also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11B at NARA, call (202) 741–6030, or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX, 76177; telephone (817) 222–5711.

**SUPPLEMENTARY INFORMATION:**

**Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it supports the removal of Class E airspace extending upward from 700 feet above the surface at Carter Airport, Pulaski, WI.

**History**

The FAA published a notice of proposed rulemaking in the **Federal Register** (82 FR 45749; October 2, 2017) for Docket No. FAA–2017–0818 to remove Class E airspace extending upward from 700 feet above the surface at Carter Airport, Pulaski, WI. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

**Availability and Summary of Documents for Incorporation by Reference**

This document amends FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

**The Rule**

This amendment to title 14, Code of Federal Regulations (14 CFR) part 71 removes the Class E airspace area extending upward from 700 feet above the surface within a 6.9-mile radius of Carter Airport, Pulaski, WI.

This action is necessary due to the cancellation of the instrument procedures at Carter Airport. The removal of these procedures results in the airport no longer qualifying for controlled airspace.

**Regulatory Notices and Analyses**

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**Environmental Review**

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

**Lists of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

**Adoption of the Amendment**

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

## PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

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

**Authority:** 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

**§ 71.1 [Amended]**

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

*Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.*

* * * * *

**AGL WI E5 Pulaski, WI [Removed]**

Issued in Fort Worth, Texas, on January 29, 2018.

**Christopher L. Southerland,**

*Acting Manager, Operations Support Group, ATO Central Service Center.*

[FR Doc. 2018–02137 Filed 2–8–18; 8:45 am]

**BILLING CODE 4910–13–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2016–0649; FRL–9972–61]**

### Cyflufenamid; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of cyflufenamid in or on cherry crop subgroup 12–12A, hops dried cones, and fruiting vegetable crop group 8–10; and amends the tolerance for cucurbit vegetable crop group 9. Nisso America, on behalf of Nippon Soda Co., Ltd. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective February 9, 2018. Objections and requests for hearings must be received on or before April 10, 2018, 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–2016–0649, 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–2016–0649 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 April 10, 2018. 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–2016–0649, 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 March 23, 2017 (82 FR 14846) (FRL–9957–99), 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 6F8512) by Nisso America on behalf of Nippon Soda Co., Ltd., 88 Pine Street, 14th Floor, New York, NY 10005. The petition requested that 40 CFR 180.667 be amended by establishing tolerances for residues of the fungicide cyflufenamid, in or on cherry crop subgroup 12–12A at 0.6 parts per million (ppm), hops at 5.0 ppm, and fruiting vegetable crop group 8–10 at 0.2 ppm. Then in the **Federal Register** of September 15, 2017 (82 FR 43352) (FRL–9965–43), EPA issued another document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing that this petition also requested the amendment of the existing tolerance for residues of cyflufenamid in or on cucurbit vegetable group 9, increasing the tolerance level from 0.07 ppm to 0.10 ppm. Those documents referenced a summary of the petition prepared by Nisso America on behalf of Nippon Soda Co., Ltd., the registrant, which is available in the docket, *http://www.regulations.gov*. Comments were received on the notices of filing. EPA's response to these comments is discussed 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 cyflufenamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyflufenamid 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.

Cyflufenamid has low acute toxicity via the oral, dermal, and inhalation routes of exposure. Though slightly irritating to the eye, cyflufenamid is not

a skin irritant or sensitizer. In the mammalian toxicology database, the liver was the primary target organ for cyflufenamid toxicity. Across species, duration and gender, changes in weight, clinical chemistry, and pathology indicated treatment-related perturbations in and adverse effects on liver function.

Thyroid effects due to treatment with cyflufenamid, seen only in the rat, included increased follicular cell hypertrophy (as well as increased organ weight) and neoplastic thyroid follicular adenomas. Kidney effects related to treatment included increased kidney weight accompanied by tubular vacuolation and slight decreases in sodium and chloride concentrations.

Treatment-related cardiotoxicity was noted in the rat and mouse feeding studies. Observed myocardial vacuolation and lipidosis may be attributed to decreased lipid metabolism; cyflufenamid caused an approximately 50% inhibition of carnitine palmitoyltransferase in both rat and mouse heart microsomal fractions in a non-guideline mechanistic study. Carnitine palmitoyltransferase is involved in the transport of long chain fatty acids into the mitochondrial matrix for oxidation. Fatty acid oxidation is an important source of energy for adenosine triphosphate (ATP) production in the mitochondria.

Cyflufenamid-induced brain vacuolation was specific to the dog and not associated with any apparent clinical sign of neurotoxicity. Supplementary studies investigating this phenomenon determined that vacuolation was due to myelin edema affecting the white matter of the cerebrum and thalamus. Furthermore, this brain lesion was partially reversed after a 13-week recovery period (following 90-day exposure) and fully reversed after a 26-week recovery period. This effect was not observed in any other species. A subchronic neurotoxicity study in rats showed no evidence of neurotoxicity.

Effects on reproductive organs and/or parameters have been previously noted in several subchronic studies; however, the effects occurred at doses above the respective lowest observed adverse effect level (LOAELs) from the studies used to derive the point of departures (POD)s. The PODs are protective of these effects. The developmental studies in rats and rabbits do not indicate any concern for increased susceptibility to offspring. Although offspring effects of decreased body weight and incomplete ossification were observed in rabbits, those effects occurred at doses higher than doses resulting in maternal effects and are believed to be related to maternal toxicity. Furthermore, the current PODs are protective of the effects seen on reproductive parameters in offspring. In addition, mating performance and fertility in the Parent/Filial $(P/F)_0$ generation were both unaffected by treatment with cyflufenamid in the 2-generation reproductive toxicity study in rats. Sex ratio, sexual maturation, estrous cyclicity, sperm quantity and quality, mating performance and fertility, gestation and viability indices in the filial 1 ($F_1$) generation were all unaffected by treatment.

When tolerances were last established for cyflufenamid (77 FR 38204, June 27, 2012), EPA had classified cyflufenamid as ''likely to be carcinogenic to humans'' based on the presence of thyroid follicular cell tumors in male rats and liver tumors in male mice. Since that time, EPA has reevaluated the carcinogenic potential of cyflufenamid and based on available data has reclassified cyflufenamid as having ''suggestive evidence of carcinogenicity.'' A well-established non-mutagenic mode of action (MOA) for thyroid follicular cell tumors in male rats was tested and found acceptable. In summary, EPA has determined that because of the thyroid hormone imbalance, thyroid follicular cell tumors in male rats are likely to occur. That lead to an increase in the size (hypertrophy) and number (hyperplasia) of the thyroid follicular cells and eventually to thyroid neoplasia (or tumors). Because of marked quantitative differences between rats and humans in their inherent susceptibility for thyroid tumors in response to an imbalance in thyroid hormones, EPA concludes that cyflufenamid is not likely to pose a risk for thyroid follicular cell tumors in humans. As a result, the database contains the following data concerning carcinogenicity: (1) There is no evidence of carcinogenicity in female rats and mice; (2) the MOA data indicates that thyroid follicular cell tumors may not be relevant to humans; (3) tumors were only found in the liver in one gender of one species, *i.e.,* male mice; and (4) there is no concern for mutagenicity or clastogenicity based on the results of the battery of genotoxicity studies. Therefore, EPA concludes that the chronic reference dose (cRfD) (0.044 mg/kg/day) will adequately account for all chronic toxicity, including carcinogenicity (which occurred only at a dose over 5000x higher than the cRfD) that could result from exposure to cyflufenamid.

Specific information on the studies received and the nature of the adverse effects caused by cyflufenamid as well as the no-observed-adverse-effect-level (NOAEL) and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document: ''Cyflufenamid. Human Health Risk Assessment for Proposed Uses on Fruiting Vegetable Group 8–10, Cherry crop Subgroup 12–12A, and Hops; and a Revised Tolerance on Cucurbit Vegetable Group 9'' on page 16 in docket ID number EPA–HQ–OPP–2016–0649.

### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological 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 based on a careful analysis of each toxicological study to determine the values of the NOAEL and 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 cyflufenamid used for human risk assessment is shown in the Table of this unit.

Table Summary of Points of Departure and Toxicity Endpoints Used in Human Risk Assessment

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CYFLUFENAMID FOR USE IN DIETARY, NON-OCCUPATIONAL AND OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENTS

| Exposure/ scenario | Point of departure | Uncertainty/FQPA safety factors | RfD, PAD, level of concern for risk dssessment | Study and toxicological effects |
|---|---|---|---|---|
| Acute Dietary (All Populations). | There were no appropriate toxicological effects attributable to a single exposure (dose) observed in appropriate toxicity studies. Therefore, a dose and endpoint were not identified for this risk assessment. | | | |
| Chronic Dietary (All Populations). | NOAEL = 4.4 mg/kg/day | $UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Chronic RfD = 0.044 mg/kg/day<br>cPAD = 0.044 mg/kg/day | Combined Chronic Toxicity/Carcinogenicity Study in Rats.<br>LOAEL = 22 mg/kg/day based on increased thyroid/parathyroid weight, increased liver weight and centrilobular hepatocytic hypertrophy. |
| Dermal Short-Term (1–30 days) and Intermediate-Term (1–6 months). | No adverse effects were observed in the dermal toxicity study and there are no concerns for developmental or neurological toxicities; therefore, no hazards are expected from these exposure scenarios. | | | |
| Inhalation Short-Term (1–30 days) and Intermediate-Term (1–6 months). | NOAEL = 5 mg/kg/day | $UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Residential/Occupational LOC for MOE = 100 | Prenatal Developmental Study in Rabbits.<br>Maternal LOAEL = 10 mg/kg/day based on decreased body weight, body weight gains and food consumption. |
| Cancer (oral, dermal, inhalation). | Classification: ''Suggestive evidence of carcinogenic potential'' and quantification of risk using a non-linear approach (*i.e.,* RfD approach) is appropriate. | | | |

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. $UF_A$ = extrapolation from animal to human (interspecies). $UF_H$ = 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. MOE = margin of exposure. LOC = level of concern.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyflufenamid, EPA considered exposure under the petitioned-for tolerances as well as all existing cyflufenamid tolerances in 40 CFR 180.667. EPA assessed dietary exposures from cyflufenamid 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 cyflufenamid; 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 U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (USDA's NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and 100% crop treated (100% CT) for all commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to cyflufenamid. 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.* EPA did not use anticipated residue and PCT information in the dietary assessment for cyflufenamid. Tolerance-level residues and 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for cyflufenamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyflufenamid. 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.*

The Agency used Tier II surface water and Tier I ground water simulations for all proposed cyflufenamid uses and label modifications. The estimated drinking water concentrations (EDWCs) of cyflufenamid for chronic exposures are 1.15 parts per billion (ppb) for surface water and 29.6 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, no toxic effects attributable to a single exposure to cyflufenamid have been identified; therefore, an acute reference dose (aRfD) has not been established and an acute dietary exposure assessment was not conducted. For chronic and cancer dietary risk assessments, the ground water concentration value of 29.6 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).

Although the Agency previously assessed residential handler exposure and risk estimates from the use of cyflufenamid on ornamental use sites, the Agency now assumes that cyflufenamid is only used by commercial applicators based on labeling requiring handlers to use personal protective equipment (PPE). Therefore, the Agency concludes that there are no residential handler exposures to assess.

The Agency has also determined that there are no post-application residential exposures to assess. Although there is a potential for residential dermal post-application exposure from the existing uses of cyflufenamid, there is no adverse systemic hazard via the dermal route of exposure. Moreover, there is no

incidental oral exposure expected from cyflufenamid use on ornamental plants.

Therefore, the Agency has concluded that there are no residential exposure scenarios to aggregate with dietary exposures for cyflufenamid.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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 cyflufenamid to share a common mechanism of toxicity with any other substances, and cyflufenamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cyflufenamid 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 *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 Food Quality Protection Act Safety Factor (FQPA 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.* There is no evidence of susceptibility following *in utero* and/or postnatal exposure in the developmental toxicity studies in rats or rabbits, and in the 2-generation rat reproduction study. Neither the rat nor rabbit developmental studies identified teratogenic effects. The marginally higher incidence of incompletely ossified epiphyses and metacarpals/phalanges seen in rabbits may be associated with low fetal weight and are indicative of delayed embryo-fetal development. The combined offspring effects of decreased body weight and incomplete ossification are believed to be related to the observed maternal toxicity. Furthermore, the PODs selected for all exposure scenarios are lower than those doses causing adverse effects in offspring.

There are no residual uncertainties concerning pre- and postnatal toxicity and no neurotoxicity concerns.

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 cyflufenamid is complete.

ii. There is no indication that cyflufenamid 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 cyflufenamid 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 were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyflufenamid in drinking water. These assessments will not underestimate the exposure and risks posed by cyflufenamid.

### *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 population adjusted dose (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, cyflufenamid 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 cyflufenamid from food and water will utilize 2.8% of the cPAD for the general U.S. population and 6.1% for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding the lack of residential use patterns, chronic residential exposure to residues of cyflufenamid is not expected.

3. *Short-term risk.* A short-term adverse effect was identified for inhalation and oral exposures; however, cyflufenamid 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 cyflufenamid.

4. *Intermediate-term risk.* An intermediate-term adverse effect was identified; however, cyflufenamid 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 cyflufenamid.

5. *Aggregate cancer risk for U.S. population.* EPA has determined that quantification of risk using the RfD approach is appropriate and will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to

cyflufenamid. Based on the conclusions of the chronic dietary assessment, EPA concludes that exposure to cyflufenamid is unlikely to pose an aggregate cancer risk.

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 cyflufenamid residues.

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (High-Performance Liquid Chromatography Method with tandem mass spectrometry detection (LC/MS/MS), Method No. RD–01307) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

### *B. International Residue Limits*

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

### *C. Response to Comments*

Several comments were received on the publication. While some comments raised issues outside the scope of the FFDCA analysis, the remaining comments primarily expressed general concerns about the potential health effects of pesticides residues in or on food and one comment asked that the combined effects of multiple pesticides be considered on food commodities. None of the comments specifically mentioned any particular safety concerns with cyflufenamid nor did any commenters provide supporting information for the Agency to evaluate or on which the Agency could rely to support a finding on the petitioned-for tolerances.

EPA recognizes that some individuals believe that pesticides should be banned on agricultural crops. The existing legal framework provided by section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), however, states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. EPA has assessed the effects of cyflufenamid on human health and determined that aggregate exposure to it will be safe. These comments provide no information to support an alternative conclusion.

As noted in Unit III.C.4., Congress has directed EPA to consider the cumulative risk of pesticide residues with residues of ''other substances that have a common mechanism of toxicity.'' FFDCA section 408(b)(2)(D)(v). At this time, EPA has not concluded that cyflufenamid has a common mechanism of toxicity with any other pesticides. The petitioner has not provided any other information to support a different conclusion.

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

EPA is establishing tolerances that vary slightly from requests in the petition by adding another significant figure to the tolerance levels for subgroup 12–12A and group 8–10 and revising commodity term for hops to match the Agency's commodity vocabulary.

## V. Conclusion

Therefore, tolerances are established for residues of cyflufenamid, in or on cherry crop subgroup 12–12A at 0.60 ppm; hop, dried cones at 5.0 ppm; and fruiting vegetable group 8–10 at 0.20 ppm; and the tolerance for residues in or on cucurbit vegetable group 9 is increased to 0.10 ppm.

## VI. Statutory and Executive Order Reviews

This action establishes and amends 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)), or Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). 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: January 24, 2018.

**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. In § 180.667, amend the table in paragraph (a) by:

■ i. Adding alphabetically the commodities ''Cherry subgroup 12–12A'', ''Hop, dried cones'', and ''Vegetable, fruiting, group 8–10'', and

■ ii. Revising the commodity ''Vegetable, cucurbit, group 9''.

The additions and revisions read as follows:

**§ 180.667 Cyflufenamid; tolerances for residues.**

(a) * * *

| Commodity | Parts per million |
|---|---|
| * * * * * | |
| Cherry subgroup 12–12A ..... | 0.60 |
| * * * * * | |
| Hop, dried cones ..... | 5.0 |
| Vegetable, cucurbit, group 9 ..... | 0.10 |
| Vegetable, fruiting, group 8–10 .... | 0.20 |

* * * * *

[FR Doc. 2018–02670 Filed 2–8–18; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2016–0681; FRL–9972–69]**

### Zoxamide; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of zoxamide in or on banana. Gowan Company, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective February 9, 2018. Objections and requests for hearings must be received on or before April 10, 2018, 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–2016–0681, 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 L. Goodis, P.E., Director, 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–2016–0681 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 April 10, 2018. 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–2016–0681, 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