JR Simplot Company Petition (14-093-01p) for Determination of Nonregulated Status for Innate™ Potatoes with Late Blight Resistance, Low Acrylamide Potential, Reduced Black Spot and Lowered Reducing Sugars: Russet Burbank Event W8

OECD Unique Identifier: SPS-000W8-4

Final Environmental Assessment

July 2015

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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)
CH_4	Methane
CO	carbon monoxide
CO_2	carbon dioxide
CWA	Clean Water Act
DNA	deoxyribonucleic acid
EA	Environmental Assessment
EIS	Environmental Impact Statement
EO	Executive Order
EPA	US Environmental Protection Agency
ESA	Endangered Species Act of 1973
FDA	US 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)

ACRONYMS AND ABBREVIATIONS

GE	genetically engineered
GHG	greenhouse gas
IPM	Integrated Pest Management
IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measures
LMO	living modified organism
M	million
NGO	non-government organization
NO_2	nitrogen dioxide
N_2O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NABI	North American Biotechnology Initiative
NAPPO	North American Plant Protection Organization
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
NRCS	Natural Resources Conservation Service
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

ACRONYMS AND ABBREVIATIONS

TES	threatened and endangered species
TPS	true potato seed
U.S.	United States
USDA	US Department of Agriculture
USDA-ERS	US Department of Agriculture-Economic Research Service
USDA-FAS	US Department of Agriculture-Foreign Agricultural Service
USDA-NASS	US Department of Agriculture-National Agricultural Statistics Service
USDA-NOP	US Department of Agriculture-National Organic Program
WPS	Worker Protection Standard (for agricultural pesticides)

1 PURPOSE AND NEED

1.1 Background

J.R. Simplot[1] of Boise, Idaho, submitted petition 14-093-01p to the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) in March 2014, seeking a determination of nonregulated status for Simplot Innate™ W8 potato genetically engineered (GE) with late blight resistance, low acrylamide potential, reduced black spot and lower reducing sugars. The petition was deemed complete by APHIS on June 26, 2014, and was published in the *Federal Register* on November 10, 2014 (79 FR 66689-66690). Public comments were due by January 9, 2015.

Simplot Innate™ W8 potato is currently regulated under 7 CFR part 340. Interstate movements and confined field releases of Simplot Innate™ W8 potato were conducted under notifications acknowledged by APHIS in 2012 and 2013. These field trials were conducted in Idaho, Minnesota, North Dakota, Washington, and Wisconsin. Data resulting from these field trials are similar to data requirements for other petitions submitted to APHIS and described in Simplot's Innate™ W8 potato petition (Simplot, 2014) and analyzed for plant pest risk in the APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2014b).

The petition stated that APHIS should not regulate Simplot Innate™ W8 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™ W8 potato, any progeny derived from crosses between Simplot Innate™ W8 potato and conventional potato, and crosses of Simplot Innate™ W8 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.

1.1.1 Regulatory Authority

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

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

[1] Referred to as the JR Simplot Company or Simplot hereinafter

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

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

1.1.2 Purpose of this Product

Simplot's Innate™ W8 potato, which contains traits for lowered acrylamide potential and reduced black spot bruise, was determined to be nonregulated on November 10, 2014 (79 FR 66688). The Simplot Innate™ W8 potato is a Russet Burbank which contains these traits, plus two other traits for lowered reducing sugars and late blight resistance.

As discussed in Simplot's petition for nonregulation of Simplot Innate™ W8 potato (Simplot, 2013), APHIS' Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2013a) and subsequent Environmental Assessment (EA) (USDA-APHIS, 2014a), Simplot Innate™ W8 potato was genetically engineered to provide a potato that produces up to a 70% reduction of the neurotoxicant and putative carcinogen, acrylamide, and decreased potential for black spot bruise. Acrylamide forms in potatoes and other starchy foods under high-temperature cooking conditions (O'Brien *et al.*, 1989), and the acrylamide reduction potential in Simplot Innate™ W8 potato is a significant human health benefit, helping to address consumer concerns about the health effects of acrylamide ingestion (NTP, 2012; FDA, 2013c). 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 (USDA-APHIS, 2014b). This blackening negatively affects tuber quality in processing French fries and chips, posing an economic deficit to growers since damaged potatoes must be trimmed or culled, significantly reducing yield (USDA-APHIS, 2014b).

The technology used to produce Simplot Innate™ W8 potato has been utilized to introduce two new additional traits into the most popular variety of potato for processing, Russet Burbank (NPC, 2013). These new traits are late blight resistance and lowered reducing sugars. There currently are no varieties available that produce potatoes with late blight resistance (McGrath, 2010), low reducing sugars, low acrylamide formation, and reduced black spot and at the same time maintaining all the other compositional, nutritional and flavor traits required by the food industry (Simplot, 2014). Late blight, caused by the oomycete pathogen, *Phytophthora infestans*, is the most destructive potato disease worldwide, and was responsible for the Irish potato famine of the 1840s. Control of this disease incurs significant costs to growers owing from fungicide applications and yield loss from diseased plants (Fry, 2008). Reducing sugars increase over the length of time that potatoes are stored prior to use in processing, with high levels leading to unacceptably brown fries and chips and alteration in flavor, contributing to acrylamide formation, and resulting in consumer rejection (Bhaskar *et al.*, 2010). Processors typically reject potato loads with a reducing sugar content above 2%, which comprises about 20% of potatoes produced (Simplot, 2014), so a trait which prevents accumulation of reducing sugars to unacceptably high levels would be economically beneficial to growers.

The intended purpose of the W8 potato line is to provide the potato processing industry with new varieties that possess late blight resistance, reduced acrylamide potential in certain processed or heated potato products, reduced black spot bruise, and lowered reducing sugars. All of these changes are intended to benefit potato consumers, producers, and processors. The late blight resistance trait may lower the need for fungicides for control of late blight disease and may lessen the discards of potatoes that are infected which may lead to increased yield and less chemical residues on potatoes, fields and waste water. The low acrylamide potential is intended to benefit consumers because of concerns about the health effects of ingesting acrylamide, and to benefit the industry relative to Proposition 65 in the State of California. The reduced black spot bruise 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 pick-outs. By lowering reducing sugars with the use of the W8 potato line, storage of potatoes for the fry and chip market could be accomplished at a lower temperature which would lower incidence of storage diseases and keep taste/color quality in the desired ranges.

1.2 Coordinated Regulatory Framework for Genetically-Engineered Organisms

In 1986, the Office of Science and Technology Policy (OSTP) described a comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products entitled "The Coordinated Framework for the Regulation of Biotechnology" (henceforth referred to here as the Coordinated Framework). The Coordinated Framework 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 required 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 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 pose a plant pest risk. 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.

1.2.2 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 (EUP) 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 the 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, 2011c).

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.

According to Simplot's petition, an experimental use permit (EUP) application was submitted to EPA on December 16, 2013, for field testing of Simplot Innate™ W8 potatoes. An EUP, also for Simplot Innate™ W8 potatoes, with a Petition for Temporary Tolerance Exemption, was submitted February 20, 2014. A Section 3 Registration will be filed after experiments are completed under the Simplot Innate™ W8 potatoes EUPs (Simplot, 2014).

1.2.3 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.

The J.R. Simplot Company submitted a letter of consultation on April 15, 2014 (BNF No. 000146). Although the safety of Innate™ W8 potato was approved by FDA on March 20, 2015 (FDA, 2015), the FDA is still reviewing the submission for W8 potato.

1.3 Purpose and Need for This APHIS Action

APHIS responds to petitioners that request a determination of nonregulated status of GE organisms (7 CFR 340.6), including GE plants such as Simplot Innate™ W8 potato. When a petition for nonregulated status is submitted, APHIS performs analyses to determine if the GE organism poses 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 pose a plant pest risk. 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.

In this EA, APHIS is responding to a petition from Simplot requesting a determination of nonregulated status for Simplot Innate™ W8 potato. APHIS considers the potential environmental effects of an agency determination of nonregulated status of Simplot Innate™ W8 potato consistent with regulations for implementing the National Environmental Policy Act (NEPA; 40 CFR parts 1500-1508), and the APHIS NEPA-implementing regulations and procedures (7 CFR part 1b, and 7 CFR part 372). This EA specifically evaluates the effects on the quality of the human environment that may result from a determination of nonregulated status for Simplot Innate™ W8 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 published in the *Federal Register*[2], 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 its EA and PPRA. The availability of the petition for public comment is announced in a *Federal Register* notice.

Second Opportunity for Public Involvement

The draft PPRA and draft EA are developed, and a notice of their availability is published in a second *Federal Register* notice. This second notice follows one of the following 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

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

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.

<u>Approach 2. For GE organisms involving substantive new issues not previously analyzed</u>

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. APHIS 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* notice published on March 6, 2012[3].

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 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™ W8 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™ W8 potato.

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

The petition was published in the *Federal Register* on November 10, 2014 (79 FR 66689-66690). Public comments were due by January 9, 2015. A total of 130 individual comments were received, of which 60 supported the petition, and 68 opposed the petition. Of the 68 opposing comments, one contained an attachment with 22,673 signatures; 22 comments were substantially similar to each other; and 7 comments were submitted by one individual. Of the 60 comments favoring determination of nonregulation, 2 were duplicates.

APHIS has analyzed and evaluated the issues described in the comments, and has included a discussion of these issues in this EA with citations where appropriate. In general, those commenters opposing the petition expressed their disagreement with GE crops; favored longer term safety testing for Simplot Innate™ W8 potato; and suggested that RNAi technology is not safe for use. Two commenters asked for the public comment period to be extended, and also stated that due to the complexity of the product, an EIS was needed.

Commenters favoring the petition cited health benefits from reduced acrylamide; reduced wastage and crop loss; lengthening of storage periods with less reliance on sprout inhibitors; and reduced use of fungicides to prevent late blight.

Additionally, on May 5, 2015, APHIS published a notice in the Federal Register (80 FR 25660-25661, Docket no. APHIS-2012-0076) announcing the availability of the Simplot Innate™ W8 potato draft EA (14-093-01p) and preliminary PPRA for a 30-day public review and comment period. A total of 24 public comments were received subsequent to the draft EA publication. Nineteen public comments supported the determination of nonregulated status, and five public comments did not support the determination of nonregulated status.

Of the public comments which opposed nonregulated status for Innate™ W8 potato, the majority of these public comments did not explain or identify elements in the Innate™ W8 potato PPRA or EA that were perceived to be inadequate or provide any supporting evidence for their claims.

Most opposing comments expressed general opposition to all forms of genetic engineering of crops used for human consumption or animal feed. Objections were based on the belief that GE crops harm the environment, are not beneficial to farmers or both. Neither issues nor information submitted in comments to support opposition to the proposed APHIS action were identified as new; they all had been addressed previously by the Agency during the NEPA decision making process related to prior regulatory actions related to GE organisms. One submission did not include a comment; only 94 attachments that included publications and articles. APHIS carefully reviewed the articles sent in by commenters. Many articles were included in the EA, many of them pertained to other dockets, but none contributed any new information relevant to Innate™ W8 potato. Thirty-one were relevant to the Simplot petition and/or the proposed APHIS action; 63 were general review papers or otherwise irrelevant to this APHIS decision making. The submitter did not specify what information APHIS failed to include in the EA or explain how what was submitted was relevant and should be used. In the absence of a comment expressing specific concerns, APHIS is unable to provide a response.

The issues that were raised in the public comments which were related to the Simplot Innate™ W8 potato petition, preliminary PPRA, or draft EA included the following positive comments:

- The late blight-resistant gene will be beneficial to growers and the potato industry, helping to control the most devastating potato disease in the world, and will have the potential to reduce fungicide usage during cultivation.
- The lowered reducing sugars trait will enable storage of potatoes at lower temperatures, thus, providing resistance to the problem of cold-sweetening.
- The resistance genes in the late blight-resistant trait are safe.

Many of the negative comments were the same arguments and issues raised during the development of the Simplot Innate™ potato, which received a determination of nonregulated status on November 10, 2014. The following new comment, specifically on the Innate™ W8 potato, was received:

- The efficacy of the late blight-resistant trait is not as high as should be expected.

A fuller discussion of these issues is contained in the FONSI and Response to Comments which accompanies this Final EA.

1.4 Issues Considered

The list of resource areas considered in this EA was 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 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 may be impacted by Simplot Innate™ W8 potato production. Relevant environmental components include the agricultural production area of Simplot Innate™ W8 potato, 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; Zaheer and Akhtar, 2014). Potato is grown in over 100 countries, with world potato production exceeding 300 million metric tons (Center, 2010). After China, India, Russia, and the Ukraine, the U.S. is the fifth largest potato producing country (FAO, 2013; Zaheer and Akhtar, 2014), with annual production over the last three years of between 404-467 million centum weight (cwt)(centum weight = 100 pounds), grown on 1.0-1.1M acres (USDA-NASS, 2013b).

The Russet Burbank potato cultivar was transformed by Simplot to produce the Simplot Innate™ W8 potato (Simplot, 2014). Russet Burbank is a brown, smooth-skinned, white-fleshed potato that is high-yielding, has a low sugar content and stores well for long periods of time (Nevada, 2014). Taste panels rate Russet Burbank highly for flavor (Nevada, 2014). Originally developed by Luther Burbank in the early 1870s (PAA, 2013), Russet Burbank is the most popular potato variety in the U.S. (Nevada, 2014), is used primarily for baking, and for processing into French fries and chips (NPC, 2013; Nevada, 2014; University, 2014). In 2012, Russet Burbank was planted on approximately 40% of the acreage devoted to potatoes in the U.S. (University, 2014), especially in the Pacific Northwest and Midwest (Nevada, 2014).

The cultivar's low sugar content is especially advantageous since high sugar contributes to acrylamide production during cooking, decreased processing quality (Driskill *et al.*, 2007), and consistent low sugar content during the storage period (Nevada, 2014; University, 2014). Russet Burbank tolerates the plant disease common scab well (PAA, 2013) but is susceptible to black spot bruise and dehydration (Nevada, 2014) and to pathogens such as *Fusarium* and *Verticillium* wilts, leafroll and net necrosis, potato virus Y, and late blight (PAA, 2013). Russet Burbank is sterile and produces only a few white flowers during production (PAA, 2013). Table 1 summarizes some of the agronomic requirements for this variety.

Table 1. Agronomic Inputs for Russet Varieties

	Russet Varieties
Planting Date	April 1 to May 10
Planting Rate	15,000 - 18,000 seed pc or 17 – 23 cwt/A
Row Spacing	34-36" between rows
Seed Spacing	10-12" within row
Fertilizer	For 600 cwt/A yields and optimum soil test levels: 250 lb N – 100 lb P_2O_5 – 330 lb K_2O per acre
Yield/Plant	2-4 lb
Yield/Acre	400-700 cwt/A
Harvest Date	September 1 to October 15

Source: (PAA, 2013)

2.1.1 Land Use

Potatoes are grown across most of the continental U.S., with six States (Idaho, Washington, Wisconsin, North Dakota, Oregon, and Colorado) accounting for approximately 73% of annual production (USDA-NASS, 2014d; 2014b)(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, lower power and labor costs, more favorable weather, and available arable land (Guenther, 2010a).

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 and 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™ W8 potato may be grown in any of the U.S. potato-growing regions.

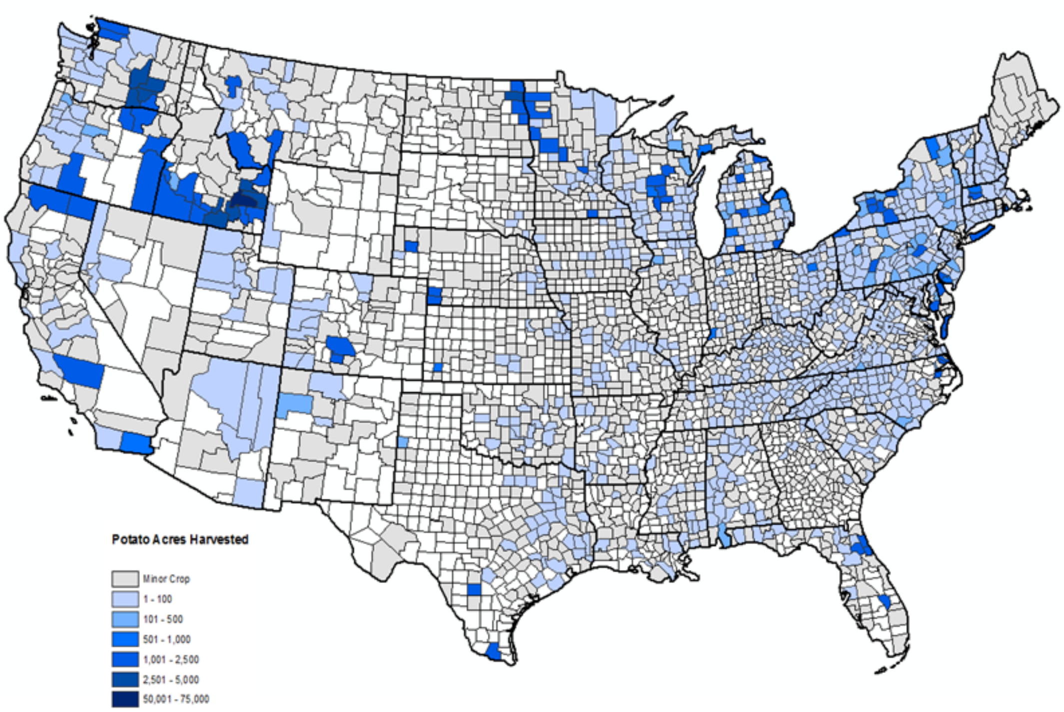

Figure 1. Potato Growing Regions of the United States (USDA-NASS, 2007)

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 harvested acreage has declined over the years, total production has increased (Guenther, 2010b). For example, in the 1930s, 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, 2010b). Total acres of potatoes harvested in 2012, 2013 and 2014 were 1.13, 1.05 and 1.07 million acres, respectively (USDA-ERS, 2014; USDA-NASS, 2014b). Total annual U.S. production has been over 400 million cwt every year since 1990, with per acre yield approximately 407 cwt (Table 2), which represents an eightfold increase in yield per acre since the 1990s (USDA-NASS, 2010). 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; 2013a).

The top ten potato producing states are shown in Table 2 (USDA-NASS, 2013c). Highest yields are in regions where daytime temperatures exceed 100° F during the hottest part of the growing season, and where nights are cool (about 65° F) (Rosen, 2010d), such as in Washington's Columbia Basin, eastern Oregon, and Idaho.

Table 2. Major Potato Production States in 2013

State	Production (1,000 cwt)	Total U.S. Production (percent)	Potato Harvest (acres)
Idaho	131,131	30.2	316,000
Washington	96,000	22.1	160,000
Wisconsin	26,040	6.0	64,000
North Dakota	22,620	5.2	78,000
Oregon	21,582	5.0	39,600
Colorado	20,304	4.7	54,000
Minnesota	17,325	4.0	45,000
Michigan	15,840	3.6	44,000
Maine	15,660	3.6	54,000
California	14,369	3.3	26,500

Source: (USDA-NASS, 2014b)

Most potatoes are harvested in July through October. Fall crops have increased because of demand for processing (Guenther, 2010b). Harvested potatoes are either used for food (~93%), feed (<1%), industrial purposes (<1%) or as "seed" for planting (5%) (NPC, 2012; USDA-NASS, 2013c; 2014a). 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, 2014b), while approximately 35% of annual output is processed into frozen products (such as frozen fries and wedges), chips, dehydrated potato and starch (25%), or canned potatoes (0.4%), and 6% is replanted as seed potato. Americans eat, on average, approximately 115 lbs. of potatoes per person per year, of which about two thirds is consumed as processed potato products (USDA-ERS, 2010).

Raw potato waste products (peels, out-of-specification raw potatoes, or other non-processed raw potato products) and processed discards (French fries, hash browns, etc.) are routinely incorporated into feed rations at livestock feedlot operations (Simplot, 2014).

2.1.2 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 (Shock, 2010). Specific guidelines for irrigation depend on geographic region and factors typical of that region such as temperature, relative humidity, and day length. 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, by preparing the soil so that infiltration of water is increased, and also by 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 black spot 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, due to limitations in conventional breeding. Each parent variety must be independently transformed to achieve the desired phenotype in that variety (USDA-APHIS, 2014b). 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; Simplot, 2014).

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 mitigate disease pressure is to till green manure crops (crops which are left to decompose on fields to provide cover or mulch for a subsequent crop) 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 with other crops increases the risk of insect, disease, and nematode pressure; decreases soil nutrient levels; and increases erosion potential (Delahaut, 2000; Hall *et al.*, 2000; Bennett and O'Rourke, 2002; Larkin, 2003; Hopkins *et al.*, 2004). 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 potato 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 insects and diseases (Johnson, 2007). More than 150 species of insects may damage potatoes, most of which cause only minor economic injury. However, several species cause more damage 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 US, 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, of which 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, are prevalent in potato crops (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).

Growers may 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 lists the major insect pests of potato.

Table 3. Major Insect Pests of Potato

Common Name	Scientific Name
Colorado potato beetle	*Leptinotarsa decemlineata*
Green peach aphid	*Myzus persicae*
Wireworms	*Limonius californicus, L. canu, Ctenicera pruinera*
Potato leafhopper	*Emposasca fabae*
Pea aphid	*Acyrthosiphon pisum*
Soybean aphid	*Aphis glycine*
Thrips	*Franklinella spp., Thrips spp.*
Flea beetle	*Epitrix spp.*
European cornborer	*Ostrinia nubilalis*
Potato psyllid	*Bactericera (Paratrioza) cockerelli*
Potato Tuberworm or Tuber Moth	*Phthorimaea operculella*

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

<u>*Disease Control*</u>

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 (Arif *et al.*, 2012; USDA-APHIS, 2014b).

There are several factors to consider in controlling potato diseases, including the part of the plant being attacked, pathogen transmission mechanism, and environmental conditions. Table 4 lists the major diseases of potato. Some of these diseases 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	*Corynebactium sepedonicum*
Bacterial brown rot	*Ralstonia solanacearum*
Bacterial soft rot	*Pectobacterium carotovorum*
Blackleg	*Erwinia carotovora*
Golden nematodes	*Globodera rostochiensis*
Potato tuber rot	*Ditylenchus destructor*
Root knot	*Meloidogyne* spp.
Columbia root knot	*Meloidogyne chitwoodi*
Root lesion	*Pratylenchus penetrans*
Viruses	

Common Name	**Scientific Name**
Potato Leafroll Virus	*Luteovirus*
Potato Spindle Tuber Viroid	Member of Pospiviridae
Potato Virus A,M, X, Y	Members of Potyviridae, *Carlavirus,*
Tobacco Rattle Virus	*Tobravirus*
Fungi	
Late blight	*Phytophthora infestans*
Pink rot	*Phytophthora erythroseptica*
Early dying	*Verticillium* spp.
Sclerotinia stalk rot or white mold	*Sclerotinia sclerotiorum*
Canker or black scurf	*Rhizoctonia solani*
Scab	*Streptomyces scabies*
Dry rot	*Fusarium* spp.
Fusarium wilt	*Fusarium solani* var *eumartii*, *Fusarium oxysporum*
Water or shell rot	*Pythium ultimum*
Early blight	*Alternaria solani*
Gray mold	*Botrytis cinerea*
Black dot	*Colletotrichum coccodes*

Common Name	Scientific Name
Ring rot	*Clavibacter michiganensis* subsp. *Sepedonicus*
Powdery scab	*Spongospora subterranea*
Silver scurf	*Helminthosporium solani*
Wart	*Synchytrium endobioticum*
Nematodes	
Golden nematodes	*Globodera rostochiensis*
Potato tuber rot	*Ditylenchus destructor*
Root knot	*Meloidogyne* spp.
Columbia root knot	*Meloidogyne chitwoodi*
Root lesion	*Pratylenchus penetrans*

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

<u>*Late Blight*</u>

The disease known as late blight of potato is caused by an oomycete pathogen, *Phytophthora infestans* (Cooke *et al.*, 2012). Late blight is renowned in history as the causative agent of the Irish potato famine during the 1840s, which resulted in widespread potato crop failure and famine, and waves of migration from Ireland (Herman and Williams, 2012). Within the U.S., the pathogen was first reported in 1843, in New York City and Philadelphia (Nowicki *et al.*, 2012; Akino *et al.*, 2014), and became widespread throughout the rest of the world by 1845 (Fry, 2008). Late blight is prevalent in many areas of the U.S. and is now found in nearly every potato state (Simplot, 2014). For example, in Idaho, the top-producing potato state, late blight has occurred in nearly every commercial potato field over the last 20 years, resulting in severe losses during some of those years (Miller *et al.*, 2006).

Worldwide, late blight is a very destructive disease capable of destroying a potato crop in only a few days (Vleeshouwers *et al.*, 2011), and outbreaks frequently turn into epidemics (Fry, 2008). Its success as a pathogen is due in part to its reproductive cycle and its ability to adapt quickly to resistant plants (Vleeshouwers *et al.*, 2011). The late blight pathogen spreads quickly through infected fields, causing widespread foliar necrosis resulting in plant death and significant yield reduction. Infected tubers can cause lesions and rot that destroys entire lots in storage (Simplot, 2014). Because the primary source of infection is infested potato tubers, potato is generally the main crop affected by late blight (McGrath, 2010). However, the pathogen will also infect other solanaceous plants and crops such as tomato and eggplant (Akino *et al.*, 2014). Agricultural areas where potato and tomato are grown near each other, and grown all year round are at greater risk of developing late blight (Nowicki *et al.*, 2012).

Phytophthora infestans is capable of reproducing either sexually or asexually (Nowicki *et al.*, 2012). Fry *et al.* (1993) note that the diversity of genotypes resulting from sexual reproduction can fuel more virulence in populations. Asexual reproduction of *P. infestans* can be viewed as a mechanism to greatly increase population growth under favorable environmental conditions (Fry, 2008), and may drive epidemics (Nowicki *et al.*, 2012). Occurrence or predominance of only 1 mating type in a geographic area suggests that asexual reproduction is the only means of propagation in these areas (Fry *et al.*, 1993). Population displacement of “old” populations or sexual recombination within the aggressive “new” population has resulted in severe outbreaks worldwide in recent decades (Chowdappa *et al.*, 2014). These “new” populations have been associated with fungicide resistance or an ability to overcome host resistance (Chowdappa *et al.*, 2014).

P. infestans usually overwinters on potato tubers or on one of its alternate hosts, tomatoes in greenhouses, so that the annual disease cycle may be difficult to break (Bush *et al.*, 2012). Infected tubers from the previous season produce infected seedlings, a significant source of late blight inoculum. In the development of late blight disease on susceptible plants, *P. infestans* produces thousands of sporangia per lesion (Nowicki *et al.*, 2012), each of which can, in turn, produce as many as 300,000 sporangia per day (Fry and Goodwin, 1997). Once a potato plant is infected, late blight spores can be propagated for as long as the foliage is still green (Bohl *et al.*, 2003). Dispersal is by wind (Bohl *et al.*, 2003; McGrath, 2010), frequently over long distances of up to 30 miles, as well as dispersal by infected tubers moved by humans and animals (Aylor *et al.*, 2001; Bohl *et al.*, 2003; Miller *et al.*, 2006; Nowicki *et al.*, 2012; Akino *et al.*, 2014; Rowe *et al.*, No Date). Dispersal during cloudy days or at night helps protect spores from the lethal effects of UV radiation (McGrath, 2010). Wind and rain may dislodge spores on infected plants, and winds may carry them into potato fields as far away as 10 miles, thereby initiating another disease cycle (Rowe *et al.*, No Date). Spores may remain viable for up to a week (McGrath, 2010; Nowicki *et al.*, 2012). Spore and infected tuber movement is critical to epidemic development (Fall *et al.*, 2014). Depending on environmental conditions, regeneration time can be short, in as little as 5-7 days (Nowicki *et al.*, 2012).

Late blight disease has several foliar symptoms in potato, including wilting, damping-off, and chlorosis (Akino *et al.*, 2014). The pathogen produces characteristic circular or irregular leaf lesions which are surrounded by a light yellowish-green margin which merges with healthy tissue. Lesions typically develop on lower leaves first because it is more humid closer to the soil, and on leaf edges or petioles where dew remains longer (Kirk *et al.*, 2004). Symptoms typically appear within 5 to 7 days after infection (Bohl *et al.*, 2003), and the disease cycle of colonization of uninfected plants, sporulation, and dispersal of spores to new plants can take place in less than five days (Fry and Goodwin, 1997). Once a potato field is infected, *P. infestans* has the potential to completely destroy the plants in the field in about a week (Nowicki *et al.*, 2012).

Lesions on tubers are shallow, sunken, coppery-brown dry rot spots which spread in an irregular pattern from the exterior of the tuber to the first 1/8 to ½ inch of the underlying flesh. The flesh beneath lesions is granular and tan to copper brown (Rowe *et al.*, No Date). Lesion formation may be slowed under cool and dry storage conditions, but if storage is prolonged, lesions appear sunken and dried (Rowe *et al.*, No Date). Lesions quickly get bigger and their color deepens to a range of dark brown to purple-black (Rowe *et al.*, No Date). Infested tubers are also vulnerable to attack from bacteria, fungi, and other pathogens, which deteriorate tubers further (Kirk *et al.*, 2004; Schumann and D'Arcy, 2005; Bush *et al.*, 2012; Rowe *et al.*, No Date). Reportedly, late blight lesions on tubers are less obvious on some cultivars, including the Russet varieties (Kirk *et al.*, 2004), which may make diagnosis more difficult.

Other parts of the potato plant also deteriorate when infected with late blight. When stems are infected, they turn brown or black (Rowe *et al.*, No Date), and all of the tissue above the stem dies (McGrath, 2010). Vine death may occur very quickly under favorable conditions (Rowe *et al.*, No Date). Even flowers show symptoms of infection (Porter *et al.*, 2004).

Besides lesions, there are several other diagnostic characters for late blight infection in potato fields. The appearance of white, velvety growth on foliage is characteristic of late blight (Kirk *et al.*, 2004). In a field hard hit with late blight, dying plants emit a distinctive odor (Kirk *et al.*, 2004).

When tomato is infected, symptoms are similar (Schumann and D'Arcy, 2005). Generally, the genotypes of *P. infestans* attacking tomato appear to be less virulent than those infecting potato (McGrath, 2010), and those strains specialized to attack tomatoes may be less pathogenic to potato than potato-adapted genotypes (Fry, 2008).

Potato crop vulnerability to late blight is influenced by factors such as weather (Sparks *et al.*, 2014) and agronomic practices. Cool, cloudy, wet or humid weather with soil temperatures < 65 F. favors disease development (Bohl *et al.*, 2003; Kirk *et al.*, 2004; Miller *et al.*, 2006; Gigot *et al.*, 2009; Bush *et al.*, 2012; Herman and Williams, 2012; Majeed *et al.*, 2014; Rowe *et al.*, No Date).

During cultivation of a potato crop, additional measures may be taken to minimize the development of late blight. These include water management such that moisture in the fields, particularly standing water, is minimized, by scheduling irrigations at times such that the foliage has the time to dry out before the next water application, and early enough in the day so that dew formation is decreased (Bohl *et al.*, 2003; Miller *et al.*, 2006).

Irrigating fields after rains or humid weather may also raise probability of disease development because water may dislodge spores from plants or soil and move to other, uninfected locations (Miller *et al.*, 2006; Rowe *et al.*, No Date). In addition, the use of sprinkler irrigation may heighten vulnerability to *P. infestans* due to the potential for subsequent heavy dew formation (Miller *et al.*, 2006). Operation of other agricultural machinery and equipment may also physically spread spores (Miller *et al.*, 2006).

There are several methods described in the literature to prevent late blight development. At present, there are no methods such as labeled fungicides which will kill late blight once the plant is infected (Miller *et al.*, 2006), so disease prevention is currently crucial for growers. Most notable is fungicide treatment, which can be highly protective, especially under "late blight weather conditions" (Cooke *et al.*, 2011; Nowicki *et al.*, 2012; Rowe *et al.*, No Date). Because fungicides operate as protectants rather than eradicators of the disease, they need to be applied prior to the expected timing for disease development. Forecasts of predicted disease assist growers with fungicide spray timing, and are available through disease forecast systems (Bohl *et al.*, 2003). Typically, growers apply fungicides about two weeks before predicted infection of fields in their geographic area (Miller *et al.*, 2006), and frequently need to be reapplied on a regular basis to achieve full protection (Wiik, 2014). For example, growers in northern Europe spray fungicides 10-15 times per season in order to control late blight (Jones *et al.*, 2014). In the U.S., more than 2000 tons of fungicides were sprayed in 2001. Such frequent chemical treatments impose a heavy economic burden on growers (Fry, 2008). Some sources (e.g., (Miller *et al.*, 2006)) recommend alternating fungicides by different chemical class to achieve greater protection. Recent research indicates that systemic fungicides perform better than do contact fungicides (Majeed *et al.*, 2014).

Crop rotation of potato with a second crop may break the cycle of infection (Miller *et al.*, 2006; Cooke *et al.*, 2011), except in some northern states where *P. infestans* spores cannot overwinter (McGrath, 2010). Cultural practices such as land sharing and shorter rotation periods between potato crops may result in increased survival of volunteer potato plants and tubers which may be infected (Gigot *et al.*, 2009).

Volunteer potatoes and tomatoes are a potential source of *P. infestans* inoculum (Eberlein *et al.*, 1998; Miller *et al.*, 2006; Everman and Long, 2010; Cooke *et al.*, 2011; Rowe *et al.*, No Date). Spores may persist in overwintered volunteer potato plants, and in the soil for two months under typical field conditions (Cooke *et al.*, 2011). Volunteers typically augment and accelerate epidemics of *P. infestans* rather than initiate them (Cooke *et al.*, 2011). In areas with warmer winter temperatures, spores may survive overwintering (Gigot *et al.*, 2009; McGrath, 2010; Cooke *et al.*, 2011), and rain can wash spores down plants into the soil (McGrath, 2010), where they can survive until the next year's growing season (Cooke *et al.*, 2011). This source of inoculum can be remedied by monitoring for and destroying any volunteer potatoes and tomatoes (McGrath, 2010; Rowe *et al.*, No Date).

Because *P. infestans* is capable of infecting alternative hosts such as such as black nightshade, *Solanum nigrum*, bittersweet, *S. dulcamara*, and hairy nightshade, *S. physafolium* (Gronberg *et al.*, 2012), management of solanaceous weeds may help to control late blight (McGrath, 2010). In addition to serving as reservoirs for infection, weeds may also contribute to infection in potato fields by restricting air movement within the potato canopy (Kirk *et al.*, 2004), and impeding adequate spray coverage with fungicides (Miller *et al.*, 2006).

Growers frequently discard defective potatoes into cull piles (Miller *et al.*, 2006; Johnson, 2010; Rowe *et al.*, No Date), which are another major source of *P.infestans* infection. In some geographic areas, if cull piles are small enough, the tubers will freeze and any infection will be killed (Kirk *et al.*, 2004). Tuber decomposition in cull piles can be hastened by covering with plastic tarps to increase temperatures within the piles (Kirk *et al.*, 2004).

Another important source of late blight disease is infested seed tubers (Kirk *et al.*, 2004; Miller *et al.*, 2006; Cooke *et al.*, 2011). Usually, tubers are infected in the field when being handled (Cooke *et al.*, 2011). To reduce the risk of late blight affecting potato crops, growers are advised to plant only certified seed potatoes (Kirk *et al.*, 2004; Johnson *et al.*, 2010; McGrath, 2010; Rowe *et al.*, No Date). Seed treatment with an appropriate product labelled for that purpose may also help to reduce chances of infection. Such treatments do not kill the spores, but decrease infection of seed tubers (Bohl *et al.*, 2003). *P. infestans* has been documented to spread in cut seed, with length of storage correlated with probability of disease spread (Lambert *et al.*, 1998).

Infection risk can also be minimized by placement position of seed during planting; planting seed deeper is preferred since tubers developing closer to the soil surface are more at risk of infection because of proximity to infected plant parts above the soil (Bohl *et al.*, 2003). Growers are also advised to restrict planting to areas which can be easily sprayed with fungicides, as well as to avoid planting in field locations which are likely to be wetter than usual, such as in low areas which may accumulate standing water, or in the path of a center pivot irrigation system (Bohl *et al.*, 2003).

Because excess nitrogen often encourages heavy vine growth and leads to an extended time period for potential late blight infection, growers are frequently advised to avoid any unnecessary fertilizing during the growth cycle (Miller *et al.*, 2006).

Prudent growers will monitor for late blight symptoms on a regular basis and begin scouting early enough to catch symptoms when they are still small and infection of nearby fields can be mitigated (Miller *et al.*, 2006). This is a challenge because such small early lesions are not easily detected visually until 2 to 4 days following infection (Fry, 2008; Nowicki *et al.*, 2012).

Late blight-prediction models (sometimes referred to as Decision Support Systems (DSS)) which indicate that weather conditions or other factor predispose a geographic area to late blight infection, provide growers with cues for when to scout fields more frequently during that time (Bohl *et al.*, 2003). In the last several years, late outbreak prediction models have been used to attempt to predict favorable weather conditions in specific geographic areas, so that growers may be able to have advance notice in order to decide when to treat fields with fungicides (Herman and Williams, 2012). Decision support systems are not perfect: growers generally do not know if late blight spores are present in their fields, thus, spraying fungicides when weather conditions are ripe for a late blight attack may actually waste resources in the form of chemicals and labor. However, these systems have become popular worldwide for forecasting potential late blight risk (Fall *et al.*, 2014).

Harvest is a sensitive time period for spread of late blight (Rowe *et al.*, No Date). Sources vary in recommendations of how long before harvest to kill vines, approximately 2-3 weeks beforehand (Johnson *et al.*, 2010; Rowe *et al.*, No Date), while Olsen *et al.* (2005) states that there is some flexibility in timing of vine kill. Growers are advised to avoid harvesting during periods of wet weather (Bohl *et al.*, 2003; Miller *et al.*, 2006) or when tuber pulp temperatures exceed 65ºF, since late blight and other pathogens are more active in warmer temperatures (Bohl *et al.*, 2003).

The use of resistant cultivars is also an important option (Johnson *et al.*, 2010), which should lead to increased yield. However, most popular potato cultivars on market are not highly resistant (Fry, 2008).

Development of late blight resistant cultivars is an important step toward protection of potato from this devastating disease. Historically, traditional breeding programs have been used toward this aim, and are slow and inefficient (Vleeshouwers *et al.*, 2011). Because of its adaptability, *P. infestans* has evolved so that resistance genes have been rapidly overcome by new *P. infestans* races (Jones *et al.*, 2014). In addition, traditional crop breeding may unintentionally break up favorable combinations of other alleles or introduce other deleterious alleles of genes linked to disease resistance (Jones *et al.*, 2014).

A benefit of plants with late blight resistance genes is that fields may require less frequent spraying with fungicides, which will reduce the costs and associated environmental impacts substantially (Jones *et al.*, 2014).

Other pathogenic microorganisms which are associated with diseases of potatoes, is discussed in Section 2.1.2, General Agronomic Practices, Disease Control.

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 (*Solanum sarrachoides*) Common lambsquarters (*Chenopodium album*) Redroot pigweed (*Amaranthus retroflexus*) Ragweed (*Ambrosia artemisiifolia*) Kochia (*Kochia scoparia*) Pennsylvania smartweed (*Polygonum*	Barnyardgrass (*Echinochloa crus-galli*) Foxtail (*Setaria* spp.) Wild oat (*Avena fatua*) Fall panicum (*Panicum dichotomiflorum*)	Nutsedges (*Cyperus* spp.) Quackgrass (*Elytrigia repens*) Canada thistle (*Cirsium arvense*)

pennsylvanicum)		

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, *S*-ethyl dipropylcarbamothioate (EPTC), and metolochlor (USDA, 2000; Bechinski *et al.*, 2001; 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 diseases 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 there is little probability of successful establishment (OECD, 1997).

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 U.S. 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) (USDA-NASS, 2008). 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 2.5.1, 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% of the 2012 annual potato crop was used as seed (NPC, 2012) in the form of seed potatoes. Certified seed potatoes are produced to ensure genetic purity and to reduce disease introduction (NPC, 2012). 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). The use of good quality seed potatoes is important to successful potato culture. It is recommended that ideal seed size is about two to four ounces, about the size of a golf ball (Hollingsworth, No Date).

There are 16 potato seed certification agencies in the U.S., including one in each major production state (NPC, 2012). 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 2013 in order of decreasing production were Idaho (>33,000 acres planted), North Dakota, Montana, Maine, Colorado, Wisconsin, Nebraska and Minnesota (>5,000 acres harvested) (USDA-NASS, 2014c).

Potato Processing and Storage

About 60% of potatoes are processed into frozen commodities such as French fries and shoestring potatoes and dehydrated potatoes (Driskill *et al.*, 2007). Typically, frozen and dehydration industries are concentrated in the Northeast, upper Midwest, and Pacific Northwest. Potato chip processers 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, 2010c).

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).

Tubers for fry processing account for 36% of all U.S. potato production, and >50% of the land area for US potato production is planted in Russet Burbank and Ranger Russet (Zhu *et al.*, 2014).

2.2 Physical Environment

2.2.1 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, 2005; 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, 2009). 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, 2011d). 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 may lead 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 pollution. 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, 2005). 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, 2005). 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, 2005). 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, 2005). 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).

2.2.2 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, 2004). Soil is characterized by its layers that can be distinguished from the initial parent material due to additions, losses, transfers, and transformations of energy and matter (USDA-NRCS, 1999). 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, 1999). 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, 1999). 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.*, 1996). 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.*, 2004).

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 (Plissey and Erhardt, 2000; Johnson and Sideman, 2006). 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), 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).

2.2.3 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 (O_3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO_2), lead (Pb), and inhalable particulates (coarse particulate matter [PM] greater than 2.5 micrometers and less than 10 micrometers in diameter [PM_{10}] 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 (SIP) (US-EPA, 2011d). Regulation of agricultural sources within a SIP 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, 2011d). 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 U.S. EPA regulates mobile source emissions by reformulated gasoline and automobile pollution control devices (US-EPA, 2011d). Stricter requirements, such as vapor recovery nozzles on gas pumps, may apply in non-attainment areas.

2.2.4 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 (CO_2), methane (CH_4), and nitrous oxide (N_2O) 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 CO_2, 148 % in CH_4, and 18 % in N_2O (US-EPA, 2012a).

Greenhouse gases vary in their global warming potential (GWP), and the U.S. EPA converts all gases to carbon dioxide (CO_2) equivalents. For the three greenhouse gases most associated with agriculture, GWPs are as follows: CO_2 = 1, methane (CH_4) = 21, and nitrous oxide (N_2O) = 310 (US-EPA, 2012a). The U.S. 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 U.S. EPA, represented 6.3% of total greenhouse gas emissions for the U.S. in 2010 (US-EPA, 2012a). However, this does not include CO_2 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 CO_2 and N_2O 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 U.S. EPA are N_2O and CH_4. The relative percent contribution to total CO_2 equivalent emissions of the various agricultural sources in 2010 was as follows: agricultural soil management (fertilizer application and other cropping practices that contribute N_2O), 49%; enteric fermentation (primarily methane emissions from cattle), 33%; manure management, 16%; and rice cultivation, 2%. 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% of the total (DEFRA, 2006; US-EPA, 2012a).

2.3 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.

2.3.1 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, 1987). 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, 2013b). 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). USDA-APHIS Wildlife Services has also received complaints for damage caused by sandhill cranes (USDA-APHIS, 2013b).

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. 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 pruinina*), flea beetles (*Epitrix* sp.), European corn borer (*Ostrinia nubilalis*), potato psyllid (*Bactericera (Paratrioza) cockerelli*), tuberworm (*Phthorimaea operculella*), and the potato leafhopper (*Emposasca fabae*) (Johnson, 2007; Simplot, 2013; 2014). 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, 2007) 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 threshholds (US-EPA, 2000; Senseman, 2007). Conventional broad-spectrum insecticides are potentially toxic to invertebrates and vertebrates. The U.S.-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; 2009b).

2.3.2 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 2.1, 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 U.S. 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 2.1.2, General Agronomic Practices. 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, 1997). Section 2.3.3, Gene Flow and Weediness, discusses this subject. Because Russet Burbank is sterile (PAA, 2009), there is virtually no chance for gene flow.

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).

2.3.3 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; and weather conditions, including temperature, wind, and humidity (Zapiola *et al.*, 2008). Seed-mediated gene flow also depends on many factors, including the absence/presence/magnitude of seed dormancy; contribution and participation in various dispersal pathways, 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 (Holm *et al.*, 1979; Muenscher, 1980; Love, 1994; OECD, 1997).

Gene flow by hybridization is not possible for the Russet Burbank cultivar because it is sterile (PAA, 2009; NSF, 2011; Simplot, 2013; 2014).

In general, pollination of fertile varieties of potato is mostly by bumblebees (*Bombus impatiens*), which have a relatively short flight range (less than three kilometers) (OECD, 1997). Pollen dispersal by nectar-seeking pollinators is limited because potato flowers have no nectar. The honeybee (*Apis mellifera*) and *Bombus fervidus* are not attracted to them, and wind plays an insignificant role in pollination (OECD, 1997). 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). In addition, the effect on pollinators is probably not important since potatoes are cloned.

For fertile potato varieties, about 80-100% 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 (Pallais, 1987; Simplot, 2013). Russet Burbank is fully sterile, precluding any possibility of TPS production. But plants produced from TPS are no weedier than volunteer plants produced from overwintered 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, 1997). *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, 1997).

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, 1994). 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 U.S. 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, there are several biological barriers to gene transfer such as multiple ploidy levels and endosperm imbalances (Love, 1994). Hybridization between native and cultivated potatoes has never been reported in the U.S., although gene transfer has been accomplished using special laboratory techniques (Love, 1994; US-EPA, 2011b).

2.3.4 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.*, 2004) 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.*, 1996; 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.*, 2004; Rosen, 2010a). 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.*, 2004).

Larkin (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 soil-borne 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 and the number of misshapen tubers. Larkin (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).

2.3.5 Biodiversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem. Biodiversity provides valuable genetic resources for crop improvement (Harlan, 1975; Wilson, 1988), 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), and 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 2.1, Agricultural Production and Agronomic Practices, and animals in Section 2.3.1, Animal Communities.

2.4 Human and Animal Health

Humans are either consumers of potato and products derived from it, or are workers who produce potato crops. Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure 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 used 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. FDA evaluates the submission and responds to the developer by letter. Simplot submitted a letter of consultation on April 15, 2014 (BNF No. 000146). Although FDA approved the safety of Innate™ potato on March 20, 2015 (FDA, 2015), FDA is still reviewing the submission for W8 potato.

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). Genetic modification, as a source of uncertainty, is common to all forms of plant breeding. 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 generally conclude that there are no significant nutritional differences in conventional versus GE plants for food or animal feed (Faust, 2002; Flachowsky *et al.*, 2005).

2.4.1 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; FAO, 2008; Bushway, 2010). They have the highest protein content (around 2.1% 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, persons with diabetes or similar conditions may need to eat potatoes sparingly.

U.S. per capita potato consumption is summarized in Table 6.

Table 6. U.S. Per Capita Potato Consumption 2012 (lb/person/yr)

Fresh Market	Processing					All Potatoes
	Canned	Frozen	Chips	Dehydrated	Total Processing	
35.5	0.9	49.8	16.9	13.2	80.8	116.3

Source: (Council, 2014)

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 baking and frying.

Glycoalkaloids

Glycoalkaloids are nitrogenous secondary metabolites found in many plant species (Friedman and Dao, 1990), whose functions are to defend against pests, predators, and pathogens (Friedman, 2006; Ruprich *et al.*, 2009). The two major glycoalkaloids present in potato are alpha-solanine and alpha-chaconine (Friedman and Dao, 1990; Friedman, 2006).

At high levels, glycoalkaloids in potatoes can be toxic, and can cause poisoning symptoms such as headache, acute gastrointestinal distress (nausea, diarrhea, vomiting, abdominal pain), and a burning sensation in the mouth (Friedman, 1997; Ruprich *et al.*, 2009; Petersson *et al.*, 2013). In more severe cases of poisoning, these symptoms may be followed by drowsiness, apathy, visual disturbance, shallow breathing, rapid and weak pulse, loss of consciousness and coma, and even death (Friedman, 1997; 2006; Ruprich *et al.*, 2009). A lethal dose for humans is approximately 1-2 mg/kg of body weight (Friedman *et al.*, 1997). Cases of mild toxicity are frequently overlooked and go undiagnosed because symptoms may be confused with other causes of stomach upset (Ruprich *et al.*, 2009). In vertebrates, glycoalkaloids disrupt cell membrane transport of calcium ions and acetylcholinesterase function (Friedman, 1997; Ruprich *et al.*, 2009).

For food safety purposes, an upper limit for glycoalkaloid content of 200 mg/kg of potato is generally accepted (Sinden, 1987; Friedman, 2006; Petersson *et al.*, 2013). Levels greater than 14 mg/kg fresh weight potatoes can be perceived as bitter to human (Friedman, 2006), which appears to be an indicator of the presence of glycoalkaloids since naturally bitter potato cultivars contain higher levels of glycoalkaloids than do cultivars that do not taste bitter (Jansky, 2010).

Although glycoalkaloids are synthesized throughout the potato plant (Friedman, 1997; Petersson *et al.*, 2013), the highest levels are in metabolically active parts of the plant such as flowers, new leaves, and sprouts (Friedman, 1997; Petersson *et al.*, 2013). Comparatively, tubers have the lowest glycoalkaloid levels in fresh potatoes (Friedman and Dao, 1990), while sprouts, leaves and roots have greater amounts (Friedman and Dao, 1990). Higher leaves contain more total glycoalkaloids than do lower leaves. Within tubers, the highest levels are within the first 1mm of the skin, decreasing significantly toward the center of the tuber (Kozukue and Kozukue, 1987), so that removing the first 3-4 mm of the skin generally removes almost all of the glycoalkaloid content in tubers (Friedman, 2006). Larger tubers have higher glycoalkaloid content (Friedman, 2006). Genetic transformation does not appear to affect glycoalkaloid levels (Birch *et al.*, 2002).

Glycoalkaloid content appears to vary by cultivar and geographic location (Sinden and Webb, 1972; Friedman *et al.*, 1997). Levels can also be affected by environmental factors such as higher temperature and more light (Friedman *et al.*, 1997). Delaying harvest date tends to decrease glycoalkaloid production (Ruprich *et al.*, 2009).

U.S. commercial potato varieties typically have glycoalkaloid ranges below the recommended rate of 200 mg/kg of fresh weigh potato (a range of 20-130 ppm) (Sinden and Webb, 1972; Friedman and Dao, 1990; Friedman, 2003). These levels are not affected by cooking (Friedman *et al.*, 1997), but may be affected by processing operations such as slicing, peeling, and preparation for freezing and chip production (Friedman *et al.*, 1997). A higher concentration of glycoalkaloids ends up in skins of frozen and processed potato products, and potato chips contain more than fries (Friedman and Dao, 1990).

During storage, when harvested tubers are exposed to light or become damaged, glycoalkaloid content may rise, and may result in green areas of coloration on potato skins (Sinden, 1987; Center, 2010) (Friedman and Dao, 1990; Friedman, 1997); these changes differ with cultivar and genotype (Petersson *et al.*, 2013).

Patatins

Patatins are a family of proteins comprising 30 to 40% of the soluble protein in potatoes (Mignery *et al.*, 1988). Allergic reactions to cooked potatoes are considered to be very uncommon and were reported only in children (De Swert *et al.*, 2002). Patatin was identified as the major allergen involved in this reaction (De Swert *et al.*, 2007). Individuals who are allergic to patatin would need to avoid eating potatoes because potato protein naturally contains a relatively large proportion of patatin.

Acrylamide

Of greatest importance 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, 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 (Arvanitoyannis *et al.*, 2008; Pedreschi, 2009; Halford *et al.*, 2012a; Kotsiou *et al.*, 2013).

Important variables leading to acrylamide formation and affecting acrylamide concentration in cooked potatoes include the reducing sugar content, processing/cooking temperature and method, cooking/processing time, moisture content, and additives (Halford *et al.*, 2012a; Kotsiou *et al.*, 2013). 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). Because of higher rates of consumption of potato chips and French fries by children, adolescents, and males under the age of twenty-five, acrylamide exposure to these groups is likely to be higher (Dybing *et al.*, 2005). Acrylamide is also present in other foods such as coffee, some breads, biscuits, gingerbread, and processed onion mix and dip mixes. Smoking may also contribute to human exposure to acrylamide (Friedman, 2003; Chawla *et al.*, 2012; Kotsiou *et al.*, 2013).

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 Food and Agriculture Organization/World Health Organization (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, 2013b).

2.4.2 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 U.S.-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 require 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)).

2.4.3 Animal Feed

Potatoes used as livestock feed accounted for approximately 1% 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, 2013c). 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, 2010d).

Table 7. **U.S. 2012 Potato Utilization**

Utilization Item	CWT (1,000) (% of potatoes harvested)
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%)

Utilization Item	CWT (1,000) (% of potatoes harvested)
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	283,220 (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%)
Total Production	**462,766**

Source: (USDA-NASS, 2013c)

Potatoes constitute at least part of the diet for several domestic animals, including dogs, 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 lbs. of grain) (Corbett, No Date).

Feed does not include the leafy green foliage of potato plants since flowers, sprouts, and foliage have abundant glycoalkaloids, which are potentially poisonous for livestock (Sinden, 1987).

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. Consequently, any uncertainty in this area is addressed during an FDA inquiry process.

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 April 15, 2014 (BNF No. 000146). Although FDA approved the safety of Innate™ W8 potato on March 20, 2015 (FDA, 2015), they are still reviewing the submission for W8 potato.

2.5 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.

2.5.1 Domestic Economic Environment

Potatoes contribute approximately 15 % of farm sales receipts for vegetables, making potatoes the leading vegetable crop in the U.S. (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. The Russet Burbank variety is primarily used for French fries, but can be used fresh for baking (Pavek *et al.*, 1992; PAA, 2009).

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, 2010d). Because potato sales for livestock feed usually receive the lowest price, potatoes are not sold for livestock feed if other uses are available (Guenther, 2010d).

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, although recently, some western growers have entered the packing business, often in partnerships or cooperatives with other growers (Guenther, 2010b).

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, 2010c).

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% 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% 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).

Sale values per acre are 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, 2010d).

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% of total production costs in eastern Idaho in 2007 (Patterson, 2010). Potato production costs for irrigation in the western U.S. 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 return 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).

In general, post-harvest losses are a significant part of the production costs of fruits and vegetables, and may reach as high as 50% (Martinez and Whitaker, 1995; Llorente *et al.*, 2011). 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.

<u>Black spot bruise</u>

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.*, 2012).

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 products (Hunt *et al.*, 1993; Steffens, 1994; Stremmel *et al.*, 2010; Llorente *et al.*, 2011; 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 multi-gene 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).

Reducing Sugars

The levels of reducing sugars (sugars which can be oxidized) in potato are critically important because of maintenance of product quality throughout storage and processing (Olsen *et al.*, 2005). In potato, the reducing sugars of interest are glucose and fructose (Olsen *et al.*, 2005). High levels of reducing sugars may lead to unacceptably dark colors when cooking frozen or processed potatoes, and bitter taste (Bethke *et al.*, 2009). In addition, reducing sugars react with amino acids during cooking in the Maillard reaction (O'Brien *et al.*, 1989; Bhaskar *et al.*, 2010), and as such, are important factors in acrylamide formation in fried potato products (Zhu *et al.*, 2014).

At harvest, most potatoes contain low levels of reducing sugars. Minimizing the time between vine kill and harvest is recommended to maintain these low levels (Olsen *et al.*, 2005). In general, the lower the storage temperature for tubers, the greater the concentration of sugars (Olsen *et al.*, 2005). Because potatoes may frequently need to be stored for up to 12 months before processing, maintenance of low levels of reducing sugars is a challenge for processors (Olsen *et al.*, 2005). If tubers are stored too long, reducing sugars tend to accumulate (Driskill *et al.*, 2007). If sugar levels rise too high, processors may reject them for use as fries or chips, and growers may be forced to sell them for lower prices to other markets (Driskill *et al.*, 2007).

Currently potatoes that are intended for fry production are kept at 46^{o}-48^{o}F (Olsen *et al.*, 2005; Driskill *et al.*, 2007; Wu *et al.*, 2011), which represents a compromise between the potential weight loss, increased disease pressure and accompanying spoilage, and sprouting, that comes with warmer temperatures, and the problems of cold-induced sweetening (CIS), which leads to increased acrylamide potential, and decreased product quality (Driskill *et al.*, 2007).

Another problem caused by high levels or reducing sugars is called sugar end defect by the potato industry (Driskill *et al.*, 2007) which can result from uneven environmental conditions during tuber initiation and early tuber bulking (Zhu *et al.*, 2014). This occurs when reducing sugar levels rise and preferentially settle in the basal end of the potato, so that there is an uneven distribution of sugars in processed potatoes and a resulting darker color in those sections: for example, one end of a French fry will be darker than the other (Zhu *et al.*, 2014). If levels of sugar ends are extremely high, the potatoes cannot be used for premium French fries, and may result in loss of economic value to the processors (Zhu *et al.*, 2014). These defects may also result in higher prices for consumers (Zhu *et al.*, 2014).

For all of these reasons, breeders and growers strive to produce potatoes destined for processing that maintain a stable, relatively low level of reducing sugars throughout storage (Driskill *et al.*, 2007).

2.5.2 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% in value and 79% in volume during the last 10 marketing years (Board, 2013). Frozen potato products comprise 60% 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 (Board, 2012; USDA-ERS, 2013). Mexico provides the U.S. with the largest market for exporting potato flakes and granules and is the second largest market destination for frozen potatoes (Board, 2012; USDA-ERS, 2013).

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 U.S. will facilitate the growth of the export market by continuing to gain new market access, as recently occurred for fresh table-stock to the Philippines (Board, 2013).

2.5.3 Organically Certified Economic Environment

In the U.S., products produced using only 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 U.S. 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 reflect 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™ W8 potato.

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™ W8 potato and progeny derived from Simplot Innate™ W8 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™ W8 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™ W8 potato.

This alternative is not the Preferred Alternative because a Plant Pest Risk Assessment (PPRA) found Simplot Innate™ W8 potato is unlikely to pose a plant pest risk (USDA-APHIS, 2014b). 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™ W8 Potato Is No Longer a Regulated Article

Under this alternative, Simplot Innate™ W8 potato and derived progeny would no longer be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of Simplot Innate™ W8 potato and progeny derived from this event. Under this alternative, growers may have future access to Simplot Innate™ W8 potato and progeny derived from this event if the developer decides to commercialize Simplot Innate™ W8 potato.

This alternative meets the purpose and need to respond appropriately to a petition for nonregulated status when there is a determination of no pest risk. Based on the PPRA conclusion that Simplot Innate™ W8 potato is unlikely to pose a plant pest risk (USDA-APHIS, 2014b), conferring nonregulated status to Simplot Innate™ W8 potato is a response that is consistent with the plant pest provisions of the Plant Protection Act and the regulations codified in 7 CFR part 340.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for Simplot Innate™ W8 potato. The agency evaluated these alternatives, in light of the agency's authority, environmental safety, efficacy, practicality, and other concerns. APHIS rejected several alternatives based on the discussions summarized in this section.

3.3.1 Prohibit Any Simplot Innate™ W8 Potato from Being Released

In response to public comments stating a preference for GE organisms to not enter the marketplace, APHIS considered prohibiting the release of Simplot Innate™ W8 potato, including denying any permits associated with the field testing. APHIS determined this alternative is not a reasonable alternative because APHIS found Simplot Innate™ W8 potato is unlikely to pose a plant pest risk (USDA-APHIS, 2014b).

In enacting the Plant Protection Act, Congress found that:

[D]ecisions affecting imports, exports, and interstate movement of products regulated under this title [the Plant Protection Act;§402(4) (7 U.S.C. 7701] shall be based on sound science…

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order 13563, to guide the development and implementation policies at the agency level for oversight of emerging technologies, such as genetic engineering. Among those identified in the memorandum, agencies were directed to adhere to the following principle to the extent permitted by law when regulating emerging technologies:

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

Based on the PPRA (USDA-APHIS, 2014), and the scientific data evaluated therein, APHIS concluded that Innate™ W8 potato is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of Innate™ W8 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™ W8 potato is unlikely to pose a plant pest risk, there is no regulatory basis for considering approval of the petition only in part.

3.3.3 Isolation Distance between Simplot Innate™ W8 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 Innate™ W8 Potato from conventional or specialty potato production. However, because APHIS has concluded that Innate™ W8 potato is unlikely to pose a plant pest risk (USDA-APHIS, 2014), 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 Innate™ W8 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 the PPRA for Innate™ W8 potato, there are no geographic differences associated with any identifiable plant pest risks for Innate™ W8 potato (USDA-APHIS, 2014). This alternative was rejected and not analyzed in detail because APHIS has concluded that Innate™ W8 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 statutory authority of APHIS under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR 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 the Agency's 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 Innate™ W8 potato or to use isolation distances and other management practices to minimize gene movement between Innate™ W8 potato and non-GE potato fields. Information to assist growers in making informed management decisions for Innate™ W8 potato is available from the Association of Official Seed Certifying Agencies (AOSCA, 2010).

3.3.4 Requirement of Testing for Simplot Innate™ W8 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 Innate™ W8 potato does not pose a plant pest risk (USDA-APHIS, 2014), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the PPA and the regulations at 7 CFR part 340. Therefore, imposing such a requirement for Innate™ W8 potato would not meet APHIS' purpose and need to respond appropriately to the petition.

3.4 Comparison of Alternatives

Table 8 includes a summary of the potential impacts associated with selection of the alternatives evaluated in this EA. The potential environmental consequences are presented in Section 4 of this EA.

Table 8. 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**

Table 8. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2014b)
Management Practices		
Acreage 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™ W8 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 8. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Water Resources	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.	Unchanged from No Action Alternative.
Soil Quality	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.	Unchanged from No Action Alternative.
Air Quality	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.	Unchanged from No Action Alternative.

Table 8. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Climate Change	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.	Unchanged from No Action Alternative.
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™ W8 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™ W8 potato with conventional varieties, resulting progeny may contain lowered polyphenol oxidase levels. However, this is not expected to be detrimental. Simplot Innate™ W8 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™ W8 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.

Table 8. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Biological Diversity	The biological diversity in potato fields is lower than in the surrounding habitats.	Unchanged from No Action Alternative.
Human and Animal Health		
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 could be reduced approximately 60-70%, which would 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, lower reducing sugars) and potential reduced wastage (low bruising, late blight resistance), Simplot Innate™ W8 potato may comprise a larger share of the domestic potato market, and may result in increased revenues.

Table 8. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
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™ W8 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™ W8 traits are approved by importing countries, it may make up a larger percentage of potato import markets.
Other Regulatory Approvals		
U.S.	FDA completed consultations, EPA tolerance exemptions and conditional pesticide registrations granted	FDA is currently reviewing Simplot's voluntary consultation of April 15, 2014.
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™ W8 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™ W8 potato does not pose a plant pest risk (Preferred Alternative). Potential environmental impacts from the No Action Alternative and the Preferred Alternative for Simplot Innate™ W8 potato are described in detail throughout this section. A summary of potential environmental impacts is presented in Table 8 (Section 3.4, Comparison of Alternatives). 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™ W8 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). 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™ W8 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™ W8 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 in potato production decreased in recent years, whereas potato yields increased dramatically. Potato acres harvested 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 in the U.S. (USDA-NASS, 2012b). Per-acre yields, which averaged 397 cwt per acre in 2011 and 401 cwt per acre in 2012 increased eight-fold since the early 1900s and doubled since the early 1960s (USDA-NASS, 2013a).

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. While harvested acreage has declined over the years, total production has increased (Guenther, 2010b). Under the No Action alternative, agricultural land used for potato production will likely decline as potato production yield increases.

Preferred Alternative: Acreage and Area of Potato Production

If APHIS chooses the Preferred Alternative, the Simplot Innate™ W8 potato event may become commercially available to the general public. Simplot Innate™ W8 potato is not expected to affect overall demand for potatoes, but growers who now purchase conventional varieties of Russet Burbank, Ranger Russet and Atlantic potato seed would have the option of purchasing the Simplot Innate™ W8 variety instead. With the traits of late blight resistance, reduced acrylamide potential, reduced black spot bruising, and lower levels of reducing sugars, the Simplot Innate™ W8 potato may replace other varieties of potato currently on the market, resulting in increased market share for the Simplot Innate™ W8 potato.

Simplot's data demonstrate no differences in morphological characteristics and agronomic requirements between Simplot Innate™ W8 potato and other potato cultivars (Simplot, 2014) and Simplot Innate™ W8 potato 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™ W8 potato.

As described in the petition (Simplot, 2014), the agronomic characteristics of the Simplot Innate**™** W8 event are essentially the same as their conventional counterparts, and therefore would be grown in the same way as their conventional counterparts. The Simplot Innate™ W8 potato event does 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 as in the No Action Alternative.

4.3.2 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 Simplot Innate™ W8 potato event is summarized in Section 11 of the petition, with details provided in Section 11.1.3; analysis of disease susceptibility is presented in petition Section 11.2 (Simplot, 2014). Since the Simplot Innate™ W8 potato event is intended for fresh, fry, chip, and dehydrated markets , 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, 2014). 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 (Simplot, 2014).

Simplot Innate™ W8 potato has been engineered to be resistant only to certain strains of one particular disease of potato, late blight. It is unknown whether this will lead to a reduction in frequency of fungicide application and volume for growers. However, no other changes to current agronomic practices will be needed to grow the potatoes, thus the incorporated traits are not expected to affect agronomic practices other than potential reduction in fungicide use and volume (Simplot, 2014; USDA-APHIS, 2014b). All events considered for deregulation were selected to exhibit comparable phenotypic characteristics to the control varieties when grown using standard industry practices.

Late Blight Resistance

The Potato Late Blight Resistance Gene (*Rpi-vnt1*) encodes a resistance protein, VNT1, which reacts with a pathogen-specific effector protein to halt the spread of infection (Simplot, 2014). Widely consumed plant species that are reported to contain disease-resistance (R) genes include the Solanaceae family, *Zea mays* (maize), *Glycine max* (soybeans), *Oryza sativa* L. (rice), and *Triticum aestivum* L. (common wheat) (Bakker *et al.*, 2011). In addition to these common cultivated crops, the *Rpi-vnt1* gene is identical to the *Rpi-phu1* gene (Rodewald and Trognitz, 2013) found in some *S. phureja* species, a potato species consisting of many varieties which are currently consumed by indigenous people in South America. The presence of similar or identical genes in frequently consumed tomatoes and potatoes that have not had negative impacts on human health establishes a history of safe use (Simplot, 2014).

Resistance to *P. infestans* occurs in many tuber-bearing wild *Solanum* species that belong to the highly diverse section *Petota* Dumort. (Vleeshouwers *et al.*, 2011). Wild relatives of potato are a source of late blight resistance genes (Jones *et al.*, 2014). To date, 21 *R*-genes that confer differential resistance specificities to *P. infestans* isolates have been cloned from various *Solanum* species crops (Vleeshouwers *et al.*, 2011). Most *Solanum R* genes appear to have coevolved with *P. infestans* at its center of origin in central Mexico (Vleeshouwers *et al.*, 2011).

Biochemical characterization and safety assessment of the VNT1 protein suggested a negligible risk associated with using VNT1 to confer late blight resistance to potato cultivars. The encoded VNT1 protein is native to *Solanum* species and provides protection against *P. infestans*, the causal agent of late-blight disease. Currently VNT1 represents only one of 68 distinct R-genes that have been characterized from wild *Solanum* species, which shows the breadth and importance of these genes to potato biology (Rodewald and Trognitz, 2013).

Additionally, Simplot Innate™ W8 potato had less evidence of scab (as measured by mean percent lesion coverage of the tuber) than did the control line, and the lesions produced by the disease were less severe than in the control line. This result will be monitored in future field and storage studies to determine if this pattern of resistance to scab persists in commercial production (USDA-APHIS, 2014b). If so, this finding will improve the agronomic properties of Simplot Innate™ W8 potato for future development, but will not change the plant pest potential of the tuber.

In summary, 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 (Simplot, 2014). Field trials conducted by Simplot over multiple years showed no evidence for altered growth characteristics such as increased plant vigor, increased tuber set, early tuber sprouting, or delayed senescence. In addition to observations on insect stressors, there were no trends observed with respect to significant differences in W8 potato responses to disease stressors in the 95 observations made, including bacterial and fungal pathogens. The only agronomic difference detected is that the W8 event is more resistant to late blight. (USDA-APHIS, 2014b).

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

4.3.3 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, 2014b), selection of the Preferred Alternative is not expected to result in any changes in potato seed production.

4.3.4 Organic Potato Production

No Action Alternative: Organic Potato Production

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

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% 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). However, certain markets or contracts may have defined thresholds (Non-GMO-Project, 2010).

4.4 Physical Environment

4.4.1 Water Resources

No Action Alternative: Water Resources

The majority of potato production utilizes irrigation as a water source. As discussed in Section 2.2.1, Water Resources, agricultural production can be detrimental to water quality by adding sediments from erosion via surface water, nutrient loading from fertilizers into groundwater, and pesticide runoff.

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™ W8 potatoes. Simplot's studies demonstrate no differences in morphological characteristics and agronomic requirements between Simplot Innate™ W8 potato and other potato varieties (Simplot, 2014). 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™ W8 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.

4.4.2 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.*, 1996).

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

Preferred Alternative: Soil Quality

A determination of nonregulated status for Simplot Innate™ W8 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. Other studies of the effect of GE crops on soil characteristics have not shown significant effects. For example, Bruinsma (2003) found no differences in soil attributable to a GE potato cultivar transformed to produce T4 lysozyme. Simplot's studies demonstrate that agronomic characteristics and cultivation practices required for Simplot Innate™ W8 potato production are indistinguishable from practices used to grow other potato varieties (Simplot, 2014). Except for the incorporated traits, the event is 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.

4.4.3 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 2.2.3, 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, 2014) demonstrate that no changes to agronomic practices will be required to grow Simplot Innate™ W8 potato. As discussed in Section 2.2.3, Air Quality, 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 event 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 event.

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.

4.4.4 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, 2014) and APHIS PPRA (USDA-APHIS, 2014b), Simplot Innate™ W8 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™

W8 potato, the agricultural impacts of potato production on climate change are also unlikely to change under the Preferred Alternative.

4.5. Biological Resources

4.5.1 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, 2014) demonstrates that changes in agronomic practices, including practices related to pesticide use and erosion mitigation, are not required for production of Simplot Innate™ W8 potato. 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™ W8 potatoes would have the same impact on other organisms as conventional potatoes (Simplot, 2014). Aside from the targeted traits, the Simplot Innate™ W8 potato is compositionally similar to conventional potatoes (Simplot, 2014; USDA-APHIS, 2014b).

APHIS reviewed Simplot's data on field trials (USDA-APHIS, 2014b) and impacts by insects, and concluded that Simplot Innate™ W8 potato would suffer no greater insect pressure than conventional potatoes (USDA-APHIS, 2014b). For example, no increase in aphid infestation or damage was reported in the field observations for the Simplot Innate™ W8 potato event (Simplot, 2014). In addition, since potatoes are propagated vegetatively from seed potato tuber pieces, pollination by bumblebees is not important to potato tuber production. It is not likely that the genetic construct components responsible for gene silencing in the W8 potatoes would contribute to silencing 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 W8 potatoes.

Simplot Innate™ W8 contains traits for reduced acrylamide formation, reduced black spot bruise, lowered reducing sugars, and late blight resistance. 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 of 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 (Plaisted, 1980; Steffens, 1994). However, the trichomes of cultivated potatoes contain low amounts of PPO which is not thought to be involved in 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 also 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). These dark-pigmented polyphenols, also referred to as melanins, result in the darkening of potato tissue following mechanical bruising (Thygesen *et al.*, 1995). Ppo5, the PPO gene silenced in W8 is the primary form found in potato tubers, and is the primary PPO gene detected in older tubers (Thygesen *et al.*, 1995). Ppo5 transcripts were down-regulated in tubers, but not in stems, roots, leaves and flowers in W8 compared to the non-transgenic control varieties (Simplot, 2014). This suggests that except for tubers, Simplot Innate™ W8 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, 2014; USDA-APHIS, 2014b).

Simplot assessed nematode damage of Simplot Innate™ W8 potato, and results showed no more nematode damage than in control potatoes (Simplot, 2014). 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™ W8 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) 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 and Marnet (2012) evaluated the role of specific phenolics in quantitative resistance to 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™ W8 potato tubers contain increased levels of glutamine (Simplot, 2014) because the enzyme asparagine synthetase also functions to deaminate glutamine to glutamate (Lam *et al.*, 1996). 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, 2014b). 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.* (2008) reported that intestinal dysfunction and atrophy were prevented when piglets' diets were supplemented with glutamine. Similarly, Boukhettala *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.* (1990) demonstrated that added glutamine protects rat intestinal mucosa following radiation therapy.

There were no significant differences between the event and its respective control varieties for mean glycoalkaloid toxin content, and levels were below the accepted safety limit (Simplot, 2014).

In its petition, Simplot (Simplot, 2014) assessed susceptibility of Simplot Innate™ W8 potato to several diseases, and showed that the potato is resistant to late blight without any change in susceptibility or loss of resistance to other diseases. Because of the specificity of the *Rpi-vnt1* protein in Simplot Innate™ W8 potato, and the observed disease susceptibility panel, the Simplot Innate™ W8 potato is highly unlikely to adversely impact soil or plant-associated fungi or bacteria (USDA-APHIS, 2014b). Potato Late Blight Resistance Gene (*Rpi-vnt1*) encodes a protein that halts the spread of the infection by the pathogen. The mechanism of action for the expressed effector protein is very specific and extremely unlikely to impact other organisms such as insects and other non-target organisms (Simplot, 2014).

There is no evidence that animal exposure to Simplot Innate™ W8 potato would have any effect or be any less attractive as food, refuge, cover and nesting sites as non-GE varieties of potatoes. Simplot Innate™ W8 potato tubers are nutritionally and compositionally similar to the respective parental control and other commercial potato varieties with the exception of the intentional changes conferred by the introduced or silenced genes (USDA-APHIS, 2014b). The results of the beneficial arthropod and pest arthropod abundance monitoring produced no significant differences between the Simplot Innate™ W8 event and the control for any of the arthropods collected (USDA-APHIS, 2014b). APHIS concludes that exposure to and/or consumption of Simplot Innate™ W8 tubers or other plant parts is unlikely to have adverse impacts on organisms beneficial to agriculture (USDA-APHIS, 2014b).

Accordingly, based on the results of the studies presented here, it seems unlikely that the VNT1 protein will have any impact on human health through allergenicity or toxicity, or any environmental impacts to non-target mammals, birds, fish, or insects due to the low expression and lack of toxic effects of the protein. There is negligible risk of environmental contamination and no persistence in the environment because of the low expression of the VNT1 protein in potato tubers. The prevalence of similar resistance genes throughout edible crops suggests that extremely low levels of similar proteins are widespread in nature and unlikely to pose risk to human health, non-targets or the environment (USDA-APHIS, 2014b).

The introduced genes did not significantly alter the observed insect pest infestation and disease occurrence or resulting damage in Simplot Innate™ W8 potato relative to the control line under the typical recommended pest management conditions. Therefore, APHIS concludes that based on the compositional similarity of Simplot Innate™ W8 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, 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 (USDA-APHIS, 2014b).

In general, migratory birds are not expected to feed on potato plants because of their glycoalkaloid content, while cover and nesting sites also appear comparable to conventional varieties because the GE plants are agronomically similar. Considering all that is known about Simplot Innate™ W8 potato lines and their production, there is nothing to indicate that migratory birds would interact or be affected any differently than they would with other potato varieties currently grown.

With regard to non-target organisms such as insects, birds or mammals, consumption of Simplot Innate™ W8 potato is unlikely to substantially affect them. Simplot's data demonstrates that the composition of Simplot Innate™ W8 potato does not substantially differ from conventional potato varieties (Simplot, 2014).

The literature contains reports of exposure of transgenic organisms to non-target organisms, although there have been no studies done with Simplot Innate™ W8 potato. Exposure may occur via feeding on the roots of GE plants or eating plant parts or exudates produced by GE plants (Cowgill *et al.*, 2002). No detectable effects have been found in studies of soil organisms (microorganisms and fungi) (Celis *et al.*, 2004; Milling *et al.*, 2004). Variables other than the genetic modification and its associated production of transgenic proteins were found to be responsible for any changes in soil populations. For example, soil type and texture had the most effect on bacterial communities; the availability and amount of organic carbon in soils greatly influenced activity and structure of bacterial communities; and host plant genotype and developmental stage contributed to any community changes (Rasche *et al.*, 2006). The effects due to the genetic changes were found to be either transient or minor compared to other factors. A study on the effect of GE potatoes on invertebrates showed that the potato did not influence the density or number of soil nematodes in the soil (Celis *et al.*, 2004).

APHIS did 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, 2014b).

4.5.2 Plant Communities

<u>No Action Alternative: Plant Communities</u>

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

<u>Preferred Alternative: Plant Communities</u>

Simplot has presented the results of field trials which demonstrate that Simplot Innate™ W8 potatoes do not require any changes to agronomic inputs when compared with conventional potatoes (Simplot, 2014).

There would be no change in herbicide use or patterns. Under the Preferred Alternative, potential impacts to plant communities are not anticipated to be different compared to the No Action Alternative.

The silencing of the gene responsible for asparagine synthesis and thus the lower acrylamide potential leads to somewhat heightened levels of glutamine in Simplot Innate™ W8 potato, but levels are within acceptable limits (OECD, 1997). In the very unlikely event of hybridization of Simplot Innate™ W8 potato, resulting progeny may have altered 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 4.5.1, Animal Communities, consumption of Simplot Innate™ W8 potato is not expected to change herbivore-plant interactions.

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.

4.5.3 Gene Flow and Weediness

<u>No Action Alternative: Gene Flow and Weediness</u>

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

<u>Preferred Alternative: Gene Flow and Weediness</u>

If APHIS selects the Preferred Alternative, no changes in agronomic practices are expected to occur (USDA-APHIS, 2014b) which might make potato, including Simplot Innate™ W8 potato more susceptible to gene flow or weediness.

As discussed in Section 2.3.3, Gene Flow and Weediness, Russet Burbank potato is sterile and produces few flowers (PAA, 2013). Fertile varieties of potato pose little potential for outcrossing because of their lack of nectar and therefore attractiveness to honey bees (OECD, 1997) and their self-pollinating biology (Gillund *et al.*, 2013). Hybridization potential is nil because of these factors and because commercial potatoes do not exhibit weedy characteristics (Love, 1994). There are few wild potato varieties in the U.S., and of those, most are geographically isolated from commercial production areas (US-EPA, 2011b).

The data presented by Simplot demonstrate that the Simplot Innate™ W8 potato is phenotypically and agronomically similar to its Russet Burbank parent variety and does not exhibit meaningful changes in characteristics that would make them weedier or more persistent than the parent variety. In fact, because of its reduction in early emergence and large tuber yield, the Simplot Innate™ W8 potato appears to have a reduced potential for weediness (USDA-APHIS, 2014b). Furthermore, Simplot did not observe any differences during the completed post-harvesting volunteer monitoring of the Simplot Innate™ W8 potato field test sites from 2 years of field testing that would lead them to conclude that these potatoes have properties that would increase their survivability compared to conventional potatoes (Simplot, 2014).

With respect to gene flow, the genetic modification in the Simplot Innate™ W8 potato is not expected to increase the potential for gene flow (USDA-APHIS, 2014b) compared to the nontransgenic recipient or other varieties of the crop commonly grown. Gene flow from Russet Burbank Event W8 is nonexistent because the variety is sterile (PAA, 2009).

The late blight resistance gene, *Rpi-vnt1*, encodes a resistance protein, VNT1, which reacts with a pathogen-specific effector protein to halt the spread of infection. This resistance would not enhance the potato survivability beyond what would be normally expected for potatoes. Therefore, Simplot Innate™ W8 potato is unlikely to be any weedier than conventional potato (USDA-APHIS, 2014b).

4.5.4 Microorganisms

No Action Alternative: Microorganisms

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

Preferred Alternative: Microorganisms

Under the Preferred Alternative, the impacts to microorganisms are expected to be the same as if the No Action Alternative is chosen. The evaluation presented in the petition (Simplot, 2014) 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 Simplot Innate™ W8 potato event (USDA-APHIS, 2014b).

Tuber browning can be a plant response to infection by microbial pathogens, so modified potato tubers may not exhibit the same degree of symptoms as conventional varieties. Plant infection can also induce the production of other compounds that produce browning (e.g. phenolics) so a complete absence of symptoms in GE varieties is unlikely (USDA-APHIS, 2014b). If there are no disease symptoms, or if symptoms are reduced below action thresholds, then it is unlikely a farmer would increase pesticide use.

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).

4.4.5 Biodiversity

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 country. This will allow for continued trends of biodiversity occurring outside the borders of agricultural fields even though biodiversity. Biodiversity is expected to continue to be fairly low within agricultural fields.

Preferred Alternative: Biodiversity

Under the Preferred Alternative, biodiversity is unlikely to be substantially changed in comparison to the No Action Alternative. First, the evaluation presented in the petition (Simplot, 2014) demonstrates that changes in agronomic practices would not be required to incorporate production of the event. This means cultivation, management, and land-use decisions related to Simplot Innate™ W8 potatoes are not different from conventional potato cultivars. With the possible exception of fungicide application and volume, which may remain the same or decrease because of the late blight resistance trait, agronomic practices such as irrigation, pesticide application, fertilizer applications, and agriculture equipment would be unchanged by the addition of these two varieties. Thirdly, flora and fauna that typically inhabit potato fields will continue to be affected by currently used management plans and production systems. 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.

4.6 Human and Animal Health

4.6.1 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 2.4.1, Consumer Health, potential toxins in potatoes are acrylamide, which forms subsequent to high-temperature cooking, and glycoalkaloids. Patatin is allergenic to a very small percentage 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™ W8 potato is widely adopted, acrylamide content in cooked potatoes could be significantly reduced, leading to potential health benefits for consumers. Compared with conventional potatoes, Simplot Innate™ W8 potato contains, on average, 78-84% less acrylamide when cooked (Simplot, 2014). As discussed in Section 2.4.1, Consumer 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 recommendations (FDA, 2013c) 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™ W8 potato in French fries and other frozen potato products. In the absence of these alternative varieties, food producers voluntarily alter their production practices to reduce acrylamide in their products. Deployment of Simplot Innate™ W8 potato genes would allow them an alternative way to produce reduced acrylamide products.

The lowered reducing sugar trait will also potentially lead to improvements in human health due to its ability to decrease acrylamide formation potential even further.

The late blight resistance gene will likely improve potato yield, and will indirectly improve human health by increasing food availability.

The data presented in the petition shows that the Simplot Innate™ W8 potato event is at least as safe and nutritious for food as the untransformed controls (Simplot, 2014). The compositional analyses of the event is summarized in the petition, with detailed results in Section 8 (Simplot, 2014). 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 2012 and 2013 in potato-growing areas of the U.S. Observed changes in asparagine 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.

Based on the results in results in the petition (Simplot, 2014), the potato event described in this petition does not appear to be compositionally different in comparison to untransformed controls, except for the intended traits. Therefore, issues with allergies are not expected to differ from those in the currently affected environment or under the No Action alternative.

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 this event 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).

4.6.2 Worker Safety

<u>No Action Alternative: Worker Safety</u>

If APHIS were to choose the No Action alternative, farm and food production workers would continue to be exposed to the same types and amounts of hazards as they currently experience in potato production and food processing.

Preferred Alternative: Worker Safety

Under the Preferred Alternative, there will be no changes in agronomic or food production practices in order to produce food and feed from Simplot Innate™ W8 potato (Simplot, 2014). Consequently, impacts to worker health resulting from approval of the petition are expected to be the same as if the No Action Alternative is chosen.

Simplot demonstrates in its petition that the agronomic inputs required to cultivate Simplot Innate™ W8 potato are functionally equivalent to those required for conventional potatoes (Simplot, 2014). Current health and safety protocols are not likely to require changes to accommodate the production or handling of Simplot Innate™ W8 potatoes because the characteristics of the potatoes are not altered. Normal harvesting, transport, and storage conditions designed to minimize the accumulation of glycoalkaloids and acrylamide do not need to be altered to accommodate these potato varieties. Since fungicide use should remain the same or decrease, but should not increase, workers should be exposed to no more than pesticides than under the No Action Alternative.

4.6.3 Animal Feed

No Action Alternative: Animal Feed

As discussed in Section 2.4.3, *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 Simplot Innate**™** W8 event is summarized in Section 8 of the petition, with detailed results in Section 8 (Simplot, 2014). Additionally, the nutritional and compositional differences between Simplot Innate™ W8 potatoes and conventional potatoes were evaluated in the PPRA (USDA-APHIS, 2014b) and found to be similar. The composition of Simplot Innate™ W8 potatoes is within the ranges of normal variation with conventional potatoes with respect to protein and carbohydrate content available in feed (USDA-APHIS, 2014b). As a result, incorporation of Simplot Innate™ W8 potatoes into animal feed is unlikely to affect palatability of the feed.

In conclusion, the data presented in the petition shows that potatoes from the event 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.

4.7 Socioeconomic Impacts

4.7.1 Domestic Economic Environment

No Action Alternative: Domestic Economic Environment

The domestic economic environment is discussed in Section 2.5.1, Socioeconomic: Domestic Economic Environment, and potato utilization in the country 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 1% 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 Simplot Innate™ W8 potato event will become available for commercial production. Because of the reduced potential for black spot bruise of Simplot Innate™ W8 potato, wastage is expected to decrease. This will lead to greater efficiency in processing, and an improved revenue stream for product producers. Overall, if APHIS chooses the Preferred Alternative, the introduction of Simplot Innate™ W8 potato are likely to have positive economic impacts on potato growers that choose to grow Simplot Innate™ W8 potato.

Potatoes with low acrylamide potential, reduced black spot bruise, lowered reducing sugars, and late blight resistance 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 and its products. As adoption of the potato event 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, 2014).

Organic potato growers are not anticipated to incur additional operating costs to as a result of the Preferred Alternative. See Section 4.3.4, Organic Potato Production, for further discussion.

Cold-induced sweetening and the resulting potential for acrylamide formation is addressed by the suppression of the *Vlnv* gene (Bhaskar *et al.*, 2010) in Simplot Innate™ W8 potato. The *VInv* gene silencing cassette in pSIM1678 resulted in decreased levels of vacuolar invertase, an enzyme which converts sucrose into glucose and fructose. When levels of invertase are decreased in potatoes, reducing sugars glucose and fructose remain at low levels during storage while sucrose increases, especially when held below typical storage temperatures of 46 - 48°F for French fry potatoes. Before testing for invertase activity, tubers were stored at 39°F for one month. Three replicates for each of Simplot Innate™ W8 and Russet Burbank control were used for the assay which was measured by the accumulation of glucose. Simplot Innate™ W8 tubers had an 85% reduction in vacuolar invertase activity in cold-stored tubers compared to controls. The reduced vacuolar invertase activity in W8 tubers is associated with reduced RNA accumulation from the *VInv* gene and lower levels of reducing sugars glucose and fructose (Simplot, 2014).

All Simplot Innate™ W8 tubers contained more sucrose than control samples at harvest and after multiple storage time points at both 38˚F and 46˚F. The increase in sucrose was expected from silencing the *VInv* gene, thus inhibiting the conversion of sucrose into the reducing sugars glucose and fructose. The mean levels of sucrose for W8 were within the tolerance interval and combined literature ranges, and therefore would be considered substantially equivalent to the controls. Human consumption of potato with increased sucrose levels would be digested by humans into fructose and glucose (Combes and Monsan, 1983).

By silencing vacuolar invertase in potato, growers should be able to store potatoes destined for processing at significantly lower temperatures, decreasing loss from disease and yield losses from higher respiration rates related to typical storage at 46 – 48 ˚F. (Simplot, 2014). Storage at lower temperatures may provide other advantages such as disease reduction, minimization of moisture loss, and reduction of anti-sprouting chemicals (Simplot, 2014).

For the Russet Burbank event Simplot Innate™ W8 potato, there should be significant economic and quality benefits from lower levels of reducing sugars. In addition, less reducing sugar will result in lower levels of acrylamide after cooking, a significant advantage considering the health concerns associated with acrylamide (NTP, 2012; FDA, 2013a).

4.7.2 Trade Economic Environment

As discussed in Section 2.5.2, 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 US exports of frozen potatoes, while Canada is the largest US export market for chips and fresh potatoes. The US also has substantial imports of potatoes and potato products from Canada and Mexico (USDA-ERS, 2012a).

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

If APHIS chooses the No Action alternative, U.S. potato exports are expected to continue as affected by market forces.

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

If APHIS chooses the preferred alternative, U.S. potato exports are expected to continue as affected by market forces. Approval for the event will be sought in Canada, Japan and Mexico (Simplot, 2014) 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. These approvals should ensure continued trade with key export markets. 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."

If APHIS chooses the Preferred Alternative, as with the domestic economic environment, the introduction of this potato event may have positive economic impacts on export markets, recognizing that some additional costs could be incurred.

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 PPA, including disease tolerance, nitrogen utilization, and herbicide tolerance, would be considered a cumulative impact.

5.1 Assumptions Used for Cumulative Impacts Analysis

Cumulative effects are qualitatively analyzed for each environmental issue assessed in Section 4, Environmental Consequences by focusing on the Preferred Alternative in consideration of related activities including past, present and reasonably foreseeable future actions including the production of potato progeny. 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 in that area.

APHIS considered the potential for Simplot Innate™ W8 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™ W8 potato are indistinguishable from practices used to grow conventional potatoes (Simplot, 2014; USDA-APHIS, 2014b). This implies 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™ W8 potato could replace other commercially available potato cultivars, without requiring production on new, previously non-cropped land. Land use changes associated with approving the petition do not appear 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 assumption that some growers have used commonly accepted best management practices (BMPs) in the past, and would continue to use these practices when reasonable under the circumstances for their chosen system and cultivars during potato production. APHIS recognizes, however, that not all growers choose to use the same BMPs.

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. The analysis showed Simplot Innate™ W8 potato is a potato cultivar that is agronomically and compositionally similar to other commercially available potato cultivars, so it is expected that Simplot Innate™ W8 potato would replace other similar cultivars without expanding the acreage of area devoted to potato production. There is no reason to anticipate changes to the availability of non-GE potato cultivars on the market based on the entry of this variety into the market.

Approving the petition for a determination of nonregulated status for Simplot Innate™ W8 potato is not expected to change current potato production practices. Studies conducted by Simplot demonstrate the agronomic characteristics and cultivation practices of Simplot Innate™ W8 potato are indistinguishable from practices used to grow other potato cultivars (Simplot, 2014; USDA-APHIS, 2014b). Consequently, progeny bearing these genes also appear unlikely to require different practices.

Organic growers use common practices to maintain the organic status in their potato production, including employing adequate isolation distances between the organic potato field and the fields of neighbors to minimize the chance that pollen will be carried among 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 is routinely utilized by growers, packers and retailers in the U.S. market to satisfy consumer preference and demand. Availability of another potato cultivar, such as Simplot Innate™ W8 potato under the Preferred Alternative, is not expected to impact the organic production of potatoes any differently than other potato cultivars currently being grown. Progeny bearing these genes may become deliberately added to specific potato cultivars based on market demand, and the choice to produce those modified varieties remains with each individual farmer.

Based on the information described in Section 4.7.1, Domestic Trade Environment, APHIS concludes that a determination of nonregulated status of Simplot Innate™ W8 potato will have no foreseeable adverse cumulative effects on domestic commerce. Simplot Innate™ W8 potato has the potential to improve potato processing capabilities and also improves 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. Progeny bearing these genes are anticipated to have the same potential for benefits. Based on these factors, no net negative cumulative impacts on domestic economics are identified associated with the production of Simplot Innate™ W8 potato.

Approving the petition for a determination of nonregulated status to Simplot Innate™ W8 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™ W8 potato is agronomically similar to other potato cultivars. Because of its similarity to other potato cultivars, adoption of Simplot Innate™ W8 potato is expected to replace other similar cultivars without impacting water, soil, air quality, and climate change differently from other potato varieties. Cumulative impacts due to climate change are anticipated to be the same for the Simplot Innate™ W8 event and conventional potatoes because their agronomic characteristics remain similar. Additionally, potato production in the U.S. occurs on less than 1% of the acreage as compared to the acreage occupied by corn and soybeans (USDA-NASS, 2012b) so the magnitude of any climate change due to potato production changes appears unlikely to be detectable.

Cumulative impacts of the Preferred Alternative to microorganisms and biodiversity are not expected to be significantly different than under the No Action Alternative because Simplot Innate™ W8 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 the Simplot Innate™ W8 potato event and conventional potatoes based on multiple years of field data, compositional analysis, and a lack of changes in 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. Consequently, this variety does not present a safety risk, or pose an increased weediness risk in relation to other currently available potatoes based on the information summarized in the PPRA (USDA-APHIS, 2014b).

Cumulative impacts to animal communities would be the same for the Simplot Innate™ W8 potato event and conventional potatoes. Three years of field data as well as compositional analysis and molecular stability show that the Simplot Innate™ W8 potato event is equivalent to conventional potatoes (Simplot, 2014). 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. Animals consuming Simplot Innate™ W8 potato may be exposed to increased levels of glutamine, but research on dietary supplementation with glutamine has not had any negative animal health effects. In the future, multiple potato varieties carrying these genes may lead to an increased risk of exposure to increased levels of glutamine, but consumers are more likely to substitute varieties rather than increasing their potato consumption.

In general, cumulative effects on human consumer health are expected to be the same for the Simplot Innate™ W8 potato event and conventional potatoes. There are two major exceptions: the Simplot Innate™ W8 potato contains significantly less acrylamide-forming potential than conventional potatoes, and less reducing sugars than conventional potatoes. Reduced levels of acrylamide in cooked potatoes are associated with human health benefits in consumers. Reduced potential to form acrylamide should result in significant human health benefits, particularly for those with a diet high in potato products produced by cooking at high temperatures. Compared with the conventional varieties, Simplot Innate™ W8 potato contained on average 78-84% less acrylamide (Simplot, 2014). 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, total protein and glycoalkaloid levels in Simplot Innate™ W8 potato were unchanged compared with the control varieties (Simplot, 2014). Although patatin was not measured during the studies (Simplot, 2014), any potential exposure to patatin is not expected to be different under the Preferred Alternative than under the No Action Alternative. 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 potatoes under the No Action Alternative; therefore, any changes in patatin levels in Simplot Innate™ W8 potato would not impact these children, as they are already avoiding potatoes due to the high proportion of patatin already occurring in conventional potato varieties (Mignery *et al.*, 1988).

Cumulative impacts to worker safety would be expected to be the same for the Simplot Innate™ W8 potato event and conventional potatoes because the agronomic practices are not expected to change.

Livestock consuming raw potatoes are not expected to realize any health benefits from reduced acrylamide-forming potential in these potatoes. Simplot submitted a safety and nutritional assessment of food and feed derived from Simplot Innate™ W8 potato to the FDA on date April 15, 2014 (BNF No. 000146). Although FDA approved the safety of Innate™ W8 potato on March 20, 2015 (FDA, 2015), they are still reviewing the W8 submission. No changes in food and feed safety are expected to occur under the Preferred Alternative.

Cumulative impacts on the domestic economic environment generally would be similar for the Simplot Innate™ W8 potato event and conventional potatoes, although some economic impact is expected because of the potential health benefits associated with these new potatoes. This event grows similarly and has similar biochemical composition to conventional potatoes, however, the low acrylamide, reducing sugars, black spot bruise, and late blight resistant traits add value that could increase the price received for these potatoes. Potatoes with these traits 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. To the extent that these traits become incorporated into many other existing varieties, this added market value is anticipated to diminish.

Cumulative impacts to the trade economic environment generally would be similar for the Simplot Innate™ W8 event and conventional potatoes, unless the potential health benefits become an important factor in international marketing. Increased demand is expected to lead to increased supply of these potatoes, but to the extent that other countries indiscriminately block importation of GE foods, these opportunities may be missed.

Introduction of Simplot Innate™ W8 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, 2014). The Simplot Innate™ W8 potato could have cumulative economic impacts on the domestic potato market and procedures developed to manage product purity in the supply chain.

Upon introduction, procedures will be implemented to prevent unintended mixing of Simplot Innate™ W8 potato 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™ W8 potatoes be found in the market from accidental mixing. The Simplot Innate™ W8 potatoes could have cumulative trade economic impacts on the potato export market and procedures developed to manage product purity in the supply chain.

Simplot Innate™ W8 potato, and the deployment of the genes in this variety, may offer protection against black spot bruise, lower reducing sugars, late blight resistance and reduced acrylamide potential. During processing, potatoes are routinely culled due to black spot bruise when making French fries or potato chips. However, with Simplot Innate™ W8 potato, fewer potatoes will be lost to black spot bruise, resulting in less waste. Similarly, the late blight resistance gene should markedly improve survival of potato crops threatened with late blight, and consequently, increase yield. As a result of increased usable yield per pound existing production becomes more efficient, so less acreage can meet the demand for potatoes. Reductions in potato acreage are associated with fewer agricultural inputs and concomitant environmental benefits with associated positive environmental impacts related to land use and agricultural inputs. For the purposes of this cumulative impacts discussion, however, it is conservatively assumed that land use and agronomic inputs would potentially decline or remain the same, and are unlikely to increase.

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 also 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 pesticide use associated with GE crops because EPA has both regulatory authority over the labeling of pesticides under FIFRA, and the necessary technical expertise to assess pesticide effects on the environment. 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 Simplot Innate™ W8 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.

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, 2015a; 2015b). Prior to this review, APHIS considered the potential for Simplot Innate™ W8 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™ W8 potato are essentially indistinguishable from practices used to grow other potato varieties (Simplot, 2014; USDA-APHIS, 2014c; 2014b). Simplot Innate™ W8 potato may be expected to replace other varieties of potato currently cultivated, and APHIS does not expect the cultivation of Simplot Innate™ W8 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™ W8 potato on TES species in the areas of the U.S. where potatoes are currently grown.

Simplot has used a genetic engineering approach to introduce into the background of commercial potato cultivars four traits that are of interest to potato consumers, producers and processors: late blight resistance, reduced acrylamide potential in certain processed or heated potato products, reduced black spot bruise, and lowered reducing sugars (Simplot, 2014). The Simplot Innate™ W8 potato event was constructed by first transforming Russet Burbank with plasmid, pSIM1278, followed by transformation with a second plasmid, pSIM1678 to produce the stacked traits. The objective was to incorporate the new phenotypes into event W8, while maintaining all of the desirable characteristics originally selected by potato breeders (Simplot, 2014).

As described in the petition and PPRA, 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 enzymes (Simplot, 2014).

For its analysis on TES plants and critical habitat, APHIS focused on the agronomic differences between Simplot Innate™ W8 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™ W8 potato, and the potential for an effect resulting from the gene silencing activity that sets Simplot Innate™ W8 potato apart from other potato lines currently in production.

6.1 Potential Effects of Simplot Innate™ W8 potato on TES and Critical Habitat

The agronomic and morphologic characteristics data provided by Simplot were used in the APHIS analysis of the weediness potential for Innate™ W8 Potato, and further evaluated for the potential to impact TES and critical habitat. Agronomic studies conducted by JR Simplot during 2012 and 2013 tested the hypothesis that there would be no change in agronomic practices used to produce Simplot Innate™ W8 potato in comparison with conventional potato (Simplot, 2014). Agronomic evaluations were conducted in geographically distinct sites selected to represent most of the main production areas for potatoes in the USA. 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, 2014). Relative to the Russet Burbank control, there was no consistent trend among the Innate™ W8 for significant increases in final emergence, stems per plant, or vine desiccation. There were no statistically significant reductions in total yield. The Simplot Innate™ W8 potato was lower than the control for early emergence (39.5% vs 61.5%), and plant vigor (3.0 vs 3.7); and shorter than the control for plant height (40.4 vs 45.1 cm). All of these detected differences were within the conventional variety range for potato. Simplot Innate™ W8 potato did not display any notable differences to the control in tolerance to abiotic stresses or biotic stresses (Simplot, 2014) .

No differences were detected between Simplot Innate™ W8 potato 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 this transformed line (Simplot, 2014).

Potatoes are not known to be weedy or persistent; they are incapable of survival outside of cultivation (Holm *et al.*, 1979; Muenscher, 1980; Love, 1994; OECD, 1997). 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 the Simplot Innate™ W8 potato is for the most part phenotypically and agronomically similar to the respective parent variety and does not exhibit meaningful changes in characteristics that would make it weedier or more persistent than the parent variety (Simplot, 2014). Because of the reductions in emergence and yield, the Simplot Innate™ W8 potato appears to have a reduced potential for weediness (USDA-APHIS, 2014b). Furthermore, post-harvest monitoring of field test plots planted with the GE crop event under USDA-APHIS notifications and permits did not reveal any differences in survivability or persistence relative to other varieties of the same crop currently being grown. Volunteers were rarely observed, were easily controlled, and are not engineered for resistance to herbicides (Simplot, 2014). No differences were observed that would suggest that the Simplot Innate™ W8 potato is more likely to become a weed than the conventional varieties of the crop (USDA-APHIS, 2014c). Based on the agronomic field data and literature survey concerning weediness potential of the crop, APHIS has determined that the Simplot Innate™ W8 potato is unlikely to persist as a troublesome weed or to have an impact on current weed management practices (USDA-APHIS, 2014b).

APHIS evaluated the potential of Simplot Innate™ W8 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 2.3.3 and 4.5.3 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™ W8 potato. Simplot Innate™ W8 potato derived from Russet Burbank produces few flowers and is male sterile (Simplot, 2014). Among native *Solanum* spp. in the U.S., cultivated potato is potentially sexually-compatible only with two tuber-bearing species, *S. jamesii* and *S. stoloniferum* (previously *S. fendleri* (Spooner *et al*., 2004)). 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 (USDA-NRCS, 2013; Simplot, 2014). 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, 1994; US-EPA, 2011b)b. 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™ W8 potato were to occur. The resulting analysis concluded that the novel phenotypes (low acrylamide potential, reduced black spot bruise, late blight resistance, and lowered reducing sugars) 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, 2014b).

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™ W8 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, 2014b).

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™ W8 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™ W8 potato and possible effects that could occur as a result of such contact. Exposure of TES species to Simplot Innate™ W8 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™ W8 potato would be those TES that inhabit potato fields and may feed on Innate™ W8 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, 2013b).

As discussed in Section 2.3.1 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, 1987). Known exceptions are whitetail deer, wild boar, and voles (O'Brien, 2005; Marinette County, 2014; 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 (*Microtus 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™ W8 potato. Detailed compositional is found in Section 8 of the petition. Simplot analyzed tubers of the Event W8 and its respective parent for the following constituents: protein, fat, ash, crude fiber, carbohydrates, calories, moisture, vitamin B_3, vitamin B_6, vitamin C, Cu, Mg, K, amino acids, and glycoalkaloids. 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) amino acids for tubers collected from events grown in 2012 and 2013 in potato-growing areas of the U.S. (Simplot, 2014). Based on the compositional analyses presented in the petition, APHIS concludes that although raw tubers had some statistically significant differences in nutritional components (vitamins C and B6; certain amino acids) compared to the parental variety (Russet Burbank), they are within the normal range for commercial potato varieties. For the few cases when significant differences were detected between Simplot Innate™ W8 potato and its parental variety, the mean values for the W8 event all fell within the tolerance interval and within the combined literature range for potatoes (Simplot, 2014; USDA-APHIS, 2014b).

As discussed in Section 4.6.1, Human Health, issues with allergies to Simplot Innate™ W8 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, lower black spot bruise, late blight resistance, and lowered reducing sugars. Simplot submitted a safety and nutritional assessment of food and feed derived from Simplot Innate™ W8 potato to the FDA on April 14, 2014 (BNF No. 000146). Although FDA approved the safety of Innate™ W8 potato on March 20, 2015, (FDA, 2015), they are still reviewing Simplot's W8 potato submission.

As discussed in Section 4.5.1, 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 the Innate™ W8 potatoes would have the same impact on other organisms as conventional potatoes (Simplot, 2014). There is no evidence that animal exposure to Simplot Innate™ W8 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™ W8 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, 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™ W8 potato 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 Innate™ W8 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™ W8 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, 1980; Love, 1994; OECD, 1997). There is no ability of Simplot Innate™ W8 potato to naturally hybridize with any wild *Solanum* species, including listed species. Simplot Innate™ W8 potato will not serve as a host species for any listed species or species proposed for listing. Consumption of Simplot Innate™ W8 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™ W8 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.

  Neither the No Action nor the Preferred Alternative is expected to have a disproportionate adverse effect on minorities, low-income populations, or children because the Simplot Innate™ W8 potato event is agronomically, phenotypically, and biochemically similar to conventional potatoes except for the low acrylamide potential and reduced black spot bruise traits. To establish that the new cultivars are nutritionally equivalent to their parent cultivars, Simplot Innate™ W8 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. This means they are not likely to have adverse effects on individuals within those populations when they are consumed. At present, studies suggest that potatoes represent over 30% of vegetable consumption in U.S. children in and out of school (Olsho and Fernandes, 2013) and that urban/minority youths are more likely to consume more fried potato products than youths living in a non-urban environment (Davis and Carpenter, 2009). Olsho and Fernandes (2013) suggest that the targeting of potato preparation methods may represent a more viable method to improve the healthfulness of potato dishes, and as such, the introduction and use of Simplot Innate™ W8 potato may improve any disparate adverse effect associated with potato consumption in the U.S.

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 could benefit consumers by addressing a food safety issue in potato industry (NTP, 2011). Other unexpected significant differences were reported, but the values are all within the normal ranges for potatoes. 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 deviations in various amino acids and vitamins, while experimentally significant, do not exceed the range of variation observed in conventional potato varieties (USDA-APHIS, 2014b).

Potatoes also were tested for reducing sugars and acrylamide after storage. The event 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 compared to conventional potato varieties. Storage up to 7 months yielded consistently lower acrylamide levels in the event 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 confirmed that the overall levels of natural glycoalkaloids, a toxin commonly found in solanaceous crops including potato, were not increased in the Simplot Innate™ W8 event. The safety limit is 20mg/100g as described by Sinden (1987). As presented in the APHIS PPRA (USDA-APHIS, 2014b), while some Simplot Innate™ W8 potato events exhibited higher glycoalkaloid content, its respective controls also exhibited higher glycoalkaloid levels and that these observed concentrations of glycoalkaloids still remain in the range of typical potato glycoalkaloid levels described in the literature. This finding suggests that there are no safety concerns with Simplot Innate™ W8 potato due to similarities in composition.

Patatin is a potato storage glycoprotein that makes up approximately 40% of the soluble protein in tubers. Although patatin was not measured during the studies (Simplot, 2013), any potential exposure to patatin is not expected to be different as a result of a determination of nonregulated status for Simplot Innate™ W8 potato. 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 potatoes under the No Action Alternative; therefore, any changes in patatin levels in Simplot Innate™ W8 potato would not impact these children, as they are already avoiding potatoes due to the high proportion of patatin already occurring in conventional potato varieties (Mignery *et al.*, 1988).

In summary, the compositional data presented in the Simplot petition (Simplot, 2014) and analyzed in the APHIS PPRA (USDA-APHIS, 2014b) indicates that Simplot Innate™ W8 potato does not substantially differ from conventional potato varieties with the exception of the introduced traits. As a result, Simplot Innate**™** W8 potato is not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

Simplot initiated the consultation process with FDA for the commercial distribution of Simplot Innate™ W8 potato and submitted a safety and nutritional assessment of food and feed derived from Simplot Innate™ W8 potato to the FDA on (Simplot, 2014). Although FDA approved the safety of Innate™ W8 potato on March 20, 2015, (FDA, 2015), they are still reviewing the W8 potato submission.

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.

Based on historical experience with potatoes and data submitted by the applicant and reviewed by APHIS, Simplot Innate™ W8 potato is not expected to become weedy or invasive. Potatoes are not listed in the U.S. 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 generally are eliminated by tilling, field preparations with herbicides, and harsh winters. To maximize an economic return, potato growers rarely leave the ground fallow. Any potatoes inadvertently growing in a fallow field are not protected with insecticides or fungicides; they would be susceptible to the Colorado potato beetle and early blight, and likely die.

Potatoes are not known to escape from fields (become feral) or show weediness potential. Potato seedlings grown from tubers have difficulty establishing because they are poor competitors against grasses, trees, and shrubs. The traits incorporated into Simplot Innate™ W8 potato are not associated with weediness and these traits will not help plants thrive outside of cultivation.

The following Executive Order sets forth guidelines for consulting with Indian tribal governments:

EO 13175, "Consultation and Coordination with Indian Tribal Governments" states that each Indian tribe has the opportunity to participate in policy development to the greatest extent practicable and permitted by law. Each tribe has the opportunity for timely and meaningful government-to-government consultation with APHIS in developing policies that may have tribal implications. Such policies that could have substantial direct effects on one or more Indian tribes, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes. "Substantial direct effects" means positive, neutral, or negative effects and potential effects that APHIS or the tribes see as significant.

APHIS' proposed action, a determination of nonregulated status of Simplot Innate™ W8 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 sent letters to Tribal entities when this petition was declared complete and made available to the public. There were no comments received from any tribal entities.

APHIS considered the impact to tribes or tribal properties in the EA (Section 7.5 National Historic Preservation Act [NHPA] of 1966 as Amended). As a result of that analysis, it was concluded that a determination of nonregulated status of Simplot Innate™ W8 potato will not adversely impact cultural resources on tribal properties. A determination of nonregulated status of Simplot Innate™ W8 potato GD743 will not adversely impact cultural resources on tribal properties. Any farming activities that may be taken by farmers on tribal lands are only conducted at the tribe's request; thus, the tribes have control over any potential conflict with cultural resources on tribal properties. A determination of nonregulated status of Simplot Innate™ W8 potato 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 they likely cause any loss or destruction of significant scientific, cultural, or historic resources. This action is limited to a determination of nonregulated status of Simplot Innate™ W8 potato. Standard agricultural practices for land preparation, planting, irrigation, and harvesting would be used on these agricultural lands including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of Simplot Innate™ W8 potato is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the apple production regions. The cultivation of Simplot

Innate™ W8 potato does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

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.

APHIS has in place a signed MOU with the FWS (USDA-APHIS and USFWS, 2012). In accordance with this MOU, APHIS has considered the potential impacts of Innate™ W8 potato on migratory birds.

Based on historical experience with potatoes and data submitted by the applicant and reviewed by APHIS, Simplot Innate™ W8 potato is expected to have the same interactions with migratory birds as conventional potatoes. The applicant provided data to demonstrate the compositional equivalency of Innate™ W8 potato and other potato varieties currently grown. The modifications did not alter the quality of potato as food other than lower levels of acrylamide after cooking, and lower black spot bruise. There would be no effect from consumption of Innate™ W8 potato plant parts because there is nothing different between the plant parts of these varieties and plant parts of other potato varieties already in production. 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. With regard to pesticide use, the Simplot Innate™ W8 potato event is similar to their conventional cultivated potato counterparts, and therefore would not require additional use of pesticide applications. No "take" of a migratory bird is expected as a result of growing Innate™ W8 potato, and APHIS could not determine any mechanism by which take would occur, or would occur any differently than production of any other potato variety.

7.2 International Implications

- ***EO 12114 (US-NARA, 2010), "Environmental Effects Abroad of Major Federal Actions"*** requires agencies to consider the potential environmental effects outside the U.S., its territories, and possessions for proposed federal actions. APHIS does not expect a significant environmental impact outside the US in the event of a determination of nonregulated status of Simplot Innate™ W8 potato because existing national and international regulatory authorities and phytosanitary regimes will apply.

  Any international trade of Simplot Innate™ W8 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). 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). This 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.

Issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are addressed through treaties, in international forums, and through national regulations. These sources include the North American Plant Protection Organization (NAPPO), the Organization for Economic Cooperation and Development (OECD), and the North American Biotechnology Initiative (NABI), among others. For example, 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. Exporters need to comply with the regulations that importing countries who are Parties to the Protocol have promulgated. 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 Federal government developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (NBII, 2010). The applicable data used in analyses of the Simplot Innate™ W8 potato event will be available to the Biosafety Clearinghouse.

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™ W8 potato (Section 4.3, Agricultural Production of Potato) and determined that the cultivation of Simplot Innate™ W8 potato would not lead to the increased production or acreage of potato in U.S. agriculture. The Simplot Innate™ W8 potato event does 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™ W8 potatoes would not result in any changes in water usage for cultivation. As discussed in Section 4.3, Agricultural Production of Potato, there are no expected negative impacts to water resources or air quality associated with Simplot Innate™ W8 potato production. Based on these analyses, APHIS concludes that a determination of nonregulated status of Simplot Innate™ W8 potatoes would comply with the Clean Water Act and the Clean Air Act.

7.4 Impacts on Unique Characteristics of Geographic Areas

A determination of non-regulated status of Simplot Innate™ W8 potato is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

The common agricultural practices that would be carried out in the cultivation of Simplot Innate™ W8 potato are not expected to deviate from current practices. The product will be deployed on agricultural land currently suitable for production of potato, will replace existing varieties, and is not expected to increase the acreage of potato production.

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' 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™ W8 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™ W8 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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