



# Case Study Simplot W8 Potato

Jason Dietz

Adapted and updated from 2016 presentation presented at SCRA

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

[Plantbiotech@fda.hhs.gov](mailto:Plantbiotech@fda.hhs.gov)

# History of W8 Potato at FDA



Note to the file available at:

<https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=NewPlantVarietyConsultations&id=SPS-000W8-4>

# FDA's Experience with Simplot Potatoes

FDA evaluated 6 potato events from Simplot previously

W8 potatoes were similar, but had additional traits from a second plasmid

1 of the additional traits is a PIP under EPA purview

# Substances New to Potato- Regulatory Framework

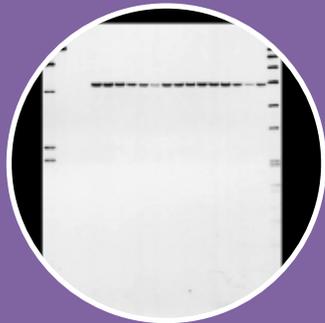
Expression products under FDA purview:

RNA interference of *Asn1*, *Ppo5*, *Rpi-VInv*, *R1* and *PhL* genes – no new protein substances under FDA purview

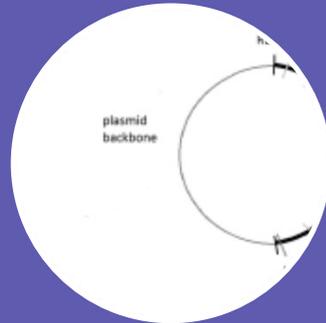
*Ppo5* encoding polyphenol oxidase 5  
*Asn1* encoding asparagine synthetase 1  
*R1* encoding R1 starch associated protein  
*PhL* encoding phosphorylase L  
*VInv* encoding vacuolar invertase

Expression products under EPA purview: *Rpi-Vnt1* from *Solanum venturii*

# The Molecular Assessment



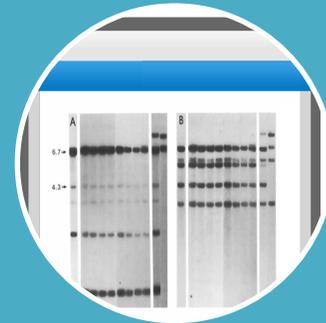
What was incorporated into the genome?



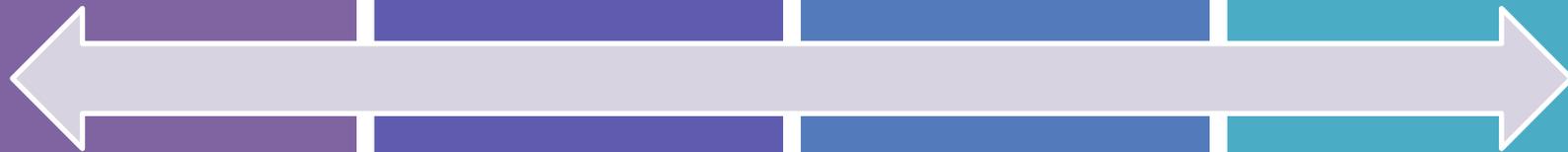
Is vector backbone present?



Are new proteins expressed?



Is the insertion stable across generations?



Information from these assessments helps identify what was added to the food.

# Molecular Assessment

## Parent

- Russet Burbank
- Sequential transformation with 2 plasmids

## Cassettes I & II From pSIM1278

- Potato *Asn1*, *R1*, *PhL* and *Ppo5* partial sequences followed by complementary sequences in reverse orientation which generates dsRNAs containing inverted repeats

## Cassettes III and IV From pSIM1678

- Potato *Vinv* partial sequence followed by complementary sequence in reverse orientation which generates dsRNAs containing inverted repeats.
- EPA regulated as a PIP: *Rpi-vnt1* gene from *S. venturii*, as well as its native promoter and terminator. Produces R-protein Vnt1.

# Molecular Assessment

## Cassettes 1 and 2

- Complex insertion- multiple copies of silencing cassettes
- Single locus

## Cassettes 3 and 4

- Single copy with deletion at left border
- Single locus

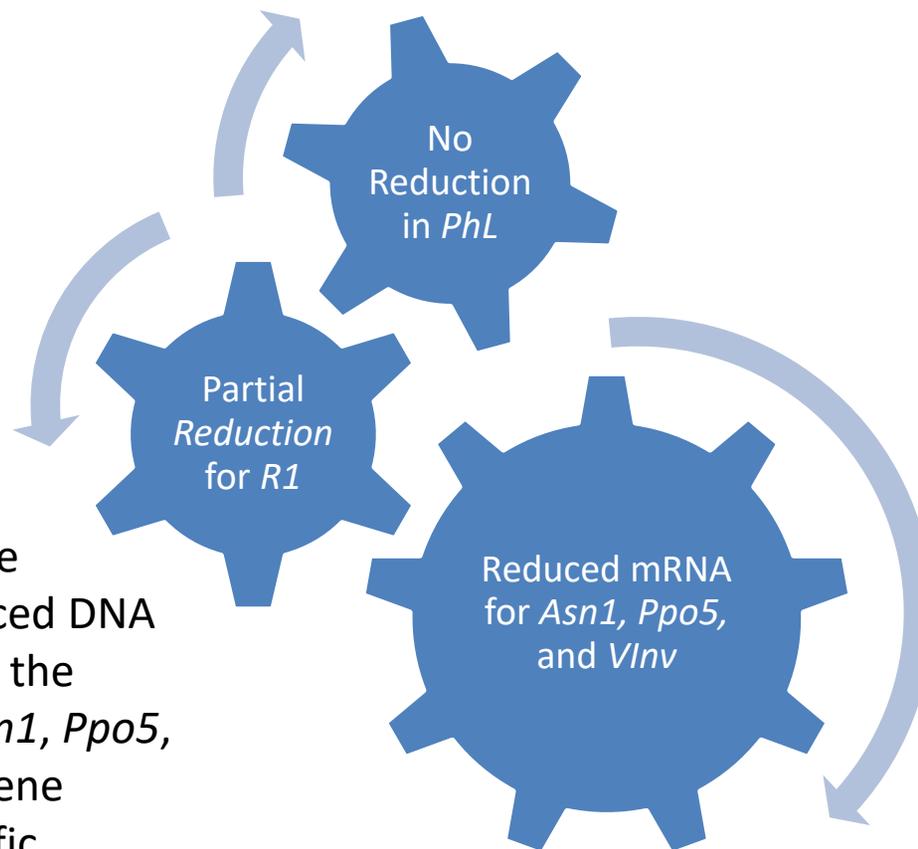
## Vector Backbone

- Not detected

# Molecular Assessment

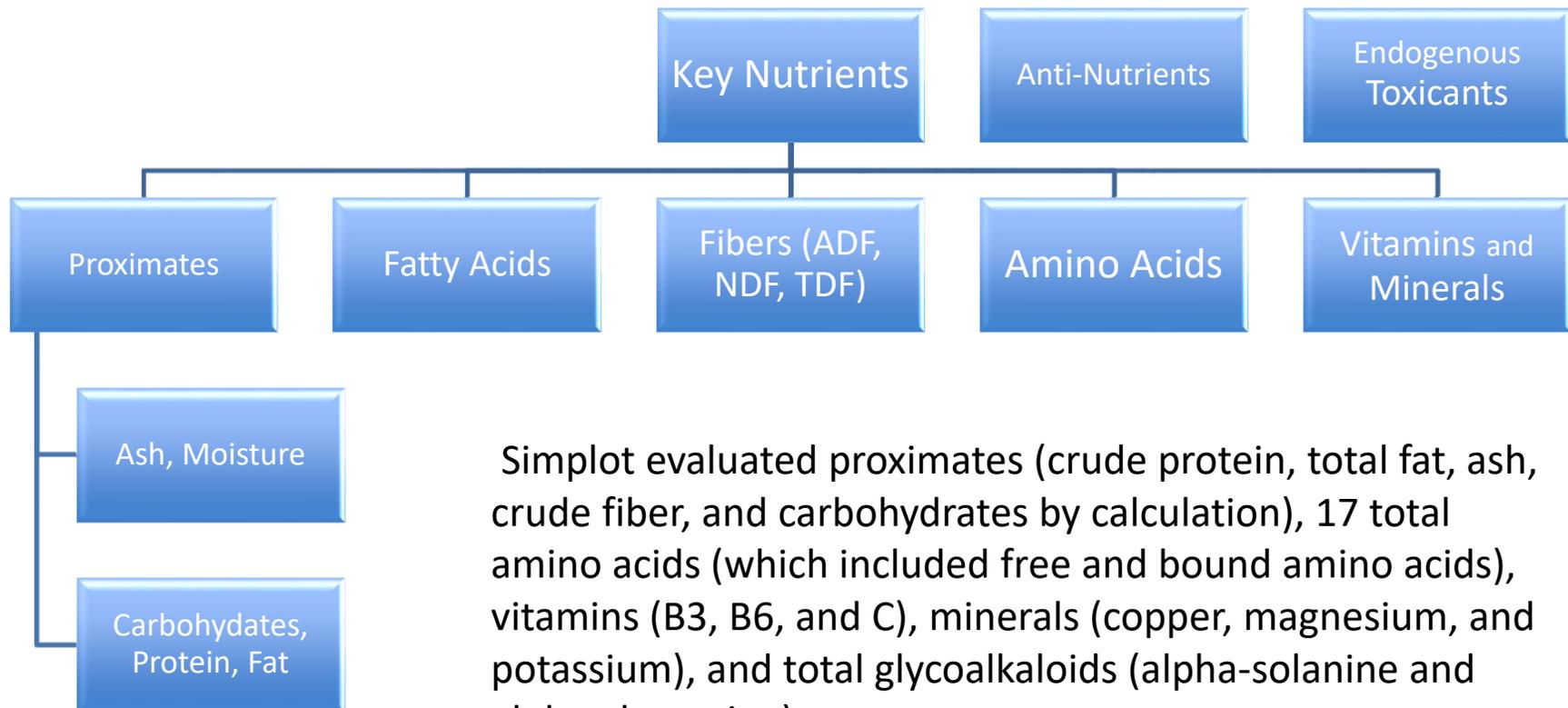
- Simplot performed bioinformatics analyses of the two DNA inserts and their known flanking sequences to assess the potential that the insertions and flanking DNA could result in expression of a peptide that is a toxin or allergen.
  - No significant similarity to known toxins identified.
  - Sequence similarities were observed between putative ORFs and two known allergens, but concerns were resolved.
    - In one case, the similarity was to a native potato gene that was part of the gene silencing cassette.
    - In the second case, the similarity was not relevant to allergenicity because the sequence was derived from a potato promoter and the sequence is not identified as a potential allergenic epitope in an allergenic epitope database.

## Intended Effects – Reduced Transcription for Targeted Genes in Tubers



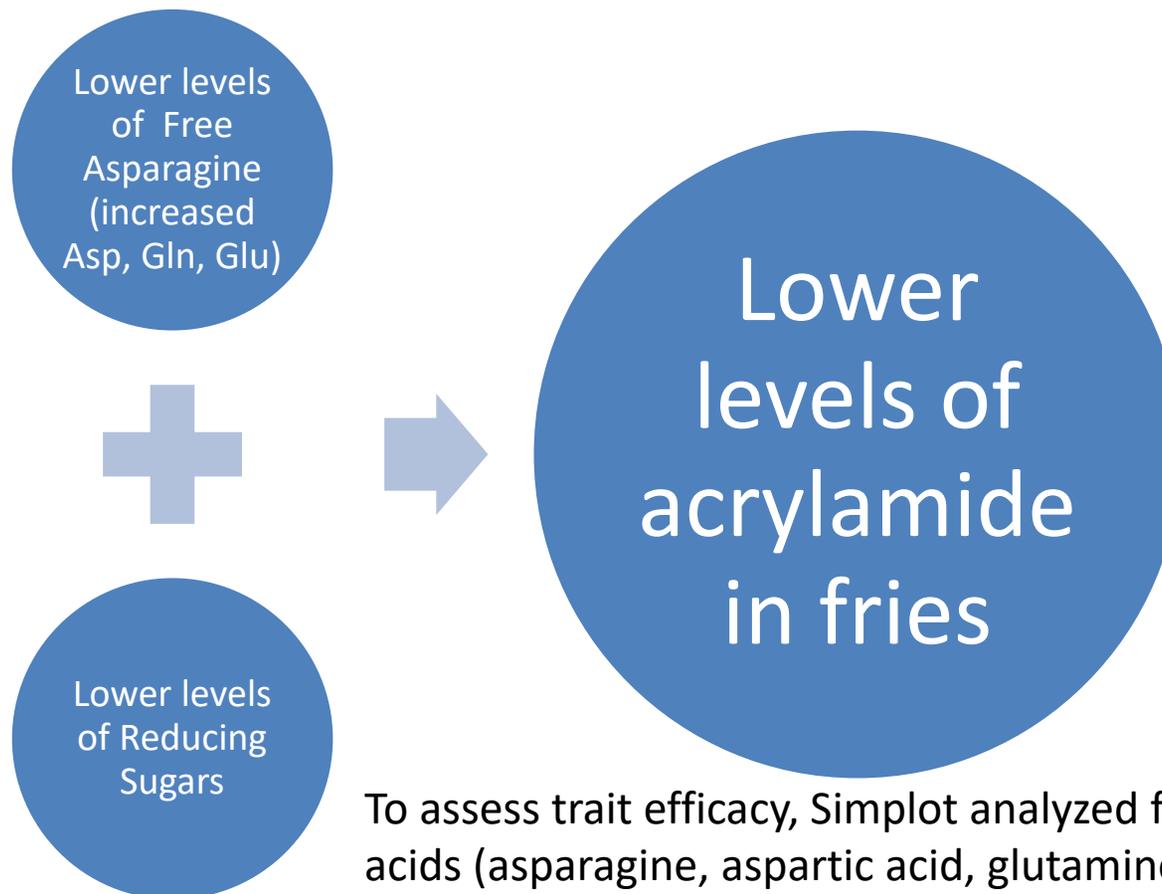
Simplot concludes that the expression of the introduced DNA in the W8 potato lowered the transcript levels of the *Asn1*, *Ppo5*, and *VInv* genes and this gene silencing was tissue-specific.

# Compositional Analysis



Simplot evaluated proximates (crude protein, total fat, ash, crude fiber, and carbohydrates by calculation), 17 total amino acids (which included free and bound amino acids), vitamins (B3, B6, and C), minerals (copper, magnesium, and potassium), and total glycoalkaloids (alpha-solanine and alpha-chaconine).

# Intended Effect on Composition



To assess trait efficacy, Simplot analyzed free amino acids (asparagine, aspartic acid, glutamine, and glutamic acid), sucrose, and reducing-sugars (fructose + glucose).

# Composition Results

- Statistically significant differences between W8 potato and control for:
  - Vitamins B6 and C
  - Amino acids: total alanine, total aspartic acid, total glutamic acid, total glycine, total leucine, total proline, total serine, total threonine and total tyrosine.
- All mean values fell within the intervals of common potato varieties and combined literature ranges, except for total aspartic acid. Simplot did not consider the statistical differences mentioned above to be biologically meaningful.
- Other components including glycoalkaloids were similar between the two potato varieties.

## The Other Question - Labeling

FDA's letter states that changes may constitute a material difference in some potato products

- Simplot met with FDA's Food Labeling and Standards Staff to discuss labeling considerations.

# Conclusions

- W8 contains no newly expressed proteins that fall within FDA's regulatory purview.
  - *Rpi-Vnt1* and its encoded R-protein Vnt1 are PIPs (premarket authority is EPA's).
- W8 has no compositional changes that raise safety or nutritional questions.
- FDA responded to Simplot with a “no questions” letter.
  - Results of this consultation and others can be found on [FDA's website](#).



# Conclusions

U.S. Department of Health & Human Services

**FDA U.S. FOOD & DRUG ADMINISTRATION**

## New Plant Variety Consultations

● FDA Home ● Food from New Plant Varieties ● Consultation Programs on Food from New Plant Varieties ● New Plant Variety Consultations ● 146

### BNF No. 146 Potato W8 SPS-000W8-4

**Developer:** J.R. Simplot Company  
5369 West Irving Street  
Boise, ID 83706

**Trait(s):** Changes in composition (reduced black spot bruise)  
(reduced free asparagine, lower level of reducing sugars)  
Blight Resistance

**Submission Date :** Apr 15, 2014

**Inserted genes (gene fragments):** Gene segments from *Fpo5* gene and Gene segments from *Asn1* and *Vinv* genes and *PhL* and *R1* promoters  
*Solanum tuberosum* var. Ranger Russet

**Contains EPA-regulated trait:** Yes

**FDA's Memos:** Human and Animal Food Uses  
Dec 31, 2015

**FDA's letter:** Human food and animal food  
Jan 12, 2016

**Completion date:**

2362

Page Last Updated: 03/16/2021

Food safety and quality

GM Foods Platform > Browse information by > OECD Unique Identifier

## FAO GM Foods Platform

### OECD Unique Identifier details

SPS-000W8-4	
<b>Commodity:</b>	Potatoes
<b>Traits:</b>	Reduced levels of arginine and reducing sugars, reduced black spot bruising, Resistance to late blight

### Australia

[View Country Profile](#)

<b>Name of product applicant:</b>	SPS International Inc
<b>Summary of application:</b>	FSANZ has received an Application from SPS International Inc (SPS), a subsidiary of J.R. Simplot Company (USA), to vary Schedule 26 in the <i>Australia New Zealand Food Standards Code</i> (the Code). The variation is to add food derived from six genetically modified (GM) potato lines from the Simplot Innate brand. These lines and their OECD Unique Identifiers are outlined in Table 1.
<b>Upload:</b>	
<b>Date of authorization:</b>	07/12/2017
<b>Scope of authorization:</b>	Food
<b>Links to the information on the same product in other databases maintained by relevant international</b>	OECD BioTrack Product Database



Plantbiotech@fda.hhs.gov