



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2015-0226; FRL-9961-02]

### Benzobicyclon; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of benzobicyclon in or on rice, grain. Gowan Company, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

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

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

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0226, 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:** Michael Goodis, Registration Division

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## **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 Printing 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-2015-0226 in the subject line on the first page of your submission. All objections and

requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [insert date 60 days after date of publication in the **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0226, 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 August 26, 2015 (80 FR 51759) (FRL-9931-74), 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 5F8343) by Gowan Company, LLC, P.O. Box 5569, Yuma, AZ 85366. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide benzobicyclon (3-[2-chloro-4-(methylsulfonyl)benzoyl]-4-(phenylthio)bicyclo[3.2.1]oct-3-en-2-one), in or on rice, grain and rice, straw at 0.1 parts per

million (ppm). That document referenced a summary of the petition prepared by Gowan Company, LLC, the registrant, which is available in the docket (EPA-HQ-OPP-2015-0226), <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is not establishing a tolerance for rice, straw as requested. The reason for this change is 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 benzobicyclon including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with benzobicyclon 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.

Benzobicyclon has low mammalian toxicity with no effects seen in mice, dogs, and female rats following oral exposure or in rabbits following dermal exposure. There is no evidence of neurotoxicity or immunotoxicity. Parental effects in the reproduction toxicity study were only observed at the highest dose tested and consisted of increased incidence of hydropic degeneration (basophilic cells) in the pituitaries of male rats only, and was observed at an increased incidence for the F<sub>1</sub> as compared to F<sub>0</sub> generation. There was no evidence of increased quantitative or qualitative fetal or offspring susceptibility in the developmental toxicity and two-generation reproduction toxicity studies in rats with no developmental, reproductive, or offspring effects observed. Benzobicyclon was categorized as having low acute toxicity via the oral, dermal, and inhalation routes of exposure. It produces minimal but reversible eye irritation, but is not a dermal irritant or dermal sensitizer. Benzobicyclon is classified as “Not likely to be Carcinogenic to Humans” based on the absence of treatment-related tumors in two adequate rodent carcinogenicity studies. There was no concern for mutagenicity.

Benzobicyclon rapidly hydrolyzes to generate the anticipated pesticidal active degradate, the triketone metabolite B (also referred to as 1315P-070). For metabolite B, a limited amount of toxicological data is available. An in vitro enzyme activity assay that was submitted indicates that metabolite B is an inhibitor of 4-hydroxyphenylpyruvate dioxygenase (HPPD). In mammals, HPPD is a key enzyme in the catabolism of the amino acid tyrosine and inhibition of HPPD results in an increase of blood tyrosine concentrations (tyrosinemia). In laboratory animals, as a class, HPPD inhibitors produce ocular (opacities and keratitis), liver, kidney, and developmental (skeletal abnormalities) effects in rats. In a 90-day toxicity study in rats with metabolite B, ocular effects (neovascularization and opacity of the cornea) consistent with

tyrosinemia were at a similar dose that elicited ocular effects for tembotrione, the most potent HPPD inhibitor currently registered. The study also demonstrated that metabolite B induces treatment-related effects at lower doses than those required to elicit effects for the parent, benzobicyclon. For metabolite B, the toxicological database does not contain any carcinogenicity studies. Some of the currently registered HPPD inhibitors have been shown to cause tumors; however, cancer risk estimates tend to be low for this class and the chronic risk assessment generally addresses this risk. A bacterial reverse-mutation assay with metabolite B to evaluate genotoxicity was found to be negative. Due to the incomplete database for metabolite B, studies from the tembotrione database were used for preliminary evaluation of risks from exposure to metabolite B, along with the appropriate database uncertainty factors to ensure the tembotrione database is protective for the proposed use pattern. Any expansion in the use of benzobicyclon would require additional data to further characterize the toxicological effects of metabolite B.

Specific information on the studies received and the nature of the adverse effects caused by benzobicyclon and metabolite B 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 at <http://www.regulations.gov> in document *Benzobicyclon Human Health Risk Assessment for the Section 3 Registration Action on Rice and the Establishment of Permanent Tolerances for Residues in/on Rice* at page 36 in docket ID number EPA-HQ-OPP-2015-0226.

#### *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 benzobicyclon and metabolite B used for human risk assessment is shown in Table 1 and Table 2 of this unit.

**Table 1. Summary of Toxicological Doses and Endpoints for benzobicyclon for Use in Human Health Risk Assessment**

<b>Exposure/Scenario</b>	<b>Point of Departure and Uncertainty/Safety Factors</b>	<b>RfD, PAD, LOC for Risk Assessment</b>	<b>Study and Toxicological Effects</b>
Acute dietary (All populations)	No appropriate toxicological effect attributable to a single dose was observed. Therefore, a dose and endpoint were not identified for this risk assessment.		
Chronic dietary (All populations)	NOAEL= 63.6 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.636 mg/kg/day  cPAD = 0.636 mg/kg/day	<u>Two-Generation Reproduction Toxicity Study (rat)</u> LOAEL = 1320 mg/kg/day based on increased incidence of hydropic degeneration (basophilic cells) in the pituitary.
Incidental oral Short-term (1 to 30 days) and Intermediate-Term (1-6 months)	NOAEL= 63.6 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Residential LOC for MOE <100	<u>Two-Generation Reproduction Toxicity Study (rat)</u> LOAEL = 1320 mg/kg/day based on increased incidence of hydropic degeneration (basophilic cells) in the pituitary.

Dermal Short-term (1 to 30 days) and Intermediate-Term (1-6 months)	No hazard was identified for dermal exposure based on a dermal toxicity study and there was no evidence of increased quantitative susceptibility; therefore, a quantitative dermal assessment is not needed.		
Inhalation Short-term (1 to 30 days) and Intermediate Term (1-6 months)	Oral NOAEL= 63.6 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Residential LOC for MOE = <100	<u>Two-Generation Reproduction Toxicity Study (rat)</u> LOAEL = 1320 mg/kg/day based on increased incidence of hydropic degeneration (basophilic cells) in the pituitary.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans: based on the absence of treatment-related tumors in two adequate rodent carcinogenicity studies.		

LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. UF = uncertainty factor. 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). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (c = chronic). RfD = reference dose.

**Table 2. Summary of Toxicological Doses and Endpoints for Metabolite B 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 (All Populations)	LOAEL=0.8 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 30x <sup>1</sup>	Acute RfD=0.00027 mg/kg/day  aPAD = 0.00027 mg/kg/day	<u>Developmental Neurotoxicity Study for Tembotrione</u> Offspring NOAEL was not established. Offspring LOAEL = 0.8 mg/kg/day based on decreased acoustic startle response on PND 60 (males), and brain morphometric changes on PND 75 (males and females).

Chronic dietary (All populations)	NOAEL= 0.04 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 10x <sup>2</sup>	Chronic RfD = 0.00004 mg/kg/day  cPAD = 0.00004 mg/kg/day	<u>Chronic/Carcinogenicity Study (rat) for Tembotrione</u> LOAEL = 0.79 mg/kg/day based on neovascularization and edema of the cornea and snow flake-like corneal opacity, unilateral or bilateral keratitis of the eye, decreased mean body weight and mean bodyweight gain, increased total cholesterol, higher ketone levels and lower pH values, higher protein levels, increased kidney weight, kidney to body weight and kidney to brain weight ratios, chronic nephropathy and atrophy of the sciatic nerve.
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NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. 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). FQPA SF = FQPA Safety Factor.

PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. PND = Postnatal Day

<sup>1</sup> The FQPA SF accounts for the database uncertainty factor and the extrapolation of a LOAEL to NOAEL.

<sup>2</sup> The FQPA SF accounts for the database uncertainty factor.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to benzobicyclon (parent), EPA considered exposure under the petitioned-for tolerances. For metabolite B, there is no anticipated exposure in food; metabolite B is only a residue of concern in drinking water. EPA assessed dietary exposures from benzobicyclon 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 benzobicyclon; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's 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 for residue levels of parent benzobicyclon in food, EPA incorporated tolerance-level residues and 100 percent crop treated (PCT) for rice. For metabolite B, there is no anticipated exposure in food; metabolite B is only a residue of concern in drinking water therefore chronic dietary exposure was considered for metabolite B separately.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that benzobicyclon does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for parent benzobicyclon so tolerance level residues and 100% CT were assumed resulting in risk estimates that were less than the LOC to EPA. For metabolite B, there is no anticipated exposure in food; metabolite B is only a residue of concern in drinking water. Because risk estimates for metabolite B in drinking water exceeded the EPA's LOC, a refined water exposure assessment was conducted which included a 10% CT assumption, which is described in detail in the following section.

2. *Dietary exposure from drinking water.* The Agency used refined water exposure models in the dietary exposure analysis and risk assessment for benzobicyclon and metabolite B in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of benzobicyclon and metabolite B. 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>.

Modeled estimates of drinking water concentrations based on the Pesticide in Flooded Applications Model (PFAM; v2.0) were directly entered into the dietary exposure model. Because no toxicological effect attributable to a single dose was observed for benzobicyclon, an acute exposure assessment was not done. Therefore, the acute dietary risk assessment was conducted for metabolite B only (the parent benzobicyclon rapidly hydrolyzes to metabolite B) using the water concentration value of 24.8 ppb to assess the metabolite B contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.0031 ppb was used to assess the contribution to drinking water for benzobicyclon and 3.0 ppb for metabolite B. Based on the data summarized in Unit III.A., EPA has concluded dietary cancer risk concerns due to long-term consumption of metabolite B residues are adequately addressed by the chronic exposure analysis using the cPAD. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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). Benzobicyclon 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 FFDCFA 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 benzobicyclon to share a common mechanism of toxicity with any other substances, and benzobicyclon does not appear to produce a toxic metabolite produced by

other substances. For the purposes of this tolerance action, therefore, EPA has assumed that benzobicyclon 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*

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. *Prenatal and postnatal sensitivity.* For benzobicyclon, there was no evidence of increased quantitative or qualitative fetal or offspring susceptibility in the developmental toxicity and two-generation reproduction toxicity studies in rats with no developmental, reproductive, or offspring effects observed. For metabolite B, there are no available toxicity data to evaluate offspring sensitivity; however, toxicological data are available from other HPPD inhibitors, including developmental toxicity studies in rats and rabbits, two-generation reproduction studies in rats, and developmental neurotoxicity studies in rats. All of the selected endpoints for risk assessment were protective of developmental and offspring effects and tembotrione provided the most sensitive endpoint.

3. *Conclusion.* For metabolite B, the database is incomplete. Nevertheless, sufficient data are available to confirm that metabolite B is an HPPD inhibitor, which supports utilization of data from tembotrione, the most potent HPPD inhibitor. To account for the lack of data, the acute dietary assessment applies a 30X FQPA SF to account for extrapolation of a LOAEL to NOAEL and the database uncertainty factor for lack of studies. This safety factor is considered sufficient given the LOAEL in the developmental neurotoxicity study for tembotrione is considered conservative given the minimal changes seen at that dose. The chronic dietary assessment applies a 10X FQPA SF to account for the database uncertainty factor for lack of studies. These safety factors will adequately account for any potential prenatal and postnatal toxicity and address any residual uncertainty concerning the toxicity database. The Agency's assessment of exposure to metabolite B was conducted for drinking water only, as there is no anticipated exposure in food. The modeled drinking water concentrations for metabolite B are based on conservative modeled estimates.

For benzobicyclon, 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 SF. That decision is based on the following findings:

- i. The toxicity database for benzobicyclon is complete.
- ii. There is no indication that benzobicyclon is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that benzobicyclon results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments for parent benzobicyclon were performed based on 100% CT and tolerance-level residues. For metabolite B, there is no anticipated exposure in food; metabolite B

is only a residue of concern in drinking water. Because risk estimates for metabolite B in drinking water exceeded the EPA's LOC, a refined water exposure assessment was conducted which includes a 10% CT assumption. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to benzobicyclon and metabolite B in drinking water. These assessments will not underestimate the exposure and risks posed by benzobicyclon or metabolite B.

#### *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. For metabolite B, the dietary exposure analyses included drinking water only and there are no uses that would result in residential exposure; therefore, an aggregate assessment was only necessary for the parent, benzobicyclon.

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, benzobicyclon 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 benzobicyclon from food and water will result in risks of <1 % of the cPAD for all populations. There are no residential uses for benzobicyclon.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background

exposure level). A short-term adverse effect was identified; however, benzobicyclon 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 and is 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.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, benzobicyclon 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 benzobicyclon.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity, benzobicyclon is not expected to pose a cancer risk to humans. Dietary cancer risk concerns due to long-term consumption of metabolite B residues are adequately addressed by the chronic exposure analysis using the cPAD.

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 benzobicyclon residues.

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

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

Adequate enforcement methodology (a liquid chromatography-tandem mass spectrometry (LC-MS/MS) method is available to enforce the tolerance expression.

#### *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 benzobicyclon in or on the commodities associated with this rule.

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

The petitioner requested a tolerance of 0.01 ppm for rice, straw and rice, grain. However, based on OCSPP 860 Guidelines, Table 1 Feedstuffs, rice straw is not a regulated food commodity. Therefore, a tolerance for rice, straw is not needed.

The registrant has proposed use only in California, and has provided residue data for only California. The available residue data for the establishment of a tolerance level for residues of benzobicyclon support a value of 0.01 ppm in rice, grain.

### **V. Conclusion**

Therefore, a tolerance associated with a regional registration in California is established for residues of benzobicyclon, in or on rice, grain at 0.01 ppm.

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

This action establishes 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 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 5, 2017,

Michael Goodis,

*Director, Registration Division, 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 § 180.693 to subpart C to read as follows:

**§ 180.693 Benzobicyclon; tolerances for residues.**

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(l), are established for residues of the herbicide benzobicyclon, including its metabolites and degradates, in or on the commodity in the table below.

Compliance with the tolerance levels specified below is to be determined by measuring only benzobicyclon, 3-[2-chloro-4-(methylsulfonyl)benzoyl]-4-(phenylthio)bicyclo-[3.2.1]oct-3-en-2-one), in or on the following raw agricultural commodities:

Commodity	Parts per million
Rice, grain	0.01

(d) *Indirect or inadvertent residues.* [Reserved]

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