TABLE 2—ATTAINMENT, MAINTENANCE, AND OTHER PLANS

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanations
* *	*	*	* *	*
Smoke Management Planning				
Department of Natural Resources 2022 Smoke Management Plan.	Statewide	8/10/22	8/10/2023, [INSERT **Federal Register** CITATION]..	
* *	*	*	* *	*

[FR Doc. 2023–16409 Filed 8–9–23; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0158; FRL–11022–01–OCSPP]

(2S)-5-Oxopyrrolidine-2-carboxylic Acid (L–PCA); 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 (2S)-5-Oxopyrrolidine-2-carboxylic Acid (L–PCA) in or on all food commodities when used as a plant growth regulator in accordance with label directions and good agricultural practices. Exponent, on behalf of Verdesian Life Sciences U.S., LLC, submitted a petition, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA), asking the EPA to amend its regulations to establish an exemption from the requirement of a tolerance for residues of the pesticide, when used as a plant growth regulator on agricultural crops, turf and ornamental plants. Instead, EPA is establishing an exemption from the requirement of a tolerance for residues L–PCA in or on all food commodities when applied in buffered end-use products and used in accordance with label directions and good agricultural practices. This regulation eliminates the need to establish a maximum permissible level for residues of L–PCA when used in accordance with this exemption.

DATES: This regulation is effective August 10, 2023. Objections and requests for hearings must be received on or before October 10, 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–2018–0158, 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: Madison Le, Biopesticides and Pollution Prevention Division (7511P), 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, greenhouse owner, 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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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–2018–0158 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 October 10, 2023. 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–2018–0158, 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 and Statutory Findings

In the **Federal Register** of May 18, 2018 (83 FR 23247) (FRL–9976–87), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 8F8663) by Exponent, on behalf of Verdesian Life Sciences U.S., LLC, 1001 Winstead Dr., Suite 480, Cary, NC 27513. The petition requested that 40 CFR part 180 be amended to establish an exemption from the requirement of a tolerance for residues of L–PCA, when used as a plant growth regulator on agricultural crops, turf, and ornamental plants, in accordance with label directions and good agricultural practices. That document referenced a summary of the petition prepared by the petitioner, Verdesian Life Sciences U.S., LLC, which is available in docket EPA–HQ–OPP–2018–0158 at *https://www.regulations.gov.* No substantive comments were received in response to this Notice of Filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA 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 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 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 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 establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. If EPA is able to determine that a tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for L–PCA including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with L–PCA follows.

A. Toxicological Profile

L–PCA is derived from L-glutamic acid via an intramolecular condensation reaction. L–PCA is naturally found in mammalian tissues. L–PCA has a non-toxic mode of action and can effectively enhance upregulation of the glutamine synthesis pathway. When applied to plants, it has demonstrated effects, such as increased growth, increased nodulation, and greater fresh weight. It also has seed priming properties. L–PCA has a long history of use in consumer products, including dietary supplements and cosmetic products.

L–PCA can be applied in various forms (free acids or salts), but it releases a common moiety that is the pesticidally-active component and serves as the basis for risk assessment and tolerance regulation. Since L–PCA is a strong acid, buffered solutions will contain some salt form, but not enough at any moment in time to be toxicologically relevant.

In the field, the above rationale continues to apply when active ingredient is in solution. If the products dry out on plants and then someone touches them, there would likely be some exposure from the salt form, however, it will not change the toxicology since it would not stay in the salt form once it was solubilized upon ingestion/contact with water.

With regard to the overall toxicological profile, L–PCA is of low toxicity. Acute toxicity data indicate that L–PCA is of low acute oral, dermal, and inhalation toxicity. However, with its low pH (2), it is likely corrosive. The available data suggest it is not a skin sensitizer.

Studies from the open scientific literature on the sodium salt analog, Na–PCA, were submitted to satisfy the 90-day oral for L–PCA. The Na–PCA toxicity database is considered appropriate for use in L–PCA risk assessment when EP formulations are buffered. There is an expectation that EP formulations for use as plant growth regulators will be buffered because unbuffered solutions will not be effective as a plant growth regulator, *i.e.,* unbuffered solutions would likely destroy the plant due to the acidity of L–PCA. This is because buffered L–PCA behaves similarly to Na–PCA. There is comparable acute toxicity between the proposed EP formulations and Na–PCA. Further, both L–PCA and Na–PCA are naturally occurring and are products of human metabolism. Using a weight of the evidence (WOE) approach, these studies allowed EPA to establish a no-observed-adverse-effect-level (NOAEL) of 849 mg/kg/day for subchronic oral toxicity for L–PCA in buffered end-use products.

For developmental toxicity, a non-guideline 1-generation reproduction toxicity screening study was submitted on Na–PCA in lieu of a developmental toxicity study. The study showed no treatment-related effects on offspring body weights, body weight gains or on post-implantation losses, mean litter size, numbers of live and dead pups born, sex ratio, or the birth or survival indices. No gross or microscopic pathology of the reproductive tract was seen, and reproductive performance was not affected by treatment. While this study is not a guideline developmental toxicity study, EPA has determined that the screening study is acceptable to satisfy the prenatal developmental toxicity data at this time for the specified products. This decision is based on the fact that no observable toxicity was produced at the limit dose

level in this study and an effect would not be expected from structurally related compounds.

EPA determined that 90-day inhalation toxicity and 90-day dermal studies were not required to assess the risks from L–PCA for the following reasons: (1) physical and chemical properties of the buffered formulations of L–PCA are similar to those of Na–PCA; (2) estimated margins of error (MOEs) are more than 10X the level of concern (LOC); and (3) no irritation was observed in studies conducted using the buffered end-use products.

The available data indicates that the active ingredient is non-mutagenic.

B. Toxicological Points of Departure/ Levels of Concern

Based on the toxicological profile, EPA did not identify any toxicological endpoints of concern for *L–PCA.*

C. Exposure Assessment

1. *Dietary exposure from food, feed uses, and drinking water.* No toxicological endpoint of concern was identified for L–PCA, and therefore, a quantitative assessment of dietary exposure is not necessary. As part of its qualitative risk assessment for L–PCA, the Agency considered the potential for dietary exposure to residues of the chemical. EPA concludes that dietary (food and drinking water) exposures are possible. However, due to the lack of a toxicological endpoint, dietary risk is not of concern.

2. *Non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). There are currently no proposed residential uses for this active ingredient, therefore a residential exposure assessment is not necessary.

3. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, 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 has not found that L–PCA shares a common mechanism of toxicity with any other substances, and it does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed L–PCA does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

FFDCA Section 408(b)(2)(C) provides that EPA shall retain an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor. An FQPA safety factor is not required at this time for L–PCA because there are no threshold effects; no dietary endpoints have been selected based on the lack of human-relevant adverse effects at limit doses in the 90-day oral toxicity study and prenatal developmental toxicity study.

E. Aggregate Risk

Based on the available data and information, EPA has concluded that a qualitative aggregate risk assessment is appropriate to support the pesticidal use of L–PCA in buffered end-use products, and that risks of concern are not anticipated from aggregate exposure to the substance in this manner. This conclusion is based on the low toxicity of the active ingredient and its salts, which release a common moiety that is the basis for the risk assessment. Due to the lack of toxicity, EPA concludes that there is no aggregate risk from exposure to L–PCA.

A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the September 20, 2022, document entitled ''Product Chemistry Review and Human Health Risk Assessment for FIFRA Section 3 Registrations of (2S)-5-Oxopyrrolidine-2-carboxylic Acid (L–PCA) Technical, containing 99.1% L–PCA, VLS 2002–03, Containing 25.0% L–PCA and VLS 2002–03–0.10, Containing 10.0% L–PCA.'' This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

IV. Determination of Safety for U.S. Population, Infants and Children

Based on the Agency's assessment, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of L–PCA.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VI. Conclusions

Therefore, EPA is establishing an exemption for residues of L–PCA in or on all food commodities when used as a plant growth regulator in accordance with label directions and good agricultural practices.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA 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 established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the

Regulatory Flexibility Act (RFA) (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, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA 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).

VIII. 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 180

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

Dated: August 4, 2023.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR part 180 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.1404 to subpart D to read as follows:

§ 180.1404 (2S)-5-Oxopyrrolidine-2-carboxylic Acid (L–PCA); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the pesticide, (2S)-5-Oxopyrrolidine-2-carboxylic Acid (L–PCA) in or on all food commodities when used as a plant growth regulator in accordance with label directions and good agricultural practices.

[FR Doc. 2023–17135 Filed 8–9–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

Select Agent Determination Concerning Coxiella burnetii Phase II, Nine Mile Strain, Plaque Purified Clone 4 With Reversion to Wildtype cbu0533

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Determination.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), has determined that an excluded attenuated strain, *Coxiella burnetii* Phase II, Nine Mile Strain, plaque purified clone 4, has, in one instance, been shown to spontaneously mutate when passaged *in vivo.* The resulting mutant, *C. burnetii* Phase II, Nine Mile Strain, plaque purified clone 4 with reversion to wildtype *cbu0533,* has enhanced pathogenicity and virulence. Therefore, *C. burnetii* Phase II, Nine Mile Strain, plaque purified clone 4 with reversion to wildtype *cbu0533* is not an excluded strain but is a select agent and subject to the HHS select agent and toxin regulations.

DATES: This determination is effective August 10, 2023.

FOR FURTHER INFORMATION CONTACT: Samuel S. Edwin Ph.D., Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–4, Atlanta, Georgia 30329, Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION: *Coxiella burnetti* is a select agent that is regulated pursuant to the HHS select agent and toxin regulations (42 CFR part 73). *C. burnetii* is a gram-negative intracellular bacterium that causes Q Fever. Q Fever is a zoonotic disease that causes flu-like symptoms in humans, including fever, chills, fatigue, and muscle pain. Humans become infected when they are in close contact with infected animal fluids and products.

The HHS select agent regulations (42 CFR part 73) established a process by which an attenuated strain of a select biological agent that does not have the potential to pose a severe threat to public health and safety may be excluded from the requirements of the regulations. On October 15, 2003, *C. burnetii* Phase II, Nine Mile Strain, plaque purified clone 4 was excluded from HHS select agent regulations as it does not pose a significant threat to public health and safety (*https://selectagents.gov/sat/exclusions/hhs.htm*).

As set forth under 42 CFR 73.4(e)(2), if an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting select agent will be subject to the requirements of the regulations. On March 20, 2023, an entity informed CDC of a reversion whereby *C. burnetii* Phase II, Nine Mile Strain, plaque purified clone 4 spontaneously mutated. The *C. burnetii* Phase II, Nine Mile Strain, plaque purified clone 4 with reversion to wildtype *cbu0533* displayed increased pathogenicity and virulence. The entity stated that after the excluded strain was injected into guinea pigs, a spontaneous reversion occurred that resulted in a mutant strain of the agent and the guinea pigs subsequently exhibited elevated fever and weight loss. The genetic mutation that led to the mutant strain was the reversion and restoration of a deletion in the *cbu0533 gene.* CDC subject matter experts have determined that this reversion in *cbu0533* restored virulence and pathogenicity. Therefore, *C. burnetii* Phase II, Nine Mile Strain, plaque purified clone 4 with reversion to wildtype *cbu0533* is determined to be a select agent and subject to 42 CFR part 73.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–16929 Filed 8–9–23; 8:45 am]

BILLING CODE 4163–18–P