

incorporation by reference of the FRAQMD rules described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available electronically through [www.regulations.gov](http://www.regulations.gov) and in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

#### IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical,

appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 22, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of this **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: February 27, 2015.

**Jared Blumenfeld**,

*Regional Administrator, Region IX.*

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

#### PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

- 1. The authority citation for part 52 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

#### Subpart F—California

- 2. Section 52.220, is amended by adding paragraphs (c)(442)(i)(E) and (c)(457) to read as follows:

#### § 52.220 Identification of plan.

\* \* \* \* \*

(c) \* \* \*

(442) \* \* \*

(i) \* \* \*

(E) Feather River Air Quality Management District.

(1) Rule 3.14, "Surface Preparation and Clean-Up," amended on August 1, 2011.

(2) Rule 3.20, "Wood Products Coating Operations," amended on August 1, 2011.

(3) Rule 3.21, "Industrial, Institutional, and Commercial Boilers, Steam Generators, and Process Heaters," adopted on June 5, 2006.

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(457) New and amended regulations for the following APCDs were submitted on November 6, 2014 by the Governor's designee.

(i) Incorporation by reference.

(A) Feather River Air Quality Management District.

(1) Rule 10.9, "Rice Straw Emission Reduction Credits and Banking," amended on October 6, 2014.

(2) Rule 3.22, "Stationary Internal Combustion Engines," amended on October 6, 2014.

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2014-0355; FRL-9926-66]

#### Bicycloprrone; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of bicycloprrone

in or on field corn, forage; field corn, grain; field corn, stover; popcorn, grain; popcorn, stover; sweet corn, forage; sweet corn, ears; sweet corn, stover; sugarcane, stalks; cattle, liver; goat, meat byproducts; sheep, meat byproducts; horse, meat byproducts; and hog, meat byproducts. Syngenta requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective April 23, 2015. Objections and requests for hearings must be received on or before June 22, 2015, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0355, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Susan Lewis, 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: [RDFFRNotices@epa.gov](mailto:RDFFRNotices@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 Government Publishing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl)

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0355 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 June 22, 2015. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0355, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.
- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

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

### **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of September 5, 2014 (79 FR 53009) (FRL-9914-98), 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 3F8225) by Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide bicyclopyrone, herbicide, in or on field corn, forage at 0.4 parts per million (ppm); field corn, grain at 0.02 ppm; field corn, stover at 0.5 ppm; popcorn, grain at 0.02 ppm; popcorn, stover at 0.5 ppm; sweet corn, forage at 0.4 ppm; sweet corn, ears at 0.02 ppm; sweet corn, stover at 0.5 ppm; sugarcane, stalks at 0.01 ppm; and cattle, liver at 0.06 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC., the registrant, which is available in the docket, <http://www.regulations.gov>. In the **Federal Register** of February 11, 2015 (80 FR 7559) (FRL-9921-94), EPA published a corrected notice of filing for the import tolerance on sugarcane petition. Comments were received for both items. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerances to corn, field, forage at 0.30 ppm; corn, field, grain at 0.02 ppm; corn, field, stover at 0.40 ppm; corn, pop, grain at 0.02 ppm; corn, pop, stover at 0.40 ppm; corn, sweet, forage at 0.40 ppm; corn, sweet, kernel plus cob with husks removed at 0.03 ppm; corn, sweet, stover at 0.70 ppm; sugarcane, cane at 0.02 ppm; cattle, meat byproducts at 1.5 ppm; goat, meat byproducts at 1.5 ppm; sheep, meat byproducts at 1.5 ppm; horse, meat byproducts at 1.5 ppm; and hog, meat byproducts at 0.15 ppm. The reasons for these changes are explained in Unit IV.C.

### **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 effects of bicyclopyrone are indicative of inhibition of 4-hydroxyphenylpyruvate dioxygenase (HPPD). Plasma tyrosine levels were consistently elevated in rats, rabbits, and dogs (levels in mice were not tested). Consistent with these elevated tyrosine levels, ocular effects (corneal opacity, keratitis) were observed for subchronic and chronic durations through the oral and dermal routes in rats, which was the most sensitive species tested (minor instances in dogs). There were also increased incidences of thyroid follicular hyperplasia and a chronic progressive nephropathy. While minor instances of ocular effects were observed in dogs, different toxicological effects were generally observed. For subchronic oral exposure, clinical signs (moderate hypoactivity, slightly unsteady gait, increased heart rate, regurgitation, and vomiting) were observed, and clinical pathological indicators of toxicity occurred in the eye and the thymus. Following chronic exposure, there was a dose-dependent increase in chromatolysis and swelling of selected neurons in the dorsal root ganglia, and degeneration of nerve fibers in the spinal nerve roots in both sexes. In one female dog at the high dose,

corneal opacity and light sensitivity were observed.

Across the database, there were decreased absolute body weights (the only finding in mice for any duration) and food consumption. There were no signs of immunotoxicity or neurotoxicity in rodents.

Bicyclopyrone treatment resulted in developmental toxicity in both rats and rabbits, and there was an increased quantitative fetal susceptibility in both species tested. In rats, maternal toxicity was not observed up to 1000 mg/kg/day. Fetal effects occurred at all doses ( $\geq 100$  mg/kg/day), and manifested as skeletal variations (increased incidences of full or rudimentary supernumerary ribs, pelvic girdle malpositioned caudal, costal cartilage 11 long). In New Zealand White rabbits, maternal effects consisted of mortality/moribundity in conjunction with minimal food consumption at 200 mg/kg/day. Fetal effects once again occurred at all doses tested ( $\geq 10$  mg/kg/day). The sole fetal effect at the lowest dose tested was the appearance of the 27th presacral vertebrae. There were two studies in Himalayan rabbits. In both studies, maternal effects consisted of macroscopic findings in the stomach wall and an increased incidence of post-implantation loss at the 250 mg/kg/day dose level. In the first study, fetal effects occurred starting at 50 mg/kg/day and consisted of skeletal variations (increased incidence of the 27th prepelvic vertebra and malpositioned pelvic girdle). In the second study, the increased quantitative fetal susceptibility was not observed due to a change in the dose selection. Fetal effects occurred at 250 mg/kg/day and consisted of external, visceral, and skeletal abnormalities, and visceral variations, skeletal, bone and cartilage variations. In total, the effects in these studies are consistent with effects of other chemicals in this class.

In the two-generation reproductive study in rats, ocular toxicity occurred in parents and offspring and there was no increased offspring susceptibility of any kind. Reproductive effects included changes in sperm parameters, and a decrease of precoital interval.

To determine the mechanism for the thyroid hyperplasia observed in the chronic/carcinogenicity study in rats, two mode-of-action studies were performed. In the *in vitro* study, bicyclopyrone was negative for thyroid peroxidase inhibition. The results from the *in vivo* study suggested that the observed thyroid hyperplasia was the result of increased metabolism of thyroid hormones indicated by (1) decreased plasma T3 and T4 levels, (2)

increased thyroid follicular cell hypertrophy, (3) increased liver weights associated, and (4) increased hepatocellular centrilobular hypertrophy and increased hepatic uridine diphosphate glucuronyl transferase (UDPGT) activities.

Bicyclopyrone is categorized as having low acute lethality via all routes of administration (Categories III and IV). Bicyclopyrone produces minimal eye irritation and mild acute inhalation toxicity (Toxicity Category IV).

Specific information on the studies received and the nature of the adverse effects caused by bicyclopyrone as well as the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document titled “Bicyclopyrone: Human Health Risk Assessment for the Section 3 Registration Action on Corn and the Establishment of Permanent Tolerances for Residues in/on Corn and Imported Sugarcane” at pp. 30–37 in docket ID number EPA–HQ–OPP–2014–0355.

#### 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 no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). 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 <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for bicyclopyrone used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BICYCLOPYRONE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age).	LOAEL = 10 mg/kg/day. UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF/UF <sub>L</sub> = 10x	Acute RfD = 0.01 mg/kg/day. aPAD = 0.01 mg/kg/day	Prenatal Developmental Study (New Zealand White Rabbits). Developmental LOAEL = 10 mg/kg/day based on skeletal variations (the appearance of the 27th presacral vertebrae).
Acute dietary (General population including infants and children).	No endpoint attributable to a single dose and appropriate for the U.S. general population was seen in the bicyclopironone toxicological database; therefore, an acute dietary point of departure for the general U.S. population was not established.		
Chronic dietary (All populations)	LOAEL = 10 mg/kg/day. UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF/UF <sub>L</sub> = 10x	Chronic RfD = 0.00028 mg/kg/day. cPAD = 0.00028 mg/kg/day	Carcinogenicity Study (rat). LOAEL = 0.28/0.35 mg/kg/day (Male/Female) based on a dose dependent increase in the incidence of opaque eyes and corneal damage in both sexes compared to controls, an increased incidence of thyroid follicular hyperplasia in males, and an increased incidence of chronic progressive nephropathy in the kidneys of males.
Dermal Short- (1–30 days) and Intermediate-Term (1–6 months).	LOAEL = 10 mg/kg/day. DAF = 20.44% UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF/UF <sub>L</sub> = 10x	LOC for MOE = 1000.	Prenatal Developmental Study (New Zealand White Rabbits). Developmental LOAEL = 10 mg/kg/day based on skeletal variations (the appearance of the 27th presacral vertebrae).
Inhalation Short- (1–30 days) and Intermediate-Term (1–6 months).	LOAEL = 10 mg/kg/day. UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF/UF <sub>L</sub> = 10x	LOC for MOE = 1000.	Prenatal Developmental Study (New Zealand White Rabbits). Developmental LOAEL = 10 mg/kg/day based on skeletal variations (the appearance of the 27th presacral vertebrae).
Cancer (Oral, dermal, inhalation).	Classification: “Suggestive evidence of cancer” based on the presence of rare ocular tumors in male rats. Quantification of bicyclopironone’s carcinogenic potential is not required. A non-linear approach ( <i>i.e.</i> , RfD) will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to bicyclopironone.		

FQPA SF=Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>L</sub> = use of a LOAEL to extrapolate a NOAEL.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary

exposure to bicyclopironone, EPA considered exposure under the petitioned-for tolerances. EPA assessed

dietary exposures from bicyclopironone 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. Such effects were identified for bicyclopyrone. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). The acute dietary analysis was conducted for bicyclopyrone assuming tolerance level residues, default processing factors, and 100% crop treated (CT) information.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 CSFII. The chronic dietary exposure assessment was conducted for bicyclopyrone assuming average field trial residues for crops, tolerance-level residues for livestock commodities, default processing factors, and 100% CT information.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that bicyclopyrone should be classified as “suggestive evidence of cancer” based on the presence of rare ocular tumors in male rats. Quantification of bicyclopyrone’s carcinogenic potential is not required. A non-linear approach (*i.e.*, RfD) will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to bicyclopyrone. Using EPA’s non-linear approach, the 1000X combined uncertainty factor used to calculate the cRfD/cPAD for the chronic dietary assessment, generates a dose which is 100,000-fold lower than the dose at which the ocular tumors were observed and is thus protective of their potential formation.

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 <http://www.epa.gov/oppefed1/models/water/index.htm>.

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 on corn were 2.87 and 0.857 µg/L, respectively. For groundwater sources of drinking water, the maximum acute and chronic EDWCs of bicyclopyrone in shallow groundwater from PRZM–GW were 3.76 and 3.23 µg/L, respectively. EDWCs of 0.00376 ppm and 0.00323 ppm were used in the acute and chronic analyses, 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 specific 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.”

There are marked differences among species in the ocular toxicity associated with bicyclopyrone’s mechanism of toxicity, the inhibition of HPPD. Ocular effects following treatment with HPPD inhibitor herbicides are seen in the rat but not in the mouse. Monkeys also seem to be recalcitrant to the ocular toxicity induced by HPPD inhibition. One explanation for this species-specific response in ocular opacity may be related to species differences in the clearance of tyrosine. A metabolic pathway exists to remove tyrosine from the blood that involves the liver enzyme tyrosine aminotransferase (TAT). In contrast to rats where ocular toxicity is observed following exposure to HPPD-inhibiting herbicides, mice and humans are unlikely to achieve the levels of plasma tyrosine necessary to produce ocular opacities because the activity of TAT in these species is much greater compared to rats.

HPPD inhibitors (*e.g.*, nitisinone) are used as an effective therapeutic agent to treat patients suffering from rare genetic diseases of tyrosine catabolism. Treatment starts in childhood but is often sustained throughout patient’s lifetime. The human experience indicates that a therapeutic dose (1 mg/kg/day dose) of nitisinone has an excellent safety record in infants,

children, and adults and that serious adverse health outcomes have not been observed in a population followed for approximately a decade. Rarely, ocular effects are seen in patients with high plasma tyrosine levels; however, these effects are transient and can be readily reversed upon adherence to a restricted protein diet. This observation indicates that an HPPD inhibitor in and of itself cannot easily overwhelm the tyrosine-clearance mechanism in humans.

Therefore, exposures to environmental residues of HPPD-inhibiting herbicides are unlikely to result in the high blood levels of tyrosine and ocular toxicity in humans due to an efficient metabolic process to handle excess tyrosine. The EPA continues to study the complex relationships between elevated tyrosine levels and biological effects in various species. In the future, assessments of HPPD-inhibiting herbicides may consider more appropriate models and cross species extrapolation methods. EPA has not conducted cumulative risk assessment with other HPPD inhibitors.

#### 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 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. The FQPA SF is retained at 10X for all exposure scenarios based on use of a LOAEL for the points of departure. The toxicology database for bicyclopyrone is adequate for characterizing toxicity and quantification of risk for food and non-food uses; however, a LOAEL from the New Zealand white rabbit developmental and chronic/carcinogenicity rat toxicity studies has been used as the POD for several scenarios.

There is no evidence of neurotoxicity in either of the neurotoxicity screening batteries, but there are effects in the chronic dog study. The level of concern is low, however, since the study and POD chosen for the chronic dietary exposure scenario is protective of these

effects. There is evidence of increased quantitative fetal susceptibility following in utero exposure in both rats and rabbits; however, these effects are well characterized and the selected endpoints are protective of the observed fetal effects. Lastly, there are no residual uncertainties in the exposure database.

#### *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.

Because there are no uses for bicyclopyrone that may result in residential exposures, the aggregate risk consists only of food and water.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to bicyclopyrone will occupy 2.9% of the aPAD for females 13–49 years old, the population group receiving the greatest exposure.

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 91% of the cPAD for children 1–2 years old the population group receiving the greatest exposure. There are no residential uses for bicyclopyrone.

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.* A non-linear approach (*i.e.*, RfD) will adequately account for all chronic toxicity, including carcinogenicity that could result 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.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology liquid chromatography-mass spectroscopy/mass spectroscopy (LC-MS/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](mailto: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 Alimentarius is a joint United Nations Food and Agriculture Organization/World Health

Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for bicyclopyrone.

##### *C. Response to Comments*

Seven comments were received in response to the September 5, 2014 notice of filing. Three of the comments were relevant to bicyclopyrone, the other four comments were relevant to other actions that were batched together with bicyclopyrone in the same **Federal Register** document. The commenters noted that pesticides and bicyclopyrone pose a risk to pollinators. The agency has determined that bicyclopyrone is moderately to practically non-toxic to young adult honey bees (*Apis mellifera*) on an acute exposure basis.

One comment was received in response to the February 11, 2015 corrected notice of filing for the import tolerance on sugarcane petition. This comment was associated with an action that was batched together with bicyclopyrone in the same **Federal Register** document and was not relevant to bicyclopyrone.

##### *D. Revisions to Petitioned-For Tolerances*

The proposed tolerance levels for most corn (field, pop, and sweet) raw agricultural commodities (RAC) differ slightly from those being set by the EPA. Although both the registrant and EPA have used the OECD (Organization for Economic Cooperation and Development) calculation procedures to obtain tolerance levels, EPA only included data from trials conducted according to the proposed label directions. The registrant proposed a tolerance level for sugarcane, cane below the method LOQ (0.01 ppm); the appropriate level is at the LOQ (0.02 ppm). EPA's tolerance levels for livestock meat byproducts were based on the highest tissue-to-feed ratio calculated from the dose closest to maximum dietary burdens. As residues are expected in both liver and kidney, the appropriate RAC is "meat byproducts." Per EPA policy, tolerances are set for all ruminants, not just cattle. EPA made numerous changes in the commodity definitions and revisions to the tolerance expression in order to conform to current Agency policy.

**V. Conclusion**

Therefore, tolerances are established for residues of the herbicide bicyclopyrone in or on corn, field, forage at 0.30 ppm; corn, field, grain at 0.02 ppm; corn, field, stover at 0.40 ppm; corn, pop, grain at 0.02 ppm; corn, pop, stover at 0.40 ppm; corn, sweet, forage at 0.40 ppm; corn, sweet, kernel plus cob with husks removed at 0.03 ppm; corn, sweet, stover at 0.70 ppm; sugarcane, cane at 0.02 ppm; cattle, meat byproducts at 1.5 ppm; goat, meat byproducts at 1.5 ppm; sheep, meat byproducts at 1.5 ppm; horse, meat byproducts at 1.5 ppm; and hog, meat byproducts at 0.15 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: April 17, 2015.

**William Jordan,**

*Acting Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

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

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

■ 2. Add § 180.682 to subpart C to read as follows:

**§ 180.682 Bicyclopyrone; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of the herbicide bicyclopyrone (4-hydroxy-3-[[2-[(2-methoxyethoxy)methyl]-6-(trifluoromethyl)-3-

pyridinyl]carbonyl]bicyclo[3.2.1]oct-3-en-2-one), including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of the common moieties SYN503780 (2-[[2-methoxyethoxy)methyl]-6-(trifluoromethyl)-3-pyridinecarboxylic acid) and CSCD686480 (2-[[2-hydroxyethoxy)methyl]-6-(trifluoromethyl)-3-pyridinecarboxylic acid), calculated as the stoichiometric equivalent of bicyclopyrone, in or on the commodities.

Commodity	Parts per million
Corn, field, forage .....	0.30
Corn, field, grain .....	0.02
Corn, field, stover .....	0.40
Corn, pop, grain .....	0.02
Corn, pop, stover .....	0.40
Corn, sweet, forage .....	0.40
Corn, sweet, kernel plus cob with husks removed .....	0.03
Corn, sweet, stover .....	0.70
Sugarcane, cane <sup>1</sup> .....	0.02
Cattle, meat byproducts .....	1.5
Goat, meat byproducts .....	1.5
Sheep, meat byproducts .....	1.5
Horse, meat byproducts .....	1.5
Hog, meat byproducts .....	0.15

<sup>1</sup> There are no U.S. Registrations on Sugarcane as of March 13, 2015.

(2) [Reserved].  
(b) [Reserved].

[FR Doc. 2015–09482 Filed 4–22–15; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 435**

**Eligibility in the States, District of Columbia, the Northern Mariana Islands, and American Samoa**

*CFR Correction*

In Title 42 of the Code of Federal Regulations, Parts 430 to 481, revised as of October 1, 2014, on page 198, in § 435.912, revise paragraphs (a) and (b); redesignate paragraphs (c), (d), and (e) as paragraphs (e), (f), and (g), respectively; and add new paragraphs (c) and (d) to read as follows:

**§ 435.912 Timely determination of eligibility. [Corrected]**

(a) For purposes of this section—  
(1) “Timeliness standards” refer to the maximum period of time in which every applicant is entitled to a determination