

NATIONAL ENVIRONMENTAL POLICY ACT DECISION

AND

FINDING OF NO SIGNIFICANT IMPACT

Simplot Company

Innate™ Potato with Low Acrylamide Potential and Reduced Black Spot Bruise Events E12 and E24 (Russet Burbank); F10 and F37 (Ranger Russet); J3, J55, and J78 (Atlantic); G11 (G); H37 and H50 (H)

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's (CEQ) regulations implementing NEPA, and the USDA APHIS' NEPA implementing regulations and procedures. 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 has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS Number 13-022-01p) by Simplot Company (hereafter referred to as Simplot) for their genetically engineered Innate™ potato that has reduced acrylamide potential and reduced black spot bruising. The EA has been prepared in order to specifically evaluate the effects on the quality of the human environment that may result from approving the petition seeking nonregulated status for Innate™ Potato. The EA assesses alternatives to a determination of nonregulated status of Innate™ Potato and analyzes the potential environmental and social effects that may result from the proposed action and 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 genetically engineered (GE) organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk.

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

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

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. 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 Cosmetics 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 and science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the Federal Plant Pest Act, and further consolidated under 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 does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest risk provisions of the Plant Protection Act or the regulations at 7 CFR 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 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

Under the authority of the plant pest provisions of the Plant Protection Act (PPA) 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™ potato. When a petition for nonregulated status is submitted, APHIS must make a determination, based upon a Plant Pest Risk Assessment (PPRA) process determination, whether the GE organism of concern is likely to pose a plant pest risk as defined by the PPA. If APHIS determines, based on its Plant Pest Risk Assessment (PPRA) determination, that the GE organism is unlikely to pose a plant pest risk, then that genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

Simplot has submitted a petition (APHIS Number 13-022-01p) to APHIS seeking a determination that their genetically engineered Innate™ Potato is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR Part 340.

Innate™ Potato

Simplot submitted a petition (APHIS Number 13-022-01p) to APHIS in 2013 for determination of nonregulated status for Innate™ potato with reduced acrylamide potential and reduced black spot bruising. A determination of nonregulated status for Innate™ potato would include Innate™ Potato, any progeny derived from crosses between Innate™ and conventional potatoes or other GE potato events that have been deregulated pursuant to Part 340 and the Plant Protection Act. If Innate™ potato is deregulated, growers and potato seed suppliers would have another variety of potato.

Innate™ potato is currently regulated under 7 CFR part 340. Interstate movements and field trials of Innate™ potato have been conducted under notifications (14) acknowledged by APHIS from 2009 through 2011 in eight states: Florida, Indiana, Idaho, Michigan, Nebraska, North Dakota, Washington, and Wisconsin. Data resulting from these field trials are described in Appendix 6 of the petition (Simplot, 2013a).

Coordinated Framework Review

Food and Drug Administration

Innate™ 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) for establishing voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including bioengineered plants. Early food safety evaluations help make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with FDA, but the information may be used later in the biotechnology consultation.

On February 12, 2013, Simplot submitted a safety and nutritional assessment of food and feed derived from Innate™ potato to the FDA (US-FDA Docket Number BNF 141). FDA is currently evaluating the submission. No questions have been raised thus far pursuant to §408(d) of the Federal Food, Drug, and Cosmetic Act.

Environmental Protection Agency

Under FIFRA, all pesticides (including herbicides) sold or distributed in the U.S. must be registered by the EPA (US-EPA, 2011a). Registration decisions are based on scientific studies

that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. All pesticides registered prior to November 1, 1984 must also be reregistered to ensure that they meet the current, more stringent standards and should have a reregistration review every 15 years (US-EPA, 2011a). Before a pesticide can be used on a food or feed crop, the EPA must establish the tolerance value, which is the maximum amount of pesticide residue that can remain on the crop or in foods or feed processed from that crop (US-EPA, 2011b).

The EPA regulates plant-incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and 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.

Scope of the Environmental Analysis

Although a determination of nonregulated status of Innate™ potato would allow for new plantings of Innate™ potato anywhere in the U.S., APHIS primarily focused the environmental analysis on those geographic areas that currently support potato production. A determination of nonregulated status of Innate™ potato is not expected to increase potato production, either by its availability alone or accompanied by other factors, or cause an increase in overall GE potato acreage. To determine areas of potato production, APHIS used data from the National Agricultural Statistics Service (USDA-NASS, 2010) to determine where potato is produced in the U.S. (USDA-NASS, 2010). Potato is primarily produced in Idaho, Washington, Wisconsin, North Dakota, Wisconsin, Colorado, Minnesota, Michigan, Maine, California, and Oregon. These eleven states comprised approximately 92.3% percent of the nation's potato production of 437,483,000 CWT in 2012 (USDA-NASS, 2012a; 2012b).

Public Involvement

On May 3, 2013, APHIS published a notice in the Federal Register (78FR 25942-25943, Docket no. APHIS-2012-0067) announcing the availability of the Simplot petition for a 60-day public review and comment period. Comments were required to be received on or before July 2, 2013. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 308 comments¹ on the petition were received from individuals during the comment period. One of the comments had 41,475 signatures appended to it. Many of the commenters did not mention their specific disagreement with APHIS' analysis of Innate™ potato detailed in the EA or PPRA (USDA-APHIS, 2013a); rather, they expressed their general opposition to

¹ . Comment documents may be viewed at: <http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;D=APHIS-2012-0067;dt=PS>

genetically modified organisms (GMOs) or GE crops. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS.

On May 30, 2014, APHIS published a notice in the Federal Register (78 FR 31080-31082, Docket no. APHIS-2012-0067) announcing the availability of the Simplot Innate™ potato draft EA (13-022-01p) and PPRA for a 30-day public review and comment period. Comments were required to be submitted before June 30, 2014. A total of 60 public comments were received subsequent to the draft EA and PPRA publication. The docket folder containing the comments can be located at

<http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=SR;D=APHIS-2012-0067>

Responses to substantive comments are included as an attachment to this Finding of No Significant Impact.

Major Issues Addressed in the EA

The issues considered in the EA were developed based on APHIS' determination that these genetically engineered potatoes are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status for Innate™ potato. Issues discussed in the EA were developed by considering public concerns as well as issues raised in public comments submitted for other environmental assessments of genetically engineered organisms, concerns raised in lawsuits, as well as those issues that have been raised by various stakeholders. These issues, including those regarding the agricultural production of potato using various production methods, and the environmental food/feed safety of genetically engineered plants were addressed to analyze the potential environmental impacts of Innate™ potato.

The list of resource areas considered were developed by APHIS through experience in considering public concerns and issues raised in public comments submitted for other EAs of GE organisms. The resource areas considered also address concerns raised in previous and unrelated lawsuits, as well as issues that have been raised by various stakeholders in the past. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25). These resource areas can be categorized as follows:

Agricultural Production Considerations:

- Acreage and Areas of Potato Production
- Agronomic/Cropping Practices
- Potato Seed Production
- Organic Potato Production

Environmental Considerations:

- Water Resources

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

Human Health Considerations:

- Public Health
- Worker Safety

Livestock Health Considerations:

- Livestock Health/Animal Feed

Socioeconomic Considerations:

- Domestic Economic Environment
- Organic Farming
- Trade Economic Environment

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of a determination of nonregulated status of Innate™ potato. To respond favorably to a petition for nonregulated status, APHIS must determine that Innate™ potato is unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS, 2013a), APHIS has concluded that Innate™ potato is unlikely to pose a plant pest risk. Therefore, APHIS must determine that Innate™ 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™ potato. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section of the EA.

No Action: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. Innate™ potato and progeny derived from Innate™ potato would continue to be regulated articles under the regulated articles under the regulations at 7 CFR part 340. Permits or notifications acknowledged by APHIS would still be required for introductions of Innate™ potato and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this

alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of Innate™ potato.

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

Under this alternative, Innate™ potato and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. Innate™ potato is unlikely to pose a plant pest risk (USDA-APHIS, 2013a). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of Innate™ potato and progeny derived from this event. The Preferred Alternative, i.e., a determination of nonregulated status of Innate™ potato, is not expected to increase potato production, either by its availability alone or associated with other factors, or result in an increase in overall acreage of GE potato. Potential impacts would be similar to the No Action Alternative. This alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that Innate™ potato is unlikely to pose a plant pest risk, a determination of nonregulated status of Innate™ potato is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Alternatives Considered but Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for Innate™ potato. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for Innate™ potato. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

Prohibit any Innate™ Potato from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of Innate™ potato, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that Innate™ potato is unlikely to pose a plant health risk (USDA-APHIS, 2013a).

In enacting the Plant Protection Act, Congress found that

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

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

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

Based on the PPRA (USDA-APHIS, 2013a), and the scientific data evaluated therein, APHIS concluded that Innate™ potato is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of Innate™ 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™ potato is unlikely to pose a plant pest risk, (USDA-APHIS, 2013a) 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™ Potato and Non-GE Potato Production and Geographical Restrictions

Because APHIS has concluded that Innate™ potato is unlikely to pose a plant pest risk (USDA-APHIS, 2013a), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340.

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating Innate™ potato from conventional or specialty potato production. APHIS also considered geographically restricting the production of Innate™ potato based on the location of production of non-GE potato in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS’ plant pest risk assessment for Innate™ potato, there are no geographic differences associated

with any identifiable plant pest risks for Innate™ potato (USDA-APHIS, 2013a). This alternative was rejected and not analyzed in detail because APHIS has concluded that Innate™ potato does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. However, individuals might choose on their own to geographically isolate their non-GE potato production systems from Innate™ potato or to use isolation distances and other management practices to minimize gene movement between Innate™ potato and non-GE potato fields. Information to assist growers in making informed management decisions for Innate™ potato is available from the Association of Official Seed Certifying Agencies (AOSCA, 2010)).

Requirement of Testing for Innate™ 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. Additionally, because Innate™ potato does not pose a plant pest risk (USDA-APHIS, 2013a), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for Innate™ potato would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

Environmental Consequences of APHIS' Selected Action

The EA contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied—risk assessment (USDA-APHIS, 2013a)
Management		

Practices		
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 Innate™ potato may reduce acreage dedicated to conventional potatoes.
Agronomic Practices	Agronomic practices will remain the same as used currently.	Unchanged from No Action Alternative
Pesticide Use	Pesticides are currently used to control insects, nematodes, fungi, and weeds.	Unchanged from No Action Alternative
Potato Seed Production	Potato seed is primarily supplied by seed potatoes.	Unchanged from No Action Alternative
Organic Potato Production	Organic potato growers use practices and standards for production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with conventional or GE crops.	Unchanged from No Action Alternative
Environment		
Land Use	Current trends in the acreage and areas of production are likely to continue to be driven by market conditions (i.e., increased demand for US potato and potato products for animal feed, etc.) and federal policy.	Unchanged from No Action Alternative
Water Resources	The primary cause of agricultural NPS pollution is increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Agronomic practices such as conservation tillage, crop nutrient management, pest management, and conservation buffers help protect water quality from agricultural runoff.	Unchanged from No Action Alternative
Soil	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 insecticides 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
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

Animals and Plants		
Animals	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 Innate™ tubers may be exposed to increased levels of glutamine, but this is not expected to be detrimental.
Plants	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 Innate™ potato with conventional varieties, resulting progeny may contain lowered polyphenol oxidase levels. However, this is not expected to be detrimental. Innate™ potato is no weedier than conventional potatoes.
Gene Movement	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.	Innate™ traits are not expected to increase weediness in potato.
Soil Microorganisms	Abundance and diversity of soil microorganisms in and around potato fields is expected to remain as it is currently.	Unchanged from No Action Alternative
Biological Diversity	The biological diversity in potato fields is lower than in the surrounding habitats.	Unchanged from No Action Alternative
Human and Animal Health		
Risk to Human Health	Glycoalkaloids and patatins would continue to pose a risk to human health. In the case of humans consuming high-temperature cooked potatoes, they would continue to be exposed to acrylamide.	Glycoalkaloid and patatin exposure would continue. For humans consuming high-temperature cooked potatoes, acrylamide levels would be reduced approximately 60-70%, which will benefit human health.
Risk to Animal Feed	Glycoalkaloids would continue to pose a risk to livestock if potato stems and foliage are fed to them, which is not likely.	Unchanged from No Action Alternative.
Socioeconomic		
Domestic and Economic Environment	Most potato production is used for food. Market utilization would likely continue as it is currently.	Because of its potential human health benefits (lower acrylamide) and potential reduced wastage (low bruising), Innate™ potato may comprise a larger share of the domestic potato market, and may result in increased revenues.
Trade Economic Environment	U.S. potatoes and potato products will continue to play a role in global potato production, and the U.S. will continue to be a supplier in the international market.	The foreign trade impacts associated with a determination of nonregulated status of Innate™ potatoes are anticipated to be similar to the No Action Alternative. However, import of each specific trait requires separate application and approval by the importing country. If the Innate™ traits are approved by importing countries, it may make up a larger percentage of potato import markets.
Other Regulatory Approvals	FDA completed consultations, EPA tolerance exemptions and conditional pesticide registrations granted	FDA is currently reviewing Simplot's voluntary consultation submission of February 12, 2013.

Compliance with Other Laws		
CWA, CAA, Eos	Fully compliant	Fully compliant

Finding of No Significant Impact

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 and therefore find that an EIS need not be prepared. 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.

In the 2012 production year, potato was cultivated in the United States on approximately 1.2 million acres, representing a 4.5% increase in potato acreage from 2011 (USDA-NASS, 2012a). Potato production in 2011 was estimated at \$336.37/CWT and valued at an estimated \$7.90 to \$23.70/CWT (USDA-NASS, 2012a). Potato acres harvested in the U.S. have declined over recent years, while total production has increased. Per-acre yields, which averaged approximately 336 CWT per acre in 2012 have increased at least by seven-fold since the early 1900s and have doubled since the early 1960s.

Potato is grown in all 48 of the continental U.S. states with production concentrated in the states of Colorado, Idaho, Minnesota, North Dakota, Washington and Wisconsin accounting for approximately 75% of annual production (USDA-NASS, 2013). Idaho and Washington, the two top potato producing states, typically account for slightly more than one-third of the total U.S. crop (USDA-ERS, 2011). In recent years, the bulk of potato production in the U.S. has shifted from the East and Midwest to the Northwest because of transportation system improvements, decline in consumption of fresh potatoes, changes in weather patterns, and advantageous power, tax, and labor costs (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). Different potato varieties have been selected for performance in the fresh and processed markets. Russet varieties store well and are the source of most fresh market potatoes and French fries, while the Atlantic variety does not store well and is used primarily to produce potato chips (Simplot, 2013a).

After China, India, Russia, and the Ukraine, the United States is the fifth largest potato producing country (FAO, 2013), with annual production over the last three years of between

404-467 million cwt, grown on 1.0-1.1M acres (USDA-NASS, 2013). In 2011, the United States produced approximately 5% of the total world supply of potato (NPC, 2012) (National Potato Council, 2013). Major importers of U.S. potatoes are Canada, Mexico, Japan, South Korea, and China (NPC, 2012; National Potato Council, 2013). In 2010, the U.S. exported 1.6 billion lb of potatoes, with a total value of \$3.8 billion (USDA-AMRC, 2012). Approximately 62% of exported potatoes are in the form of frozen fries (National Potato Council, 2013) .

A determination of nonregulated status of Innate™ potato is not expected to directly cause an increase in agricultural acreage devoted to potato production. The availability of Innate™ 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.*

Public health concerns associated with the use of GE potato, such as Innate™ 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™ 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™ 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™ 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™ 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™ potato (Simplot, 2013a), APHIS has concluded that the availability of Innate™ potato would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE potato seed production (Simplot, 2013a). A determination of nonregulated status of Innate™ potato will not require a change to seed production practices, nor current production practices.

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

Non-GE potato varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the U.S. for human food or animal feed safety prior to release in the market. Under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and labeled properly. As a GE product, however, food and feed derived from Innate™ potato must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far all applicants who have wished to commercialize a GE variety that would be included in the food supply have completed a consultation with the FDA. In such consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. This process includes: 1) an evaluation of the amino acid sequence introduced into the food crop to confirm whether the protein is related to known toxins and allergens; 2) an assessment of the protein's potential for digestion; and 3) an evaluation of the history of safe use in food (Hammond and Jez, 2011). FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require. Several international agencies also review food safety associated with GE-derived food items, including the European Food Safety Agency (EFSA) and the Australia and New Zealand Food Standards Agency (ANZFS). Simplot provided the FDA with information on the identity, function, and characterization of the genes for Innate™ potato, including expression of the gene products, on February 12, 2013. The FDA is currently reviewing Simplot's submission.

A determination of nonregulated status of Innate™ 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 effects if Innate™ potato continues to be regulated. Other than lowered asparagine and PPO, and increased glutamine, Innate™ 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™ 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™ 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™ 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™ 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 effects on the quality of the human environment from a determination of nonregulated status of Innate™ potato are not highly controversial. Although there is some opposition to a determination of nonregulated status of Innate™ 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™ 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™ 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™ 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 effect of Innate™ 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™ 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 effects on the human environment are well understood. The effects 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™ potato is not expected to directly cause an increase in agricultural acreage devoted to potato production. A determination of nonregulated status of Innate™ 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 effect of Innate™ 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™ 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™ potato would not establish a precedent for future actions with significant effects 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 this 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™ 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 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. 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 effects were identified through this environmental assessment. Human health effects of consuming cooked Innate™ potato are expected to be positive. A cumulative effects analysis is provided in Chapter 5 of the EA. In the event APHIS reaches a determination of nonregulated status of Innate™ potato, APHIS would no longer have regulatory authority over this potato. In the event of a determination of nonregulated status of Innate™ 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™ 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™ 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™ 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™ 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™ potato is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the use and enjoyment of a historic property when common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the potato production regions. The cultivation of Innate™ 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™ 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™ potato, APHIS has determined that a determination of nonregulated status of Innate™ 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™ potato is unlikely to pose a plant pest risk, a determination of nonregulated status of Innate™ potato is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

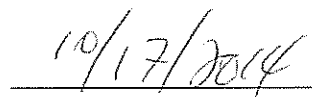
NEPA Decision and Rationale

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™ 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™ potato, the continued regulated status of Innate™ potato would be inconsistent with the plant pest provisions of the PPA, 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™ potato will not have any significant environmental effects.



Michael J. Firko, Ph.D.



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™ Potato

On May 3, 2013, APHIS published a notice in the Federal Register (78 FR 25942-25943, Docket no. APHIS-2012-0067) announcing the availability of the Simplot Innate™ potato petition (13-022-01p) for a 60-day public review and comment period. Comments were required to be received on or before July 2, 2013. The docket folder containing the comments can be located² at <http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=APHIS-2012-0067-0001>.

APHIS received a total of 308 submissions to the docket from various individuals and groups on the Simplot potato petition. Eighty-five public comments supported a determination of nonregulated status of Innate™ potato, including submissions from universities, growers, trade associations, growers' associations, and private individuals. Comments supporting the determination of nonregulated status included the following areas:

- Innate™ potato will be healthier, safer, and more nutritious for consumers.
- Because of its reduced black spot bruising potential, Innate™ potato will reduce potato wastage, and therefore, increase efficiency for the potato industry.
- Using native potato genes for genetic engineering greatly reduces ecological and evolutionary risks.
- Innate™ potato is a better quality potato, with improved texture and taste.
- Innate™ potato production can reduce use of fertilizers and pesticides.
- Innate™ potato can reduce potato production costs.
- Gene silencing technology is safe.
- Innate™ technology will help accelerate potato development and improvement, including disease resistance.
- Innate™ technology represents a significant improvement over conventional breeding techniques, especially when those techniques fail to eliminate negative traits.
- Innate™ potato can be safely stored and shipped separate from conventional potatoes.
- Innate™ potato will enhance global food security.
- Innate™ potato has no potential for weediness and clonal propagation is an effective barrier to gene flow in potato.
- There is no evidence that GE crops are unsafe, even after years of use.

The docket received 223 public comments opposing a determination of nonregulated status of Innate™ potato. These comments included submissions from private individuals, and from two nongovernmental organizations (NGOs). One of the comments was a letter with 41,745 signatures. The majority of the comments broadly opposed the development of GE crops and the domestic regulatory process surrounding GE plants, as well as perceived negative effects on public and animal health, biodiversity, and the environment; and the public right to choose non-

² Hyperlink cannot be directly opened. The hyperlink must be pasted in web browser address bar to be functional.

GE containing food products. Comments opposing the determination of nonregulated status included:

- More research is needed before the petition should be approved.
- Reduction of asparagine synthetase in Innate™ potato could have unintended effect because asparagine is needed for nitrogen transport and storage in plants.
- PPO synthetase may play a role in resistance to pathogens and pests, and reduction of the enzyme may result in unintended effects on plant fitness.
- RNAi technology may have unintended results.
- There is potential for hybridization of Innate™ potato with wild potato species, as well as potential contamination of conventional potatoes with Innate™ potato.

On May 30, 2014, APHIS published a notice in the Federal Register (78 FR 31080-31082, Docket no. APHIS-2012-0067) announcing the availability of the Simplot Innate™ potato draft EA (13-022-01p) and draft PPRA for a 30-day public review and comment period. Comments were required to be received on or before June 30, 2014. The docket folder containing the comments can be located at

<http://www.regulations.gov/#!/docketBrowser;rpp=25;po=0;dct=SR;D=APHIS-2012-0067>

A total of 60 public comments were received subsequent to the draft EA publication. The majority of those public comments supported the determination of nonregulated status; however, some public comments did not support the determination of nonregulated status. Supporting commenters included individuals from 7 different universities, three trade associations, one industry organization, and 10 farmers.

Comments supporting the determination of nonregulated status included the following new issues:

1. *Innate™ potato may lead to an increase in exported potatoes.*
2. *Innate™ potato will be marketed to other countries through and excellence in stewardship program.*
3. *It is inconsistent to approve some genetically modified crops such as corn and soybean, and not potato.*
4. *APHIS has experience reviewing crops genetically modified through RNA silencing.* A commenter from a university stated that “APHIS has over 20 years of experience conducting risk assessments on GE plants modified to exhibit a desired trait that relies upon an RNAi mechanism. The risk assessment parameters and methodologies APHIS used to evaluate these earlier products are entirely appropriate for the Innate™ potatoes.”

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

Three of the dissenting comments did not contain a letter, but only attached publications and articles. A fourth dissenting comment contained a letter to which 35,451 signatures of citizens were appended.

APHIS carefully reviewed the articles sent in by commenters. Many of them were included in the EA, many of them pertained to other dockets, but none contributed any new information relevant to InnateTM potato.

Issues related to the InnateTM potato EA were organized into categories and addressed below.

Issue 1: *Four commenters asked for a 90-day public comment extension. They stated that there was insufficient time to adequately review the EA, given that growers are currently busy managing crops.*

APHIS Response:

APHIS deemed the 30-day comment period sufficient opportunity for the public to provide meaningful comments on this EA. Following the comment period, the Agency thoroughly reviewed the comments and carefully considered other inputs as it prepared APHIS' EA, FONSI, and regulatory determination in response to this petition for nonregulated status of InnateTM potato.

Issue 2: *A commenter from an NGO stated that if InnateTM potato has reduced acrylamide, this may actually encourage more consumer demand for fried potato products, with the overall effect of no benefits to human health.*

APHIS Response:

APHIS disagrees with this comment. Simplot's compositional testing have shown that acrylamide is reduced, on average, 58-72% in InnateTM potato, compared with conventional potato (NTP, 2011; Simplot, 2013a). Potato chips and fried potato products represent only about 1/3 of a human's 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).

As noted in Section 4.6.1 of the EA, Human Health, concerns over acrylamide safety may lead to processor preference for Simplot InnateTM 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 InnateTM potato.

Issue 3: *An EIS is needed.* A comment by an NGO stated that APHIS' NEPA analysis is inadequate because it does not take a "hard look at the environmental consequences "of the proposed action. The comment stated that the EA does not ensure "comprehensive, timely, and transparent environmental review of agency action."

APHIS Response:

APHIS disagrees with the comment that it failed to take a hard look at the environmental consequences of the proposed action to possibly deregulate the genetically engineered Innate™ potato. APHIS believes that the EA is the comprehensive and appropriate environmental review document for this proposed action. Moreover, APHIS is confident that the EA has sound and reliable environmental and scientific analysis. APHIS carefully considered and analyzed the possible environmental impacts of the proposed action, and is satisfied that the EA developed for the proposed deregulation of the Innate™ potato is adequate and sufficient. Additionally, APHIS' analysis and decision in the PPRA regarding the potential, if any, plant pest risk posed by the Innate™ 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 the Innate™ potato, and has concluded that the Innate™ 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™ potato.

In the EA, APHIS has made sure to consider and evaluate opposing and/or contrary views; it has reviewed data submitted by those who supported or opposed the determination of nonregulated status, and has made sure to use objective, reliable environmental and scientific 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 trustworthy sources to support its analysis of the potential impacts of a determination of nonregulated status for Innate™ potato. 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 effects on the quality of the human environment that may result from a determination of nonregulated status of Innate™ Potato. APHIS assembled a list of alternatives that might be considered for determining whether or not the Innate™ Potato should be given non-regulated status. The agency evaluated these alternatives, in light of the agency's statutory 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 the appropriate ones to consider in reference to making a decision on whether to deregulate the Innate™ potato. As described in the EA, APHIS evaluated two alternatives; (1) no action and (2) determination of nonregulated status of Innate™ 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.

APHIS has prepared the EA to specifically evaluate the potential effects on the quality of the human environment that may result from the deregulation of Innate™ potato. The environmental analysis in the EA has not indicated that any significant impacts on the environment would result from the deregulation and therefore, APHIS does not need to prepare an EIS for this proposed action.

Issue 4: *APHIS needs to provide more opportunity for public participation.* A comment from an NGO stated that APHIS did not make an “adequate effort to engage public participation in its review of this petition for the deregulation of GE potatoes.” The commenter noted that most Americans do not check the Federal Register for regulatory actions, and would be better served by APHIS holding “open houses” as a form of public outreach.

APHIS Response:

APHIS disagrees with the comment. The Simplot petition (13-022-01p) for determination of nonregulated status and PPRA were published in the Federal Register on May 3, 2013 (78 FR 25942-25943, Docket no. APHIS-2012-0067), and the EA was published in the Federal Register on May 30, 2014 (78 FR 31080-31082, Docket no. APHIS-2012-0067) announcing the availability of the Simplot Innate™ potato draft EA. APHIS routinely seeks public participation thru the Federal Register as the official method of notifying the public of regulatory actions. The 60 day notice of the petition and PPRA and the 30 day comment period for this EA allowed for ample public participation. This proven method rendered over 300 comments including a letter with over 41,000 signatures.

Issue 5: *APHIS needs to provide a valid purpose and need for approving GE potatoes.* A comment from an NGO stated that APHIS needs to define the purpose of the action, and APHIS’ statement in the EA that it “must respond to petitioners that request a determination of the regulated status of GE organisms” is not sufficient: “the purpose and need of a proposed action is not just the agency is considering the action; rather, the purpose and need statement must actually describe the underlying purpose and need for the proposed action”. The commenter asserts that APHIS needs to “identify a purpose and/or need for approving deregulation of the GE potatoes”, and “describe why either facilitating more consumption of potatoes or reducing visible signs of damage (i.e., browning) is a compelling enough problem.”

APHIS Response:

As mentioned in Section 1.1 of the EA, a person may petition the agency for a determination that a particular regulated article is unlikely to pose a plant pest risk, and therefore, is no longer regulated under the plant pest provisions of the PPA or the regulations at 7 CFR 340. Under § 340.6(c)(4), the petitioner must provide information related to plant pest risk that the agency can use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. APHIS must respond to petitioners that request a determination of the regulated status of GE organisms (7 CFR 340.6), including GE plants such as Simplot Innate™ potato. When a petition for nonregulated status is submitted, APHIS must determine if the GE organism is unlikely to pose a plant pest risk.

APHIS does not have the regulatory authority to evaluate the efficacy of a petitioner’s product, nor the need for the product.

Issue 6: *APHIS does not consider a “reasonable range of alternatives” in its EA.* A comment from an NGO that the alternatives considered in the EA are too limited in scope, and that “NEPA requires APHIS to consider and evaluate a wide range of alternatives capable of addressing the same problem,” which “might meet the goals of the agency by using different approaches which may reduce the environmental impacts of the agency’s action.” The commenter suggested that APHIS include consideration of alternative ways to stop browning in potatoes such as selectively breeding non-GE potato varieties with lower susceptibility to browning or with lower acrylamide potential. The commenter refers to a guidance document from FDA which suggests that conventional breeding has “shown promise” in reducing acrylamide potential. The commenter lists several other alternatives such as assessing sugar levels in potatoes coming into processors, managing storage conditions to control sprouting, and handling potatoes gently during harvest, transport, and delivery.

APHIS Response:

APHIS disagrees with this comment. The commenter suggested alternatives that are not within the range of alternatives that reasonably needed to be considered. Those suggested alternatives are neither economical nor practical. Therefore, APHIS did not evaluate these alternatives because they are outside the scope of this EA. The analysis presented for each of the alternatives within this EA provides the agency decisionmaker and the public with as full a picture as practicable of the effects of its determination. The agency believes the analysis of these alternatives in this EA provides the decisionmaker and public with the impacts of each of these alternatives and differences in environmental impacts that would result. Even so, in the end, the analysis contained in this EA does not expand the agency’s authority or impose a duty to select what some view as the most environmentally friendly result. This decision does not prevent potato processors from choosing the method to prevent browning that they wish to employ. The EA has been prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from a determination of nonregulated status of Innate™ potato.

As discussed in Section 2.1 of the EA, Agricultural Production and Agronomic Practices of Potato, Potato Breeding, potato breeding by conventional methods is very difficult and time-consuming and may take years to successfully introduce as single trait. Innate™ potato uses a single construct to transform 5 different commercial parent varieties and create 10 events (USDA-APHIS, 2013a). The objective of Innate™ potato was to incorporate the same new phenotypes into each of these important varieties, while maintaining all of the desirable characteristics originally selected by potato breeders. If a single variety was transformed, it would take decades to move these new traits into the other commercial varieties by conventional breeding, and even then, it would be difficult to reconstitute the desirable characteristics of the original variety.

The EA referenced FDA's guidance document (FDA, 2013) in its EA, in Section 2.4.1, Human Health. FDA specifically notes that the recommendations contained in the document are for guidance only, and do not represent endorsement by FDA. The guidance report also lists benefits and drawbacks for available methods to reduce acrylamide, noting that some of these methods are more efficacious than others, and that some may affect product qualities such as flavor and texture.

Issue 7: *APHIS did not "properly" consider cumulative impacts.* A comment from an NGO stated that the cumulative impacts section in the EA did not have enough quantitative data or detailed information, and was too general. In particular, the commenter asserted that APHIS "does not account for the fact that Simplot has stated its intention to cross these potatoes with other varieties, and to introduce other GE potatoes." The commenter further stated that APHIS did not consider the potential for harms introduced by the deregulation of InnateTM potato to adversely affect nontarget organisms such as pollinators and on the potato market. In particular, the commenter states that APHIS should consider cumulative impacts on "consumer preferences." The commenter states that APHIS needs to consider socioeconomic impacts and the cumulative effects of "possible increased pesticide use as a result of the GE potatoes," as well as the "pathogen-resistance effects of Simplot's genetic engineering." The commenter concluded that an EIS is needed for these reasons.

APHIS Response:

APHIS disagrees with the commenter. Section 5.1 of the EA, Assumptions Used for Cumulative Impacts Analysis, discusses this issue. The cumulative effects analysis is focused on the incremental impacts of the Preferred Alternative taken in consideration with related activities including past, present and reasonably foreseeable future actions. In this analysis, if there are no direct or indirect impacts identified by a resource area, then APHIS assumes there can be no cumulative impacts.

With regard to the commenter's concern that APHIS did not evaluate the cumulative effects of Simplot's stated objective of crossing InnateTM potato with other potato varieties, because APHIS has determined that InnateTM potato is not a plant pest risk (USDA-APHIS, 2013a), by definition, any progeny resulting from crosses between InnateTM and conventional potato varieties will not be a plant pest risk. Simplot InnateTM potato is agronomically and compositionally similar to other potato cultivars (USDA-APHIS, 2013a).

The commenter misstates our regulatory process. If Simplot introduces other GE potatoes, those potatoes will have to undergo the same regulatory process as InnateTM potato. In other words, a new Simplot GE potato would be evaluated under 7 CFR part 340.

The commenter recommends that APHIS consider the cumulative impacts of InnateTM potato on consumer preferences. There are no data available to suggest that determination of nonregulated status will alter consumer preferences.

The commenter also suggests that APHIS should consider the potential for increased use of pesticides with the deregulation of Innate™ potato. As specifically stated in Section 5.2, Past and Present Reasonably Foreseeable Actions, Simplot's multi-year field trial data showed no increase in pesticide use for Innate™ performance versus that of conventional potato controls. Nine comments, including those from representatives of three universities and an agribusiness, submitted after the publication of the petition, stated that Innate™ potato production may decrease pesticide use. EPA regulates the use of pesticides under FIFRA. EPA sets the conditions for pesticide use on the label to achieve a standard of a "reasonable certainty of no harm." Therefore, the impact of pesticide use is outside the scope of this EA.

The "pathogen-resistance effects" of Innate™ potato was also raised by the commenter as a potential cumulative effect not evaluated by APHIS. This issue is covered in the APHIS Response to Issue 11, below.

Issue 8: *APHIS did not "adequately" consider socioeconomic impacts.* The commenter stated that APHIS must consider "past contamination episodes from GE crops" in its analysis. The commenter further stated that contamination of conventional potatoes with Innate™ potato could adversely affect foreign markets. The commenter concluded that APHIS must prepare an EIS to analyze the potential for contamination prior to deregulation.

APHIS Response:

APHIS has considered the past contamination episodes from GE crops. Specifically for GE potato, it is difficult to commingle a crop of its size. Furthermore, potato is asexually propagated so it doesn't have cross pollinations issues like other crops. Therefore it is relatively easy to identity preserve potato.

APHIS discussed socioeconomic impacts in Section 4.7 of the EA, Socioeconomic Impacts. Because of the reduced black spot bruise potential of Simplot Innate™ potato, it is expected that wastage will decrease significantly, and therefore, revenues will increase. Overall, if APHIS chooses the Preferred Alternative, the introduction of Simplot Innate™ events are likely to have positive economic impacts. Potatoes with low acrylamide and reduced black spot bruise potential are expected to have higher market value for the same inputs, representing potential increased revenue for growers and processors, and an overall increase in the value of potato production.

Issue 9: *APHIS did not adequately consider transboundary impacts.* A comment from an NGO stated that APHIS did not consider the effect of a determination of nonregulated status of Innate™ potato on other nations. The commenter specifically cited Canada because "much of the U.S. potato industry is in northern states." The commenter also stated that relying on voluntary grower agreements, isolation distances and processor requirements is not sufficient.

APHIS Response:

Global sensitivities to GE products, including international restrictions on import of GE products and inability of the petitioner to gain approval for cultivation or importation, will continue to affect trade with those countries. These challenges to international trade in GE products are already in place. Restrictions on international trade in GE products, including Innate™ potato, are unlikely to change with a determination of nonregulated status of Innate™ potato.

Issue 10: *Data on the function of PPO and pathogen susceptibility is inadequate to make a determination of nonregulated status.* A comment from an NGO disagreed with Simplot's data conclusions with regard to susceptibility to pathogens. The commenter stated that Simplot should have performed pathogen challenge tests on its potatoes to address this issue. The commenter also noted that if gene silencing is incomplete in leaves, an intermediate phenotype which is more susceptible to pathogens might occur. The commenter stated that if disease susceptibility is increased, this could lead to increased use of pesticides to control the diseases.

APHIS Response:

The literature contains large numbers of publications discussing the metabolic pathway of PPO (polyphenol oxidase), including nine which have been referenced in this EA (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, 2013a) 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, 2013a). 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).

With regard to the comment that Simplot should have performed assays challenging Innate™ potato with pathogens, Simplot did this (Simplot, 2013a). As described in the petition, disease susceptibility was evaluated by intentionally infecting the events and their untransformed controls with late blight and soft rot, and results confirmed that silencing of the target genes did not enhance susceptibility to disease.

In Appendix 8 of its petition, Simplot compared laboratory and field disease assays that were designed to generate response data to two important diseases of potato: late blight caused by *Phytophthora infestans* and bacterial soft rot caused by *Erwinia carotovora* (Simplot, 2013a). In some of the comparisons, Innate™ potato had more disease stress than controls. However, with the exception of early blight in event F10 at Grand Forks, ND in 2011, these observed differences were small, and 14 other observations demonstrated no difference between F10 and controls in stress due to early blight. There were few observations for late blight (*P. infestans*), and no observations were systematically collected for Fusarium dry rot (*Fusarium* spp.), ring rot (*Clavibacter michiganensis* spp. *sepedonicus*), and water rot/Pythium leak (*Pythium ultimum*). However, there were no significant differences between events J3, J55, J78, H37, and H50 and their controls in the number of tubers discarded at harvest due to quality issues, i.e. rot or mold, while the number of tubers discarded for event G11 was significantly lower than its control (Simplot, 2013a), Appendix 6. Discards for Events F10, F37, E12 and E24 were not recorded. During the cold storage period for trials in three locations in either 2009 or 2010, pink rot (*Phytophthora erythroseptica*) and soft rot and Pythium leak diseases were occasionally observed on both untransformed and unspecified Innate™ potato events, but no data were provided, and the disease incidence was attributed to environmental soil conditions that favored infection (Simplot, 2013a). While a number of viruses also affect tubers (e.g., potato leaf roll virus), these also have above-ground symptoms and such symptoms were not observed during the field trials. Based on analyses of results presented in the petition (Simplot, 2013a), the PPRA (USDA-APHIS, 2013a) concluded that Innate™ potato is unlikely to be more susceptible than control potatoes to diseases such as late blight or tuber rot.

Simplot evaluated how Innate™ potato performed in the field with respect to control potatoes (Appendix 6). Pest and disease characteristics were monitored, and data were collected that would help to analyze if these events were less, equal, or more susceptible to pest and diseases than control potatoes (Simplot, 2013a). If PPO were involved in pest and disease resistance, through a role in the hypersensitivity response, then one might expect a systematic increase in the sensitivity of PPO suppressed Innate™ potato to a wide variety of agents. Simplot did not observe such a change in phenotype in their field observation of Innate™ potato (Simplot, 2013a). Standard agronomic practices were sufficient to prevent pests and diseases in Innate™ potato and no additional control measures were required (Simplot, 2013a). Innate™ potato is expected to be no more susceptible to the same plant pathogens and insect pests as the conventional potato varieties (USDA-APHIS, 2013a). Standard field agronomic practices will be used to control for disease and pests in Innate™ potato as they would in non-GE potato fields.

Issue 11: *Concern that silencing of asn1 genes could have some unintended adverse effects.*
This comment was made by an NGO.

APHIS Response:

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 Innate™ method used to produce these 10 events is one such method that does not involve the transfer of genes) to be among the methods least likely to have unintended effects – less likely than conventional pollen-based crossing of closely related species – and far less likely than methods such as ionizing radiation and chemical mutagenesis, which are not subject to regulation and are not excluded methods under the NOP (Sciences, 2004).

Data on performance of Innate™ potato from Simplot's petition (Simplot, 2013a) indicates that there are no statistically significant differences from performance of conventional potatoes. Although total nitrogen was not measured, APHIS would have expected plant growth performance to have suffered if asparagine levels were so depressed that nitrogen transport and storage was negatively affected.

Issue 12: *Yield data results are inconclusive.* A comment from an NGO stated that Simplot's field trials data showed that 50% of the trial yields were significantly lower than control yields. The commenter also stated that "high yield is typically one of the most important characteristics of crop varieties that farmers look for, because it tends to result in higher profits."

APHIS Response: APHIS does not regulate the actions of individual market participants. Farmers can choose to either use or not use the lower yielding potatoes. Those decisions rest solely on market participants and are outside APHIS regulatory authority.

Issue 13: *APHIS' scientific analysis and data are "incomplete and inadequate."* A comment from an NGO stated that because of uncertainty, APHIS' analyses are deficient, and APHIS should collect their own data, especially on nutritional composition and RNAi effects.

APHIS 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™ 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™ potato, and has concluded that Innate™ 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™ potato. APHIS carefully considered the possible environmental impacts of the proposed product, and is satisfied that the EA developed for Innate™ 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 InnateTM 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 raised in any of the feeding studies, including the multigenerational studies and long-term studies.

Similarly, Snell (Snell *et al.*, 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.

With regard to the comment about safety of RNAi, 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™ 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™ 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.

The PPRA (USDA-APHIS, 2013a) showed that there were no significant differences between any of the 10 Innate™ potato events and conventional potatoes for mean glycoalkaloid toxin content. No new proteins are expected to be produced based on the inserted genetic elements and the genetic modification.

APHIS conducted a PPRA, and concluded that Innate™ potato does not constitute a plant pest risk (USDA-APHIS, 2013a). FDA regulates food safety of GE organisms under the authority of the FFDCA (21 U.S.C. 301 *et seq.*).

Issue 14: *APHIS did not adequately consider public health impacts.* A comment from an NGO stated that APHIS improperly “passes the buck to FDA” on public health impacts. The commenter also criticized FDA’s voluntary consultation process as “extraordinarily weak,” and should not be relied upon by APHIS. The commenter further stated that APHIS did not evaluate the “direct and indirect potential side effects from changes in pathogen resistance likely caused by reducing browning.”

APHIS Response:

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™ potato. These sources include, but are not limited to, the Simplot petition and appendices, technical reports, and peer-reviewed literature.

APHIS disagrees with the commenter that there is improper reliance on FDA for its public health expertise; instead, FDA is the Federal authority that regulates food safety. We disagree that APHIS should take on this role instead of deferring to the FDA. We also disagree with the commenter that the voluntary consultation process is extraordinarily weak; especially given that every developer of a biotech crop has consulted with the FDA prior to market.

During the first comment period, APHIS received 43 comments, including those from 3 growers' associations, 5 universities, and 3 agribusinesses, that Innate™ potato will be healthier than conventional potatoes. One commenter from a university stated that "the proposed modifications offer a simple method to reduce the levels of (acrylamide) in our food." Another commenter at another university asserted that "no novel proteins are produced, meaning there is no known biological mechanism whereby silencing these genes could increase weediness potential or provide a plant pest risk." A commenter from a third university stated: "The process results in potato lines that demonstrate reduced black spot bruise, low asparagine, and lower levels of reducing sugars. These are all traits that are critical to the potato industry and will reduce potential risk to humans consuming fried potato products."

As discussed in Section 4.6.1 of the EA, Human Health, a decision to deregulate Innate™ potato should decrease exposure to acrylamide by between 58 and 72%, a significant reduction in a toxic compound (NTP, 2011; Simplot, 2013a). Further, the data presented in the petition show that the Simplot Innate™ potato events are at least as safe and nutritious for food as the untransformed controls (Simplot, 2013a). The compositional analyses of the ten events are summarized in the petition, with detailed results in Appendix 9 (Simplot, 2013a).

Issue 15: *APHIS did not consult with tribes.* A comment from an NGO stated that "APHIS has made no showing in this EA to indicate that it has considered the potential impacts of this action upon tribes or whether it has sought out any input from tribal officials."

APHIS Response:

APHIS disagrees with this comment. Prior to the publication of this EA, APHIS sent a letter to tribal leaders in the continental United States on May 3rd, 2013. This letter contained information regarding the JR Simplot Company petition and the Innate™ potato varieties. Additionally, this same notification also asked tribal leaders to contact APHIS if they believed that there were potentially significant impacts to tribal lands or resources that should be considered. No responses were received by APHIS from tribal leaders regarding the JR Simplot Company petition or Innate™ potato varieties.

Furthermore, APHIS considered the impact to tribes or tribal properties in the EA (Section 7.6 National Historic Preservation Act [NHPA] of 1966 as Amended) and this FONSI (Item 8 above,

directly under *Intensity*). As a result of that analysis, it was concluded that a determination of nonregulated status of Innate™ potato will not adversely impact cultural resources on tribal properties.

Issue 16: *APHIS did not adequately consider the impacts on beneficial organisms, including pollinators.*

APHIS Response:

Section 4.5.1 of the EA, Animal Communities, discusses projected effects of Innate™ potato on non-target animals. Consumption of Simplot Innate™ potato is unlikely to substantially affect non-target organisms, such as mammals, birds, or insects. Simplot data demonstrates that the composition of Simplot Innate™ potato does not substantially differ from conventional potato varieties (Simplot, 2013a). Simplot indicated that they have submitted a safety and nutritional assessment of food and feed derived from Simplot Innate™ potato to the FDA on February 12, 2013 (Simplot, 2013a). FDA is presently evaluating the submission. There is no evidence that animal exposure to Simplot Innate™ potato would have any effect or be any less attractive as food, refuge, cover and nesting sites as non GE varieties of potatoes.

APHIS evaluated in the EA, Simplot's data on agronomic performance, disease and insect susceptibility, and compositional profiles of Innate™ potato. APHIS analysis indicates no significant differences between Innate™ potato and non-transgenic counterparts that would be expected to cause either a direct or indirect adverse effect on non-target organisms. Field trials conducted over a 3-year period with Innate™ potato have not shown any observable significant differences between Innate™ potato and non-transgenic controls. Because of this, there is no scientific reason to expect that the transformed Innate™ potato would have a negative impact on non-target organisms. Insect population diversity represents one measure of general impacts, and there were no differences observed at various times during development of the crop. In the absence of any observable acute stresses or impacts, there is no reason to presume that long term impacts would be expected, nor that a need exists to monitor for them. APHIS has carefully considered the possible environmental impacts of the proposed action, and is satisfied that the EA prepared by APHIS is adequate and sufficient.

As discussed in Section 2.3.3 of the EA, Gene Flow and Weediness, because potato is primarily clonally propagated, exposure of pollinators to pollen is limited. Furthermore, the site of gene silencing is primarily limited to the tuber and stolons, not the leaves and stems, thereby leading to restricted access of the gene silencing to insects and other nontarget organisms. Muttucumaru et al. (Muttucumaru *et al.*, 2014) notes that "the strategy of targeting asparagine synthesis specifically in the tuber makes sense because asparagine has been shown not to be a major transported amino acid in potato, so the free asparagine that accumulates in tubers must be synthesized there."

Furthermore, no new proteins are being introduced as a product of Innate™ technology (Simplot, 2013a). Llorente et al. (2010) fed nonbrowning potato transformed by gene silencing to mice, and determined that there were no adverse effects to the mice. Llorente et al. (2010) also determined that given a choice, mice consumed significantly more of the GE potatoes than the conventional potatoes, and suggested that the odor of the GE potatoes might be more attractive to the mice (Llorente *et al.*, 2010). The field trial results reported by Simplot (Simplot, 2013a) also demonstrated that there were no differences between infestation of insects in the Innate™ potatoes compared to their untransformed controls.

The EA has reported on the safety of Innate™ potato in the environmental consequences and cumulative impacts sections under various headings, including those on animals, plants, biodiversity, microbes and human health. Based upon information and analysis presented in the petition, PPRA, and EA, APHIS has not identified any potential for harm to the environment from Innate™ potato

Issue 17: *APHIS did not “properly” consider its obligations to migratory birds.* A comment from an NGO stated that APHIS failed to properly consider and disclose its obligations to migratory birds. Specifically, Executive Order 13186 requires federal agencies to develop and implement a Memorandum of Understanding (MOU) with the FWS to promote the conservation of migratory bird populations. Further, that APHIS did not adequately assess impacts to migratory birds, and that APHIS did not consider the permitting requirements that allow the “take” of a migratory bird under certain activities, none of which include the types of activities discussed in the EA, and therefore no take of even a single migratory bird is allowed.

APHIS Response:

APHIS disagrees with the commenter. First, as required by Executive Order 13186, APHIS has in place a signed MOU with the FWS (APHIS-USFWS, 2012). Second, APHIS has considered its obligations under the Migratory Bird Treaty Act and acknowledged in the EA that migratory birds, particularly waterfowl, may forage in agricultural fields including potato fields. However, APHIS came to the conclusion that granting nonregulated status to Innate™ potato would have no impact on any migratory birds because Innate™ potato is similar to other potato varieties, with the exception the silencing of four different genes in potato: asparagine synthetase-1 (*Asn1*), polyphenol oxidase-5 (*Ppo5*), potato phosphorylase L (*PhL*) and the starch-associated R1 gene (*R1*). The suppression of *Asn1* results in potatoes with reduced free asparagine, and the suppression of *PhL* and *R1* results in potatoes with a lower content of reducing sugars. Collectively, the silencing of these 3 genes should result in potato tubers with a reduced acrylamide potential. The suppression of *Ppo5* confers the Innate™ potato with a non-browning phenotype resulting in tubers with reduced black spot bruising (Simplot, 2013b), (USDA-APHIS, 2013b). APHIS has determined that there is no reason to believe that reduced free asparagine or reduced black spot bruising would have any effect on migratory birds. The applicant provided data to demonstrate the compositional equivalency of Innate™ potato and

other potato varieties currently grown. The modifications did not alter the quality of potato as food other than lower levels of acrylamide after cooking, and lower black spot bruise. There would be no effect from consumption of Innate™ potato plant parts because there is nothing different between the plant parts of these varieties and plant parts of other potato varieties already in production. Further, there is no reason to suspect that migratory birds would interact with Innate™ potato any differently than any other potato plant. Lastly, no “take” of a migratory bird is expected as a result of growing Innate™ potato, and APHIS could not determine any mechanism by which take would occur, or would occur any differently than production of any other potato variety.

Issue 18: *APHIS did not “adequately” assess impacts on threatened and endangered species.*

One commenter from an NGO stated that Innate™ potato may significantly affect threatened and endangered species (TES) and expressed concern that APHIS had “failed to consult” with the United States Fish and Wildlife Service (USFWS) or the National Marine Fisheries Service (NMFS) on the potential effects to threatened and endangered species and their critical habitats, as required under section 7 of the Endangered Species Act (ESA), and that “APHIS must prove” its deregulation of Innate™ Potato will neither jeopardize any species nor harm any critical habitat anywhere the crop may be grown. Further, that APHIS failed to obtain information from USFWS/NMFS on species that may be present in the area where Innate™ potato would be grown.

APHIS 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 Innate™ 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 as well as 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 February 19, 2014 at http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp) (USDA-APHIS, 2014a), (USDA-APHIS, 2014b). After analyzing the potential for any effect, APHIS concluded that the determination of nonregulated status for Innate™ 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.

References

- AOSCA (2010) "General IP Protocols Standards." The Association of Official Seed Certifying Agencies. <http://www.identitypreserved.com/handbook/aosca-general.htm>.
- APHIS-USFWS (2012) "Memorandum of Understanding Between USDA-APHIS and DOI-FWS." USDA-APHIS, DOI-FWS.
- Carrington, J (2014) "comment to the EPA " Donald Danforth Plant Science Center [http://www.danforthcenter.org/news-media/news-releases/news-item/\(genomeweb\)-advocacy-group-urges-caution-over-agricultural-rnai](http://www.danforthcenter.org/news-media/news-releases/news-item/(genomeweb)-advocacy-group-urges-caution-over-agricultural-rnai).
- Cellini, F; Chesson, A; Colquhoun, I; Constable, A; Davies, HV; Engel, KH; Gatehouse, AM; Karenlampi, S; Kok, EJ; Leguay, JJ; Lehesranta, S; Noteborn, HP; Pedersen, J; and Smith, M (2004) "Unintended effects and their detection in genetically modified crops. ." *Food and Chemical Toxicology*. 72 (7): p 1089-125. <http://www.sciencedirect.com/science/article/pii/S0278691504000444#>.
- 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.
- FAO (2013) "Top Production, Potatoes, 2011." FAOSTAT Statistics Division, Food and Agriculture Organization of the United Nations. <http://faostat.fao.org/site/339/default.aspx>.
- FDA (2013) "Guidance for Industry: Acrylamide in Foods, Draft Guidance." FDA.
- Felton, GW; Donato, K; Del Vecchio, RJ; and Duffey, SS (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=c648dc51b85f5c83e8be2ad2ef86c5ba1>.
- Friedman, M (2003) "Chemistry, Biochemistry, and Safety of Acrylamide: a Review." *Journal of agricultural and food chemistry*. 51 p 4504-26.
- Guenther, J (2010) "Marketing and Economics." *Commercial Potato Production in North America: the Potato Association of America Handbook*. Potato Association of America. p 13-15.

- 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, AL; Bartz, SR; Schelter, J; Kobayashi, SV; Burchard, J; Mao, M; Li, B; Cavet, G; and Linsley, PS (2003) "Expression profiling reveals off-target gene regulation by RNAi." *Nature Biotechnology*. 6 p 635-37. <http://www.nature.com/nbt/journal/v21/n6/full/nbt831.html>.
- 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>.
- Llorente, B; Rodriguez, V; Alonso, G; Torres, H; Flawia, M; and Bravo-Almonacid, F (2010) "Improvement of Aroma in Transgenic Potato as a Consequence of Impairing Tuber Browning." *PLoS One*. 5 (11): p e14030.
- 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, GD (1989) "The Biochemical Basis of Resistance of Potatoes to Soft Rot *Erwinia* spp.--a Review." *Plant Pathology*. 38 (3): p 313-39.
- Martinez, MV and Whitaker, JR (1995) "The Biochemistry and Control of Enzymatic Browning." *Trends in Food Science & Technology*. 6 p 195-200.
- Mayer, AM (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>

<http://www.scopus.com/inward/record.url?eid=2-s2.0-33749517866&partnerID=40&md5=0d679d8f3b4e90a165674171fbbee3a1>.

Muttucumaru, N; Powers, SJ; Elmore, JS; Briddon, A; Mottram, DS; and Halford, N (2014) "Evidence for the Complex Relationship between Free Amino Acid and Sugar Concentrations and Acrylamide-Forming Potential." *Annals of Applied Biology*. 164 p 286-300.

National Potato Council (2013) "2013 Potato Statistical Yearbook." National Potato Council.
<http://nationalpotatocouncil.org/>.

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 Chem Toxicol*. 48 (7): p 1773-90.
<http://www.ncbi.nlm.nih.gov/pubmed/20399824>.

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.

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&listuids=11238371>.

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

Simplot (2013a) "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 (Finger Russet); J3, J55, and J78 (Atlantic); G11(G); H37 and H50 (H) " J.R. Simplot Company.

Simplot, J (2013b) "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 (Finger Russet); J3, J55, and J78 (Atlantic); G11 (G); H37and H50 (H)." 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 Riccio, 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, JC (1994) "Polyphenol Oxidase." *Genetic Engineering of Plant Secondary Metabolism*. New York: Plenum Press. p 275-312.

Stremmel, N; Praeger, U; König, C; Fehrle, I; Erban, A; Geyer, M; Kopka, J; and van Dongen, JT (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, LT; Taylor, JS; and Constabel, CP (2012) "The Polyphenol Oxidase Gene Family in Land Plants: Lineage-specific Duplication and Expansion." *BMC Genomics*. 13 p 395.

US-EPA (2011a) "Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)." <http://www.epa.gov/agriculture/lfra.html> >.

US-EPA (2011b) "Summary of the Federal Food, Drug, and Cosmetic Act (FFDCA)." U.S. Environmental Protection Agency. <http://www.epa.gov/regulations/laws/ffdca.html>.

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-AMRC (2012) "Potato Profile." USDA- Agricultural Marketing Resource Center. <http://www.agmrc.org/>.

USDA-APHIS (2013a) "J.R. Simplot Company Petition (13-022-01p) for Determination of Non-regulated Status of Low Acrylamide Potential and Reduced Black Spot Bruise Potato Events F10, F37, E12, E24, J3, J78, G11, H37, and H50: Plant Pest Risk Assessment." USDA-APHIS.

USDA-APHIS (2013b) "Plant Pest Risk Assessment JR Simplot Company Petition 13-022-01p "

USDA-APHIS (2014a) "Listed Species in States with Commercial potato Production."

USDA-APHIS (2014b) "Proposed Species in States where Potatoes are Commercially Grown." Last Accessed: February 19, 2014

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 (2011) "Feed Outlook, FDS-11a, January 14, 2011." Last Accessed: March 21, 2011
<http://usda.mannlib.cornell.edu/usda/ers/FDS/2010s/2011/FDS-01-14-2011.pdf>.

USDA-NASS (2010) "Acreage." <http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-30-2010.pdf>.

USDA-NASS (2012a) "Acreage." USDA, National Agricultural Statistics Service, Agricultural Statistics Board. Last Accessed: 17 July 2012 <http://usda01.library.cornell.edu/usda/current/Acre/Acre-06-29-2012.pdf>.

USDA-NASS (2012b) "Crop Production, 2011 Summary " USDA, National Agricultural Statistics Service.

USDA-NASS (2013) "Crop Production: 2012 Summary." United States Department of Agriculture, National Agricultural Statistics Service.
[http://www.agcensus.usda.gov/Publications/2007/Full_Report/Volume_1, Chapter_1_State_Level/Texas/](http://www.agcensus.usda.gov/Publications/2007/Full_Report/Volume_1,_Chapter_1_State_Level/Texas/).

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