Captain of the Port Maryland-National Capital Region or designated representative. Access to the zone will be determined in consultation with the lead federal agency on a case-by-case basis when the zone is enforced. To request permission to enter or transit the security zone, the Captain of the Port Maryland-National Capital Region or designated representatives can be contacted at telephone number 410–576–2693 or on marine band radio, VHF–FM channel 16 (156.8 MHz). Coast Guard vessels that enforce this section can be contacted on marine band radio, VHF–FM channel 16 (156.8 MHz). The operator of a vessel shall proceed as directed upon being hailed by a U.S. Coast Guard vessel, or other Federal, State, or local law enforcement agency vessel, by siren, radio, flashing light, or other means. When authorized by the Coast Guard to enter the security zone all persons and vessels must comply with the instructions of the Captain of the Port Maryland-National Capital Region or designated representative and proceed at the minimum speed necessary to maintain a safe course while within the security zone.

(3) The U.S. Coast Guard may be assisted by federal, state, and local law enforcement agencies in the patrol and enforcement of the security zone described in paragraph (a) of this section.

(d) *Enforcement.* The Captain of the Port Maryland-National Capital Region will provide the affected segments of the public with notice of enforcement of security zone by Broadcast Notice to Mariners (BNM), Local Notice to Mariners, and on-scene notice by designated representative or other appropriate means in accordance with 33 CFR 165.7.

Dated: June 22, 2017.

M.W. Batchelder,

Commander, U.S. Coast Guard, Acting Captain of the Port Maryland-National Capital Region.

[FR Doc. 2017–14395 Filed 7–7–17; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R05–OAR–2016–0137; FRL–9964–63–Region 5]

Air Plan Approval; Indiana; Redesignation of the Muncie Area to Attainment of the 2008 Lead Standard; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to the receipt of an adverse comment, the Environmental Protection Agency (EPA) is withdrawing the May 30, 2017, direct final rule approving the redesignation of the Muncie nonattainment area to attainment for the 2008 national ambient air quality standards (NAAQS) for lead, the state's plan for maintaining the 2008 lead NAAQS through 2030 for the area, and the 2013 attainment year emissions inventory for the area.

DATES: The direct final rule published at 82 FR 24553 on May 30, 2017, is withdrawn effective July 10, 2017.

FOR FURTHER INFORMATION CONTACT: Anthony Maietta, Environmental Protection Specialist, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8777, *maietta.anthony@epa.gov.*

SUPPLEMENTARY INFORMATION: In the direct final rule, EPA stated that if adverse comments were submitted by June 29, 2017, the rule would be withdrawn and not take effect. EPA received an adverse comment prior to the close of the comment period and, therefore, is withdrawing the direct final rule. EPA will address the comment in a subsequent final action based upon the proposed action also published on May 30, 2017. EPA will not institute a second comment period on this action.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Lead, Reporting and recordkeeping requirements.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

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

Dated: June 20, 2017.

Robert A. Kaplan,

Acting Regional Administrator, Region 5.

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Accordingly, the amendments to 40 CFR 52.770 and 40 CFR 52.797 published in the **Federal Register** on May 30, 2017 (82 FR 24553) on page 24559 are withdrawn effective July 10, 2017.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

Accordingly, the amendment to 40 CFR 81.315 published in the **Federal Register** on May 30, 2017 (82 FR 24553) on page 24559 is withdrawn effective July 10, 2017.

[FR Doc. 2017–14316 Filed 7–7–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0595; FRL–9962–06]

Buprofezin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of buprofezin in or on rice grain. Nichino America, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 10, 2017. Objections and requests for hearings must be received on or before September 8, 2017, 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–2016–0595, 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 (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 Government Printing Office's e-CFR site at *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–2016–0595 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 September 8, 2017. 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–2016–0595, 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 December 9, 2016 (81 FR 89036) (FRL–9953–69), 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 6E8494) by Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington, DE, 19808. The petition requested that 40 CFR 180.511 be amended by establishing a tolerance for residues of the insecticide buprofezin in or on rice at 0.3 parts per million (ppm). That document referenced a summary of the petition prepared by Nichino America, Inc., the registrant, which is available in the docket, *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 has modified the level at which the tolerance is being established. 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 buprofezin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with buprofezin 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 primary organs of buprofezin toxicity are the liver and the thyroid. In subchronic toxicity studies in rats increased microscopic lesions in liver and thyroid, increased liver weights, and increased thyroid weight in males were seen. In chronic studies in the rat, an increased incidence of follicular cell hyperplasia and hypertrophy in the thyroid of males were reported. In chronic studies in the dog, increased relative liver weights were reported in females. Effects observed in a 24-day dermal toxicity study in rats included inflammatory infiltrate of the liver and an increase in acanthosis and hyperkeratosis of the skin in females.

The developmental toxicity study in the rat showed reduced ossification and reduced pup weight at maternally toxic doses (death, decreased pregnancy rates,

increased resorption rates). No developmental toxicity was observed in the rabbit at or below maternally toxic dose levels. The reproductive toxicity study showed decreased pup body weights at dose levels where liver effects (increased relative and/or absolute liver weights) and decreased body weight gains were observed in the parental generations. However, in a comparative thyroid toxicity assay, pup toxicity (decreased pup body weight during early lactation and increased TSH levels) occurred at a dose that was not maternally toxic. Maternal toxicity resulted in increased serum TSH concentration, decreased serum T4 levels in pregnant rats and histopathological findings in the thyroid (increased follicular cell height and follicular cell hypertrophy). In this same study, fetal and maternal toxicity occurred at the same dose. Fetal toxicity was expressed as increased thyroid weight in males and increased TSH levels in males and females. No neurotoxic effects were observed in a subchronic neurotoxicity study in rats at the highest dietary dose tested of 5,000 ppm. There was no evidence of neurotoxicity or immunotoxicity in the submitted studies.

EPA has classified buprofezin into the category of ''Suggestive Evidence of Carcinogenicity, but not sufficient to assess human carcinogenic potential'' based on liver tumors in female mice only. Buprofezin was negative in *in vitro* and *in vivo* genotoxicity assays. The Agency noted findings from the published literature indicate that buprofezin causes cell transformation and induces micronuclei *in vitro,* but determined that, in the absence of a positive response in an *in vivo* micronucleus assay, buprofezin may have aneugenic potential which is not expressed *in vivo.* The Agency has determined that the cPAD is protective for carcinogenic effects.

Specific information on the studies received and the nature of the adverse effects caused by buprofezin 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 the document titled ''*Buprofezin: Human Health Risk Assessment for Proposed New Tolerance with No U.S. Registration in/on Imported Rice Grain*'' on page 29 in docket ID number EPA–HQ–OPP–2016–0595.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

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

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BUPROFEZIN 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 (General population including infants and children).	An acute RfD for the general population or any population subgroups (other than females 13–50 years of age) was not selected because no effect attributable to a single (or few) day(s) oral exposure was observed in animal studies.		
Acute dietary (Females 13–50 years of age).	NOAEL = 200 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 2.0 mg/kg/day. aPAD = 2.0 mg/kg/day.	Developmental Toxicity Study—Rat. Developmental LOAEL = 800 mg/kg/day based on reduced ossification & decreased body weight in offspring. Maternal LOAEL = 800 mg/kg/day based on mortality, decreased food consumption, weight loss, clinical signs, decreased pregnancy rates and increased resorption rates.
Chronic dietary (All populations)	LOAEL= 10 mg/kg/day. UF_A = 3x UF_H = 10x UF_L = 10x FQPA SF = 1x	Chronic RfD = 0.033 mg/kg/day. cPAD = 0.033 mg/kg/day.	Comparative Thyroid Toxicity Study-rats. Offspring LOAEL = 10.0 mg/kg/day based on significantly decreased pup body weight (↓8–13% in males during LD 4–10 and ↓8–9% in females during LD 4–7) compared to controls and increased TSH levels on LD 4 and LD 21 (↑23–34% in males).
Cancer (Oral, dermal, inhalation).	Possible human carcinogen. (No Q_1*). The cRfD is considered protective of the cancer effects.		

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. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to buprofezin, EPA considered exposure under the petitioned-for tolerances as well as all existing buprofezin tolerances in 40 CFR 180.511. EPA assessed dietary exposures from buprofezin 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 buprofezin.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA; 2003–2008). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) for all commodities. Total residues of concern in crop commodities (*i.e.,* buprofezin and the BF4 Conjugate which is *not* detectable by data collection methods but which may be estimated from metabolism data) were based on tolerance level residues of buprofezin and available metabolism/magnitude of the data to estimate other residues of concern. Given the potential for BF9 and BF12 to concentrate to a greater degree than buprofezin in processed commodities, Dietary Exposure Evaluation Model (DEEM) default processing factors were retained for all commodities, except for tomato paste and puree, which were reduced based on empirical data. Based on the submitted lemon metabolism data, which indicated that residues of concern are primarily found in/on the peel, the maximum theoretical concentration factor for peel was used to estimate residues of concern in citrus peel. Total residues of concern in meat (*i.e.,* buprofezin and BF2) and milk (*i.e.,* buprofezin and BF23) were based on the feeding study data which were used to establish meat and milk tolerances. Based on the submitted data, which indicated a 5x concentration of residues into milk cream and fat and a Log K_{ow} of 4.31, a default 25x concentration factor was applied for milk fat.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA (2003–2008). A partially refined chronic dietary analysis was conducted using the same residue estimates used for the acute dietary analysis and average percent crop treated estimates when available.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to buprofezin. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure.*

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, 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 Agency estimated the PCT for existing uses as follows:

The acute dietary exposure analyses assumed 100 PCT. Average PCT was used for the following crops for refinement of the chronic analyses: almond 1%, apple 2.5%, apricot 10%, broccoli 5%, Brussels sprout 2.5%, cabbage 5%, cantaloupe 5%, cauliflower 10%, cherry 2.5%, cotton 1%, grapefruit 5%, grape 5%, lemon 2.5%, lettuce 10%, nectarine 5%, olive 2.5%, orange 2.5%, peach 5%, pear 10%, pepper 2.5%, pistachio 10%, plum/prune 5%, pomegranate 15%, pumpkin 1%, spinach 1%, squash 1%, strawberry 15%, tomato 1%, walnut 1%, and watermelon 2.5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis.

Average percent of crop treated—Values are calculated by merging data sources together; averaging by year, averaging across all years, & rounding to the nearest multiple of 5. **Note:** *If the estimated value is less than 2.5, then the value is labeled <2.5. If the estimated value is less than 1, then the value is labeled <1.*

Maximum percent of crop treated—Value is the single maximum value reported across all data sources, across all years, & rounded up to the nearest multiple of 5. *Note: If the estimated value is less than 2.5, then the value is labeled <2.5.*

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

Based on the Pesticide Root Zone Model version 5 and Variable Volume Water Model (PRZM5/VVWM) and Pesticide Root Zone Model Ground Water (PRZM GW) model, the estimated drinking water concentrations (EDWCs) of buprofezin for acute exposures are estimated to be 78.8 parts per billion (ppb) for surface water and for chronic

exposures are estimated to be 19 ppb for surface water. There was no breakthrough of buprofezin into ground water during a 100-year simulation using the PRZM–GW model. Buprofezin, therefore, is not expected to be detected in shallow ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 78.8 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 19 ppb was used to assess the contribution to drinking water.

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). Buprofezin 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.''

EPA has not found buprofezin to share a common mechanism of toxicity with any other substances, and buprofezin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that buprofezin 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 Web site at *http://www2.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.* Developmental toxicity studies in rats and rabbits and the reproduction studies in rats provided no indication of increased susceptibility of rats or rabbits following *in utero* exposure or of rats following pre/postnatal exposure to buprofezin. However, the comparative thyroid toxicity study demonstrated offspring susceptibility, but not fetal susceptibility to buprofezin oral (gavage) administration. The point of departure (POD) for risk assessment is derived from this study and is based on the most sensitive endpoint of concern. Previous risk assessments imposed a database uncertainty factor of 10X for a lack of a comparative thyroid toxicity study. With the submission of an acceptable comparative thyroid study, and lack of susceptibility in the developmental and reproduction studies, the FQPA factor is now reduced to 1x.

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. That decision is based on the following findings:

i. The toxicity database for buprofezin is complete.

ii. Thyroid toxicity was seen following subchronic and chronic exposures to rats as well as chronic exposures to dogs characterized by decreases in serum thyroxine levels and increased thyroid weights in dogs and histopathological lesions in in rats. Disruption of thyroid homeostasis is the initial, critical effect that may lead to adverse effects on the developing nervous system.

Normally, if a neurodevelopmental concern is raised by existing data on a pesticide, a rat developmental neurotoxicity (DNT) study is requested. However, a DNT study is not required for buprofezin since this study would not address thyroid toxicity concerns. Thus, *in lieu* of the rat DNT study, a special study evaluating the hormonal responses associated with the developing fetal nervous system was required and has since been conducted and submitted to the Agency. This study demonstrated offspring susceptibility, but not fetal susceptibility to buprofezin oral (gavage) administration.

Based on the lack of any neurotoxic effects in a subchronic neurotoxicity study at doses as high as 5,000 ppm and the absence of neurotoxicity in subchronic and chronic tests, an acute neurotoxicity study was waived.

iii. Developmental toxicity studies in rats and rabbits and the reproduction studies in rats provided no indication of increased susceptibility of rats or rabbits following *in utero* exposure or of rats following pre/postnatal exposure to buprofezin. However, the comparative thyroid toxicity study demonstrated offspring susceptibility, but not fetal susceptibility to buprofezin oral (gavage) administration. The chronic point of departure (POD) for risk assessment is derived from this study and is based on the most sensitive endpoint of concern.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessment uses conservative assumptions which result in protective estimates of dietary exposure. The dietary drinking water assessment uses values generated by model and associated modeling parameters which are designed to provide protective, high-end estimates of water concentrations. These assessments will not underestimate the exposure and risks posed by buprofezin.

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. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to buprofezin will occupy 4.8% of the aPAD for females 13–49 years old, the only population group of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to buprofezin from food and water will utilize 48% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for buprofezin.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, buprofezin is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or 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 short- or intermediate-term risk), no further assessment of short-or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for buprofezin.

4. *Aggregate cancer risk for U.S. population.* As explained in Unit III.A., the Agency has determined that the quantification of risk using a non-linear (*i.e.,* RfD) approach will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to buprofezin. Therefore, based on the results of the chronic risk assessment discussed in Unit III.E.2., buprofezin is not expected to pose a cancer risk to humans.

5. *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 buprofezin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available in PAM I and PAM II for enforcement of buprofezin tolerances, including GC methods with nitrogen phosphorus detection (GC/NPD), and a GC/mass spectrometry (MS) method for confirmation of buprofezin residues in plant commodities.

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 buprofezin in or on rice grain.

C. Revisions to Petitioned-For Tolerances

The petitioned-for tolerance in/on rice, grain has been revised from 0.3 ppm to 1.5 ppm. The proposed tolerance level (0.3 ppm) is actually for the processed rice commodity, hulled rice grain (*i.e.,* brown rice), and not for the recognized rice raw agricultural commodity (RAC), unhulled/whole rice grain. The recommended tolerance (1.5 ppm) in/on rice, grain (*i.e.,* unhulled/whole rice grain) will cover residues in/on hulled rice grain (*i.e.,* brown rice) treated at the maximum proposed use rate.

V. Conclusion

Therefore, a tolerance is established for residues of buprofezin in or on rice, grain at 1.5 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: May 18, 2017.

Michael L. 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. In § 180.511, add alphabetically the commodity ''Rice, grain'' to the table in paragraph (a); redesignate footnote 1 to the table as footnote 2; and add a new footnote 1 to the table to read as follows:

§ 180.511 Buprofezin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Rice, grain [1]	1.5
* * * * *	

[1] There are no U.S. registrations as of July 10, 2017 for use on rice.

* * * * *

[FR Doc. 2017–14085 Filed 7–7–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[Docket No. CDC–2016–0068]

RIN 0920–AA63

Control of Communicable Diseases; Correction

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

ACTION: Final rule; correcting amendments.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces technical corrections to the final rule (82 FR 6890) published on January 19, 2017. These technical corrections remove grammatical errors, remove a reference to reports of deaths or illness by ''radio,'' change regulatory text to match previously updated and approved language, and amend a reporting date for a retrospective review so that the date does not coincide with a Federal holiday.

DATES: These correcting amendments are effective July 10, 2017.

FOR FURTHER INFORMATION CONTACT: Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–E03, Atlanta, Georgia 30329. Telephone: (404) 498–1600.

SUPPLEMENTARY INFORMATION: On January 19, 2017, HHS/CDC published a final rule that included some technical errors (82 FR 6890). HHS/CDC is correcting those technical errors in this document. A summary of those corrections follows below.

Section 553(b)(B) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. We have determined that it is unnecessary to provide prior notice and the opportunity for public comment because the technical corrections being made, as discussed below, address only minor publication errors that do not substantially change agency actions taken in the final rule. For the same reasons we find good cause to make these corrections effective on publication.

Summary of Technical Corrections to 42 CFR 71 Foreign Quarantine

The final rule contains two sections, respectively, relating to the transmission of passenger and crew information for airlines and vessels, sections 71.4 and 71.5. Section 71.4 is titled, ''Requirements relating transmission of airline passenger, crew and flight information for public health purposes.'' Section 71.5 is titled, ''Requirements relating transmission of vessel passenger, crew, and voyage information for public health purposes.'' We are changing the title of 71.4 by adding ''to the'' in between ''relating'' and ''transmission'' and by adding a comma after ''crew.'' We are changing the title of 71.5 by adding ''to the'' in between ''relating'' and ''transmission.''

The final rule lists two different dates for a retrospective review report evaluating the burden of transmission of passenger and crew information for airlines and vessels. Section 71.4 lists February 18, 2019 while Section 71.5 lists February 21, 2019. Since February 18, 2019 is President's Day, a Federal holiday, and the **Federal Register** is not published on Federal holidays, we are changing the date of the report in Section 71.4 to February 21, 2019.

In the preamble of both the proposed rule (81 FR 54230) and the final rule (82 FR 6890), HHS/CDC discussed deleting the term ''radio'' from Section 71.21 because the term is antiquated, but failed to make the change in the regulatory text. The term ''radio'' still appears in the regulatory text and in the Table of Contents. This technical correction deletes this term.

Finally, also in Section 71.21, HHS/CDC is changing the term ''diarrhea'' to ''acute gastroenteritis (AGE).'' This change was discussed in the final rule and is consistent with the language found in CDC's Vessel Sanitation Program Manual. *See https://www.cdc.gov/nceh/vsp/pub/pub.htm.*

List of Subjects in 42 CFR Part 71

Apprehension, CDC, Communicable diseases, Conditional release, Director, Ill person, Isolation, Non-invasive, Public health emergency, Public health prevention measures, Quarantine, Quarantinable communicable diseases.

PART 71—FOREIGN QUARANTINE

■ 1. The authority citation for part 71 continues to read as follows:

Authority: Secs. 215 and 311 of Public Health Service (PHS) Act. as amended (42 U.S.C. 216, 243); secs. 361–369, PHS Act, as amended (42 U.S.C. 264–272).

■ 2. In § 71.4, amend the section heading and paragraph (c) to read as follows:

§ 71.4 Requirements relating to the transmission of airline passenger, crew, and flight information for public health purposes.

* * * * *

(c) No later than February 21, 2019, the Secretary or Director will publish and seek comment on a report evaluating the burden of this section on affected entities and duplication of activities in relation to mandatory passenger data submissions to DHS/CBP. The report will specifically recommend actions that streamline and facilitate use and transmission of any duplicate information collected.

■ 3. In § 71.5, revise the section heading to read as follows:

§ 71.5 Requirements relating to the transmission of vessel passenger, crew, and flight information for public health purposes.

* * * * *

■ 4. In § 71.21, revise the section heading to read as follows: