NATIONAL ENVIRONMENTAL POLICY ACT DECISION

AND

FINDING OF NO SIGNIFICANT IMPACT

Simplot Company

Innate™ W8 Potatoes with Late Blight Resistance, Low Acrylamide Potential, Reduced Black Spot and Lowered Reducing Sugars: Russet Burbank Event W8

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) has developed this decision document to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality (CEQ) regulations implementing NEPA, and the USDA APHIS NEPA implementing regulations and procedures (7 CFR part 372). This NEPA decision document, a Finding of No Significant Impact (FONSI), sets forth APHIS' NEPA decision and its rationale. Comments from the public involvement process were evaluated and considered in developing this NEPA decision.

In accordance with APHIS procedures implementing NEPA (7 CFR Part 372), APHIS prepared its Environmental Assessment (EA) to evaluate and determine if any potentially significant impacts to the human environment would result from a determination of the nonregulated status of a genetically engineered (GE) organism. This determination was requested in a petition submitted to APHIS (APHIS No. 14-093-01p) by Simplot Company (henceforth referred to as Simplot). The organism is a plant, Innate™ W8 potato, genetically engineered with late blight resistance, low acrylamide potential, reduced black spot and lower reducing sugars (henceforth referred to as Innate™ W8 potato). The EA process included identification of the alternatives the Agency needed to consider, when making a determination about the regulatory status of Innate W8 potato. It also included an analysis and comparison of the potential environmental and social impacts that may result from implementing the proposed action by selecting one of the alternatives.

Regulatory Authority

"Protecting American agriculture" is the basic charge of 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.

Since 1986, the United States government has regulated GE organisms pursuant to a regulatory framework described as the Coordinated Framework for the Regulation of Biotechnology (henceforth referred to as the "Coordinated Framework"). The Coordinated Framework was published by the Office of Science and Technology Policy (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products. It also explains how Federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on three guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; and (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 U.S. government agencies involved in regulating GE organisms: USDA's APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

APHIS is authorized to regulate GE organisms that are potential plant pests under the plant pest provisions of the Plant Protection Act of 2000, as amended (7 USC §§ 7701 *et seq.*) APHIS regulates GE organisms and plants to ensure that they do not pose a plant pest risk based on requirements in 7 CFR part 340.

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods, 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. 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 foods.

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.

Regulated Organisms

The APHIS Biotechnology Regulatory Services' (BRS) mission is to protect America's agriculture and environment using a dynamic, science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at Title 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is considered a regulated article under 7 CFR part 340 if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa defined in the regulation (7 CFR 340.2) as a plant pest. A GE organism is also regulated under 7 CFR part 340 if APHIS lacks sufficient information to determine if the GE organism is unlikely to pose a plant pest risk.

An individual may petition APHIS for a determination that a particular regulated article is unlikely to pose a plant pest risk, and therefore, is not subject to the authority of plant pest risk provisions of the Plant Protection Act or the regulations at 7 CFR part 340. Under §340.6(c) (4), petitioners are required to provide information related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest risk provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS' Response to Petition for Nonregulated Status

When a petition for nonregulated status is submitted, APHIS must determine if the GE organism poses a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

Innate™ W8 Potato

Simplot submitted a petition (APHIS No. 14-093-01p) that was received by APHIS on April 3, 2014. It included a request for a determination of nonregulated status for Simplot Innate™ W8 potato. It is genetically engineered for late blight resistance, low acrylamide potential, reduced black spot and lower reducing sugars. The petition was accepted as complete by APHIS on June 26, 2014. In a notice published in the *Federal Register* on November 10, 2014 (79 FR 66689-

66690, Docket No. APHIS-2014-0076), APHIS announced the availability of the Simplot petition for public comment. The public comment period closed on January 9, 2015.

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. Comments were required to be received on or before June 5, 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 authorized 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 described in the Simplot petition (Simplot, 2014) for Innate™ W8 potato. They were analyzed for plant pest risk in the preliminary PPRA (USDA-APHIS, 2014).

Coordinated Framework

Food and Drug Administration

Innate™ W8 potato is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced by genetic engineering. 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, 2011). These recommendation established voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties, including GE plants, intended for use as food. Early food safety evaluations are designed to ensure 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.

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). The FDA is currently evaluating this assessment. To date, no questions have been presented pursuant to §408(d) of the FFDCA.

Environmental Protection Agency

The EPA is responsible for regulating the sale, distribution, and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology. The EPA regulates plant incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 et seq.) and certain biological control organisms under the Toxic Substances Control Act (TSCA) (15 U.S.C. 53 et seq.). Before planting a crop

containing a PIP, a company must seek an experimental use permit from the EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 registration with the EPA. When assessing the potential risks of genetically engineered PIPs, EPA requires extensive studies examining numerous factors, such as risks to human health, nontarget organisms and the environment, potential for gene flow, and the need for insect resistance management plans.

Under FIFRA (7 U.S.C. 136 et seq.), the EPA regulates the use of pesticides (requiring registration of a pesticide for a specific use prior to distribution or sale of the pesticide for a proposed use pattern). The EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; and storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, the EPA must determine through testing that the pesticide will not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions. The EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide's label or labeling. The overall intent of the label is to provide clear directions for effective product performance while minimizing risks to human health and the environment. The Food Quality Protection Act of 1996 amended FIFRA, enabling the 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.

The EPA also sets tolerances for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA). The EPA is required, before establishing pesticide tolerance, to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the Food Quality Protection Act of 1996. The FDA enforces the pesticide tolerances set by the EPA.

On December 16, 2013, an experimental use permit (EUP) application was submitted to EPA 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).

Scope of the Environmental Analysis

Although a determination of nonregulated status of Innate™ W8 potato would allow for new plantings of Innate™ W8 potato anywhere in the United States, APHIS limited the environmental analysis on those geographic areas that currently support potato production. A determination of nonregulated status of Innate™ W8 potato is not expected to increase total U.S.

GE potato production nor U.S. acreage utilized for GE potatoes production. To determine areas of potato production, APHIS used data from the National Agricultural Statistics Service to determine where potato is produced in the U.S. (USDA-NASS, 2014b; 2014a). Potato is primarily produced in Idaho, Washington, Wisconsin, North Dakota, Oregon, Colorado, Minnesota, Michigan, Maine, and California. These ten states produced approximately 87.7% of the nation's potatoes in 2013 (USDA-NASS, 2014b; 2014a).

Public Involvement

To evaluate the petition and prepare its EA, APHIS considered public comments submitted while the petition was available for public review. The Agency also considered comments and concerns previously submitted for other EAs of GE organisms, concerns addressed in lawsuits and legal decisions related to GE organisms, and those expressed by various stakeholders. These issues, included those regarding the agricultural production of Simplot Innate™ W8 potato using various production methods and the environmental and food/feed safety of GE plants. They were addressed to analyze the potential environmental impacts of Simplot Innate™ W8 potato to determine if these were likely to cause significant impacts.

The notice of availability of the petition for public review and comment was published in the *Federal Register* on November 10, 2014 (79 FR 66689-66690). The deadline for submission of public comments was January 9, 2015. A total of 128 individual comments were received. Sixty supported the action requested by the petition (non-regulatory status for Innate™ W8 potato) and 68 opposed it. Among the 68 opposing comments, one contained an attachment with 22,673 signatures. Twenty-two comments were substantially similar to each other and one individual submitted seven comments. Two of the 60 comments favoring a determination of nonregulatory status for Innate™ W8 potato were duplicates.

On May 5, 2015, APHIS published a notice in the *Federal Register* (80 FR 25660) announcing the availability of the draft EA and preliminary PPRA (Docket No. APHIS-2014-0076) for a 30-day public review and comment period. APHIS received 24 comments. Nineteen supported the conclusion of the preliminary PPRA that Simplot Innate™ W8 potato does not pose a plant pest risk, so should not be subject to the plant pest provisions of the Plant Protection Act, and therefore, should not be regulated under 7 CFR part 340. Five commenters opposed this proposed APHIS regulatory action and the conclusions of the EA. Comment documents are available for review at:

http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=N;D=APHIS-2014-0076.

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. These issues and information submitted in comments to support opposition to the proposed APHIS action were not new; they all had been addressed previously by the Agency during the NEPA decisionmaking process

related to prior regulatory actions related to GE organisms. One submission was 94 attachments with publications and articles but did not include a comment per se. Thirty-one of the attachments were relevant to the Simplot petition and/or the proposed APHIS action; 63 were general review papers or otherwise irrelevant to this APHIS decisionmaking. The submitter did not specify what information APHIS failed to include in the EA and did not explain how the submitted information 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 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 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.

APHIS responses to public comments received on the draft EA for Innate™ W8 potato are included as an addendum to this Finding of No Significant Impact.

Major Issues Addressed in the EA

The issues considered in the EA were developed by APHIS from public comments submitted for this petition and through experience in considering public concerns and issues identified from public comments submitted for 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 the current petition and past petitions. The resource areas considered in this EA can be categorized as follows:

Agricultural Production Considerations:

- Land Use for 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

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of a determination of nonregulated status of Innate™ W8 potato. To make a determination of nonregulated status for a petition, APHIS must determine that Innate™ W8 potato is unlikely to pose a plant pest risk. Based on the PPRA (USDA-APHIS, 2014), APHIS has concluded that Innate™ W8 potato is unlikely to pose a plant pest risk. Therefore, APHIS must determine that Innate™ W8 potato is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of Innate™ W8 potato. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section of the EA.

No Action Alternative: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. Innate™ W8 potato and progeny derived from 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 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 unlikely plant pest risk from the unconfined cultivation of Innate™ W8 potato.

This alternative is not the preferred alternative because APHIS has concluded through a Plant Pest Risk Assessment that Innate™ W8 potato is unlikely to pose a plant pest risk (USDA-APHIS, 2014). 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.

Preferred Alternative: Determination that 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 an unlikely pest plant 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 consistent with the plant pest provisions of the Plant Protection Act and the regulations codified in 7 CFR part 340.

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 these alternatives based on the discussions summarized in this section.

Prohibit any Innate™ W8 Potato from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of Innate™ W8 potato, including denying any authorizations associated with the field testing. APHIS determined that this

alternative is not appropriate given that APHIS has concluded that Innate™ W8 potato is unlikely to pose a plant health risk (USDA-APHIS, 2014).

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.

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 Innate™ W8 potato is unlikely to pose a plant pest risk, (USDA-APHIS, 2014) there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

Isolation Distance between 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).

Requirement of Testing for Innate™ W8 Potato

During the comment periods for other petitions for nonregulated status, some commenters requested that USDA require and provide testing for GE products in non-GE production systems. APHIS notes that there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. The imposition of any type of testing requirements is also inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework because Innate™ W8 potato does not pose a plant pest risk (USDA-APHIS, 2014). Therefore, imposing such a requirement for Innate™ W8 potato would not meet the purpose and need to respond appropriately to the petition in accordance with APHIS regulatory authorities.

Environmental Consequences of APHIS' Selected Action

The EA contains a full analysis of the alternatives to allow readers to review specific details. Table 1 briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

Table 1. Summary of Issues of Potential Impacts and Consequences of Alternatives

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2014)
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 1. 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 1. 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 potato 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 potato 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 1. 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 1. 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 potato 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 submission 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

Finding of No Significant Impact

This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27).

Context - The term "context" recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. This action has potential to affect conventional and organic potato production systems, including surrounding environments and agricultural workers; human food and animal feed production systems; and foreign and domestic commodity markets.

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, 2014a). Potatoes contribute approximately 15 % of farm sales receipts for vegetables, making potatoes the leading vegetable crop in the U.S. (USDA-ERS, 2012). The total value of U.S. potato production in 2012 was $3.9 billion, the average yield was 409 centum weight (cwt)/acre (centum weight = 100 pounds) and the average price received was $7.26/cwt (USDA-NASS, 2012). Potato acres harvested in the U.S. have declined over recent years, while total production has increased. Per-acre yields, which averaged 397 cwt/acre in 2011 and 401 cwt/acre in 2012 increased eight-fold since the early 1900s and doubled since the early 1960s (USDA-NASS, 2013a).

Potatoes are grown throughout most of the continental United States. Six states (Idaho, Washington, Wisconsin, North Dakota, Oregon, and Colorado) account for approximately 73% of annual production (USDA-NASS, 2014b; 2014a). In 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, advantages associated with processing potatoes in the Northwest such as lower taxes, lower power and labor costs, more favorable weather, and availability of arable land (Guenther, 2010). The average American consumes about 115 lb of potato annually, of which about two-thirds is consumed as processed potato products (USDA-ERS, 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), grown on 1.0-1.1M acres (USDA-NASS, 2013b). In 2011, the United States produced approximately 5% of the total world supply of potato (NPC, 2012; Council, 2013). Major importers of U.S. potatoes are Canada, Mexico, Japan, South Korea, Malaysia and China (NPC, 2012; Council, 2013). 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).

A determination of nonregulated status of Innate™ W8 potato is not expected to directly cause an increase in agricultural acreage devoted to potato production. The availability of Innate™ W8 potato will not change cultivation areas for potato production in the U.S. and there are no anticipated changes to the availability other potato varieties on the market.

Intensity – Intensity is a measure of the degree or severity of an impact based upon the ten factors. The following factors were used as a basis for this decision:

1. *Impacts that may be both beneficial and adverse.*

   A determination of nonregulated status of Innate™ W8 potato will have no significant environmental impact in relation to the availability of GE, conventional, and organic potato varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of Innate™ W8 potato is not expected to directly cause an increase in agricultural acreage devoted to potato production, or those potato acres devoted to GE potato cultivation. The availability of Innate™ W8 potato will not change the cultivation areas for potato production in the U.S. and there are no anticipated changes in the availability of GE and non-GE potato varieties on the market. A determination of nonregulated status of Innate™ W8 potato could add another potato variety to the conventional potato market and is not expected to change the market demands for GE potato or potato produced using organic methods.

   Based on data provided by Simplot for Innate™ W8 potato (Simplot, 2014), APHIS has concluded that the availability of Innate™ W8 potato would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE potato seed production (Simplot, 2014). A determination of nonregulated status of Innate™ W8 potato will not require a change of seed production practices, nor current production practices.

2. *The degree to which the proposed action affects public health or safety.*

   As a GE product, food and feed derived from Innate™ W8 potato must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release into the market. Although voluntary, all petitioners for a GE plant variety that would be included in the food supply have completed a consultation with the FDA. FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require. Simplot provided the FDA with information on the identity, function, and characterization of the genes for Innate™ W8 potato, including

expression of the gene products, on April 15, 2014. The FDA is currently reviewing Simplot's submission.

Public health concerns associated with the use of GE potato, such as Innate™ W8 potato, and GE potato products focus primarily on human and animal (livestock) consumption of GE food and feed commodities. A determination of nonregulated status of Innate™ W8 potato would have the potential to improve human health because of its lower acrylamide-forming potential. Since acrylamide is not contained in raw potato, impacts to animal health would not be any different than impacts if Innate™ W8 potato continues to be regulated. Other than lowered asparagine and PPO, and increased glutamine, Innate™ W8 potato is compositionally similar to currently available potato on the market.

3. *Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.*

There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would adversely impacted by a determination of nonregulated status of Innate™ W8 potato. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property, wildlife habitat, or landscapes; and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of Innate™ W8 potato. 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. This action would not convert land to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to Innate™ W8 potato including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of Innate™ W8 potato, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to potato production sites.

4. *The degree to which the effects on the quality of the human environment are likely to be highly controversial.*

The impacts on the quality of the human environment from a determination of nonregulated status of Innate™ W8 potato are not highly controversial. Although there is

some opposition to a determination of nonregulated status of Innate™ W8 potato, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status is not expected to directly cause an increase in agricultural acreage devoted to potato production. The availability of Innate™ W8 potato will not change cultivation areas for potato production in the U.S., and there are no anticipated changes to the availability of potato varieties on the market. A determination of nonregulated status of Innate™ W8 potato could add another potato variety to the potato market and is not expected to change the market demands for potato produced using organic methods. A determination of nonregulated status of Innate™ W8 potato will not result in changes in the current practices of planting, tillage, fertilizer application/use, cultivation, pesticide application use/volunteer control. Management practices and seed standards for production of certified potato seed would not change. The impact of Innate™ W8 potato on wildlife or biodiversity is not different than that of crops currently used in agriculture, or other potato produced in conventional agriculture in the U.S. During the public comment period, APHIS received comments opposing a determination of nonregulated status of Innate™ W8 potato. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. APHIS has addressed substantive comments in the response to public comments document attached to this FONSI based on scientific evidence found in peer-reviewed, scholarly, and scientific journals.

5. *The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.*

Based on the analysis documented in the EA, the possible impacts on the human environment are well understood. The impacts of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status of Innate™ W8 potato is not expected to directly cause an increase in agricultural acreage devoted to potato production. A determination of nonregulated status of Innate™W8 potato will not result in changes in the current practices of planting, tillage, fertilizer application/use, and volunteer control. Management practices and seed standards for production of certified potato seed would not change. The impact of Innate™ W8 potato on wildlife or biodiversity is no different than that from other crops currently used in agriculture, or other potato produced in conventional agriculture in the U.S. As described in Chapter 2 of the EA, well established management practices, production controls, and production practices (GE, conventional, and organic) are currently being used in potato production systems (commercial and seed production) in the U.S. Therefore, it is reasonable to assume that farmers, who produce conventional potato varieties, Innate™ W8 potato, or produce potato using organic methods, will

continue to use these reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural potato production.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*

A determination of nonregulated status for Innate™ W8 potato would not establish a precedent for future actions with significant impacts or represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340. Each petition that APHIS receives is specific to a particular GE organism and undergoes an independent review to determine if the regulated article poses a plant pest risk. Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as Innate™ W8 potato. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment that a genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340. APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have enough information to determine if the GE organism is unlikely to pose a plant pest risk. A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act or the regulations at 7 CFR part 340. The petitioner is required to provide information under §340.6(c) (4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the

plant pest provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

7. Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.

No significant adverse cumulative impacts were identified through this environmental assessment. Human health effects of consuming cooked Innate™ W8 potato are expected to be positive. A cumulative impacts analysis is provided in Chapter 5 of the EA. In the event APHIS reaches a determination of nonregulated status of Innate™ W8 potato, APHIS would no longer have regulatory authority over this potato. In the event of a determination of nonregulated status of Innate™ W8 potato, APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of Innate™ W8 potato when added to past, present, and reasonably foreseeable future actions.

8. The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historic resources.

A determination of nonregulated status of Innate™ W8 potato 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 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 Innate™ W8 potato. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of 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 impacts on the use and enjoyment of a historic property. For example, there is potential for audible impacts 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 impacts

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 impacts. Additionally, these cultivation practices are already being conducted throughout the potato production regions. The cultivation of Innate™ W8 potato does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

9. The degree to which the action may adversely affect the endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.

As described in Chapter 4 of the EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of Innate™ W8 potato on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. After reviewing possible effects of a determination of nonregulated status of Innate™ W8 potato, APHIS has determined that a determination of nonregulated status of Innate™ W8 potato would have no effect on Federally listed TES and species proposed for listing, or on designated critical habitat or habitat proposed for designation.

10. Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.

The proposed action would be in compliance with all federal, state, and local laws. Because the agency has concluded that Innate™ W8 potato is unlikely to pose a plant pest risk, a determination of nonregulated status of Innate™ W8 potato is a response that is consistent with the plant pest provisions of the Plant Protection Act, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

NEPA Decision and Rationale

I have carefully reviewed the EA prepared for this NEPA determination and the input from the public involvement process. I believe that the issues identified in the EA are best addressed by selecting Alternative 2 (Determination that Innate™ W8 potato is No Longer a Regulated Article). This alternative meets APHIS' purpose and need to allow the safe development and use of genetically engineered organisms consistent with the plant pest provisions of the Plant Protection Act.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been

selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative 2 is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with Innate™ W8 potato, the continued regulated status of Innate™ W8 potato would be inconsistent with the plant pest provisions of the Plant Protection Act, the regulations codified at 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status of Innate™ W8 potato will not have any significant environmental impacts. Furthermore, the analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. I agree with this conclusion. Therefore, I find that an Environmental Impact State (EIS) is not required.

Michael Firko, Ph.D.

7/31/2015
Date

APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Response to Public Comments on Simplot Innate™ W8 Potato

On May 5, 2015, APHIS published a notice in the *Federal Register* (80 FR 25660) announcing the availability of the draft EA and preliminary PPRA (Docket No. APHIS-2014-0076) for a 30-day public review and comment period. APHIS received 24 comments. Nineteen supported the conclusion of the preliminary PPRA that Simplot Innate™ W8 potato does not pose a plant pest risk, so should not be subject to the plant pest provisions of the Plant Protection Act, and therefore, should not be regulated under 7 CFR part 340. Five commenters opposed this proposed APHIS regulatory action and the conclusions of the EA. Comment documents are available for review at:

http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=N;D=APHIS-2014-0076.

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. The information submitted in comments to support opposition to the proposed APHIS action did not raise new issues; they all had been addressed previously by the Agency during the NEPA decisionmaking process related to prior regulatory actions on GE organisms. One submission was a collection of 94 attachments that included publications and articles. 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 decisionmaking. The submitter did not specify how the provided information should be included or used in the EA. 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™ W8 potato, which received 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.

The major issues raised by opposing commenters include the following issues:

Issue 1: *The method of RNA interference (RNAi) has only been used in a handful of approved crops, and the USDA must tread carefully when considering the approval of new crops engineered with this relatively new technology.* The RNAi technique used to create these potatoes could silence more than just the intended action and could cause unpredicted off-target effects. Many studies have shown that RNAi can actually suppress unintended genes that are similar to the target gene. These unintended effects may also be heritable through reproduction, which could have serious ramifications for plant and animal populations. The impact on humans through consumption of these potatoes is especially important since food that has undergone RNA interference will not be labeled and therefore any unintended health consequences cannot be tracked by any regulatory agency.

Response: RNA interference (RNAi) is an RNA-based mechanism that changes endogenous gene expression in eukaryotes including plants, insects, fungi, nematodes, and mammals. RNAi-mediated gene suppression generally requires sequence homology of at least 90% between the silencing construct and the target sequence to be successful and even higher degrees of homology over 21-23 nucleotide stretches (Sharp, 2001a). A complementarity between siRNAs (short interfering RNA) and their target RNA sequences is necessary for an effective and efficient gene silencing. Short interfering RNA-mediated silencing of non-target genes, termed off-target effects (OTE), often appears to be caused by silencing genes homologs to the targeted gene and/or other genes sharing partial sequence complementarity or similarity to the siRNA (Jackson et al., 2003).

The potential unintended effects in biotech crops (e.g., compositional or agronomic changes) are important factors in the evaluation of crop safety assessment process (Cellini et al., 2004). RNAi-induced changes could be manifested in compositional or phenotypic changes in the genetically modified plant (Parrott et al., 2010).

According to a recent publication, (Petrick et al., 2013), GE crops utilizing RNA-mediated technology, including RNAi, are safe for human and animal consumption. Nucleic acids are natural components of all foods and feeds and presumed to be safe based on long history of past consumption. RNAi-mediated gene suppression generally requires sequence homology of at least 90% between the silencing construct and the target sequence to be successful and even higher degrees of homology over 21-23 nucleotide stretches (Sharp, 2001b). It is not likely that the genetic construct components responsible for gene silencing in the Innate™ W8 potato events would contribute to silencing of genes in other non-target organisms through direct consumption of pollen by pollinators or through secondary exposure of beneficial predator or parasitic arthropods or other potential biological control agents for potato pests (Lacey et al., 2001) since sequences from arthropods, bacteria, fungi and viruses are expected to be highly

divergent from the sequences used to silence genes in Innate™ W8 potatoes. Furthermore, indirect exposure scenarios are unlikely to lead to impacts to non-target predators and parasitic arthropods since 1) they may not receive effective doses, 2) intracellular amplification of siRNA, the active gene silencing component derived from dsRNA, is not widely found in insects, 3) environmental and physiological conditions in the gut may destroy the RNA, 4) and they may not have the appropriate receptors to allow transmembrane movement of dsRNA or the appropriate enzyme to direct RNAi (e.g. Dicer, Argonaute, RdRP, RNA and DNA helicases) (Lundgren and Duan, 2013).

There is no confirmed evidence in the scientific literature that associates consumption of plant-derived RNA molecules of any kind with any hazards in humans, other mammals, or domesticated animals" (Carrington, 2014). It is not likely that the gene silencing in the Innate™ events would contribute to silencing of other genes or off target affects.

Issue 2: *APHIS's EA for these GE Innate™ W8 potatoes is based on incomplete and inadequate science and analyses, lacks critical data and vital risk assessments, and ignores potential consequences and uncertainties.*

Response: APHIS disagrees that its scientific analysis and data are incomplete and inadequate. APHIS' analysis and decision within the PPRA regarding the plant pest risk posed by Innate™ W8 potato is based on the best available scientific and technical information. APHIS used sound science to inform its regulatory decision regarding the plant pest risk of Innate™ W8 potato, and has concluded that Innate™ W8 potato is unlikely to pose a plant pest risk (USDA-APHIS, 2014). APHIS carefully reviewed the information provided by the petitioner and others and considered all other relevant information sufficient to make the determination on the regulated status of Innate™ W8 potato. APHIS carefully considered the possible environmental impacts of the proposed product, and is satisfied that the EA developed for Innate™ W8 potato is adequate and sufficient.

In the EA, APHIS has considered opposing views, has reviewed data submitted by those who supported or opposed the determination of nonregulated status, and has not relied on biased information. APHIS has included an analysis of each of the alternatives and evaluated and used the best available information from various sources, including peer-reviewed scientific literature that was reviewed and incorporated into APHIS' analysis. APHIS relied on a variety of sources to support its analysis of the potential impacts of a determination of nonregulated status for Innate™ W8 potato. These sources include, but are not limited to, the Simplot petition and appendices, technical reports, and peer-reviewed literature.

As an example of the safety and data analysis of GE crops, Ricroch (Ricroch, 2013) examined data from animal feeding studies and 60 recent GE vs. non-GE crop lines comparisons, including 33 long-term animal feeding studies, 16 of which spanned multiple generations. The comparisons showed that GE transformation has less impact on plant expression and

composition than does conventional plant breeding. Ricroch (Ricroch, 2013) noted that no new safety concerns were raised in any of the feeding studies, including the multigenerational studies and long-term studies.

Similarly, Snell (2012) reviewed data from 12 long-term animal feeding studies (including GE potato, although not these traits) of durations >90 days to up to 2 years, and 12 multigenerational studies (from 2 to 5 generations). No statistically significant differences were observed on animal health parameters when compared with control animals.

Issue 4: *APHIS did not "adequately" assess impacts on threatened and endangered species.* The agency's failure to consult with the U.S. Fish and Wildlife Service is unlawful. APHIS's claim that this proposed action would have no effects on threatened or endangered species is premised on inadequate data and poorly supported assumptions.

Response: APHIS disagrees with this comment. As required under Section 7 of the ESA, APHIS considered the potential for effects from the proposed determination of nonregulated status for Simplot Innate™ W8 potato on federally listed threatened and endangered species and species proposed for listing, as well as effects on designated critical habitat and habitat proposed for designation. APHIS considered possible effects on all listed species and on all species proposed for listing, as well as all designated critical habitat and habitat proposed for designation in States where potatoes are commercially grown. Species information was obtained from the USFWS Environmental Conservation Online System (ECOS; as accessed January 20, 2015 at http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp) (USDA-APHIS, 2015a), (USDA-APHIS, 2015b). After analyzing the potential for any effect, APHIS could not identify any stressor that would affect the reproduction, numbers, or distribution of any species, or affect their critical habitat. Based on this analysis, APHIS concluded that the determination of nonregulated status for Simplot Innate™ W8 potato will have no effect on any federally listed threatened and endangered species or species proposed for listing, as well no effect on any designated critical habitat or habitat proposed for designation. Because of this no effect determination, consultation with, or the concurrence of, the USFWS and/or NMFS is not required.

Issue 5: *USDA should prohibit the commercial use and planting of Innate™ W8 Potato, until and unless it can fully protect the environment, farmers, and consumers from its harms.*

Response: APHIS makes its decision regarding the regulatory status of Innate™ W8 Potato based on plant pest risk. APHIS has not found a greater plant pest risk associated with the production of Innate™ W8 Potato than that with conventional potatoes (USDA-APHIS, 2014). The Agency completed its review as required by NEPA by preparing an EA and found no evidence that its regulatory decision for Innate™ W8 Potato would result in significant environmental impacts. APHIS thoroughly considered possible environmental impacts of the proposed action, and is satisfied that the EA prepared by the Agency fulfills NEPA requirements.

Issue 6: *APHIS has failed to take a hard look at the Simplot GE Innate™ W8 Potato petition, but has instead interpreted incomplete, ambiguous, or troubling data as insignificant.* A science-based evaluation of the data instead shows that there are significant gaps in our understanding of the possible impacts of Simplot potatoes. Coupled with the science literature, these gaps show reasonably foreseeable impacts. Overall, APHIS's extremely deficient analyses and lack of basic data flouts NEPA's fundamental tenets of ensuring comprehensive, timely, and transparent environmental review of agency actions.

Response: APHIS disagrees with the suggestion that it failed to base its analysis on sound science. APHIS' analysis and decision within the PPRA regarding the plant pest risk posed by Innate™ W8 potato is based on the best available scientific and technical information. APHIS used sound science to inform its regulatory decision regarding the plant pest risk of Innate™ W8 potato, and has concluded that Innate™ W8 potato is unlikely to pose a plant pest risk. APHIS carefully reviewed the information provided by the petitioner and others, and considered all other relevant information sufficient to make the determination on the regulated status of Innate™ W8 potato. APHIS carefully considered the possible environmental impacts of the proposed product, and is satisfied that the EA developed for Innate™ W8 potato is adequate and sufficient.

In the EA, APHIS has considered opposing views, has reviewed data submitted by those who supported or opposed the determination of nonregulated status, and has not relied on biased information. APHIS has included an analysis of each of the alternatives and evaluated and used the best available information from various sources, including peer-reviewed scientific literature that was reviewed and incorporated into APHIS' analysis. These sources include, but are not limited to, the Simplot petition, technical reports, and peer-reviewed literature.

The EA has been prepared in order to specifically evaluate the potential impacts on the quality of the human environment that may result from a determination of nonregulated status of Innate™ W8 potato. APHIS assembled a list of alternatives that might be considered for Innate™ W8 potato. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for Innate™ W8 potato. As described in the EA, APHIS evaluated two alternatives: (1) no action and (2) determination of nonregulated status of Innate™ W8 potato. In addition, APHIS rejected several other alternatives. These alternatives are discussed briefly in Chapter 3 of the EA along with the specific reasons for rejecting each.

The EA was prepared to consider the potential environmental impacts of the proposed action and the reasonable alternative to that action, the no action alternative, consistent with NEPA requirements (40 CFR parts 1500-1508, 7 CFR lb, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the potential impacts on the quality of the human environment that may result from the deregulation of Innate™ W8 potato. In addition, APHIS has no reason to believe, based on the EA, that the deregulation of Innate™ W8 potato would

cause significant impacts on the environment and, therefore, APHIS does not need to prepare an EIS for this product.

Issue 7: *If reduced acrylamide encourages increased consumption of fried potato products, it is possible that the GE Innate™ W8 Potato may not improve overall health outcomes.*

Response: FDA has released recent guidance concerning the safety of acrylamide in food (FDA, 2013a), and guidance to industry (FDA, 2013b) and to consumers (FDA, 2013c) on ways to reduce acrylamide in the diet. The toxicity of acrylamide has been well documented e.g., (Friedman, 2003; Ye et al., 2010).

With respect to Simplot Innate™ W8 potatoes, Simplot's compositional testing on the Innate™ potato has shown that acrylamide is reduced, on average, 58-72% , compared with conventional potato (NTP, 2011; Simplot, 2013). Potato chips and fried potato products represent only about 1/3 of a human dietary exposure to acrylamide (Chawla et al., 2012). Section 2.4.1 of the EA, human health, describes several other exposure routes of humans to acrylamide, including bread, biscuits, gingerbread, coffee, and smoking (Friedman, 2003; Chawla et al., 2012; Kotsiou et al., 2013).

Concerns over acrylamide safety may lead to processor preference for Simplot Innate™ W8 potato in French fries and other frozen potato products. There are no data suggesting that consumer preferences for fried potato products will increase if a determination of nonregulation is reached for Innate™ W8 potato.

Issue 8: *The reduction of asparagine synthetase expression to reduce acrylamide levels could have unintended effects since asparagine is important for nitrogen storage and transport in plants.* The side effects of reducing asparagine levels in these potatoes have not been examined by the USDA and must be thoroughly examined in an Environmental Impact Statement.

Response: APHIS disagrees with this comment. 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™ W8 Potato 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. It is less likely than that from conventional pollen-based crossing of closely related species, and much 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).

Data on performance of Innate™ W8 Potato from Simplot's petition (Simplot, 2014) indicate that there are no statistically significant differences between it and the performance of

conventional potatoes. Although total nitrogen was not measured, APHIS would have expected reduced plant growth performance if asparagine levels were depressed enough to negatively impact nitrogen transport and storage. There was no evidence of this in the currently available scientific literature, which the Agency reviewed as part of its PPRA process.

Issue 9: *USDA needs to consider if these potatoes are a significant improvement over conventional potatoes.* Simplot has failed to demonstrate that there is a significant advantage of these potatoes over conventional potatoes.

Response: APHIS disagrees with this comment on the basis of relevance. The Agency's regulatory authority requires that it make a decision based on whether or not Innate™ W8 Potato poses a plant pest risk. APHIS does not regulate plant characteristics or the products of plants, other than the potential to pose a plant pest risk. The Agency determined from the results of its PPRA that Innate™ W8 Potato does not pose a plant pest risk (USDA-APHIS, 2014).

Issue 10: *Once GE potatoes enter a potato processing plant, it is likely that some GE potatoes will be mixed in with non-GE potatoes, resulting in consumers buying products with undisclosed GE content.* This end result has not been analyzed at all by the USDA and is an unacceptable outcome for these potatoes without an examination of the associated risks. Difficulty segregating potatoes at the processing level will also threaten U.S. producers' access to the export market. If an importing nation finds that there is GE content in shipments of potatoes, the shipments may be rejected. Even without proof of contamination, these countries may suspect contamination in dense potato-growing regions, like Washington and Idaho, and buy potatoes elsewhere. The economic loss for U.S. growers caused by loss of export markets is a risk that the potato industry cannot afford to take.

Response: APHIS has considered the past episodes of inadvertent mixing from GE crops. Potato is asexually propagated so it does not have cross pollinations issues like other crops. Therefore, it is relatively easy to identity-preserve potato.

The Agency analyzed and evaluated potential economic impacts in its EA with regard to a decision on the regulatory status of Innate™ W8 Potato, and concluded that there would be no significant impacts in the market place if Innate™ W8 Potato were not regulated as a plant pest.

APHIS also notes that growers with adjacent fields can establish production practices, such as isolation distances to ensure that their crops meet their market-driven standards.

Issue 11: *Pushing GE potatoes onto the market would result in a loss of consumer confidence and potential market rejection of not just GE potatoes, but of all domestic potatoes.* "If the USDA approves Simplot's petition, GE potatoes could be sold unlabeled, leading to market confusion and possibly leading some consumers to avoid potatoes altogether." A commenter also noted that "the American public would have no way to avoid GE potatoes if they wish to since

they would not be labeled as genetically engineered" and that not labeling Innate™ W8 Potato as GE would not allow consumers to make informed decisions.

Response: APHIS did not evaluate labeling of GE food in this assessment because it is not within the scope of the APHIS regulatory authority or the Agency's NEPA requirement. This responsibility falls under the authority of the FDA.

Issue 12: *Although Simplot has been able to lower amounts of fructose and glucose in the potatoes during storage, silencing the acid invertase protein results in much higher sucrose concentrations than are found in the control potatoes.* Yet Simplot has offered no explanation of what nutritional impacts that change will have on these potatoes when digested.

ResponseSucrose levels are elevated in Simplot Innate™ W8 potato, however glucose and fructose were reduced. Sucrose is digested by humans into glucose and fructose (Miloski et al., 2008). Compositional analyses of Simplot Innate™ W8 potato found that values of other nutrients were in the tolerance interval or in the combined literature range and considered normal for potato and Simplot concluded that tubors of W8 potatoes were substantially equivalent to other potatoes. (Simplot, 2014). FDA, which has responsibility for food safety, is currently reviewing the Simplot submission (BNF No. 000146), which was delivered to them on April 15, 2014.

Issue 13: *The functions of PPO genes are not adequately understood.* Some of these functions may include protection of the potato crops from pathogens, and others may be unknown. Triggering the browning process, the PPO enzyme is also involved in a plant's natural defense against pests and pathogens. There is a growing body of scientific literature confirming the role of PPO in plant defenses, including this study showing that an overexpression of PPO can increase plant defenses.

Response: The literature contains large numbers of publications discussing the metabolic pathway of PPO (polyphenol oxidase), see, e.g. (Felton et al., 1989; Steffens, 1994; Martinez and Whitaker, 1995; Friedman, 1997; Yoruk and Marshall, 2003; Mayer, 2006; Stremmel et al., 2010; Tran et al., 2012; Navarre et al., 2013). The metabolic pathway has, therefore, been well studied. APHIS' response to the above comment describes research conducted to date on function of PPO.

As discussed in the PPRA (USDA-APHIS, 2014) and in Section 4.5.1 of the EA, Animal Communities, the biological function of PPO in plants has not been conclusively determined (Mayer, 2006), although there are suggestive data that the oxidation products of PPO appear to play a role in general plant defense mechanisms against pathogens and pests. Phenolics can inhibit the growth of specific pathogens and can also inhibit enzymes involved in pathogenesis (Lyon, 1989). Researchers have studied the effect of phenols on disease resistance (e.g., (Lyon,

1989; Kroner and Marnet, 2012)) but have no proof that phenols are important mediators of interactions between potato and disease organisms.

The issue of the relationship between PPO and resistance to herbivores was discussed in the PPRA (USDA-APHIS, 2014). Although trichomes in some plants produce defensive compounds involving PPO in response to insect attack, the trichomes of cultivated potatoes contain low amounts of PPO which is not thought to be involved resistance to pests (Friedman, 1997).

Issue 14: *Asn1 genes are crucial and multifunctional nitrogen metabolism genes in plants, with multiple effects, many of which are not well understood.* Asn1 genes respond to multiple environmental and developmental cues, many of which may not be experienced in the limited field trials conducted by Simplot, and may only be encountered after commercialization. Silencing of this gene may therefore produce undesirable agronomic effects over time.

Response: APHIS disagrees with this commenter for several reasons. The Agency reviewed all of the best available information as required by NEPA. The data presented by JR Simplot demonstrate that the Innate™ W8 Potato are phenotypically and agronomically similar to the respective parent varieties and do not exhibit meaningful changes in characteristics that would make them weedier or more persistent than their respective parent varieties (Simplot, 2014). Simplot's studies also indicated that there are no undesirable agronomic effects, changes in agronomic characteristics, toxicants produced, nor impacts on the environment (Simplot, 2014). The available scientific data indicate the speculated concern expressed by the commenter is unlikely. APHIS reviewed the data submitted by Simplot as part of the Agency's PPRA process and determined that Innate™ W8 Potato does not pose a plant pest risk (USDA-APHIS, 2014). APHIS also evaluated potential environmental impacts during the development of its EA and found no significant impacts.

Issue 15: *The efficacy of the late blight-resistant gene is not as high as should be expected.*

Response: APHIS' role in this regulatory process is to determine whether or not the plant constitutes a plant pest risk. APHIS' PPRA established that this potato is not a plant pest risk (USDA-APHIS, 2014). APHIS does not have the responsibility to evaluate other characters such as efficacy.

With respect to the commenter, inoculated field trial data submitted by Simplot as part of their petition showed a decrease in susceptibility to late blight of Innate™ W8 potato foliage and tubers (Simplot, 2014). However, disease observation studies (in which plants were allowed to be naturally infected with pathogens), did not show any difference in incidence of the late blight pathogen in the Innate™ W8 potato compared to the conventional cultivar. Simplot has stated that the latter test described is not intended as an efficacy study (Rood, 2015), and is submitting more extensive efficacy data to EPA in the near future.

References

AOSCA (2010) "General IP Protocols Standards." The Association of Official Seed Certifying Agencies. http://www.identitypreserved.com/handbook/aosca-general.htm >.

Board, USP (2012) http://www.uspotatoes.com/downloads/Frozen%20Potato%20Products-Export_NEW.pdf >.

Board, USP (2013) "Press Release." http://www.uspotatoes.com/pressRoom/pr.php?id=270 >.

Carrington, J (2014) "Comment to the EPA." Danforth Science Center.

Cellini, F; Chesson, A; Colquhoun, I; Constable, A; Davies, H; Engel, K; Gatehouse, M; Karenlampi, S; Kok, E; Leguay, J; Lehesranta, S; Noteborn, H; Pedersen, J; and Smith, M (2004) "Unintended Effects and their Detection in Genetically Modified Crops." *Food and Chemical Toxicology.* 72 (7): p 1089-125.

Chawla, R; Shakya, R; and Rommens, C (2012) "Tuber-Specific Silencing of Asparagine Synthetase-1 Reduces the Acrylamide-Forming Potential of Potatoes Grown in the Field without Affecting Tuber Shape and Yield." *Plant Biotechnology Journal.* 10 p 913-24.

Council, NP (2013)

FAO (2013) "Top production, potatoes, 2011." FAOSTAT, Statistics Division, Food and Agriculture Organization of the United Nations. Last Accessed: June 17, 2013 < http://faostat.fao.org/site/339/default.aspx >.

FDA (2013a) "Commodity-Specific Food Safety Guidelines for the Production, Harvest, Storage, and Packing of Potatoes."

FDA (2013b) "Guidance for Industry: Acrylamide in Foods, Draft Guidance." FDA.

FDA (2013c) "You Can Help Cut Acrylamide in Your Diet."

Felton, G; Donato, K; Del Vecchio, R; and Duffey, S (1989) "Activation of Plant Foliar Oxidases by Insect Feeding Reduces Nutritive Quality of Foliage for Noctuid Herbivores." *Journal of Chemical Ecology.* 15 (12): p 2667-94.

Friedman, M (1997) "Chemistry, Biochemistry, and Dietary Role of Potato Polyphenols. A Review." *Journal of Agricultural and Food Chemistry.* 45 (5): p 1523-40. http://www.scopus.com/inward/record.url?eid=2-s2.0-0642271751&partnerID=40&md5=c648dc51b85f5c83ebe2ad2ef86c5ba1 >.

Friedman, M (2003) "Chemistry, Biochemistry, and Safety of Acrylamide: a Review." *Journal of Agricultural and Food Chemistry.* 51 p 4504-26.

Guenther, J (2010) "Introduction." *Commercial Potato Production in North America: the Potato Association of America Handbook.* Potato Association of America. p 1.

Hammond, BG and Jez, JM (2011) "Impact of food processing on the safety assessment for proteins introduced into biotechnology-derived soybean and corn crops." *Food and chemical toxicology : an international journal published for the British Industrial Biological Research Association.* 49 (4): p 711-21. http://www.ncbi.nlm.nih.gov/pubmed/21167896 >.

Jackson, A; Bartz, S; Schelter, J; Kobayashi, S; Burchard, J; Mao, M; Li, B; Cavet, G; and Linsley, P (2003) "Expression Profiling Reveals Off-target Gene Regulation by RNAi." *Nature Biotechnology.* 6 p 635-37.

Kotsiou, K; Tasioula-Margari, M; Fiore, A; Gokmen, V; and Fogliano, V (2013) "Acrylamide Formation and Colour Development in Low-Fat Baked Potato Products as Influenced by Baking Conditions and Oil Type." *European Food Research and Technology* 236 p 843-51.

Kroner, A and Marnet, N (2012) "Nicotiflorin, Rutin and Chlorogenic Acid: Phenylpropanoids Involved Differently in Quantitative Resistance of Potato Tubers to Biotrophic and Necrotrophic Pathogens." *Plant Physiology and Biochemistry:PPB / Societe Francaise de Physiologie Vegetale.* 57 p 23-31.

Lacey, LA; Horton, DR; Unruh, TR; Pike, K; and Marquez, M (2001) "Biological control of insect pests of potato in North America. Excerpts." *2001 Washington State Potato Conference and Trade Show.* Last Accessed: August 5, 2013 < http://aenews.wsu.edu/May01AENews/May01AENews.htm >.

Lundgren, JG and Duan, JJ (2013) "RNAi-Based Insecticidal Crops: Potential Effects on Nontarget Species." *BioScience.* 63 (8): p 657-65. Last Accessed: 2013/09/12 < http://www.bioone.org/doi/abs/10.1525/bio.2013.63.8.8 >.

Lyon, G (1989) "The Biochemical Basis of Resistance of Potatoes to Soft Rot *Erwinia* spp.--a Review." *Plant Pathology.* 38 (3): p 313-39.

Martinez, M and Whitaker, J (1995) "The Biochemistry and Control of Enzymatic Browning." *Trends in Food Science & Technology.* 6 p 195-200.

Mayer, A (2006) "Polyphenol Oxidases in Plants and Fungi: Going Places? A Review." *Phytochemistry.* 67 (21): p 2318-31. http://www.ncbi.nlm.nih.gov/pubmed/16973188

Miloski, K; Wallace, K; Fenger, A; Schneider, E; and Bendiskas, K (2008) "Comparison of Biochemical and Chemical Digestion and Detection Methods for Carbohydrates." *American Journal of Undergraduate Research.* 7 (2): p 7-18.

Navarre, DA; Payyavula, RS; Shakya, R; Knowles, NR; and Pillai, SS (2013) "Changes in Phenylpropanoid Metabolism During Tuber Development." *Plant Physiology and Biochemistry.* 65 p 89-101.

NPC (2012) "National Potato Council 2012 Statistical Yearbook." National Potato Council.

NTP (2011) "Report on Carcinogens." U.S. Department of Health and Human Services, Public Health Service. Last Accessed: July 8, 2013 < http://ntp.niehs.nih.gov/ntp/roc/twelfth/roc12.pdf >.

Parrott, W; Chassy, B; Ligon, J; Meyer, L; Petrick, J; Zhou, J; Herman, R; Delaney, B; and Levine, M (2010) "Application of Food and Feed Safety Assessment Principles to Evaluate Transgenic Approaches to Gene Modulation in Crops." *Food and Chemical Toxicology.* 48 (7): p 1773-90.

Petrick, JS; Brower-Toland, B; Jackson, AL; and Kier, LD (2013) "Safety Assessment of Food and Feed from Biotechnology-Derived Crops Employing RNA-Mediated Gene Regulation to Achieve Desired Traits: A Scientific Review." *Regulatory Toxicology and Pharmacology.* 66 p 167-76.

Ricroch, AE (2013) "Assessment of GE Food Safety Using '-omics' Techniques and Long-Term Animal Feeding Studies." *New Biotechnology.* 30 (4): p 349-54.

Rood, T, Simplot to: Karen Walker, USDA-APHIS. (2015). Personal Communication.

Sciences, NAo (2004) "Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects."

Sharp, PA (2001a) "RNA interference -- 2001." *Genes & Development.* 15 (5): p 485-90. http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=11238371 >.

Sharp, PA (2001b) "RNA Interference: 2001." *Genes & Development.* 15 (5): p 485-90. http://genesdev.cshlp.org/content/15/5/485.short >.

Simplot (2013) "Petition for Determination of Nonregulated Status for Innate Potatoes with Low Acrylamide Potential and Reduced Black Spot Bruise: Events E12 and E24 (Russet Burbank); F10 and F37 (Fanger Russet); J3, J55, and J78 (Atlantic); G11(G); H37 and H50 (H) " J.R. Simplot Company.

Simplot (2014) "Petition for Determination of Nonregulated Status for InnateTM Potatoes with Late Blight Resistance, Low Acrylamide Potential, Reduced Black Spot, and Lowered Reducing Sugars: Russet Burbank Event W8." Submitted by Clark, Pete, Registration Manager. JR Simplot Company. Boise, ID.

Snell, C; Bernheim, A; Berge, J-B; Kuntz, M; Pascal, G; Paris, A; and Ricroch, AE (2012) "Assessment of the Health Impact of GM Plant Diets in Long-Term and Multigenerational Animal Feeding Trials: a Literature Review." *Food and Chemical Toxicology.* 50 p 1134-48.

Steffens, J (1994) "Polyphenol Oxidase." *Genetic Engineering of Plant Secondary Metabolism.* New York: Plenum Press. p 275-312.

Stremmel, N; Praeger, U; Konig, C; Fehrle, I; Erban, A; Geyer, M; Kopka, J; and van Dongen, J (2010) "Time Course Effects on Primary Metabolism of Potato (*Solanum tuberosum*) Tuber Tissue after Mechanical Impact." *Postharvest Biology and Technology.* 56 p 109-16.

Tran, L; Taylor, J; and Constabel, C (2012) "The Polyphenol Oxidase Gene Family in Land Plants: Lineage-specific Duplication and Expansion." *BMC Genomics.* 13 p 395.

US-FDA (2011) "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use." Office of Food Additive Safety, Division of Biotechnology & GRAS Notice Review, Center for Food Safety and Applied Nutrition, Food and Drug Administration. Health and Human Services. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096156.htm >.

USDA-APHIS (2014) "JR Simplot Company Petition (14-092-01p) for Determination of Non-Regulated Status for InnateTM Potatoes with Late Blight Resistance, Low Acrylamide Potential, Reduced Black Spot, and Lowered Reducing Sugars: Russet Burbank Event W8: Plant Pest Risk Assessment."

USDA-ERS (2010) "Vegetables and Melons Outlook." USDA, Economic Research Service. http://usda01.library.cornell.edu/usda/ers/VGS/2010s/2010/VGS-10-28-2010.pdf >.

USDA-ERS (2012) "Vegetables and Pulses Outlook."

USDA-ERS (2013) http://www.ers.usda.gov/data-products/vegetables-and-pulses-data/data-by-commodity-imports-and-exports.aspx?reportPath=/TradeR3/TradeTables&programArea=veg&stat_year=2007&top=5&HardCopy=True&RowsPerPage=25&groupName=Vegetables&commodityName=Potatoes#P182b5a9620b445baa8f47d4e33f25793_6_652 >.

USDA-ERS (2014) "USDA Economic Research Service: Crops/Vegetables and Pulses/Potatoes." http://www.ers.usda.gov/tpis/crops/vegetables-pulses/potatoes.aspx >.

USDA-NASS (2012) "QuickStats Ad-hoc Query Tool." USDA National Agricultural Statistical Service.

USDA-NASS (2013a)

USDA-NASS (2013b) "Crop production: 2012 summary." United States Department of Agriculture, National Agricultural Statistics Service. Last Accessed: March 1, 2013 < http://www.agcensus.usda.gov/Publications/2007/Full_Report/Volume_1,_Chapter_1_State_Level/Texas/ >.

USDA-NASS (2014a) "Potatoes, 2013 Summary (September 2014)." USDA National Agricultural Statistics Service.

USDA-NASS (2014b) "USDA National Agricultural Statistics Service--Quick Stats." http://www.nass.usda.gov/ >.

Ye, J; Shakya, R; Shreshtha, P; and Rommens, C (2010) "Tuber-specific Silencing Of the Acid Invertase Gene Substantially Lowers the Acrylamide-Forming Potential of Potato." *Agricultural and Food Chemistry.* 58 p 12162-67.

Yoruk, R and Marshall, M (2003) "Physicochemical Properties and Function of Plant Polyphenol Oxidase: a Review." *Journal of Food Biochemistry.* 27 p 361-422.

Zaheer, K and Akhtar, H (2014) "Recent Advances in Potato Production, Usage, Nutrition--a Review." *Food Science and Nutrition.*