



**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 174**

**[EPA-HQ-OPP-2014-0457; FRL-9939-49]**

**VNT1 Protein in Potato; Amendment to a Temporary Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the VNT1 protein in or on potatoes when used as a plant-incorporated protectant in accordance with the terms of Experimental Use Permit (EUP) (8917-EUP-2). J.R. Simplot Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment of the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of VNT1 protein in potato. The temporary tolerance exemption expires on April 1, 2017, concurrent with the EUP (8917-EUP-2).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0457, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency

Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www2.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [BPPDFRNotices@epa.gov](mailto:BPPDFRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCa section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0457 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0457, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www2.epa.gov/dockets>.

## II. Background and Statutory Findings

In the **Federal Register** of October 24, 2014 (79 FR 63594) (FRL-9916-03), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition ((PP) 4F8251) by J.R. Simplot Company, 5369 W. Irving St., Boise, ID 83706. Also, in the **Federal Register** of December 17, 2014 (79 FR 75107) (FRL-9918-90), EPA inadvertently re-announced the filing of this same petition. The petition requested that 40 CFR part 174 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of Potato Late Blight Resistance protein VNT1 in or on potato. Those documents referenced a summary of the petition prepared by the petitioner J.R. Simplot Company, which is available in the docket EPA-HQ-OPP-2014-0457, <http://www.regulations.gov>. Upon determining that such exemption meets the FFDCA safety standard, EPA established a temporary exemption from the requirement of a tolerance for residues of Potato Late Blight Resistance protein VNT1 in or on potato when used in accordance with the terms of EUP 8917-EUP-2, with an expiration date of December 31, 2015, in the **Federal Register** of February 23, 2015 (80 FR 9387) (FRL-9922-53).

In the **Federal Register** of September 9, 2015 (80 FR 54257) (FRL-9933-26) EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition ((PP) 5G8375) by J.R. Simplot Company, 5369 W. Irving St., Boise, ID 83706. The petition requested that 40 CFR 174.534 be amended. That document referenced a summary of the petition prepared by the petitioner J.R. Simplot Company, which is available in the docket

EPA-HQ-OPP-2014-0457, <http://www.regulations.gov>. No comments were received on this FR notice.

Because the pesticide petition ((PP) 5G8375) was submitted concurrently with a request to amend the EUP linked to this tolerance exemption, EPA only considered amendments to the tolerance exemption relevant to the pending request to extend the associated EUP. The request to amend the EUP involved increased acreage, locations and extending the expiration date of EUP No. 8917-EUP-2 to April 1, 2017. Because EPA is extending the EUP until April 1, 2017, EPA is revising the expiration date of the existing tolerance exemption to April 1, 2017.

Section 408(c)(2)(A)(i) of FFDCFA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCFA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCFA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCFA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....” Additionally, FFDCFA section 408(b)(2)(D) requires that the Agency consider “available information concerning the cumulative effects of a particular pesticide’s residues” and “other substances that have a common mechanism of toxicity.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

### **III. Determination of Safety for U.S. Population, Infants and Children**

The Agency previously assessed the toxicological profile of the VNT1 protein and the likely exposure from its use as a plant-incorporated protectant in or on potato in accordance with the terms of EUP No. 8917-EUP-2. Based on the Agency's assessment, the Agency concluded that there is a reasonable certainty that no harm will result from aggregate exposure to VNT1 protein when used as a plant-incorporated protectant in or on potato in accordance with the terms of EUP No. 8917-EUP-2. *See* (80 FR 9387) (February 23, 2015). Because the toxicological profile has not changed, any additional exposure to the VNT1 protein as a result of the extension of the associated EUP will not affect the Agency's previous safety finding. Therefore, the Agency is relying on its previous assessment to support the extension of the expiration date for 40 CFR 174.534. Therefore, based on its previous assessment, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of VNT1 protein in potato when it is used as a plant-incorporated protectant. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information.

### **IV. Analytical Enforcement Methodology**

The Agency has determined that an analytical method is not required for enforcement purposes since the Agency is establishing a temporary exemption from the

requirement of a tolerance without any numerical limitation in association with use under EUP No. 8917-EUP-2.

## **V. Conclusion**

The Agency is extending the expiration date of this temporary tolerance exemption to April 1, 2017. The temporary tolerance exemption will expire on the same date as the concurrent EUP for VNT1 protein (8917-EUP-2).

## **VI. Statutory and Executive Order Reviews**

This action amends an exemption from the requirement of a tolerance under FFDC section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are amended on the basis of a petition under FFDC section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDC section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

#### **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 174**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 17, 2015.

John E. Leahy, Jr.,  
*Acting Director, Biopesticides and Pollution Prevention Division,  
Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 174--[AMENDED]**

1. The authority citation for part 174 is revised to read as follows:

**Authority:** 7 U.S.C. 136-136y; 21 U.S.C. 321(q), 346a and 371.

2. Section 174.534 is revised to read as follows:

**§174.534 VNT1 protein in potato; temporary exemption from the requirement of a tolerance.**

Residues of VNT1 protein in potato are exempt from the requirement of a tolerance when the *Rpi-vnt1* gene that expresses the VNT1 protein is used as a plant- incorporated protectant in potato in accordance with the terms of Experimental Use Permit No. 8917-EUP-2. This temporary exemption from the requirement of a tolerance expires on April 1, 2017.

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