(ii) The amount payable at the 30th consecutive day of ADL loss is an additional $25,000.

(iii) The amount payable at the 60th consecutive day of ADL loss is an additional $25,000.

(iv) The amount payable at the 90th consecutive day of ADL loss is an additional $25,000.

(v) Duration of coma and inability to perform ADLs include date of onset of coma or inability to perform ADLs and the first date on which member is no longer in a coma or is able to perform ADLs.

(18) *Hospitalization due to traumatic brain injury:* (i) The amount payable at the 15th consecutive day of hospitalization is $25,000.

(ii) Payment for hospitalization may only replace the first ADL milestone in loss 17. Payment will be made for 15-day hospitalization, coma, or the first ADL milestone, whichever occurs earlier. Once payment has been made for the first payment milestone in loss 17 for coma or ADL, there are no additional payments for subsequent 15-day hospitalization due to the same traumatic injury. To receive an additional ADL payment amount under loss 17 after payment for hospitalization in the first payment milestone, the member must reach the next payment milestones of 30, 60, or 90 consecutive days.

(iii) Duration of hospitalization includes the dates on which member is transported from the injury site to a hospital as defined in 42 U.S.C. 1395x(e) or skilled nursing facility as defined in 42 U.S.C. 1395i–3(a), admitted to the hospital or facility, transferred between a hospital or facility, leaves the hospital or facility for a therapeutic trip, and discharged from the hospital or facility.

(iv) In cases where a member is hospitalized for 15 consecutive days for a diagnostic assessment for a mental illness and/or brain or neurologic disorder, and the assessment determines the member has a mental illness or brain or neurologic disorder, and not TBI, this loss is not payable because the loss was due to illness or disease and is excluded from payment. If a member is hospitalized for 15 consecutive days for a diagnostic assessment to determine whether the member has TBI and is diagnosed with TBI, TBI and PTSD, or PTSD and not TBI, the loss is payable for $25,000. If a member is hospitalized for 15 consecutive days for a diagnostic assessment to determine whether the member has PTSD and is diagnosed with TBI or TBI and PTSD, the loss is payable for $25,000.

(19) *Genitourinary losses:* (i) Amputation of the glans penis or any portion of the shaft of the penis above glans penis (*i.e.,* closer to the body) or damage to the glans penis or shaft of the penis that requires reconstructive surgery—the amount payable for this loss is $50,000.

(ii) Permanent damage to the glans penis or shaft of the penis that results in complete loss of the ability to perform sexual intercourse—the amount payable for this loss is $50,000.

(iii) Amputation of or damage to a testicle that requires testicular salvage, reconstructive surgery, or both—the amount payable for this loss is $25,000.

(iv) Amputation of or damage to both testicles that requires testicular salvage, reconstructive surgery, or both—the amount payable for this loss is $50,000.

(v) Permanent damage to both testicles requiring hormonal replacement therapy—the amount payable for this loss is $50,000.

(vi) Complete or partial amputation of the vulva, uterus, or vaginal canal or damage to the vulva, uterus, or vaginal canal that requires reconstructive surgery—the amount payable for this loss is $50,000.

(vii) Permanent damage to the vulva or vaginal canal that results in complete loss of the ability to perform sexual intercourse—the amount payable for this loss is $50,000.

(viii) Amputation of an ovary or damage to an ovary that requires ovarian salvage, reconstructive surgery, or both—the amount payable for this loss is $25,000.

(ix) Amputation of both ovaries or damage to both ovaries that requires ovarian salvage, reconstructive surgery, or both—the amount payable for this loss is $50,000.

(x) Permanent damage to both ovaries requiring hormonal replacement therapy—the amount payable for this loss is $50,000.

(xi) Permanent damage to the urethra, ureter(s), both kidneys, bladder, or urethral sphincter muscle(s) that requires urinary diversion and/or hemodialysis—the amount payable for this loss is $50,000.

(xii) Losses due to genitourinary injuries may be combined with each other, but the maximum benefit for genitourinary losses may not exceed $50,000.

(xiii) Any genitourinary loss may be combined with other injuries listed in § 9.21(b)(1)–(18) and treated as one loss, provided that at all losses are the result of a single traumatic event. However, the total payment may not exceed $100,000.

(20) *Traumatic injury, other than traumatic brain injury, resulting in inability to perform at least 2 activities of daily living (ADL):* (i) The amount payable at the 15th consecutive day of ADL loss is $25,000.

(ii) The amount payable at the 30th consecutive day of ADL loss is an additional $25,000.

(iii) The amount payable at the 60th consecutive day of ADL loss is an additional $25,000.

(iv) The amount payable at the 90th consecutive day of ADL loss is an additional $25,000.

(v) Duration of inability to perform ADL includes the date of the onset of inability to perform ADL and the first date on which member is able to perform ADL.

(21) *Hospitalization due to traumatic injury other than traumatic brain injury:* (i) The amount payable at 15th consecutive day of ADL loss is $25,000.

(ii) Payment for hospitalization may only replace the first ADL milestone in loss 20. Payment will be made for 15-day hospitalization or the first ADL milestone, whichever occurs earlier. Once payment has been made for the first payment milestone in loss 20, there are no additional payments for subsequent 15-day hospitalization due to the same traumatic injury. To receive an additional ADL payment amount under loss 20 after payment for hospitalization in the first payment milestone, the member must reach the next payment milestones of 60, 90, or 120 consecutive days.

(iii) Duration of hospitalization includes the dates on which member is transported from the injury site to a hospital as defined in 42 U.S.C. 1395x(e) or skilled nursing facility as defined in 42 U.S.C. 1395i–3(a), admitted to the hospital or facility, transferred between a hospital or facility, leaves the hospital or facility for a therapeutic trip, and discharged from the hospital or facility.

(Authority: 38 U.S.C. 501(a), 1980A)

[FR Doc. 2023–05069 Filed 3–14–23; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2020–0237; 10775–01–OCSPP]

Modified Potato Acetolactate Synthase (StmALS) in Potato; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of modified potato acetolactate synthase (StmALS) in potato when used in accordance with label directions and good agricultural practices. J.R. Simplot Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of StmALS under FFDCA when used in accordance with this exemption.

DATES: This regulation is effective March 15, 2023. Objections and requests for hearings must be received on or before May 15, 2023 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–2020–0237, is available at *https://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 and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Biopesticides and Pollution Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1400; email address: *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 174 through the Government Publishing Office's e-CFR site at *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-174?toc=1.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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–2020–0237 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 May 15, 2023. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b), although EPA strongly encourages those interested in submitting objections or a hearing request to submit objections and hearing requests electronically. *See* Order Urging Electronic Service and Filing (April 10, 2020), *https://www.epa.gov/sites/default/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf.* At this time, because of the COVID–19 pandemic, the judges and staff of the Office of Administrative Law Judges are working remotely and not able to accept filings or correspondence by courier, personal delivery, or commercial delivery, and the ability to receive filings or correspondence by U.S. Mail is similarly limited. When submitting documents to the U.S. EPA Office of Administrative Law Judges (OALJ), a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf.*

Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions during this time that the Agency continues to maximize telework due to the pandemic; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. If it is impossible for a person to submit documents electronically or receive service electronically, *e.g.,* the person does not have any access to a computer, the person shall so advise OALJ by contacting the Hearing Clerk at (202) 564–6281. If a person is without access to a computer and must file documents by U.S. Mail, the person shall notify the Hearing Clerk every time it files a document in such a manner. The address for mailing documents is U.S. Environmental Protection Agency, Office of Administrative Law Judges, Mail Code 1900R, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

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–2020–0237, by one of the following methods:

- *Federal eRulemaking Portal: https://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 *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Background

In the **Federal Register** of June 24, 2020 (85 FR 37806) (FRL–10010–82) EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP IN–11411) by J.R. Simplot Company, 5369 W Irving Street, Boise, ID 83706. The petition requested that 40 CFR part 174 be amended by establishing an exemption from the requirement of a

tolerance for residues of StmALS in potato. That notice referenced a summary of the petition prepared by the petitioner J.R. Simplot Company, which is available in the docket via *https://www.regulations.gov.* EPA received no comments in response to the notice of filing.

III. Final Rule

A. EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of 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 FFDCA 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 FFDCA 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 FFDCA 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 or tolerance exemption 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, FFDCA section 408(b)(2)(D) requires that EPA consider ''available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity.''

EPA evaluated the available toxicological and exposure data on StmALS and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A full summary of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled ''Review of the Application for an Experimental Use Permit for Gen 3 Potatoes expressing transgenic R-proteins BLB2, AMR3 and VNT1, PVY Coat Protein Hairpin RNA and inert ingredient StmALS and associated FFDCA Petitions for the Temporary Exemption from a Tolerance for AMR3 and BLB2, as well as FFDCA Petition for the Exemption from a Tolerance for StmALS'' (Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action, EPA–HQ–OPP–2020–0237, as described under **ADDRESSES**.

Available data have demonstrated that, with regard to humans, StmALS is not anticipated to be toxic or allergenic via any reasonably foreseeable route of exposure. StmALS (modified potato acetolactate synthase), is a plant-incorporated protectant (PIP) inert ingredient produced within the plant to be a selective marker for PIP transformation events. StmALS is a protein derived from the native acetolactate synthase (ALS) protein found in potato (*Solanum tuberosum*) and has been modified from the naturally occurring form by two amino acid substitutions. StmALS does not have any pesticidal activity of its own; rather, the modified protein confers tolerance to sulfonylureas and imidazolinone herbicides by interfering with their binding to native ALS protein within the plant. Thus, the herbicide tolerance serves as a positive selectable marker allowing for the identification of transformed PIP plants.

There is likely to be dietary exposure to StmALS through consumption of potato-derived foods containing this protein. However, the Agency has concluded that any potential dietary risk from the use of StmALS protein to human health is considered negligible for the following reasons. (1) As described above, the mode-of-action of StmALS protein is tolerance to sulfonylureas and imidazolinone herbicides; the protein is otherwise not pesticidal or toxic. (2) Bioinformatics analyses showed that there is no significant homology between StmALS and known toxins or allergens. (3) Data were submitted to demonstrate that the StmALS protein is denatured and becomes insoluble after heat treatment. Since potatoes are cooked by frying, boiling, or baking at high temperatures, and not consumed raw, StmALS is expected to become denatured during potato processing. (4) Additionally submitted data support the lack of allergenic potential for StmALS. The protein is not glycosylated and is rapidly and completely digested by stomach and pancreatic proteases, indicating that StmALS is not sufficiently stable or persistent enough to interact with the immune system and induce allergy. (5) ALS protein, from which StmALS is derived, has a history of safe use through the consumption of potatoes. The StmALS protein is 99.7% similar to the native ALS found in potato, differing by only two amino acids. These modifications do not affect the mode of action of StmALS and do not result in the production of a toxic protein. Since potatoes are a staple of the human diet, people have long been exposed to ALS without documented adverse effects.

Oral exposure from ingestion of drinking water is unlikely because StmALS is present at low levels and is confined within the plant cells. If StmALS does enter the water column, it is expected to degrade rapidly in the presence of soil microbes, or upon normal communal water-treatment procedures. In addition, there is unlikely to be residential or non-occupational exposure given that the inert ingredient is confined within the potato plant. Therefore, the only possible route of non-occupational exposure, other than dietary, is via handling of the plants and plant products. However, there are no risks associated with these exposure routes because, based on bioinformatics analysis and the history of safe use of the highly similar ALS protein, the StmALS protein is not toxic or allergenic.

Although FFDCA section 408(b)(2)(C) provides for an additional tenfold margin of safety for infants and children in the case of threshold effects, EPA has determined that there are no such effects due to the lack of toxicity and allergenicity for StmALS. As a result, an additional margin of safety for the protection of infants and children is unnecessary.

Based upon its evaluation described above and in the Human Health Risk 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 residues of StmALS protein in potatoes. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the mode-of-action, history of safe use of the highly similar ALS protein, and lack of toxicity and allergenicity for StmALS protein.

B. Analytical Enforcement Methodology

EPA 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. Nonetheless, the petitioner has submitted an immunoblot assay for detection of StmALS with an antibody that is specific to the protein but does not show cross reactivity with native

potato ALS protein. The assay adequately detects StmALS in potato leaf and tuber tissues.

C. Conclusion

Based upon its evaluation in the Human Health Risk 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 residues of StmALS protein in potatoes. Therefore, an exemption from the requirement of a tolerance is established for residues of StmALS protein in potato when used in accordance with label directions and good agricultural practices.

IV. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. 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, 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 established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA 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, EPA 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 (2 U.S.C. 1501 *et seq.*).

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

V. 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: March 7, 2023.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 174—PROCEDURES AND REQUIREMENTS FOR PLANT-INCORPORATED PROTECTANTS

■ 1. The authority citation for part 174 continues to read as follows:

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

■ 2. Add § 174.544 to subpart W to read as follows:

§ 174.544 Modified Potato Acetolactate Synthase (StmALS) in potato; exemption from the requirement of a tolerance.

Residues of modified potato acetolactate synthase (StmALS) in potato are exempt from the requirement of a tolerance when used as a plant-incorporated protectant inert ingredient.

[FR Doc. 2023–04979 Filed 3–14–23; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, 423, 424, 425, and 455

[CMS–1770–F2]

RIN–0938–AU81

Medicare and Medicaid Programs, CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID–19 Interim Final Rules; Corrections

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction and correcting amendment.

SUMMARY: In the November 18, 2022 issue of the **Federal Register**, we published a final rule entitled ''Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID–19 Interim Final Rules'' (referred to hereafter as the ''CY 2023 PFS final rule''). The effective date was January 1, 2023. This document corrects a limited number of technical and typographical errors identified in the November 18, 2022 final rule.

DATES: This document is effective March 15, 2023, and is applicable beginning January 1, 2023.

FOR FURTHER INFORMATION CONTACT: Terri Plumb, (410) 786–4481, Gaysha