notifying the Judges that they have agreed not to seek a quinquennial adjustment in the existing Section 111 royalty rates or gross receipts limitations pursuant to 17 U.S.C. 804(b)(1)(A)–(B) for the 2020–2024 period.[5] They requested that the Judges terminate this proceeding without making any changes in the applicable royalty rates and gross receipts limitations.

Section 801(b)(7)(A) allows for the adoption of rates and terms negotiated by ''some or all of the participants in a proceeding at any time during the proceeding'' provided the parties submit the negotiated rates and terms to the Judges for approval. That provision directs the Judges to provide those who would be bound by the negotiated rates and terms an opportunity to comment on the agreement. Unless a participant in a proceeding objects and the Judges conclude that the agreement does not provide a reasonable basis for setting statutory rates or terms, or the Judges find the negotiated rates and terms are contrary to law, the Judges adopt the negotiated rates and terms. 17 U.S.C. 801(b)(7)(A).

On February 4, 2021, the Judges published the proposed settlement in the **Federal Register** and requested comments from interested parties pursuant to 17 U.S.C. 801(b)(7)(A). 86 FR 8222 (Feb. 4, 2021). The Judges received no comments. Therefore, the Judges adopt the existing rates and terms in 37 CFR 387.2 (c) and (d) for the 2020–2024 rate period and close the proceeding. The Judges hereby give notice that the adopted rates and terms and gross receipts limitations will continue to be binding on all cable systems that retransmit over-the-air television and radio broadcast stations to their subscribers and on all copyright owners of the broadcast programming that the cable systems retransmit during the license period 2020–2024.

Dated: December 9, 2021.

Suzanne M. Barnett,

Chief Copyright Royalty Judge.

Approved:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2021–27913 Filed 12–22–21; 8:45 am]

BILLING CODE 1410–72–P

[5] As with other filings in this docket, the Joint Notice of Settlement of Participating Parties addressed the 2020–2025 period. As indicated *supra,* this final action corrects the prior misstated dates and addresses a narrower period beginning January 1, 2020, and ending December 31, 2024.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0542; FRL–9199–01–OCSPP]

Bicyclopyrone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bicyclopyrone in or on the fresh and dried forms of lemongrass, rosemary, and wormwood. Syngenta Crop Protection, LLC., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 23, 2021. Objections and requests for hearings must be received on or before February 22, 2022 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–2019–0542, 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 is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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 EPA's tolerance regulations at 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, 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–2019–0542 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 February 22, 2022. 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–2019–0542, 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/contacts.html.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 22, 2021 (86 FR 21317) (FRL–10022–59), and of June 1, 2021 (86 FR 29229) (FRL–10023–95), 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 9F8777) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide bicyclopyrone, 4-hydroxy-3-}2-[(2-methoxyethoxy)methyl{-6-(trifluoromethyl) 3pyridylcarbonyl{bicyclo[3.2.1]oct-3-en-2-one, in or on rosemary, fresh at 0.03 parts per million (ppm); rosemary, dried at 0.3 ppm; lemongrass, fresh at 0.3 ppm; lemongrass, dried at 0.5 ppm; wormwood, fresh at 0.05 ppm and wormwood, dried at 0.09 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC., the registrant, which is available in the docket, *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(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. Section 408(b)(2)(C) of FFDCA requires 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. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), 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 bicyclopyrone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with bicyclopyrone follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The bicyclopyrone database is considered complete for risk assessment purposes.

Bicyclopyrone is a 4-hydroxyphenylpyruvate dioxygenase (HPPD)-inhibiting chemical. HPPD is an enzyme involved in the catabolism of tyrosine, an essential amino acid for mammals. Recently OPP evaluated (*HPPD Inhibiting Herbicides: State of the Science.* 9/18/2020. Authors: K. Yozzo and M. Perron) a proposed mode-of-action (MOA)/adverse-outcome pathway (AOP) for HPPD inhibitors in mammals and determined there was sufficient evidence to establish the MOA/AOP. The initiating event in the MOA/AOP for HPPD-inhibiting chemicals, including bicyclopyrone, involves binding of the chemical to the HPPD enzyme causing complete or virtually complete enzyme inhibition, which leads to a build-up of systemic tyrosine levels (tyrosinemia) and a spectrum of tyrosine-mediated effects. In laboratory animals, these have been identified as ocular and skeletal developmental effects.

Bicyclopyrone is classified as ''Suggestive Evidence of Carcinogenic Potential'' based on the presence of rare ocular tumors in male rats. The EPA has determined that using a non-linear approach (*i.e.,* chronic reference dose (cRfD)) will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to bicyclopyrone.

A complete discussion of the toxicological profile for bicyclopyrone as well as specific information on the studies received and the nature of the adverse effects caused by bicyclopyrone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found in the document titled ''Bicyclopyrone: Human Health Risk Assessment for the Establishment of Permanent Tolerances for Residues in/on Lemongrass, Rosemary, and Wormwood'' (hereinafter ''Bicyclopyrone Human Health Risk Assessment'') in docket ID number EPA–HQ–OPP–2019–0542 in *regulations.gov.*

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

The ability of a species to clear excess tyrosine can impact its sensitivity to HPPD-inhibiting chemicals and its relevance for human health risk assessment. Therefore, during the evaluation of the MOA/AOP for HPPD inhibitors in mammals, endpoints for human health risk assessment of HPPD inhibitors, including bicyclopyrone, were selected from studies available in mice and dogs. The developmental and reproduction toxicity studies in mice

are not available for bicyclopyrone; however, mouse developmental and reproduction toxicity studies for other HPPD inhibitors are available for bridging across the chemical class. The reproduction toxicity study for mesotrione (a HPPD inhibitor) provides the lowest point of departure (no-observed adverse-effect level (NOAEL) = 71 mg/kg/day) for these studies and was considered in conjunction with the bicyclopyrone database for endpoint selection.

A summary of the toxicological endpoints for bicyclopyrone used for human risk assessment can be found in the Bicyclopyrone Human Health Risk Assessment in the docket.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to bicyclopyrone, EPA considered exposure under the petitioned-for tolerances as well as all existing bicyclopyrone tolerances in 40 CFR 180.682. EPA assessed dietary exposures from bicyclopyrone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for bicyclopyrone; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the 2003–2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA conducted a partially refined analysis that assumed average field trial residues for registered crops, tolerance levels for the proposed crops, average empirical processing factors for registered crops, anticipated residues for livestock commodities, and percent crop treated (PCT) for registered crop commodities.

iii. *Cancer.* Based on the data discussed in Unit III.A., EPA has determined that a separate cancer exposure assessment does not need to be conducted and that using a non-linear approach (*i.e.,* reference dose (RfD)) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to bicyclopyrone.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The chronic dietary assessment incorporated the following average PCT estimates: Barley, 1%; field corn, 10%; sweet corn, 5%; pop corn, 10% (used the higher of the corn PCTs); and wheat, 5% (used spring wheat PCT which was higher than winter wheat PCT). The PCT for livestock commodities is based on the PCT value for the livestock feed item used in the dietary burden with the highest percent crop treated (field corn, 10%).

In most cases, EPA uses available data from the United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which bicyclopyrone may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for bicyclopyrone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of bicyclopyrone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *https://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

The Surface Water Concentration Calculator (SWCC) computer model was used to generate surface water Estimated

Drinking Water Concentrations (EDWCs), while the Pesticide Root Zone Model for Groundwater (PRZM–GW) and the Screening Concentration in Ground Water (SCI–GROW) models were used to generate groundwater EDWCs. The maximum acute and chronic surface water EDWCs associated with bicyclopyrone use were 3.43 and 1.02 parts per billion (ppb), respectively. For groundwater sources of drinking water, the maximum acute and chronic and cancer EDWCs of bicyclopyrone in shallow groundwater from PRZM–GW were 4.82 and 4.2 ppb, respectively.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Bicyclopyrone is not registered for any use patterns that would result in residential exposure.

4. *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.''

The Agency is required to consider the cumulative risks of chemicals sharing a common mechanism of toxicity per OPP's *Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity,* which can be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-identifying-pesticide-chemicals-and-other.* As a result, the Agency has determined that the (p-hydroxyphenyl-pyruvate dioxygenase) HPPD inhibitors, including bicyclopyrone, share a common mechanism of toxicity as discussed in the *HPPD Inhibiting Herbicides: State of the Science* paper (*HPPD Inhibiting Herbicides: State of the Science.* 9/18/2020. Authors: K. Yozzo and M. Perron). As explained in that document, the members of this group share the ability to bind to and inhibit the HPPD enzyme resulting in elevated systemic tyrosine levels and common apical outcomes that are mediated by tyrosine, including ocular and developmental effects. In 2021, after establishing a common mechanism grouping for the HPPD inhibitors, the Agency conducted a cumulative risk assessment (CRA) (J. Godshall; 30-June-2021; D462487) and concluded that cumulative exposures to HPPD inhibitors (based on proposed and registered pesticidal uses at the time the assessment was conducted) did not present risks of concern.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply 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.

2. *Prenatal and postnatal sensitivity.* Although there is potential evidence of neurotoxicity and increased quantitative susceptibility, concern is low because neurotoxicity was only observed in the rat, which is not considered a relevant model for evaluating HPPD inhibitors, and selected endpoints are protective of the potential sensitivity/susceptibility for animal models appropriate for evaluating HPPD inhibitors.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for all exposure scenarios, except for the chronic dietary endpoint where the FQPA SF is being retained as a database UF because of the use of a LOAEL as the point of departure (UF_L). That decision is based on the following findings:

i. The toxicity database for bicyclopyrone is complete.

ii. There is no evidence of neurotoxicity in the bicyclopyrone database, including in the rat acute or subchronic neurotoxicity studies; however, histopathological findings were observed in the chronic dog study (swelling of the dorsal root ganglion and nerve fiber degeneration). Concern is low since the chronic dietary endpoint is based upon these effects, and these are the most sensitive effects in the bicyclopyrone hazard database in one of them most appropriate species for risk assessment.

iii. There was evidence of increased susceptibility in rat and rabbit developmental studies for bicyclopyrone. Since developmental and reproduction toxicity studies in mice are not available for bicyclopyrone, mouse developmental and reproduction toxicity studies for other HPPD inhibitors are available for bridging. In some instances, increased quantitative susceptibility was also observed in these mouse studies, including the 2-generation reproduction toxicity study for mesotrione. Although there was evidence of increased susceptibility, concern is low because: (1) Rat and rabbits were not considered appropriate animal models for assessing human health risk for HPPD inhibitors, (2) there are clear NOAEL/LOAEL values for the observed developmental and offspring effects, (3) developmental/offspring effects in mice for other HPPD inhibitors were seen at doses ≥600 mg/kg/day, except the mesotrione 2-generation reproduction toxicity study, (4) the offspring LOAEL of 300 mg/kg/day in the mesotrione reproduction toxicity study was set conservatively based on a low incidence of opaque/cloudy eyes, and (5) selected endpoints are protective of any potential sensitivity observed in mice.

iv. There are no residual uncertainties identified in the exposure databases. The dietary assessment does not underestimate exposure. In addition, there are no currently proposed residential uses.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, bicyclopyrone is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to bicyclopyrone from food and water will utilize 9.5% of the cPAD for all infants, the population group receiving the greatest exposure.

3. *Short-term risk.* A short-term adverse effect was identified; however, bicyclopyrone is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for bicyclopyrone.

4. *Intermediate-term risk.* An intermediate-term adverse effect was identified; however, bicyclopyrone is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for bicyclopyrone.

5. *Aggregate cancer risk for U.S. population.* Because the Agency has determined that the chronic RfD will be protective of any potential cancer risk and there are no chronic risks that exceeds the Agency's level of concern, EPA concludes that there is not a concern for cancer risk from exposure to bicyclopyrone.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to bicyclopyrone residues.

More detailed information about the Agency's analysis can be found in the Bicyclopyrone Human Health Risk Assessment in docket ID number EPA–HQ–OPP–2019–0542 in *regulations.gov* at *https://www.regulations.gov.*

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology liquid chromatography-mass spectroscopy/mass spectroscopy (LCMS/MS) methods for tolerance enforcement have been developed and independently validated. For all matrices and analytes, the level of quantification (LOQ), defined as the lowest spiking level where acceptable precision and accuracy data were obtained, was determined to be 0.01 ppm for each of the common moieties, SYN503780 and CSCD686480, for a combined LOQ of 0.02 ppm is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

The Codex has not established a MRL for residues of bicyclopyrone in/on lemongrass, rosemary, or wormwood.

V. Conclusion

Therefore, tolerances are established for residues of bicyclopyrone, 4-hydroxy-3-{2-[(2-methoxyethoxy)methyl]-6-(trifluoromethyl)-3-pyridylcarbonyl}bicyclo[3.2.1]oct-3-en-2-one, including its metabolites and degradates in or on lemongrass, dried at 0.5 ppm; lemongrass, fresh at 0.3 ppm; rosemary, dried at 0.3 ppm; rosemary, fresh at 0.03 ppm; wormwood, dried at 0.09 ppm; and wormwood, fresh at 0.05 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances 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 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).

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 180

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

Dated: December 9, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I 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. In § 180.682, amend paragraph (a)(1) by:

■ a. In the introductory text, removing ''table below'' and ''specified below'' and adding ''following table'' and ''specified in this paragraph (a)(1)'' in their places, respectively; and

■ b. In the table, adding a table heading and entries in alphabetical order for ''Lemongrass, dried''; ''Lemongrass, fresh''; ''Rosemary, dried''; ''Rosemary, fresh''; ''Wormwood, dried''; and ''Wormwood, fresh''.

The additions read as follows:

§ 180.682 Bicyclopyrone; tolerances for residues.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	
Lemongrass, dried	0.5
Lemongrass, fresh	0.3
Rosemary, dried	0.3
Rosemary, fresh	0.03
* * * * *	
Wormwood, dried	0.09
Wormwood, fresh	0.05

* * * * *

[FR Doc. 2021–27602 Filed 12–22–21; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 385

[Docket No. FMCSA–2021–0063]

RIN 2126–AC40

Incorporation by Reference; North American Standard Out-of-Service Criteria; Hazardous Materials Safety Permits

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FMCSA amends its Hazardous Materials Safety Permits regulations to incorporate by reference the updated Commercial Vehicle Safety Alliance (CVSA) handbook containing inspection procedures and Out-of-Service Criteria (OOSC) for inspections of shipments of transuranic waste and highway route controlled quantities of radioactive material. The OOSC provide enforcement personnel nationwide, including FMCSA's State partners, with uniform enforcement tolerances for inspections. Through this rule, FMCSA incorporates by reference the April 1, 2021, edition of the handbook.

DATES: Effective February 22, 2022. The incorporation by reference of the material described in the rule is approved by the Director of the Federal Register as of February 22, 2022.

FOR FURTHER INFORMATION CONTACT: Mr. José Cestero, Vehicle and Roadside Operations Division, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–5541, *jose.cestero@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION: This final rule is organized as follows:

I. Availability of Rulemaking Documents

To view any documents mentioned as being available in the docket, go to *https://www.regulations.gov/docket/FMCSA-2021-0063/document* and choose the document to review. To view comments, click this final rule, then click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations at U.S. Department of Transportation, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Executive Summary

This final rule updates an incorporation by reference found at 49 CFR 385.4(b)(1) and referenced at § 385.415(b). The provision at § 385.4(b)(1) currently references the April 1, 2019, edition of CVSA's handbook titled ''North American Standard Out-of-Service Criteria and Level VI Inspection Procedures and Out-of-Service Criteria for Commercial Highway Vehicles Transporting Transuranics and Highway Route Controlled Quantities of Radioactive Materials as defined in 49 CFR part 173.403.'' The CVSA handbook contains inspection procedures and Out-of-Service Criteria (OOSC) for inspections of shipments of transuranic waste and highway route controlled quantities of radioactive material. The OOSC, while not regulations, provide enforcement personnel nationwide, including FMCSA's State partners, with uniform enforcement tolerances for inspections. The material is available, and will continue to be available, for inspection at the FMCSA, Office of Enforcement and Compliance, 1200 New Jersey Avenue SE, Washington, DC 20590 (Attention: Chief, Compliance Division) at (202) 366–1812. The document may be purchased from the Commercial Vehicle Safety Alliance, 6303 Ivy Lane, Suite 310, Greenbelt, MD 20770, telephone (301) 830–6143, *www.cvsa.org.*

Twenty-one updates distinguish the April 1, 2021, handbook edition from the 2019 edition. The updates are all