frito-Lay, Kettle Foods and Lance, Inc. for failing to provide such warnings. In the settlement, the potato chip manufacturers agreed to reduce the acrylamide in their products to 275 ppb, low enough to avoid the Proposition 65 warning. These three companies also agreed to pay close to \$2M in penalties and court costs. The potato processing industry now has a strong financial incentive to reduce the levels of acrylamide in their retail products.

Worker Health

Worker hazards in farming are common to all types of agricultural production, and include hazards from equipment and plant materials. Pesticide application represents the primary exposure route to pesticides for farm workers. Workers engaged in potato production may encounter insecticides, herbicides, fungicides or fertilizers that may pose a worker health or safety risk, unless used in accordance with the US-EPA -established agriculture-specific requirements in the Worker Protection Standard (WPS) (40 CFR Part 170) that protect workers from the hazards of chemical exposure. 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. The Occupational Safety and Health Administration requires all employers to protect their employees from hazards associated with agricultural chemicals. The EPA pesticide registration process, however, involves the design of use restrictions that if followed have been determined to be protective of worker health.

A potato field is a highly managed environment which incorporates the use of agricultural chemicals, including herbicides and insecticides. Pesticides are used on most potato 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. Worker safety precautions and use restrictions are noted clearly on pesticide registration labels. Growers are required to use pesticides consistent with the application instructions provided on the EPA-approved pesticide labels. These restrictions provide instructions as to the appropriate levels of personal protection required for agricultural workers. These may include instructions on personal protective equipment, specific handling requirements, and field reentry procedures (see, e.g. (Carroll and Robinson, 2006) (Carroll and Robinson, 2006).

2.2.7 Animal Feed

Potatoes used as livestock feed accounted for approximately 1.2 percent of all potatoes produced in the U.S. in 2012 (see Table 7). This quantity includes potatoes sold specifically as livestock feed and potatoes used as livestock feed on farms where the crop was grown. It does not include the potato waste that was used for livestock feed (USDA-NASS, 2013

). Use of potatoes for livestock feed is generally dependent on quality and price: for example, when potatoes are low in both price and quality, more of the crop tends to be used for livestock feed. Prices for feed are usually the lowest of all potato usage categories (Guenther, 2010c).

Table 7. U.S. 2012 Potato Utilization

Utilization Item	CWT (1,000) (%)
Sales – fresh and processing	
Table stock (fresh)	118,535 (25.6%)
Processing	
Chips and shoestrings	56,349 (12.2%)
Dehydrated (except starch and flour)	50,559 (10.9%)
Frozen French fries	144,910 (31.3%)
Other frozen products	20,912 (4.5%)
Canned products	1,764 (0.4%)
Other canned products (hash, stews, soup)	695 (0.2%)
Starch, flour and other	8,031 (1.7%)
Total processing	282,220 (61.0%)
Other sales	
Livestock feed	4,080 (0.9%)
Seed	23,706 (5.1%)
Non-sale	
Seed used on farms where grown	3,286 (0.7%)
Household and feed use on farms where grown	1,583 (0.3%)
Shrinkage and loss	28,356 (6.1%)

Utilization Item	CWT (1,000) (%)
Total Production	462,766

Source: (USDA-NASS, 2013

)

Potatoes constitute at least part of the diet for several domestic animals, including cattle, horses, pigs, and poultry. The recommended rate of feed is approximately 25-40 lb potatoes/1,000 lb live weight, but can vary with the type of animal. Potatoes are considered to be a palatable feed, and are high in moisture content, but are not as nutritious as grain or corn silage (e.g., it takes 400-500 lb of potatoes to provide the same nutritive value as 100 lb of grain (Corbett, No Date). Feed does not include the leafy green foliage of potato plants since flowers, sprouts, and foliage has abundant glycoalkaloids, which are potentially poisonous for livestock (Sinden, 1987a). Similar to the regulatory control for direct human consumption of potato under the FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from GE potato must comply with all applicable legal and regulatory requirements, which in turn protects human health. To help ensure compliance, GE organisms used for feed may undergo a voluntary consultation process with FDA before release onto the market, which provides the applicant with any needed direction regarding the need for additional data or analysis, and allows for interagency discussions regarding possible issues.

Although a voluntary process, thus far all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. FDA evaluates the submission and responds to the developer by letter. Simplot submitted a letter to FDA on February 12, 2013, which FDA is currently reviewing (BNF No. 141).

2.3 Socioeconomics

As part of an evaluation of impacts on the human environment, NEPA requires consideration of economic and social effects (40 CFR 1508.8), whether direct, indirect, or cumulative. However, under CEQ regulations (40 CFR 1508.14), “. . . economic or social effects are not intended by themselves to require preparation of an environmental impact statement.”

The following socioeconomic factors are considered in this EA: the interaction of social and economic factors that affect agricultural production and products, including farm income and employment, crop production expenses, crop value and trade. The main focus of this assessment is the socioeconomic effect on the crop industry, including production and domestic and international trade, and crop producers.

2.3.1 Domestic Economic Environment

Potatoes contribute approximately 15 percent of farm sales receipts for vegetables, making potatoes the leading vegetable crop in the United States (USDA-ERS, 2012b). The total value of U.S. potato production in 2012 was \$3.9 billion, the average yield was 409 CWT/acre and the average price received was \$7.26/CWT (USDA-NASS, 2012c). Unlike true commodity crops such as corn and soybeans, most potatoes are grown for a specific market. As shown in Table A, the Russet Burbank and Ranger Russet are primarily used for fries, and the Atlantic, “H”, and “G” varieties are primarily used for chips. Atlantic is the standard for making potato chips from the field or from very short storage (PAA, 2009b). Any of these varieties can also be sold on the fresh market. On the fresh market, Russet Burbank and Ranger Russet potatoes are the standard for baking (PAA, 2009a); (Pavek *et al.*, 1992). Other varieties are used for canning and are well-suited for boiling. There are thousands of potato varieties, some intended for very small markets (FAO, 2008).

Uses for all potato varieties combined in the United States are summarized in Table 8. Specific varieties are not grown for the dehydration market or for livestock feed; rather, food-grade potatoes considered unsuitable for their intended fresh or other processing markets are usually used for these purposes (Guenther, 2010c). Because potato sales for livestock feed usually receive the lowest price, potatoes are not sold for livestock feed if other uses are available (Guenther, 2010c).

Table 8. A Sample of U.S. Potato Varieties and their Uses

Variety ¹	Use
Russet Burbank	Boiling, baking, chipping, French frying
Ranger Russet	Baking, French frying
Atlantic	Fresh market, chipping
Kennebec	Boiling, pan frying, chipping, French frying
Norland	Boiling, French frying, chipping
Yukon Gold	Fresh market, boiling, baking, French frying

¹ <http://potatoes.wsu.edu/varieties/vars-all.htm>

Fresh market potatoes in North America can be classified broadly as russets, reds, yellows or whites based on skin color. Most eastern potato growers also are involved in packing; in the west, the businesses are usually separate. Recently, western growers have entered the packing business, often in partnerships or cooperatives with other growers (Guenther, 2010a).

Fresh potatoes may be shipped in refrigerated rail cars or trucks to maintain a high standard of quality whereas frozen and dehydration processing typically occurs near potato production areas. The fragility of chips and the high cost of shipping low-density products results in most chipping plants being located near populated areas. Except for dehydrators, processors typically contract for most of their needs and buy the remainder on the open market. Some dehydrators segregate potatoes that are suitable for the fresh market, and then sell those on the fresh market, processing

the rest. Others purchase off-grade potatoes from fresh packers for processing (Guenther, 2010b).

Revenues and costs of potato production vary widely, depending on geography, growing conditions, the local economy, the type of potato, farm size, and other factors. For example, the 2011 per acre operating cost of growing Russet Burbank potatoes in Southwestern Idaho, including on-farm storage and fumigation, was \$2,811 (Patterson, 2011). In the same year, the gross return per acre averaged \$4,107.50, resulting in a net return of \$1,297. When that same variety was grown in South-Central Idaho, the 2011 per acre operating cost, including on-farm storage and fumigation, was \$2,560 (Patterson, 2011), and the gross return per acre averaged \$3681.25, resulting in a net return of \$1,121.

Approximately 90 percent of U.S. potatoes are planted in the spring and harvested in the fall, and western states produce two-thirds of the fall potatoes. The storage abilities of potatoes enable fall-season potato varieties to be sold in fresh or processing markets throughout the September-August marketing year. Less than 10 percent of potatoes are harvested in winter, spring and summer; however, these potatoes meet specific market needs (e.g., new potatoes) and tend to yield higher prices than fall potatoes (USDA-ERS, 2012b).

Sales value per acre is normally highest for the winter crop and lowest for fall potatoes, but varies widely among the producing states. Prices for fresh potatoes are usually higher than prices for processing potatoes due to crop-quality standards. Domestic potato prices may vary not only in response to changes in weather, yield or demand, but also to changes in supply from imported potatoes and potato products. If a large quantity of frozen French fries enters the country, U.S. potato processors may cut back on contracts for processing potatoes, which would be diverted to the fresh market. Fresh market prices would likely fall as a result (USDA-ERS, 2012b).

Not all potatoes are sold for food. The largest non-sales category is “shrinkage and loss”, which accounts for the water weight loss and loss due to respiration during storage. Also in this category are potatoes that do not meet market quality standards due to decay, bruising, greening, sprouting and disease. Crops that suffer frost damage also are added to this category (Guenther, 2010c).

Potato production requires numerous expenditures, including for specialized machinery. The largest conventional operating cost items are fertilizer, chemicals and pesticides, storage and seed potatoes. Fertilizer and seed accounted for 25 percent of total production costs in eastern Idaho in 2007 (Patterson, 2010). Potato production costs for irrigation in the western United States ranges between \$1,500 and \$3,500 per acre (Patterson, 2010). Costs do not stop accumulating at harvest unless the potatoes are sold out of the field. Additional costs are incurred to store potatoes.

For those producing organic potatoes, an organic production system is required in addition to a relatively long crop rotation to minimize pest problems. Profitability margins differ between organic farm sizes, but a study conducted in southern Idaho indicated that net returns over variable costs for a small farm (30-50 acres) with 100% organic premiums is \$1,026/acre and

\$1,148/acre for a large farm (100-120 acres) (Painter *et al.*, 2010). Smaller farms have higher operating costs as a result of smaller, less efficient machinery, and their machine hours for potato production are more than double the hours on a large organic farm. While larger farms reduce labor expenses by half with more efficient machinery, they do have an increase in capital costs. Organic potato growers face challenges, including growing sufficient fall cover crops to supply soils with additional nitrogen, but profit margins for organic potatoes have the potential to exceed those for conventional potatoes if these and other challenges are addressed (Painter *et al.*, 2010).

One of the traits of Simplot Innate™ Potato, reduced black spot bruising, is of major significance to economic markets. In general, post-harvest losses are a significant part of the production costs of fruits and vegetables, and may reach as high as 50% (Llorente *et al.*, 2011) (Martinez and Whitaker, 1995). Browning of fruits and vegetables negatively affects consumer acceptance because of altered appearance and perceived nutritional deficit (Llorente *et al.*, 2011). Specifically, potato growers can lose up to 20% of income through potato injury at harvest (Preston, 2010). The potato industry, therefore, has a vested interest in minimizing these losses. Black spot bruise is typically caused by mechanical injury to tubers during harvest, handling, storage, or processing such as scuffing and cracking of the skin (Dirks-Hofmeister *et al.*, 2013). Injury leads to a bluish-grey to black discoloration of internal tuber tissue (Stremmel *et al.*, 2010). Bruising symptoms do not appear until 3 hours to 24 hours following mechanical impact, and are not visible until the skin is removed from the tuber (Stremmel *et al.*, 2010) (Urbany *et al.*, 2011). Because bruising cannot be observed until the potato skin is removed, it is more difficult to identify damaged tubers, and makes conventional means of breeding to eliminate this trait more problematic (Urbany *et al.*, 2011).

Physical tuber properties, such as tissue stiffness and elasticity, affect transfer of the impact energy to the tuber and may affect susceptibility of the tuber to bruising. For example, if potato tissue does not crack during injury, the force of the impact is more evenly distributed throughout a larger area of the tuber, which results in greater changes to metabolism, and, hence more bruising (Stremmel *et al.*, 2010). Therefore, bruising susceptibility varies widely among potato cultivars (Stremmel *et al.*, 2010). To a large extent, susceptibility is dependent on multiple genetic traits, as well as on maturity of tubers and environmental factors (Urbany *et al.*, 2011). Potato genotypes with high tuber starch content are more susceptible to bruising (Urbany *et al.*, 2012).

The chemical basis for black spot bruising lies in the cellular release of phenolic compounds, normally compartmentalized in the vacuoles, following injury (Tran *et al.*, 2012). The phenolic compounds are converted to *o*-phenols and *o*-quinones by the enzyme polyphenol oxidase (PPO) (Dirks-Hofmeister *et al.*, 2013). These quinoids auto-oxidize, forming melanin, leading to blackened tissue which is called enzymatic browning and is undesirable in processed potato product (Hunt *et al.*, 1993; Llorente *et al.*, 2011) (Steffens, 1994) (Stremmel *et al.*, 2010; Vitti *et al.*, 2011). Oxidative browning reactions generally cause deterioration in food quality by changing nutritional and organoleptic properties, and can involve changes in texture and flavor as well as color (Yoruk and Marshall, 2003). The side chains of essential amino acids in plant

proteins may interact with quinones, leading to a reduction in nutritional quality (Yoruk and Marshall, 2003). Degree of discoloration is strongly related to PPO activity (Urbany *et al.*, 2011). Polyphenol oxidase expression is mediated by a multigene family in potato (Thygesen *et al.*, 1995) (Llorente *et al.*, 2011).

Storage temperatures also affect the likelihood of black spot bruise (Preston, 2010) since increased temperature heightens PPO activity (Yoruk and Marshall, 2003); (Vitti *et al.*, 2011).

2.3.2 Trade Economic Environment

U.S. and global trade are greatly affected by the growth and stability of world markets, including changes in world population, economic growth, and income. Other factors affecting agricultural trade are global supplies and prices, changes in exchange rates, government support for agriculture, and trade protection policies.

U.S. farmers and agricultural firms rely heavily on export markets to sustain prices and revenues because productivity of U.S. agriculture increases faster than the demand for domestic food and fiber. U.S. food imports have increased with the corresponding increase in demand for greater diversity in the food supply. U.S. consumers benefit from imports because imports expand food variety. This also tends to stabilize year-round supplies of and prices for fresh fruits and vegetables.

U.S. exports of potatoes and potato products have grown 133 percent in value and 79 percent in volume during the last 10 marketing years (Board, 2013). Frozen potato products comprise 60 percent of the U.S. potato exports. During the 2012/ 2013 market year (September-August), U.S. exports of potatoes and potato products totaled \$1.6 billion—up from \$1.4 billion in the previous market year (USDA-ERS, 2013). Exports to target markets were led by an increase in shipments to Mexico, South Korea, Malaysia, and Vietnam. During the 2012/ 2013 market year, Canada was the largest market for chips while Japan was the largest market for frozen potato products and dried, flour, and meal potato products (USDA-ERS, 2013); (Board, 2012). Mexico provides the United States with the largest market for exporting potato flakes and granules and is the second largest market destination for frozen potatoes (USDA-ERS, 2013); (Board, 2012). U.S. potato and potato product exports are expected to grow during the upcoming marketing year (Board, 2013). Growth rates will depend upon economic growth in the markets and the supply and price of competitor products. The United States will facilitate the growth of the export market by continuing to gain new market access, as just occurred for fresh table-stock to the Philippines (Board, 2013).

2.3.3 Organically Certified Economic Environment

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

In accordance with NOP, each year an accredited organic certifying agent must review an operation. This must include a review of its organic system plan and record-keeping practices, and an on-site inspection of the production area(s). Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards. Section 205.105 of the regulations identifies “Allowed and prohibited substances, methods, and ingredients in organic production and handling.

“To be sold or labeled as ‘100 percent organic,’ ‘organic,’ or ‘made with organic’ (specified ingredients or food group(s)),” the product must be produced and handled without the use of: . . . (e) Excluded methods”

Excluded methods identified at 7 CFR Section 205.2, are defined as follows:

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

Organic farming operations, as described by the NOP, are required to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods (USDA-AMS, 2010).

Common practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops, so that the crops will flower at different times, and employing adequate isolation distances between organic and neighboring fields to minimize the chance for pollen exchange between fields (NCAT, 2003). Although the national organic standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the national organic standards (USDA-AMS, 2010). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation if excluded methods were used and reasonable practices were implemented to avoid contact with products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche, 2006; USDA-AMS, 2010).

Organic market and products

The organic sector is rapidly growing both in the United States and the EU. Consumer purchases in these two regions made up 95% of estimated world retail sales of organic food products in 2003(Dimitri and Oberholtzer, 2009). Annual manufacturer survey results (Organic Trade Association, 2011), indicated that estimated U.S. organic food sales for 2010 were \$26.7 billion. This represented a 7.7 % growth rate from the previous year. The market sector experiencing the highest growth rate during 2010 was organic fruits and vegetables, which increased 11.8 % compared with 2009 sales. The market share for organic fruits and vegetables was 11% of all U.S. fruit and vegetable sales (Organic Trade Association, 2011). Organic products represented approximately 4% of total 2010 sales in the food and beverage sector (Organic Trade Association, 2011).

Organic Potatoes

In 2008, 2.2 million CWT of organic potatoes were harvested, with a total sales value of almost \$29 million (\$13.24/CWT)(USDA-NASS, 2012a). Prices for organic potatoes are typically substantially higher than the overall average conventional potato price, and probably reflects both the organic premium and the fact that most organic potatoes are sold fresh. Organic growers typically receive a significant price premium when they can sell their potatoes as organic (Dufour *et al.*, 2009); however, that market is not always available (Esplin, 2009). The organic potato market is not highly structured (Dufour *et al.*, 2009). At least one manufacturer produces organic potato chips (Foods, 2009)

3. ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of Simplot Innate™ Potato. To respond favorably to a petition for nonregulated status, APHIS must determine that Simplot Innate™ Potato is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2013a), APHIS has concluded that Simplot Innate™ Potato is unlikely to pose a plant pest risk. Therefore APHIS must determine that Simplot Innate™ Potato is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

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

3.1 No Action Alternative: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. Simplot Innate™ Potato and progeny derived from Simplot Innate™ Potato would continue to be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of Simplot Innate™ Potato 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 Simplot Innate™ Potato.

This alternative is not the Preferred Alternative because APHIS has concluded through a Plant Pest Risk Assessment that Simplot Innate™ Potato is unlikely to pose a plant pest risk (USDA-APHIS, 2013a). 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 Simplot Innate™ Potato Is No Longer a Regulated Article

Under this alternative, Simplot Innate™ Potato and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. Simplot Innate™ Potato is unlikely to pose a plant pest risk (USDA-APHIS, 2013a). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of Simplot Innate™ Potato and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that Simplot Innate™ Potato is unlikely to pose a plant pest risk, a determination of nonregulated status of Simplot Innate™ Potato is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Under this alternative, growers may have future access to Simplot Innate™ Potato and progeny derived from this event if the developer decides to commercialize Simplot Innate™ Potato.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for Simplot Innate™ Potato. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for Simplot Innate™ Potato. 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 Simplot Innate™ Potato 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 Simplot Innate™ Potato, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that Simplot Innate™ Potato is unlikely to pose a plant pest risk (USDA-APHIS, 2013a).

In enacting the PPA, Congress included findings in Section 402(4) that: “decisions affecting imports, exports, and interstate movement of products regulated under this title [i.e., the PPA] shall be based on sound science;”

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee

established principles consistent with Executive Order 13563 to guide agencies in the development and implementation of policies for oversight of emerging technologies such as GE that included the following guidance:

“Decisions 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; . . .”

Consistent with this guidance and based on the findings and scientific data evaluated for the PPRA (USDA-APHIS, 2013a), APHIS concluded that Simplot Innate™ Potato is unlikely to pose a plant pest risk. Therefore, there is no basis in science for prohibiting the release of Simplot Innate™ Potato.

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 Simplot Innate™ Potato is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3.3.3 Isolation Distance between Simplot Innate™ Potato and Non-GE Potato Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating Simplot Innate™ Potato from conventional or specialty potato production. However, because APHIS has concluded that Simplot Innate™ Potato is unlikely to pose a plant pest risk (USDA-APHIS, 2013a), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of Simplot Innate™ Potato based on the location of production of non-GE potato in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' plant pest risk assessment for Simplot Innate™ Potato, there are no geographic differences associated with any identifiable plant pest risks for Simplot Innate™ Potato (USDA-APHIS, 2013a). This alternative was rejected and not analyzed in detail because APHIS has concluded that Simplot Innate™ Potato does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest

provisions of the Plant Protection Act. However, individuals might choose on their own to geographically isolate their non-GE potato production systems from potato or to use isolation distances and other management practices to minimize gene movement between potato fields. Information to assist growers in making informed management decisions for Simplot Innate™ Potato is available from Association of Official Seed Certifying Agencies (AOSCA, 2010).

3.3.4 Requirement of Testing for Simplot Innate™ Potato

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing for GE products in non-GE production systems. APHIS notes there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because Simplot Innate™ Potato does not pose a plant pest risk (USDA-APHIS, 2013a), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for Simplot Innate™ Potato 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 9 includes 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 9. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2013a)
Management Practices		
Acreeage and Areas of Potato Production	Total commercial potato production has increased while land area dedicated to potato has decreased. Based on potato production trends and projections, potatoes will continue to be a major crop in the U.S. for the foreseeable future.	Total acreage dedicated to potato is unlikely to change, but adoption of Simplot Innate™ Potato may reduce acreage dedicated to conventional potatoes.
Agronomic Practices	Agronomic practices will remain the same as used currently.	Unchanged from No Action Alternative
Pesticide Use	Pesticides are currently used to control insects, nematodes, fungi, and weeds.	Unchanged from No Action Alternative
Potato Seed Production	Potato seed is primarily supplied by seed potatoes.	Unchanged from No Action Alternative
Organic Potato Production	Organic potato growers use practices and standards for production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with conventional or GE crops.	Unchanged from No Action Alternative
Environment		

Table 9. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Water Resources	<p>The primary cause of agricultural non-point source pollution is increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Agronomic practices such as crop nutrient management, pest management, and conservation buffers help protect water quality from agricultural runoff. Water usage for irrigation would be expected to continue to increase.</p>	<p>Unchanged from No Action Alternative</p>
Soil Quality	<p>Agronomic practices such as crop type, tillage, and pest management can affect soil quality. Growers will adopt management practices to address their specific needs in producing potatoes. Erosion potential may continue to increase.</p>	<p>Unchanged from No Action Alternative</p>
Air Quality	<p>Agricultural activities such as burning, tilling, harvesting, spraying pesticides, and fertilizing, including the emissions from farm equipment, can directly affect air quality. Aerial application of herbicides may impact air quality from drift, diffusion, and volatilization of the chemicals, as well as motor vehicle emissions from airplanes or helicopters.</p>	<p>Unchanged from No Action Alternative</p>
Climate Change	<p>Agriculture-related activities are recognized as both direct sources of greenhouse gases (GHGs) (e.g., exhaust from motorized equipment) and indirect sources (e.g., agriculture-related soil disturbance, fertilizer production).</p>	<p>Unchanged from No Action Alternative</p>

Table 9. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Animal Communities	Potato fields may be host to many animal and insect species. Many of these animals are typically considered pests and may be controlled by the use of integrated pest management strategies.	Animals consuming Simplot Innate™ tubers may be exposed to increased levels of glutamine, but this is not expected to be detrimental.
Plant Communities	Potatoes are a labor intensive, highly managed crop. Members of the plant community that adversely affect potato production may be characterized as weeds. Weed control is an important aspect of potato production. Potato growers use production practices to manage weeds in and around potato fields.	In the unlikely event of hybridization of Simplot Innate™ Potato with conventional varieties, resulting progeny may contain lowered polyphenol oxidase levels. However, this is not expected to be detrimental. Simplot Innate™ Potato is no weedier than conventional potatoes.
Gene Flow	Since potato is primarily vegetatively propagated, gene flow between cultivars is low. Volunteer potatoes would continue to need to be controlled, although their survival is low.	Simplot Innate™ traits are not expected to increase weediness in potato.
Soil Microorganisms	Abundance and diversity of soil microorganisms in and around potato fields is expected to remain as it is currently.	Unchanged from No Action Alternative
Biological Diversity	The biological diversity in potato fields is lower than in the surrounding habitats.	Unchanged from No Action Alternative
Human and Animal Health		

Table 9. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Risk to Human Health	Glycoalkaloids and patatins would continue to pose a risk to human health. In the case of humans consuming high-temperature cooked potatoes, they would continue to be exposed to acrylamide.	Glycoalkaloid and patatin exposure would continue. For humans consuming high-temperature cooked potatoes, acrylamide levels would be reduced approximately 60-70%, which will benefit human health.
Risk to Animal Feed	Glycoalkaloids would continue to pose a risk to livestock if potato stems and foliage are fed to them, which is not likely.	Unchanged from No Action Alternative.
Socioeconomic		
Domestic Economic Environment	Most potato production is used for food. Market utilization would likely continue as it is currently.	Because of its potential human health benefits (lower acrylamide) and potential reduced wastage (low bruising), Simplot Innate™ Potato may comprise a larger share of the domestic potato market, and may result in increased revenues.
Trade Economic Environment	U.S. potatoes and potato products will continue to play a role in global potato production, and the U.S. will continue to be a supplier in the international market.	The foreign trade impacts associated with a determination of nonregulated status of Simplot Innate™ potatoes are anticipated to be similar to the No Action Alternative. However, import of each specific trait requires separate application and approval by the importing country. If the Simplot Innate™ traits are approved by importing countries, it may make up a larger percentage of potato import markets.
Other Regulatory Approvals		
U.S.	FDA	FDA is currently reviewing Simplot's voluntary consultation submission of February 12, 2013.

Table 9. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Other countries	Countries importing potatoes would continue to do so.	Simplot would need to obtain regulatory approvals from any nations which plan to import Simplot Innate™ Potato.
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	Fully compliant

4 ENVIRONMENTAL CONSEQUENCES

4.1 Environmental Consequences

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, namely taking no action and a determination by the agency that Simplot Innate™ Potato does not pose a plant pest risk. Potential environmental impacts from the No Action Alternative and the Preferred Alternative for Simplot Innate™ Potato are described in detail throughout this section. A cumulative effects analysis is presented for potentially affected environmental concerns. Certain aspects of this product and its cultivation would be no different between the alternatives: those instances are described below.

4.2 Scope of Analysis

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

A cumulative effects analysis is also included for each environmental issue. A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. Examples include breeding Simplot Innate™ Potato with other deregulated events. If there are no direct or indirect impacts identified for a resource area, then there can be no cumulative impacts. Cumulative impacts are discussed in Section 5.

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

Although the preferred alternative would allow for new plantings of Simplot Innate™ Potato to occur anywhere in the U.S., APHIS will limit the environmental analysis to those areas that currently support potato production.

4.3 Agricultural Production of Potato

4.3.1 Acreage and Area of Potato Production

Acreage of potato production has decreased in recent years, whereas potato yields have increased dramatically. Potato acres harvested in the U.S. have ranged between 1.0 and 1.5 million acres

since 1951, with highs of 1.5 million in 1953, 1966 and 1967 and lows of 1.0 million in 2008, 2009 and 2010 (USDA NASS 2012). Per-acre yields, which averaged 397 CWT per acre in 2011 and 401 CWT per acre in 2012 have increased eight-fold since the early 1900s and have doubled since the early 1960s (USDA-NASS, 2013).

No Action Alternative: Acreage and Area of Potato Production

USDA projects potato production will increase by 4.6% between 2012 and 2021 (USDA, 2012). Based upon historical trends in productivity, this increase in supply is unlikely to result in an increase in potato acreage. Therefore, under the No Action alternative, agricultural land used for potato production is expected to remain at approximately the same as at present.

Preferred Alternative: Acreage and Area of Potato Production

If APHIS chooses the Preferred Alternative, some of the Simplot Innate™ Potato events may become commercially available to the general public. Growers who now purchase conventional varieties of Russet Burbank, Ranger Russet and Atlantic potato seed would have the option of purchasing the Simplot Innate™ varieties instead of their conventional counterparts. With the reduction in black spot bruising and lower levels of reducing sugars, the Ranger Russet may gain more market share, partially replacing the Russet Burbank. The lower levels of reducing sugars in the Atlantic potato may result in increased market share for that variety, as well.

However, the introduction of these varieties is not expected to have an impact on overall demand for potatoes. As described in the petition (Simplot, 2013a), the agronomic characteristics of the ten Simplot Innate events are essentially the same as their conventional counterparts, and therefore would be grown in the same way as their conventional counterparts. The ten Simplot Innate™ Potato events do not possess traits that would allow them to be grown in areas other than those where their conventional counterparts are grown. Therefore, under the Preferred Alternative, acreage dedicated to potato would remain about the same.

Simplot's data demonstrate no differences in morphological characteristics and agronomic requirements between Simplot Innate™ Potato and other potato cultivars (Simplot, 2013a) and is not likely to change land acreage or any cultivation practices for potato production. It is expected that similar agronomic practices commonly utilized in commercially available potato cultivars would also be used by growers of Simplot Innate™ Potato.

4.2.2 Agronomic Practices

No Action Alternative: Agronomic Practices

If APHIS chooses the No Action alternative, general production practices are expected to continue as they are now.

Preferred Alternative: Agronomic Practices

The agronomic evaluation of the ten Simplot Innate™ Potato events is summarized in Section 7 of the petition, with details provided in Appendix 6; analysis of disease susceptibility is presented in petition Appendix 8 (Simplot, 2013a). Since all ten Simplot Innate™ Potato events are intended for fry and chip production, agronomic evaluations were conducted in geographically distinct sites that represent most of the main production areas for potatoes destined for fry and chip production in the U.S. (Simplot, 2013a). The agronomic practices and pest control measures employed were location-specific and typical for potato cultivation. They were recommended by both regional potato extension specialists and field agronomists including soil preparation, fertilizer application, irrigation, cultivation and pesticide-based control methods. Events and untransformed varieties received identical inputs and treatments at each site. The following characteristics were evaluated over multi-year trials: time to emergence, vigor, leaf size, leaf curl, vine maturity, disease susceptibility, insect damage, yield and specific gravity. These trials indicated that no changes to current agronomic practices will be needed to grow the potatoes, thus the incorporated traits are not expected to affect agronomic practices. All events considered for deregulation were selected to exhibit comparable phenotypic characteristics to the control varieties when grown using standard industry practices. There were no differences in disease susceptibility that would require additional treatments, nor did the potatoes have different nutrient requirements that would alter fertilizer programs. Planting, cultivation, management and harvesting processes were not affected by the incorporated traits.

APHIS could not identify any significant changes to agricultural or cultivation practices (e.g. pesticide applications, tillage, irrigation, harvesting, etc.) that would result from adoption of the GE crop; therefore, no impact on plant diseases or pests or their management is likely to occur (USDA-APHIS, 2013a).

Based on these analyses, if APHIS chooses the preferred Alternative, there would be no expected differences in general production practices than if the No Action alternative is chosen.

4.2.3 Potato Seed Production

No Action Alternative: Potato Seed Production

If APHIS chooses the No Action Alternative, potato seed production is expected to continue as it is currently.

Preferred Alternative: Potato Seed Production

Since APHIS has determined that agronomic practices will be the same if the petition is approved (USDA-APHIS, 2013a), selection of the Preferred Alternative is not expected to result in any changes in potato seed production.

4.2.4 Organic Potato Production

No Action Alternative: Organic Potato Production

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

The organic sector is rapidly growing both in the U.S. and the European Union (EU). Together, consumer purchases in these two regions made up 95 percent of estimated world retail sales of organic food products in 2003 (Dimitri and Oberholtzer, 2005). In 2009, world retail sales of organic products were estimated to be on the order of \$54.9 billion (USD), up from \$50.9 billion in 2008 (Organic Monitor, 2006).

If APHIS chooses the No Action Alternative, organic potato production is expected to continue, but trends in production may be affected by unpredictable variables such as demand for both fresh and processed organic potatoes, overseas competition and production costs.

Preferred Alternative: Organic Potato Production Practices

Potato cultivar selection and breeding practices are similar between organic and conventional potato production. Risks to organic growers would be most likely to occur with accidental mixing of planting material or of potatoes in farming, transportation, or processing channels. These risks are the same as those that organic growers already experience when keeping their organically grown potatoes separate from potatoes grown with conventional methods. Because potatoes are clonally propagated, the risk of affecting seed supplies through cross-pollination is negligible. Organic farmers routinely plant organic seed potato material and any incidence of cross-pollination in production fields will not affect the harvested potatoes.

If APHIS chooses the Preferred Alternative, organic growers would not be expected to modify production practices, and so no impacts to organic potato production would be expected. Some organic potatoes are grown in the same areas as conventional potatoes and some are grown in more isolated regions. Based on USDA data, organic potato acreage from 1997 to 2008 showed a general increasing trend ranging from a low of 4,335 acres in 1997 to a high of 11,664 in 2007 (USDA-ERS, 2009).

It is important to note that the current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouche, 2006; USDA-AMS, 2010) (USDA-AMS, 2010). However, certain markets or contracts may have defined thresholds (Non-GMO-Project, 2010).

4.3 Physical Environment

4.3.1 Water Resources

No Action Alternative: Water Resources

The majority of potato production utilizes irrigation as a water source. As discussed in Section 2.3.1, agricultural production can be detrimental to water quality by adding sediments from erosion via surface water, and nutrient loading from fertilizers into groundwater.

If APHIS chooses the No Action alternative, water usage for irrigation would be expected to continue. Supplemental irrigation may increase in some areas where potatoes have traditionally been grown without irrigation. Potential for water quality impacts will continue.

Preferred Alternative: Water Resources

No changes to agronomic practices which might affect water resources will be necessary to grow Simplot Innate™ potatoes (Simplot, 2013a). Simplot's studies demonstrate no differences in morphological characteristics and agronomic requirements between Simplot Innate™ Potato and other potato varieties (Simplot, 2013a). Again, as with the No Action Alternative, supplemental irrigation may increase in some areas where potatoes have traditionally been grown without irrigation, and potential for water quality impacts will continue.

A determination of nonregulated status of Simplot Innate™ potatoes is not expected to change the management practices currently employed for potato cultivation. Water quality impacts are expected to be the same under the Preferred Alternative as under the No Action Alternative.

4.3.2 Soil Quality

No Action Alternative: Soil Quality

Increased erosion potential of soil for potato production may result from fairly high tillage requirements, and the small amount of post-crop plant material left in the soil. Cover crops are often planted to help mitigate this potential.

Land management practices for potato production can affect soil quality. While practices such as tillage, fertilization, the use of pesticides and other management tools can improve soil health, they can also cause substantial damage if not properly used. Several concerns relating to agricultural practices include increased erosion, soil compaction, degradation of soil structure, nutrient loss, increased salinity, change in pH, and reduced biological activity (USDA-NRCS, 2001). Methods to improve soil quality include careful management of fertilizers and pesticides; use of cover crops to increase plant diversity and limit the time soil is exposed to wind and rain; and, increased landscape diversity with buffer strips, contour strips, wind breaks, crop rotations, and varying tillage practices (USDA-NRCS, 2006). Living cover also protects against erosion, provides habitat and substrate for soil organisms, and increases soil organic residue inputs (Doran *et al.*, 1996a).

If APHIS chooses the No Action alternative, impacts on soil quality are expected to continue.

Preferred Alternative: Soil Quality

A determination of nonregulation for Simplot Innate™ Potato is not expected to change the management practices currently employed for potato production. If APHIS chooses the Preferred Alternative, potential impacts on soil quality are expected to be similar to those under the No Action Alternative. Bruinsma (Bruinsma *et al.*, 2003) found no differences in soil attributable to a GE potato cultivar (not this trait). Simplot's studies demonstrate that agronomic characteristics and cultivation practices required for Simplot Innate™ Potato production are indistinguishable from practices used to grow other potato varieties (Simplot, 2013a). Except for the incorporated traits, the ten events are substantially equivalent to their conventional counterparts, thus no changes in plant/soil interaction are expected.

If APHIS chooses the preferred alternative, agricultural impacts on soil quality are expected to remain the same as they would if the No Action alternative is chosen.

4.3.3 Air Quality

No Action Alternative: Air Quality

If APHIS chooses the No Action alternative, emissions associated with vehicles, fugitive dust particles and pesticides are expected to continue.

Preferred Alternative: Air Quality

As discussed in Section 2.3.3 Air Quality, emissions associated with crop production include vehicular emissions from the use of farm equipment, fugitive dust particles and releases of pesticides. Fugitive dust can arise from fields and unpaved roadways and can be generated by disturbance of bare soil through vehicle traffic, harvesting operations or wind. These impacts are highly variable across potato growing regions and over time, depending on such factors as vehicle type, crop type, utilization of pesticides, method of application, soil type and weather conditions.

Simplot's analyses presented in its petition (Simplot, 2013a) demonstrate that no changes to agronomic practices will be required to grow Simplot Innate™ Potato. As discussed in Section 2.3.3, agronomic practices that could affect air quality, such as soil preparation, cultivation, pesticide application and harvesting, were based on practices appropriate for each site, and were the same for the events and the controls. The results indicated that no changes from the site-specific practices used for conventional varieties would be needed for production of the ten events.

Therefore, if APHIS chooses the preferred alternative, impacts to air quality resulting from this action are expected to be the same as if the No Action alternative had been chosen.

4.3.4 Climate Change

No Action Alternative: Climate Change

If APHIS selects the No Action Alternative, impacts to climate change are expected to continue.

Preferred Alternative: Climate Change

The range and area of U.S. potato production is not likely to change under the Preferred Alternative. As described in the Simplot petition (Simplot, 2013a) and APHIS PPRA (USDA-APHIS, 2013a), Simplot Innate™ potatoes use identical management strategies to those for conventional potato production. Therefore, no changes are expected in agricultural activities that might affect climate change, such as machine usage and fertilizer application. Collectively, because the range, area, and agronomic practices of potatoes are unlikely to change following a determination of nonregulated status of Simplot Innate™ Potato, the agricultural impacts of potato production on climate change are also unlikely to change under the Preferred Alternative.

4.4. Biological Resources

4.4.1 Animal Communities

No Action Alternative: Animal Communities

If APHIS chooses the No Action Alternative, animal communities living both within and outside of potato fields are expected to continue to experience impacts similar to the current impacts of agriculture. Animals living in or near agricultural fields are the most likely to be affected by crop production, including aquatic communities, which may be affected by sedimentation and turbidity from erosion, or by pesticide runoff.

Preferred Alternative: Animal Communities

No changes in land use are expected if APHIS chooses the preferred alternative. In addition, the evaluation presented in the petition (Simplot, 2013a) demonstrates that changes in agronomic practices, including practices related to pesticide use and erosion mitigation, are not required for production of Simplot Innate™ Potato. In addition, there are a large number of insects that feed on potato leaves and other insects that feed on those pests. Many of these insects, including the Colorado potato beetle, potato aphid, European corn borer, potato leafhopper and potato psyllid are considered pests. The events have not been modified to exhibit any pesticidal activities and do not contain pesticide-expressing genes. No differences were observed for insects or other animals interacting within the potato ecosystem during the field trials, leading to the conclusion that the Simplot Innate™ potatoes would have the same impact on other organisms as conventional potatoes (Simplot, 2013a).

APHIS reviewed Simplot's data on field trials (USDA-APHIS, 2013a) and impacts by insects, and concluded that Simplot Innate™ Potato would suffer no greater insect pressure than

conventional potatoes (USDA-APHIS, 2013a). For example, no increase in aphid infestation or damage was reported in the field observations for all ten Simplot Innate™ Potato events (Simplot, 2013a). Similarly, although aphids are vectors for viruses such as potato virus Y (USDA-APHIS, 2013c), no increase in viral disease was reported in field observations for seven of the events (Simplot, 2013a).

In addition, since potatoes are propagated vegetatively from seed potato tuber pieces, pollination by bumblebees is not important to potato tuber production. Simplot Innate™ Potato has been genetically engineered to silence genes that lead to acrylamide formation and produce PPOs. Acrylamide only forms after cooking potatoes at high heat, so this toxic compound is not expected to be a concern for herbivores. Consumption of PPOs by animals would still occur.

Phenols occur in wide distribution of plants (Felton *et al.*, 1989), but their biological function remains unclear (Bachem *et al.*, 1994) (Mayer, 2006). The oxidation products of PPO appear to play a role in general plant defense mechanisms against pathogens and pests. The relationship between PPO and resistance to herbivores has also been studied. PPO activity increases when potato leaves are wounded and at higher rates in response to regurgitant from the pest Colorado potato beetle (Kruzmane *et al.*, 2002). In other plants, the increase of PPO activity is a direct induced defense against insect pests that decreases nutrient availability (Baldwin and Preston, 1999; Partington *et al.*, 1999). In addition, PPO in glandular trichomes of wild potatoes (and other plants) is involved in resistance to insects (Steffens, 1994) (Plaisted, 1980). However, the trichomes of cultivated potatoes contain low amounts of PPO which is not thought to be involved resistance to pests (Friedman, 1997). Phylogenetic surveys of PPO in land plants shows that the gene family has undergone evolutionary expansion in some plant families, but is reduced or absent in others, which suggests that PPO function is probably diverse (Tran *et al.*, 2012). PPO has also been implicated in other functions such as buffering of plastid oxygen levels, wound healing, and chloroplast metabolism (Steffens, 1994).

In potato, PPO is involved in black spot bruise formation, which reduces the quality of harvested tubers (Bachem *et al.*, 1994; Corsini *et al.*, 1999; Partington *et al.*, 1999) (Partington *et al.*, 1999). PPO oxidizes monophenols and *o*-diphenols to *o*-quinones, which are then further oxidized non-enzymatically to polyphenols. These dark-pigmented polyphenols, also referred to as melanins, result in the darkening of potato tissue following mechanical bruising (Thygesen *et al.*, 1995).

This suggests that Simplot Innate™ Potato is expected to be unchanged relative to PPO gene expression and PPO levels in leaves and therefore unchanged in any potential interactions between potato foliar PPO and foliar pathogens or pests. No consistent differences were observed in foliar pest and pathogens on Simplot potatoes compared to their control varieties (Simplot, 2013a) (USDA-APHIS, 2013a). Simplot did not assess nematode damage of Simplot Innate™ Potato, but Osman *et al.* (Osman *et al.*, 2012) suggest that PPO might be involved in resistance to some plant parasitic nematodes, but do not provide data demonstrating such a role or address the species that affect potatoes. Conversely, lower PPO levels might increase the

resistance of Simplot Innate™ Potato to some nematodes. Other researchers found that tubers of potato cultivars resistant to the potato cyst nematode, *Globodera pallida*, have lower levels of phenols and discolored less than tubers of susceptible cultivars (Mondy *et al.*, 1985). They suggest that PPO-mediated tanning of nematode cysts enables eggs to remain viable in soil for a longer time. Lyon 1989 (Lyon, 1989) reviewed the biochemical basis for resistance of potato to bacterial soft rot caused by *Erwinia* spp. Because it is the dominant monophenol, chlorogenic acid has been a focus in many of these studies. Chlorogenic acid did not inhibit the *in vitro* growth of *Erwinia* spp. or *P. infestans* (the causal agent of late blight), and there remains no proof that phenols are important in the interaction between potato and *Erwinia* spp. (Lyon, 1989).

Kroner et al 2012 (Kroner and Marnet, 2012) evaluated the role of specific phenolics in quantitative resistance to the elicitors of two pathogens, *P. infestans*, the causal agent of late blight, and *Pectobacterium atrosepticum* (synonym: *E. carotovora* subsp. *atroseptica*), the causal agent of bacterial soft rot. Increasing concentrations of total phenolics tended toward a positive correlation with quantity of symptoms due to the late blight pathogen, but were negatively correlated with increased tuber rot severity due to the soft rot pathogen. Because chlorogenic acid accumulates in response to soft rot elicitors, these authors suggest that chlorogenic acid could be used as a marker for resistance to soft rot (Kroner and Marnet, 2012). Since chlorogenic acid is a PPO substrate, silencing of PPO would not be expected to reduce the level of chlorogenic acid in potato tubers.

Although animals would not be exposed to acrylamide, Simplot Innate™ Potato tubers contain increased levels of glutamine (Simplot, 2013a) because the enzyme asparagine synthetase also functions to deaminate glutamine to glutamate (USDA-APHIS, 2013a). In all of the field trials tested by Simplot, these differences were within the 99% tolerance intervals generated from nine non-GE commercial control potato varieties grown concurrently at the same field sites (USDA-APHIS, 2013a). Souba (Souba, 1991) noted that in mammalian cells, glutamine acts as a nitrogen donor for the biosynthesis of important compounds such as nucleotides and amino acid. Consumption of increased glutamine has been tested by some researchers. For example, Wang et al. (Wang *et al.*, 2008) reported that intestinal dysfunction and atrophy were prevented when piglets' diets were supplemented with glutamine. Similarly, Boukhattala et al. (Boukhattala *et al.*, 2010) showed that adding glutamine to rat diets reduced injury to the intestinal mucosa following a course of chemotherapy, and Klimberg et al. (Klimberg *et al.*, 1990) demonstrated that added glutamine protects rat intestinal mucosa following radiation therapy.

There were no significant differences between any of the ten events and their respective control varieties for mean glycoalkaloid toxin content (Simplot, 2013a).

RNAi-mediated gene suppression generally requires sequence homology of at least 90% between the silencing construct and the target sequence to be successful and even higher degrees of homology over 21-23 nucleotide stretches (Sharp, 2001). It is not likely that the genetic construct components responsible for gene silencing in the Simplot events would contribute to silencing of genes in other non-target organisms through direct consumption of pollen by

pollinators or through secondary exposure of beneficial predator or parasitic arthropods or other potential biological control agents for potato pests (Lacey *et al.*, 2001) since sequences from arthropods, bacteria, fungi and viruses are expected to be highly divergent from the sequences used to silence genes in the Simplot potatoes. Furthermore, indirect exposure scenarios are unlikely to lead to impacts to non-target predators and parasitic arthropods since 1) they may not receive effective doses, 2) intracellular amplification of siRNA, the active gene silencing component derived from dsRNA, is not widely found in insects, 3) environmental and physiological conditions in the gut may destroy the RNA, 4) and they may not have the appropriate receptors to allow transmembrane movement of dsRNA or the appropriate enzyme to direct RNAi (e.g. Dicer, Argonaute, RdRP, RNA and DNA helicases)(Lundgren and Duan, 2013).

The introduced genes did not significantly alter the observed insect pest infestation and disease occurrence or resulting damage in Simplot Innate™ Potato relative to the control line under the typical recommended pest management conditions. Therefore, APHIS concludes that based on the compositional similarity of Simplot potato tubers to the parent varieties, the observed interactions of Simplot potatoes with insects and pathogens, and the unlikely impacts of nontarget effects due to RNAi, APHIS concludes that the consumption of or indirect exposure to Simplot tubers or other plant parts is unlikely to have adverse impacts on animals in or near potato fields.

Consumption of Simplot Innate™ Potato is unlikely to substantially affect non-target organisms, such as mammals, birds, or insects. Simplot data demonstrates that the composition of Simplot Innate™ Potato does not substantially differ from conventional potato varieties (Simplot, 2013a). Simplot indicated that they have submitted a safety and nutritional assessment of food and feed derived from Simplot Innate™ Potato to the FDA on February 12, 2013 (Simplot, 2013a). FDA is presently evaluating the submission. There is no evidence that animal exposure to Simplot Innate™ Potato would have any effect or be any less attractive as food, refuge, cover and nesting sites as non GE varieties of potatoes.

4.4.2 Plant Communities

No Action Alternative: Plant Communities

If APHIS selects the No Action Alternative, impacts to plant communities as a result of potato production are expected to continue.

Preferred Alternative: Plant Communities

Simplot has presented the results of field trials which demonstrate that Simplot Innate™ potatoes do not require any changes to agronomic inputs when compared with conventional potatoes(Simplot, 2013a). There would be no change in herbicide use or patterns.

The silencing of acrylamide potential leads to somewhat heightened levels of asparagine in Simplot Innate™ potato, but levels are within acceptable limits (OECD, 1997b). In the very unlikely event of hybridization of Simplot Innate™ potato, resulting progeny may have increased levels of asparagine. Plants use asparagine as a nitrogen source when they are unable to store nitrogen in the form of protein, and can accumulate to very high concentrations (Halford *et al.*, 2012b).

As discussed in Section 4.4.1, Animal Communities, consumption of Simplot Innate™ Potato is not expected to change herbivore-plant interactions.

Under the Preferred Alternative, potential impacts to plant communities are not anticipated to be different compared to the No Action Alternative.

Land use and agricultural production of potatoes under the Preferred Alternative is likely to continue as currently practiced. Consequently, any impact to plant communities as a result of potato production practices under the Preferred Alternative is the same as the No Action Alternative.

4.4.3 Gene Flow and Weediness

No Action Alternative: Gene Flow and Weediness

If APHIS selects the No Action Alternative, there would continue to be little problem with gene flow or weediness for potato.

Preferred Alternative: Gene Flow and Weediness

If APHIS selects the Preferred Alternative, no changes in agronomic practices are expected to occur (USDA-APHIS, 2013a) which might make potato, including Simplot Innate™ Potato more susceptible to gene flow or weediness.

4.4.4 Microorganisms

No Action Alternative: Microorganisms

If APHIS chooses the No Action Alternative, potato crop interactions with microorganisms are expected to remain the same.

Preferred Alternative: Microorganisms

The evaluation presented in the petition (Simplot, 2013a) demonstrates that changes in agronomic practices, including practices related to soil preparation (which may impact soil organic material and pH) and to pesticide application (which may directly impact microorganisms), would not be required for production of the ten Simplot Innate™ Potato events. In addition, the ten Simplot Innate™ Potato events are substantially similar to their

conventional counterparts. Simplot Innate™ Potato would therefore be expected to have the same interactions with soil microorganisms.

A safety assessment of mice fed a diet of GE non-browning potatoes showed no adverse effects in mouse gut microbiota (Llorente *et al.*, 2011).

Based on these results, if APHIS chooses the preferred alternative, impacts to microorganisms resulting from this action are expected to be the same as if the No Action Alternative is chosen.

4.4.5 Biodiversity

Potato biodiversity can be enhanced by the introduction of new genetic material from the large number of existing genetic resources available.

No Action Alternative: Biodiversity

If APHIS chooses the No Action alternative, increases in potato productivity are expected to continue to offset increased demand, resulting in a fairly constant acreage devoted to potato production in the U.S. This will allow for continued biodiversity outside the borders of agricultural fields. Biodiversity is expected to continue to be fairly low within agricultural fields.

Preferred Alternative: Biodiversity

The evaluation presented in the petition (Simplot, 2013a) demonstrates that changes in agronomic practices would not be required for production of the ten events. Based on these results, if APHIS chooses the Preferred Alternative, any impacts to biodiversity would be expected to be the same as if the No Action Alternative is chosen.

In addition, if APHIS chooses the Preferred Alternative, potato diversity will be enhanced by the introduction of the new events.

Under the Preferred Alternative, cultivation, management, and land-use decisions related to Simplot Innate™ potatoes are not different from conventional potato cultivars. Agronomic practices associated with potato such as cultivation, irrigation, pesticide application, fertilizer applications and agriculture equipment would be unchanged. Animal and plant species that typically inhabit potato fields will continue to be affected by currently used management plans and systems, which include the use of mechanical, cultural, and chemical control methods. The consequences of current agronomic practices associated with potato production on the biodiversity of plant and animal communities are unlikely to be altered.

Consequently, any impact to biodiversity as a result of potato production practices under the Preferred Alternative is likely to be identical to the No Action Alternative.

4.4.6 Human Health

Potato is primarily grown for human consumption. U.S. per capita potato consumption is approximately 112 pounds per year. Of this, approximately 65 pounds is used for frozen fries or

chips. Per capita consumption data are shown in Table 6. As discussed in Section 2.5, potential toxins in potatoes are acrylamide, which forms subsequent to high-temperature cooking, and glycoalkaloids. Patatin is allergenic to a very small percent of children.

No Action Alternative: Human Health

Under the No Action alternative, consumption of potatoes would be expected to continue at the same rate as currently. Consumers will continue to be exposed to similar levels of acrylamide in cooked potatoes if other methods are not employed to reduce levels. Glycoalkaloids would be expected to remain at sufficiently low levels such that health impacts would not occur. Patatin would remain a concern for allergic individuals.

Preferred Alternative: Human Health

If APHIS chooses the Preferred Alternative, and Simplot Innate™ Potato is widely adopted, acrylamide content in cooked potatoes should be significantly reduced, leading to health benefits for consumers. Compared with conventional potatoes, Simplot Innate™ Potato contains, on average, 58 to 72 percent less acrylamide when cooked (NTP, 2011; Simplot, 2013a). As discussed in Section 2.2.6, Human Health, the State of California listed acrylamide as a potential carcinogen under Proposition 65 in 1990 and established a No Significant Risk Level (NSRL) of 0.2 µg/day (CEPA-OEHHA, 2005), which was later revised to 1.0 µg/day (CEPA-OEHHA, 2005). The FDA is considering issuing guidance concerning safety of acrylamide (FDA, 2009), and in 2013, published (FDA, 2013b) recommendations that health-conscious consumers may want to avoid the consumption of fried potato products. Especially since American consumption of French fries is high (USDA-NASS, 2012c), these developments regarding acrylamide safety may lead to processor preference for Simplot Innate™ Potato in French fries and other frozen potato products.

The data presented in the petition shows that the Simplot Innate™ Potato events are at least as safe and nutritious for food as the untransformed controls (Simplot, 2013a). The compositional analyses of the ten events are summarized in the petition, with detailed results in Appendix 9 (Simplot, 2013a). The compositional assessments determined the amounts of 1) moisture, protein, total fat, ash, crude fiber, carbohydrate and calories; 2) vitamins B6, B3 and C; 3) minerals copper, magnesium and potassium; 4) glycoalkaloids; 5) free amino acids; and 6) total amino acids for tubers collected from events grown in 2009, 2010, and 2011 in potato-growing areas of the United States. Observed changes in ASN and reducing sugars accomplished through transformation of various potato varieties resulted in lower acrylamide levels in French fries and potato chips. These modifications did not alter the quality of potato as food because all results fell within normal ranges for potato. In addition, the research confirmed that glycoalkaloid levels were unchanged compared with the control varieties.

The potato events described in this petition are no different compositionally compared to untransformed controls, except for the intended traits. Therefore, issues with allergies would not be expected to exist beyond what individuals with potato allergies would normally experience. The National Academy of Sciences (NAS) has ranked methods of genetic modification according to the relative likelihood of unintended effects, such as the increase in a plant's

production of certain allergens. The NAS considered methods that involve recombinant DNA via *Agrobacterium* transfer of genes from closely related species (the Simplot Innate™ method used to produce these ten events is one such method that does not involve the transfer of genes) to be among the methods least likely to have unintended effects – less likely than conventional pollen-based crossing of closely related species – and far less likely than methods such as ionizing radiation and chemical mutagenesis, which are not subject to regulation and are not excluded methods under the NOP (Sciences, 2004).

Worker Safety

No Action Alternative: Worker Safety

If APHIS were to choose the No Action alternative, farm workers would continue to be exposed to the same kinds of hazards as they are currently.

Preferred Alternative: Worker Safety

There will be no changes in agronomic practices in order to produce Simplot Innate™ Potato. If APHIS chooses the preferred alternative, impacts to worker health resulting from approval of the petition are expected to be the same as if the No Action Alternative is chosen.

Under the Preferred Alternative, cultivation practices and corresponding worker exposures to agronomic inputs are unlikely to change. Simplot demonstrates in its petition that the agronomic inputs required to cultivate Simplot Innate™ Potato are functionally equivalent to those required for conventional potatoes (Simplot, 2013a). Accordingly, the health and safety protocols currently employed by farm workers in the production of potatoes do not require changes to accommodate the production of Simplot Innate™ potatoes.

Based on these findings, APHIS has determined that approval of a petition for nonregulated status of Simplot Innate™ Potato will not impact worker safety.

4.4. 7 Animal Feed

No Action Alternative: Animal Feed

As discussed in Section 2.6, *Animal Feed*, a small portion of the potato crop and waste from processing are sold as livestock feed. If APHIS selects the No Action Alternative, a small percent of the potato crop would continue to be used for livestock feed.

Preferred Alternative: Animal Feed

The compositional analyses of the ten Simplot Innate events are summarized in Section 8 of the petition, with detailed results in Appendix 9 (Simplot, 2013a).

In conclusion, the data presented in the petition shows that potatoes from the events are as safe and nutritious for feed as the untransformed controls, and if APHIS were to choose the preferred

alternative, the use of potatoes as livestock feed would be no different than if the No Action alternative was chosen.

4.5 Socioeconomic Impacts

4.5.1 Domestic Economic Environment

No Action Alternative: Domestic Economic Environment

The domestic economic environment is discussed in Section 2.7, Socioeconomic: Domestic Economic Environment, and potato utilization in the U.S. is summarized in Table 8. Potatoes are grown on approximately 1.1 million acres in the U.S., with an annual value of approximately \$3.5 billion. Major products include fresh potatoes, frozen fries and chips. Organic potatoes account for less than one percent of the market.

If APHIS chooses the No Action alternative, domestic potato production, including organic production, is expected to continue at rates similar to the present. The USDA projects an approximate 4.6% increase in production between 2012 and 2021 (USDA, 2012).

Preferred Alternative: Domestic Economic Environment

If APHIS chooses the Preferred Alternative, the ten Simplot Innate™ Potato events will become available for commercial production. Because of the reduced black spot bruise of Simplot Innate™ Potato, it is expected that wastage will decrease significantly, and therefore, revenues will increase. Consumers are likely to be willing to pay a premium for a healthier food product (such as reduced acrylamide and black spot bruise) developed by methods of biotechnology which use no foreign DNA (Huffman, 2010); (Colson *et al.*, 2011). Overall, if APHIS chooses the Preferred Alternative, the introduction of Simplot Innate™ events are likely to have positive economic impacts, recognizing that some additional costs could be incurred, and as discussed in Section 4.1, no impacts on organic production are expected.

Potatoes with low acrylamide potential and reduced black spot bruise are expected to have higher market value for the same inputs, representing potential increased revenue for growers and processors, and an overall increase in the value of potato production. The initial crop introduction will build up slowly as seed becomes available and will be controlled within existing processing channels to ensure that potatoes enter only the intended markets. This will provide a period of time to assess consumer acceptance and to address grower and industry concerns. A limited introduction that is initially in a vertically integrated supply chain will be well controlled by grower and processor agreements. In this situation, conventional products will be considered “identity preserved” with respect to the well-controlled stewardship of the potato event(s) and its products. As adoption of the potato events increases, programs for identity preservation will be implemented as needed. It is expected that development and implementation of identity preservation systems will add some cost to the supply chain; the total costs will depend upon the type and extent of market penetration (Simplot, 2013a).

4.5.2 Trade Economic Environment

As discussed in Section 2.7, *Socioeconomic: Trade Economic Environment*, the U.S. exports more than \$1 billion in potato products annually, primarily consisting of frozen fries and other processed potatoes. Demand from Canada, Mexico and Asia is driving growth in exports. Japan is the largest market for U.S. exports of frozen potatoes, while Canada is the largest U.S. export market for chips and fresh potatoes. The U.S. also has substantial imports of potatoes and potato products from Canada and Mexico (USDA-ERS, 2012a).

No Action Alternative: Trade Economic Environment

If APHIS chooses the No Action alternative, U.S. potato exports are expected to continue.

Preferred Alternative: Trade Economic Environment

If APHIS chooses the preferred alternative, U.S. potato exports are expected to continue. Approval for the events will be sought in Canada, Japan and Mexico (Simplot, 2013) prior to commercial production beginning in the U.S.

Previous recalls of potato products that were shipped to Japan and then found to contain genetically modified material were related to unapproved events; Japan has zero tolerance for unapproved events (Reuters, 2001). To assist in the prevention of trade disruptions, as has been experienced with other potato events, international approvals will be pursued from key trading partner countries prior to beginning commercial production in the U.S. Simplot intends to follow the recommended stewardship policy statement released by the Biotechnology Industry Organization in May 2007:

To help ensure the continued adoption of agricultural biotechnology globally and to continue to have products of agricultural biotechnology bring value to the marketplace, BIO's Food and Agriculture Section supports actions that facilitate the flow of goods in commerce and minimize trade disruptions. BIO's Food and Agriculture Section believes that henceforth individual member companies should, prior to commercialization meet applicable regulatory requirements in key countries identified in a market and trade assessment that have functioning regulatory systems and are likely to import the new biotechnology-derived plant products.

The voluntary guideline was adopted because, according to BIO "asynchronous authorizations combined with importing countries maintaining 'zero tolerance' for recombinant-DNA products not yet authorized results in the potential for major trade disruptions. The potential occurrences of trade disruptions will only increase given the substantial amount of research that will bring many new products and combinations of products to market."

In addition, compared to some biotech crops, the Simplot Innate™ Potato is expected to be viewed more favorably by regulatory organizations due to the lack of pesticidal traits and marker-free transformation methods, and therefore have fewer implications for export markets. In any case, these approvals should ensure continued trade with key export markets.

If APHIS chooses the preferred alternative, as with the domestic economic environment, the introduction of these potato events may have positive economic impacts on export markets, recognizing that some additional costs could be incurred. Impacts to export markets will be mitigated by approvals in key trading countries such as Japan, Canada, and Mexico.

5 CUMULATIVE IMPACTS

A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. For example, the potential effects associated with a determination of nonregulated status for a GE crop in combination with the future production of crop seeds with multiple deregulated traits (i.e., “stacked” traits), including drought tolerance, herbicide tolerance, and pest resistance, would be considered a cumulative impact.

Regulations promulgated by the Council on Environmental Quality (CEQ) under the National Environmental Policy Act (NEPA) define cumulative impact as “the impact on the environment which results from the incremental impact of the action when added to other past, present and reasonably foreseeable future actions” (40 CFR 1508.7). For example, the potential effects associated with a determination of nonregulated status of a GE crop in combination with the future production of crop plants with multiple traits that are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the Plant Protection Act, including disease tolerance, nitrogen utilization, and herbicide tolerance, would be considered a cumulative impact.

5.1 Assumptions Used for Cumulative Impacts Analysis

Cumulative effects have been analyzed for each environmental issue assessed in Section 4, Environmental Consequences. 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. In this analysis, if there are no direct or indirect impacts identified by a resource area, then APHIS assumes there can be no cumulative impacts. APHIS provides a qualitative assessment of potential cumulative impacts. APHIS considered the potential for Simplot Innate™ Potato to extend the range of potato production and affect the conversion of land to agricultural purposes. Simplot’s studies demonstrate that agronomic characteristics and cultivation practices required to produce Simplot Innate™ Potato are indistinguishable from practices used to grow conventional potatoes (Simplot, 2013a; USDA-APHIS, 2013a). This implies that its cultural requirements would neither differ from other potatoes nor change the areas where potatoes are currently grown. If the petition is approved, Simplot Innate™ Potato could replace other commercially available potato cultivars, without requiring production of new, natural lands. As such, land use changes associated with approving the petition are not expected to be any different than those associated with conventional potato production. APHIS focused the analysis of cumulative impacts on the areas in the U.S. that currently produce potatoes.

Potential reasonably foreseeable cumulative effects are analyzed under the assumptions that growers have used in the past and would continue to use reasonable, commonly accepted best management practices (BMPs) for their chosen system and cultivars during potato production. APHIS recognizes, however, that not all growers will use such BMPs. Thus, the cumulative impact analysis will make the assumption that not all growers would do so.

5.2 Past and Present and Reasonably Foreseeable Actions

The Preferred Alternative is not expected to directly cause a measurable change in agricultural acreage or area devoted to potato production in the U.S. Because Simplot Innate™ Potato is another potato cultivar that is agronomically and compositionally similar to other commercially available potato cultivars, it is expected that Simplot Innate™ Potato would replace other similar cultivars without expanding the acreage of area devoted to potato production. There are also no anticipated changes to the availability of non-GE potato cultivars on the market.

Approving the petition for a determination of nonregulated status for Simplot Innate™ Potato is not expected to result in changes to current potato production practices. Studies conducted by Simplot demonstrate that agronomic characteristics and cultivation practices required for Simplot Innate™ Potato are indistinguishable from practices used to grow other potato cultivars (Simplot, 2013a; USDA-APHIS, 2013a). Consequently, no changes to current potato production practices associated with the adoption of Simplot Innate™ Potato are expected.

Organic growers use common practices to maintain the organic status of their potatoes including employing adequate isolation distances between the organic potato field and the fields of neighbors to minimize the chance that pollen will be carried between the fields. Given the importance of maintaining varietal traits and consumer recognition and preference for specific potato cultivars, the separation of production and processing of potatoes by cultivars have been utilized by growers, packers and retailers in the United States market to satisfy consumer preference and demand. Availability of another potato cultivar, such as Simplot Innate™ Potato, under the Preferred Alternative, is not expected to impact the organic production of potatoes any differently than other potato cultivars currently being grown.

Based on the information described in Section 4.5.1, Domestic Trade Environment, APHIS concludes that a determination of nonregulated status of Simplot Innate™ Potato will have no foreseeable adverse cumulative effects on domestic commerce. Simplot Innate™ Potato has the potential to improve potato processing capabilities and also improve the economics of potato processing and consumer nutrition. There may also be a reduction in cost of processing associated with a reduction in potato browning and in providing alternatives to conventional technologies to prevent browning. Based on these factors, no net negative cumulative impacts on domestic economics have been identified associated with the production of Simplot Innate™ Potato.

Approving the petition for a determination of nonregulated status to Simplot Innate™ Potato would have the same impacts to water, soil, air quality, and climate change as that of potato cultivars currently available. Agronomic practices that have the potential to impact soil, water and air quality, and climate change would not change because Simplot Innate™ Potato is

agronomically similar to other potato cultivars. Because of its similarity to other potato cultivars, adoption of Simplot Innate™ Potato is expected to replace other similar cultivars without changing the acreage or area of potato production that could impact water, soil, air quality, and climate change. Cumulative impacts due to climate change would be the same for Simplot Innate™ events and conventional potatoes. Potato production in the United States has a fairly small production footprint (approximately 1 million acres,(USDA-NASS, 2012b)) when compared to row crops like corn (approximately 97 million) and soybeans (approximately 86 million acres). Considering the production acres, potatoes, including the Simplot Innate™ Potato varieties, will have less impact on climate change than the higher acreage crops.

Cumulative impacts of the Preferred Alternative to microorganisms and biodiversity would not be significantly different than that experienced under the No Action Alternative. Simplot Innate™ Potato is agronomically and compositionally similar to other potato cultivars. Cumulative impacts to plant communities resulting from gene flow or weediness potential would be the same for Simplot Innate™ Potato events and conventional potatoes. Multiple years of field data as well as compositional analysis show that Simplot Innate™ Potato events are agronomically equivalent to conventional potatoes. Also, no changes were observed in land use or agronomic inputs including pesticides and herbicides. Gene flow from potatoes whether biotech or conventional is unlikely due to the cropping practices of rotation and the clonal propagation of potato varieties in U.S. agriculture. Thus, it would not require any different agronomic practices to produce, and does not represent a safety or increased weediness risk that is any different from other currently available potatoes. There are no differences in the potential for gene flow and weediness under the Preferred Action Alternative. Outcrossing and weediness are addressed in the PPRA (USDA-APHIS, 2013a). Simplot Innate™ Potato is similar to other potato cultivars. The risk of gene flow and weediness of Simplot Innate™ Potato is no greater than that of other potato cultivars.

Cumulative impacts to animal communities would be the same for Simplot Innate™ Potato events and conventional potatoes. Three years of field data as well as compositional analysis and molecular stability show that Simplot Innate™ Potato events are equivalent to conventional potatoes. Even in cases where asparagine was lower (for reducing acrylamide), the levels were still within the combined literature ranges. In addition, no changes were observed in land use or agronomic inputs including pesticides. These data show that there is the same impact (and expected cumulative impacts) on non-target animals or animal communities within the potato agroecosystem for Simplot Innate™ events as the conventional potatoes (Simplot, 2013a). Animals consuming Simplot Innate™ Potato may be exposed to increased levels of glutamine, but research on dietary supplementation with glutamine has not had any negative animal health effects.

Cumulative effects on human consumer health are expected to be the same for Simplot Innate™ Potato events and conventional potatoes, with one exception: the Simplot Innate™ Potato contains significantly less acrylamide-forming potential than conventional potatoes. This should result in significant human health benefits, particularly for those with a diet high in French fries and other baked and/or fried potato products. Compared with the conventional varieties, Simplot Innate™ Potato contained on average 58 to 72 percent less acrylamide (Simplot, 2013a). Adoption of these potatoes could result in a significant reduction in dietary intake of acrylamide

and decrease exposure to this naturally occurring substance found to cause cancer in laboratory animals (NTP, 2011).

In addition, glycoalkaloid levels in Simplot Innate™ Potato were unchanged compared with the control varieties (Simplot, 2013a). Although patatin was not measured during the studies, total protein did not differ between Simplot Innate™ and conventional potatoes and it was concluded that any potential allergy to patatin would be the same.

Cumulative impacts to worker safety would be expected to be the same for Simplot Innate™ Potato events and conventional potatoes.

Similarly, Simplot Innate™ Potato is not expected to have any adverse effects on livestock.

Simplot submitted a safety and nutritional assessment of food and feed derived from Simplot Innate™ Potato to the FDA on date February 12, 2013 (BNF No. 141). FDA is presently evaluating the submission. No change in food and feed safety is expected to occur under the Preferred Alternative.

Cumulative impacts on the domestic economic environment would be similar for Simplot Innate™ Potato events and conventional potatoes, although some economic impact is expected because of the benefits of the new potatoes. These events grow similarly and have similar biochemical composition to conventional potatoes, however, the low acrylamide, reducing sugars, and black spot bruise traits add value that could increase the price received for these potatoes. Potatoes with low acrylamide potential and reduced black spot bruise are expected to have higher market value for the same inputs, representing potential increased revenue for growers and processors, and an overall increase in the value of potato production.

Cumulative impacts to the trade economic environment would be similar for Simplot Innate™ events and conventional controls, although some economic impact is expected because of the benefits of the new potatoes. The U.S. exports more than \$1 billion in potato products annually, primarily consisting of frozen fries and other processed potatoes (Council, 2013). Japan is the largest market for U.S. exports of frozen potatoes, while Canada is the largest U.S. export market for chips and fresh potatoes (Council, 2013).

Introduction of Simplot Innate™ Potato will require channeling of the new potatoes into the desired markets. The careful supply chain introduction would be similar to all potato variety management systems already in place for product purity. It is expected that development and implementation of identity preservation systems will add some cost to the supply chain; the total costs will depend upon the type and extent of market penetration (Simplot, 2013a). The Simplot Innate™ Potato could have cumulative economic impacts on the domestic potato market and procedures will be developed to manage product purity in the supply chain.

Upon introduction, procedures will be implemented to prevent unintended mixing of Simplot Innate™ with conventional potatoes as part of the stewardship program. In addition, Simplot is seeking international regulatory approvals in areas such as Japan and Mexico for import approval. Also, approval in Canada is being sought for import and cultivation. Approval in these key trading countries will minimize market disruption should a low level presence of Simplot

Innate™ potatoes be found in the market from accidental mixing. In conclusion, the Simplot Innate™ potatoes could have cumulative trade economic impacts on the potato export market and procedures will be developed to manage product purity in the supply chain.

In conclusion, Simplot Innate™ Potato may offer protection against black spot bruise, slight changes in reducing sugars, and reduced acrylamide potential. During processing, potatoes are routinely culled out due to black spot bruise when making French fries or potato chips, however, with Simplot Innate™ Potato, fewer potatoes will be lost to black spot bruise, resulting in less waste. As a result, there could be increases in yield, with associated positive environmental impacts related to land use and agricultural inputs. For the purposes of the cumulative impacts discussion, however, it is assumed conservatively that land use and inputs would potentially decline or remain the same, and are unlikely to increase. Reduced levels of acrylamide in cooked potatoes will benefit human health.

6 THREATENED AND ENDANGERED SPECIES

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

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

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

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

Section 7 (a)(2) of the ESA requires that federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is "not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat." It is the responsibility of the federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or designated critical habitat. To facilitate their ESA consultation requirements, APHIS met with the USFWS from 1999 to 2003 to discuss factors

relevant to APHIS' regulatory authority and effects analysis for petitions for nonregulated status and developed a process for conducting an effects determination consistent with the Plant Protection Act (PPA) of 2000 (Title IV of Public Law 106-224). APHIS uses this process to help fulfill its obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

APHIS met with USFWS officials on June 15, 2011, to discuss whether APHIS has any obligations under the ESA regarding analyzing the effects of herbicide use associated with all GE crops on TES. As a result of these joint discussions, USFWS and APHIS have agreed that it is not necessary 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 pesticides used by potato growers. Under APHIS' current Part 340 regulations, APHIS only has the authority to regulate the Innate™ Potato or any GE organism as long as APHIS believes they may pose a plant pest risk (7 CFR § 340.1). APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of herbicides or other pesticides on those organisms.

After completing a plant pest risk analysis, if APHIS determines that seeds, plants, or parts thereof from Simplot Innate™ Potato do not pose a plant pest risk, then these articles would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR Part 340, and therefore, APHIS must reach a determination that these articles are no longer regulated. As part of its EA analysis, APHIS is analyzing the potential effects of these potato events on the environment including, as required by the ESA, any potential effects to threatened and endangered species and critical habitat. As part of this process, APHIS thoroughly reviews the GE product information and data related to the organism (generally a plant species, but may also be other genetically engineered organisms). For each transgene/transgenic plant, APHIS considers the following:

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

In following this review process, APHIS, as described below, has evaluated the potential effects that a determination of nonregulated status of the potato events may have, if any, on federally-

listed TES species and species proposed for listing, as well as designated critical habitat and habitat proposed for designation.

Based upon the scope of the EA and production areas identified in the Affected Environment section of the EA, APHIS reviewed the USFWS list of TES species (listed and proposed) for each state where potato is commercially produced from the USFWS Environmental Conservation Online System (ECOS; as accessed February 19, 2014 at http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp), (USDA-APHIS, 2014c; 2014a). Prior to this review, APHIS considered the potential for Simplot Innate™ Potato to extend the range of potato production and also the potential to extend agricultural production into new natural areas. APHIS has determined that agronomic characteristics and cultivation practices required for Simplot Innate™ Potato are essentially indistinguishable from practices used to grow other potato varieties (USDA-APHIS, 2013b; 2013a),(Simplot, 2013a). Simplot Innate™ Potato may be expected to replace other varieties of potato currently cultivated, and APHIS does not expect the cultivation of Simplot Innate™ Potato to result in new potato acres to be planted in areas that are not already devoted to agriculture. Accordingly, the issues discussed herein focus on the potential environmental consequences of the determination of nonregulated status of Simplot Innate™ Potato on TES species in the areas of the US where potatoes are currently grown.

JR Simplot has used a genetic engineering approach to introduce into the background of commercial potato cultivars two traits that are of interest to potato consumers, producers and processors: reduced acrylamide potential in certain processed or heated potato products and reduced black spot bruise (Simplot, 2013a; Simplot, 2013b). Simplot used the single construct pSIM1278 to transform 5 different commercial parent varieties and created the ten events described in the petition. The objective was to incorporate the same new phenotypes into each of these important varieties, while maintaining all of the desirable characteristics originally selected by potato breeders (Simplot, 2013a). Unlike most GE agricultural products that have been commercialized to date, the transformation in this instance does not result in production of proteins. The inserted DNA contains silencing cassettes that, when expressed, generate variably-sized and unprocessed transcripts. These transcripts trigger the degradation of mRNAs that would normally code for an enzyme, like asparagine synthetase. This results in much reduced levels of the targeted “silenced” enzymes (Simplot, 2013a). As described in the petition and PPRA, the potato lines were transformed to silence four different genes in potato: asparagine synthetase-1 (*Asn1*), polyphenol oxidase-5 (*Ppo5*), potato phosphorylase L (*PhL*) and the starch-associated R1 gene (*RI*). The suppression of *Asn1* results in potatoes with reduced free asparagine, and the suppression of *PhL* and *RI* results in potatoes with a lower content of reducing sugars. Collectively, the silencing of these 3 genes should result in potato tubers with a reduced acrylamide potential. The suppression of *Ppo5* confers the Simplot Innate™ Potato with a non-browning phenotype resulting in tubers with reduced black spot bruising(Simplot, 2013a), (USDA-APHIS, 2013b).

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

For its analysis of effects on TES animals, APHIS focused on the implications of exposure to Simplot Innate™ Potato, and the potential for an effect resulting from the gene silencing activity that sets Simplot Innate™ Potato apart from other potato lines currently in production.

Potential Effects of Simplot Innate™ Potato on TES and Critical Habitat

Threatened and Endangered Plant Species and Critical Habitat

The agronomic and morphologic characteristics data provided by JR Simplot were used in the APHIS analysis of the weediness potential for Simplot Innate™ Potato, and further evaluated for the potential to impact TES and critical habitat. Agronomic studies conducted by JR Simplot over several years tested the hypothesis that there would be no change in agronomic practices used to produce Simplot Innate™ Potato in comparison with conventional potato (Simplot, 2013a; Simplot, 2013b). Agronomic evaluations were conducted in geographically distinct sites selected to represent most of the main production areas for each of the five varieties. Characteristics evaluated included time to emergence, vigor, leaf size, leaf curl, vine maturity, disease susceptibility, insect damage, yield, specific gravity, and abiotic stressors (frost, hail, heat, herbicide, and wind) (Simplot, 2013b). Five events (F37, E12, E24, G11 and H37) had statistically significant increased plant vigor, but the relative difference was small. Five events (F10, F37, E24, G11 and H37) had significant reductions in total yield. There was no obvious correlation between decreased yield and increased disease or pest stress except possibly for event G11, since greater insect stress was observed than in the parental control at four of 48 insect observations on this event. Event J55 had significantly reduced early emergence (Simplot, 2013a). However, no differences were detected between the transformed potato lines and conventional potato in growth, reproduction, or interactions with pests and diseases, that would indicate a significant change in agronomic practices would be necessary for the commercial production of these transformed lines (Simplot, 2013a).

Potatoes are not known to be weedy or persistent; they are incapable of survival outside of cultivation (Holm *et al.*, 1979), (Love, 1994b), (Muenscher, 1980a), (OECD, 1997a; 1997b). Potato tubers have a fairly low frost tolerance; shallow tubers and those exposed to the surface are often destroyed by frost, but in temperate climates up to 20% of tubers left in the soil show no dormancy and will sprout the next season (Andersson and de Vicente, 2010). Volunteer potatoes, growing from overwintered tubers, can be a weed problem in the following crop but are easily controlled with cultivation and herbicides and do not persist as weeds for more than a few years (Andersson and de Vicente, 2010).

The data presented by Simplot demonstrate that Simplot Innate™ Potato is, for the most part, phenotypically and agronomically similar to the respective parent varieties and do not exhibit meaningful changes in characteristics that would make them weedier or more persistent than their respective parent varieties (Simplot, 2013a). Because of the reductions in emergence and yield, some of the Simplot Innate™ Potato events appear to have a reduced potential for weediness (USDA-APHIS, 2013a). Furthermore, JR Simplot did not observe any differences during the completed post-harvesting volunteer monitoring of the Simplot Innate™ Potato field test sites from 3 years of field testing that would indicate that these potatoes have properties that

would increase their survivability compared to conventional potatoes. Volunteers were rarely observed, were easily controlled, and are not engineered for resistance to herbicides (Simplot, 2013a). Based on the agronomic field data and literature survey concerning weediness potential of the crop, APHIS has determined that the Simplot Innate™ Potato is unlikely to persist as a troublesome weed or to have an impact on current weed management practices (USDA-APHIS, 2013a).

APHIS evaluated the potential of Simplot Innate™ Potato to cross with native plants and listed species, and the possibility that such crosses could result in hybrids that could affect critical habitat. As discussed thoroughly in sections 2.4.3 and 4.4.3 Gene Flow and Weediness, APHIS has determined that there is little risk of gene flow to related plant species and no risk to unrelated plant species from the cultivation of Simplot Innate™ Potato. The events derived from Russet Burbank produces few flowers and is male sterile, and those derived from variety “H” are completely sterile (Simplot, 2013a; Simplot, 2013b). The events derived from Ranger Russet, Atlantic, and “G” are likely to produce fertile pollen, but this should have little consequence in regards to gene flow to related plants. Among native *Solanum* spp. in the US, cultivated potato is potentially sexually-compatible only with two tuber-bearing species, *S. jamesii* and *S. stoloniferum* (previously *S. fendleri* (Spooner *et al.*, 2004a; Spooner *et al.*, 2004b)). These two species are found only in Texas, New Mexico, and Arizona, and *S. jamesii* is further found in Colorado and Utah. In some cases these species are found in counties with commercial potato production (Simplot, 2013a), (USDA-NRCS, 2013b; 2013a), (USDA-NRCS, 2013a; 2013b). As discussed thoroughly in the PPRA, numerous biological and geographic obstacles make gene flow from these cultivated potato varieties to the two wild relatives a highly unlikely occurrence, and there have been no reports that such crosses have ever occurred naturally (Love, 1994a; Love, 1994b), (US-EPA, 2011b; 2011c). However, because it is scientifically plausible that cultivated potatoes could hybridize with *S. stoloniferum*, the PPRA considered the potential impact on the weediness of *S. stoloniferum* if gene introgression from Simplot Innate™ Potato were to occur. The resulting analysis concluded that the novel phenotypes (low acrylamide potential and reduced black spot bruise) did not impart any significant change in the agronomic properties or response to biotic or abiotic stresses that would cause them to be more weedy (USDA-APHIS, 2013b; 2013a).

A review of the USFWS database of listed species indicates that there are three species of the Solanaceae family in the genus *Solanum* that are listed as endangered. Aiakeakua popolo (*S. sandwicense*) and popolo ku mai (*S. incompletum*) both found only in Hawaii, and Erubia (*S. drymophilum*) found only in Puerto Rico. There are also two candidate species: popolo (*S. nelsonii*) found only in Hawaii, and marron bacora (*S. conocarpum*) found only in the U.S. Virgin Islands (USFWS, 2014a). Crosses between these species and Simplot Innate™ Potato would be highly unlikely because these species are not found in areas of potato production and even if they were found together, crosses would be unlikely because the biology of potato as described in sections 2.4.3 and 4.4.3 Gene Flow and Weediness, and in the PPRA (USDA-APHIS, 2013a).

Based on agronomic field data, literature surveyed on potato weediness potential, and the unlikelihood of crosses with wild relatives, APHIS has concluded that Simplot Innate™ Potato will have no effect on threatened or endangered plant species or critical habitat.

Threatened and Endangered Animal Species

For its effects analysis on TES animal species, APHIS focused on the likelihood of species to be exposed to Simplot Innate™ Potato and possible effects that could occur as a result of such contact. Exposure of TES species to Simplot Innate™ Potato is only likely if the species occur in the areas where potato is grown, because potato plant parts (seeds, tubers, pollen, vegetation, crop debris) are not readily transported long distances without human intervention. Threatened and endangered animal species that may be exposed to Simplot Innate™ Potato would be those TES that inhabit potato fields and may feed on Simplot Innate™ Potato. Few if any TES are likely to use potato fields because they do not provide suitable habitat. In general, the majority of threatened and endangered species are found in more natural habitats (USFWS, 2011). Little information can be found concerning threatened or endangered species in farm fields, especially potato fields. In an Environmental Assessment on the use of genetically engineered corn and soybean in refuges in the mid-west, the USFWS reported that whooping crane (*Grus americana*), sandhill crane (*Grus canadensis pulla*), piping plover (*Charadrius melodus*), interior least tern (*Sterna antillarum*), and Sprague's pipit (*Anthus spragueii*; a candidate species) occasionally feed in farmed sites (USFWS, 2011). Although possible that these bird species may visit potato fields during migratory periods, it is unlikely they would be present during normal farming operations (USFWS, 2011). USDA-APHIS Wildlife Services has received complaints for damage to corn, wheat, and potatoes caused by sandhill cranes (USDA-APHIS, 2013d).

As discussed in Section 2.4.1, Animal Communities, there are few animals reported to consume potato plants in an agricultural setting. This is not surprising considering the foliage and stems of potato contain toxic glycoalkaloids known to cause illness when consumed (Sinden, 1987b). Known exceptions are whitetail deer, wild boar, and voles (Marinette County, 2014), (O'Brien, 2005), (Taylor, 2014). There are two listed sub-species of white-tailed deer and three listed vole species within States that have commercial potato production. The Columbia white-tailed deer (*Odocoileus virginianus leucurus*) has two populations; one population in Douglass County, Oregon was delisted in 2003. The other, listed as endangered, is located in the lower Columbia River Valley in Washington State (USFWS, 1983). Neither population is found in areas of significant potato production as indicated in Figure 1, Potato Growing Regions of the U.S. (USDA-NASS, 2007). The endangered Key deer (*Odocoileus virginianus clavium*) is found only on the extreme tip of southern Florida far from any commercial potato production (USFWS, 2014c). The three vole species are listed as endangered. The Amargosa vole (*Micrurus californicus scirpensis*) is found in Inyo County in southeast California which is not an area of potato production (USFWS, 2014b). The Florida salt marsh vole (*Microtus pennsylvanicus dukecampbelli*) is found in saltmarshes of Levy County in coastal Florida, also not in areas of potato production (USFWS, 2014d). The Hualapai Mexican Vole (*Microtus mexicanus hualapaiensis*) is found in Mohave County, Arizona, where potatoes are a minor crop. However, the species would be unlikely to be found in potato fields because it is found only in woodlands and grasslands in the canyons of the Hualapai Mountains (USFWS, 1991).

Although unlikely, APHIS considered the possible effects on TES if they were to consume Simplot Innate™ Potato. Detailed compositional analyses of the ten events are found in Appendix 9 of the petition. The compositional assessments determined the amounts of 1)

moisture, protein, total fat, ash, crude fiber, carbohydrate and calories; 2) vitamins B6, B3 and C; 3) minerals copper, magnesium and potassium; 4) glycoalkaloids; 5) free amino acids; and 6) total amino acids for tubers collected from events grown in 2009, 2010, and 2011 in potato-growing areas of the United States (Simplot, 2013a; Simplot, 2013b). The potato events described in the petition were found to be no different compositionally when compared to untransformed controls, except for the intended traits (Simplot, 2013a; Simplot, 2013b). As discussed in Section 4.4.6 Human Health, issues with allergies to Simplot Innate™ Potato would be unlikely beyond what individuals with potato allergies would normally experience. The modifications did not alter the quality of potato as food other than lower levels of acrylamide after cooking, and lower black spot bruise. Simplot submitted a safety and nutritional assessment of food and feed derived from Simplot Innate™ Potato to the FDA on February 12, 2013 (BNF No. 141) (Simplot, 2013a; Simplot, 2013b). FDA is presently evaluating the submission.

As discussed in Section 4.4.1, Animal Communities, there are a large number of insects that feed on potato leaves and other insects that feed on those pests. No differences were observed for insects or other animals interacting within the potato ecosystem during the field trials, leading to the conclusion that Simplot Innate™ potatoes would have the same impact on other organisms as conventional potatoes (Simplot, 2013a; Simplot, 2013b). There is no evidence that animal exposure to Simplot Innate™ Potato would have any effect or be any less attractive as food, refuge, cover and nesting sites as non GE varieties of potatoes.

APHIS considered the possibility that Simplot Innate™ Potato 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 *Solanum* that serve as a host plant for any threatened or endangered species (USDA-APHIS, 2014a; 2014b).

Considering the lack of expected exposure and the expectation that such exposure would produce no response different than potato varieties currently in production, cultivation of Simplot Innate™ Potatoes and their progeny are expected to have no effect on threatened or endangered animals.

Summary

After reviewing the possible effects of allowing the environmental release of Simplot Innate™ Potato, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. APHIS also considered the potential effect of a determination of nonregulated status of Simplot Innate™ Potato on designated critical habitat and habitat proposed for designation, and could identify no differences from effects that would occur from the production of other potato varieties. Potato is not considered a particularly competitive plant species and has been selected for domestication and cultivation under conditions not normally found in natural settings (Holm *et al.*, 1979; Muenscher, 1980b; Muenscher, 1980a; Love, 1994a; Love, 1994b; OECD, 1997a; 1997b). There is no ability of Simplot Innate™ Potato to naturally hybridize with any wild *Solanum* species, including listed species. Simplot Innate™ Potato will not serve as a host species for any listed species or species

proposed for listing. Consumption of Simplot Innate™ Potato 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 Simplot Innate™ Potato, and the corresponding environmental release of these potato events will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no-effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the USFWS or NMFS is not required.

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

7.1 Executive Orders with Domestic Implications

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

- ***Executive Order (EO) 12898 (US-NARA, 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,"*** requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.
- ***EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks,"*** acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

The No Action and Preferred Alternatives were analyzed with respect to EO 12898 and EO 13045. Neither alternative is expected to have a disproportionate adverse effect on minorities, low-income populations, or children. Based on the information submitted by the applicant and reviewed by APHIS, Simplot Innate™ Potato is agronomically, phenotypically, and biochemically similar to conventional potatoes except for the low acrylamide potential and reduced black spot bruise trait. To establish that the new cultivars are nutritionally equivalent to their parent cultivars, Simplot Innate™ Potato and the control Ranger Russet potato were subjected to nutritional and proximate analysis, and measured for free amino acids, total amino acids, glycoalkaloids, sugars, and acrylamide levels. Results of the analysis are described below.

Reduced free asparagine (ASN) and total ASP + ASN, increased free GLN and total GLU + GLN, reduced acrylamide, and lowered reducing sugars were observed and expected as a result of gene silencing. This reduction would benefit consumers by addressing a food safety issue that is of concern to the potato industry (NTP, 2011). Other significant differences occurred that were not expected. J3 tubers contained an average of 0.117 mg/100 g pyridoxine (vitamin B6) as compared to the controls, which had 0.124 mg/100g. J55 also had decreased pyridoxine. J3 tubers had an average of 134 ppm of free VAL as compared to the controls, which had 147 ppm. J55 also experienced decreased VAL; H37 had decreased LYS; F37 had increased free ARG; G11 had increased total LYS and PRO; F10 and F37 had increased vitamin C and niacin; E12 and E24 had decreased sucrose; and H37 had increased sucrose. These observed differences fall within the normal ranges for potatoes.

Potatoes also were tested for reducing sugars and acrylamide after storage. Many of the events had lowered levels of reducing sugars at the time of harvest or one month of storage, but significant differences were not routinely observed after 2-5 months. Storage up to 7 months yielded consistently lower acrylamide levels in most events than in the controls, although there were exceptions with the G and H varieties. Overall, the modifications from insertion of pSIM1278 resulted in reductions in acrylamide that persisted throughout the storage period.

Research also confirmed that there the levels of natural glycoalkaloids, a toxin commonly found in solanaceous crops including potato, were not increased overall in the events. The safety limit is 20mg/100g as described by Sinden (Sinden, 1987a). There were, however, higher mean levels of glycoalkaloids in the G event (20.3 mg/100g) and the comparative untransformed control (19.8 mg/100g), but this was attributed to additional handling at the storage sites and subsequent exposure to light and temperature fluctuations. This finding indicates that there would not be safety issues as a result of the introduction of the reduced acrylamide potential and low black spot bruise traits in Simplot Innate™ Potato.

Patatin is a storage glycoprotein found in potatoes that makes up approximately 40 percent of the soluble protein in tubers. Some allergies have been detected in children as a result of patatin; however, these allergies are only in children and are uncommon (De Swert *et al.*, 2002; 2007). Children who are allergic to potatoes would avoid them; therefore, any changes in patatin levels in Simplot Innate™ Potato would not impact these children.

The nutritional analysis establishes the safety of Simplot Innate™ Potato 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.

Simplot initiated the consultation process with FDA for the commercial distribution of Simplot Innate™ Potato and submitted a safety and nutritional assessment of food and feed derived from Simplot Innate™ Potato to the FDA (Simplot, 2013a). FDA is presently evaluating the submission.

Based on these factors, a determination of nonregulated status of Simplot Innate™ Potato 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.

Potatoes are not listed in the United States as a noxious weed species by the Federal government (7 CFR Part 360; (USDA-NRCS, 2014), nor is it listed as an invasive species by major invasive plant databases. Standard potato growing practices make it highly unlikely that potatoes would persist in a field from one crop cycle to the next. In areas where potatoes are grown as a rotation crop, any potatoes left in the field would be eliminated by tilling, field preparations with herbicides, and harsh winters. Potato growers rarely leave the ground fallow to maximize economic return; however, any potatoes that grew inadvertently in a fallow field would not be protected with insecticide or fungicide and would be susceptible to the Colorado potato beetle and early blight.

Potatoes are not known to escape from fields or show weediness potential. Potato seedlings grown from tubers have difficulty establishing themselves as they are poor competitors against grasses, trees, and shrubs. This characteristic significantly reduces the chance that potatoes will become feral. In addition, the traits incorporated into Simplot Innate™ Potato are not associated with weediness and will not help plants thrive outside of cultivation. Based on historical experience with potatoes and data submitted by the applicant and reviewed by APHIS, Simplot Innate™ Potato is not expected to become weedy or invasive.

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

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

Migratory birds are not attracted to potato fields for potatoes; however, waterfowl forage extensively in agricultural fields in the fall and winter and are at risk for exposure to pesticides. In addition, raptors are at risk of exposure to pesticides if they consume dead or dying waterfowl from the fields. However, the ten Simplot Innate™ Potato events are similar to their conventional counterparts and would not require additional use of pesticide applications. Simplot Innate™ Potato is therefore expected to have the same interactions with migratory birds as conventional potatoes.

7.2 International Implications

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

APHIS has given this EO careful consideration and does not expect a significant environmental impact outside the U.S. in the event of a determination of nonregulated status of Simplot Innate™ Potato. All existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new potato cultivars internationally apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340.

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

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

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

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

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

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

7.3 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the potential changes in potato production associated with a determination of nonregulated status of Simplot Innate™ Potato (Section 4.2) and determined that the cultivation of Simplot Innate™ Potato would not lead to the increased production or acreage of potato in U.S. agriculture. The ten Simplot Innate™ Potato events do not possess traits that would allow them to be grown in areas other than those where their conventional counterparts are grown. The low acrylamide potential and reduced black spot bruise trait conferred by the genetic modification to Simplot Innate™ Potatoes would not result in any changes in water usage for cultivation. As discussed in Section 4.3, there are no expected negative impacts to water resources or air quality associated with Simplot Innate™ Potato production. Based on these analyses, APHIS concludes that a determination of nonregulated status of Simplot Innate™ Potatoes would comply with the Clean Water Act and the Clean Air Act.

7.4 Impacts on Unique Characteristics of Geographic Areas

This EA evaluated the potential changes in potato production associated with a determination of nonregulated status of Simplot Innate™ Potato (Section 4.2) and determined that the cultivation of Simplot Innate™ Potato would not lead to the increased production or acreage of potato in U.S. agriculture. The ten Simplot Innate™ Potato events do not possess traits that would allow them to be grown in areas other than those where their conventional counterparts are grown. The low acrylamide potential and reduced black spot bruise trait conferred by the genetic modification to Simplot Innate™ Potatoes would not result in any changes in water usage for cultivation. As discussed in Section 4.3, there are no expected negative impacts to water resources or air quality associated with Simplot Innate™ Potato production. Based on these

analyses, APHIS concludes that a determination of nonregulated status of Simplot Innate™ Potatoes would comply with the Clean Water Act and the Clean Air Act.

7.5 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 Simplot Innate™ Potato is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

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

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

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