E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2022-0645; FRL-11459-01-OCSPP]

Cyprodinil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of cyprodinil in or on cranberry. The Interregional Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [**INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER***]. Objections and requests for hearings must be received on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2022-0645, is available online at *https://www.regulations.gov.* Additional information about dockets generally, along with instructions for visiting the docket in person, is available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; 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).

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. *How can I get electronic access to other related information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40*.

C. *How do 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. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. 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-2022-0645 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***].

The EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. *See* "Revised Order Urging Electronic Filing and Service," dated June 22, 2023, which can be found at *https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf*. Although the EPA's regulations require submission via U.S. Mail or hand delivery, the EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, the EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf*.

II. Summary of Petitioned-For Tolerance

In the ***Federal Register*** of September 23, 2022 (87 FR 58047) (FRL-9410-05-OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petition (2E9006) by the Interregional Research Project No. 4 (IR-4), North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requests to amend 40 CFR 180.532 by establishing a tolerance for residues of the fungicide cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine, in or on the following raw agricultural commodity: cranberry at 0.4 parts per million (ppm). That document referenced a summary of the petition prepared by IR-4, the petitioner, which is available in the docket, https://www.regulations.gov. There were no comments received in response to the Notice of Filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty

that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . ."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, 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 cyprodinil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyprodinil 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 major target organs of cyprodinil are the liver in both rats and mice and the kidney in rats. Liver effects observed in subchronic and chronic studies in rats and mice include increased liver weights, increases in serum clinical chemistry parameters associated with adverse effects on liver function, hepatocyte hypertrophy, hepatocellular necrosis, and spongiosis hepatis. Adverse kidney effects include tubular lesions and inflammation following subchronic exposure of male rats. The hematopoietic system was also a target of cyprodinil, which caused mild anemia in rats following subchronic exposure. There was no evidence of increased *in utero* or postnatal susceptibility in the developmental rat or rabbit study or in the 2-generation reproduction study in the rat. An acute neurotoxicity study (ACN) indicated systemic toxicity with signs of hunched

posture, piloerection, reduced responsiveness to sensory stimuli and reduced motor activity, and hypothermia, but no neurotoxicity was observed in the subchronic neurotoxicity study (SCN). A 28-day dietary immunotoxicity study in mice resulted in no effects. No dermal or systemic toxicity was seen following repeated dermal application up to the limit dose in a 21-day dermal toxicity study in rats. There was no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies. There was no evidence of a mutagenic or cytogenetic effect *in vivo* or *in vitro* in studies with cyprodinil.

Based on the lack of evidence of carcinogenicity in mice and rates at doses that were judged to be adequate to the carcinogenic potential, cyprodinil is classified as "not likely to be carcinogenic to humans."

Specific information on the studies received and the nature of the adverse effects caused by cyprodinil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found in the document titled "Cyprodinil. Human Health Risk Assessment to Support the Registration of the Proposed New Use on Cranberry." (hereinafter "Cyprodinil Human Health Risk Assessment") on pages 33-37 in docket ID number EPA-HQ-OPP-2022-0645.

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

A summary of the toxicological endpoints and PODs for cyprodinil used for human risk assessment can be found in the Cyprodinil Human Health Risk Assessment on page 19.

C. *Exposure Assessment*

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to cyprodinil, EPA considered exposure under the petitioned-for tolerance as well as all existing cyprodinil tolerances in 40 CFR 180.572. EPA assessed dietary exposures from cyprodinil 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 cyprodinil.

In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software using the Food Commodity Intake Database (DEEM-FCID) Version 4.02, which uses the 2005-2010 food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The acute dietary exposure assessment is unrefined, assuming tolerance-level residues, default processing factors, and 100 percent crop treated (PCT) for all crop and livestock commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA also used the food consumption data from the USDA's 2005-2010 NHANES/WWEIA and DEEM-

FDIC version 4.02. As to residue levels in food, the chronic dietary exposure assessment is partially refined, assuming tolerance-level residues for some commodities, average field trial residues for the remaining commodities, default and empirical processing factors, and average PCT estimates for some crops.

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

iv. *Anticipated residue and PCT information*. FFDCA section 408(b)(2)(E) 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.

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

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section

408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the average PCT for existing uses as follows: almond 25%; apple 30%; apricot 20%; artichoke 5%; beans, snap 2.5%; blackberry 40%; blueberry 35%; broccoli 1%; brussels sprout 2.5%; cabbage 10%; cantaloupe 1%; carrot 1%; cauliflower 1%; celery 1%; cherries 2.5%; cucumber 1%; garlic 10%; grapes, wine 25%; grapes, raisin 15%; grapes, table 55%; kiwi 20%; lemon 1%; lettuce 15%; lima bean 1%; nectarine 15%; onion 10%; peach 30%; pear 15%; peppers 2.5%; pistachio 2.5%; plum/prune 30%; pumpkin 5%; raspberry 65%; squash 5%; strawberry 60%; tomato 2.5%; and watermelon 15%. EPA assumed 100 PCT for all remaining commodities included in the chronic assessment.

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

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c,

regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which cyprodinil may be applied in a particular area.

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

Based on the Pesticide Flooded Application Model (PFAM) along with the Pesticide in Water Calculator (PWC); groundwater and surface water model, the estimated drinking water concentration (EDWC) of cyprodinil for acute exposures is estimated to be 185 parts per billion (ppb) for surface water. The EDWC of cyprodinil for chronic exposures is estimated to be 119 ppb. These modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

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).

There are no new proposed residential (non-occupational) uses for cyprodinil. Cyprodinil is currently registered for use on ornamental landscapes on golf courses and around residential,

institutional, public, commercial, and industrial buildings, parks, recreational areas, and athletic fields, that could result in residential exposure. Currently, those labels require handlers to wear specific clothing (e.g., long sleeve shirt/long pants) and/or use personal protective equipment. Therefore, the Agency has made the assumption that these products are not for homeowner use and has not conducted a quantitative residential handler assessment. There are existing residential uses of cyprodinil on ornamentals and therefore the potential for short-term post-application dermal exposure to adults and children. However, a quantitative residential post-application assessment was not conducted because EPA did not identify a dermal hazard up to the limit dose of 1,000 mg/kg/day to select a dermal endpoint. Therefore, no residential exposures are applicable for the aggregate assessment.

4. *Cumulative effects from substances with a common mechanism of toxicity*. FFDCA section 408(b)(2)(D)(v) 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."

In 2016, EPA's Office of Pesticide Programs released a guidance document entitled Pesticide Cumulative Risk Assessment: Framework for Screening Analysis (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework*)*. This document provides guidance on how to screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and, if necessary, followed by a risk-based screening approach. This framework supplements the existing guidance documents for establishing common mechanism groups (CMGs) and conducting cumulative risk assessments (CRA). The Agency has utilized this framework for cyprodinil and determined that cyprodinil along with pyrimethanil form a candidate CMG. This group of pesticides is considered a candidate CMG because they share characteristics to support a testable hypothesis for a common mechanism of action.

Following this determination, the Agency conducted a screening-level cumulative

assessment for the candidate CMG of anilinopyrimidines. This assessment indicated that cumulative aggregate risk estimates are below the Agency's level of concern. The screening-level assessment for the anilinopyrimidines has been updated to incorporate the proposed new use of cyprodinil on cranberry. The current screening-level assessment indicates that cumulative risk estimates from cyprodinil and pyrimethanil are below the Agency's levels of concern and therefore, no further cumulative evaluation is necessary for cyprodinil at this time. For more information about the anilinopyrimidines cumulative screening assessment, see Appendix E of the Cyprodinil Human Health Risk Assessment in docket ID number EPA-HQ-OPP-2022-0645.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at https://www.epa.gov/pesticides/cumulative.

D. *Safety Factor for Infants and Children*

1. *In general*. FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There was no evidence of increased *pre-* or *post-utero* susceptibility in the developmental rat or rabbit studies or in the two-generation reproduction study. In the rat developmental toxicity study, there were significantly lower mean fetal weights in the high-dose group compared to controls, as well as a significant increase in skeletal anomalies in the high-dose group due to abnormal ossification. The skeletal anomalies/variations were considered to be a transient developmental delay that occurs

secondary to the maternal toxicity (reduced body weight/body weight gain and reduced food consumption) noted in the high-dose group. In the rabbit study, the only treatment-related developmental effect was indication of an increased incidence of a 13th rib at maternally toxic doses. Signs of offspring effects in the rat 2-generation reproduction study included significantly lower F_1 and F_2 pup weights in the high-dose group during lactation, which continued to be lower than controls post-weaning and after the pre-mating period (examination in F_1 generation only). The offspring effects occurred at the same high-dose levels at which maternal toxicity (decreased body weight) was observed and were considered to be secondary to maternal toxicity.

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 from 10X to 1X. That decision is based on the following findings:

i. The toxicity database for cyprodinil is sufficient for a full hazard evaluation and is considered adequate to evaluate risks to infants and children. Acceptable studies have been submitted for developmental toxicity, reproductive toxicity, acute and subchronic neurotoxicity, and immunotoxicity. In addition, EPA recommends a subchronic inhalation toxicity study be waived.

ii. In a subchronic neurotoxicity study in rats, there were no treatment related effects on mortality, clinical signs, or gross or histological neuropathology. Functional Observational Battery and motor activity testing revealed no treatment related effects up to the highest dose tested. In an acute neurotoxicity study in mice, clinical signs, hypothermia, and changes in motor activity were all found to be reversible and were no longer seen at day 8 and day 15 investigations. There were no treatment related effects on mortality, gross, or histological neuropathology.

iii. The available developmental guideline studies indicated no increased susceptibility of rats or rabbits to *in utero* and/or from postnatal exposure to cyprodinil. In the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproduction study in

rats, toxicity to the fetuses/offspring, when observed, occurred at the same doses at which effects were observed in maternal/parental animals.

iv. There are no residual uncertainties in the exposure database. The dietary risk assessment is conservative and will not underestimate dietary exposure to cyprodinil. The acute and chronic dietary assessments utilized tolerance-level residues, average residue values from field trial data (chronic only), empirical or HED's default processing factors, and 100 PCT (acute only) or average PCT estimates (chronic only). The dietary analyses also used modelled drinking water estimates. For these reasons, it can be concluded that the dietary analyses do not underestimate risk from acute or chronic exposure to cyprodinil. There are no proposed residential uses and, for reasons aforementioned, no quantitative residential assessment was conducted.

E. *Aggregate Risk and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population adjusted dose (aPAD) and the chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic term aggregate risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cyprodinil will occupy 7.6% of the aPAD for children 1 to 2 years old, the most highly exposed population subgroup. Acute residential exposure to cyprodinil is not expected. Therefore, the acute dietary risk estimates serve as the acute aggregate risk assessment, which are below the Agency's level of concern of 100% of the aPAD.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyprodinil from food and water will utilize 47% of the cPAD for all infants less than one year old, the most highly exposed

population subgroup. Chronic residential exposure to cyprodinil is not expected. Therefore, the chronic dietary risk estimates serve as the chronic aggregate risk assessment, which is below the Agency's level of concern of 100% of the cPAD.

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, residential exposures anticipated from the registered uses are not applicable for the aggregate risk assessment because no dermal hazard was identified. Therefore, the short-term and intermediate-term aggregate risks are equivalent to the chronic dietary risk estimates, which are not of concern.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, cyprodinil is classified as "not likely to be carcinogenic to humans." Therefore, cyprodinil is not expected to pose an aggregate cancer risk to humans.

5. *Determination of safety*. Based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to cyprodinil residues. More detailed information on this action can be found in the Cyprodinil Human Health Risk Assessment in docket ID EPA-HQ-OPP-2022-0645.

IV. Other Considerations

A. *Analytical Enforcement Methodology*

Adequate enforcement methodologies are available for enforcing tolerances of cyprodinil in/on plant commodities, specifically high performance liquid chromatography with UV detection (HPLC/UV) method with column switching. Method AG-631B also contains procedures for confirmatory analysis by gas chromatography with nitrogen phosphorus detection

(GC/NPD).

The methods 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 established MRLs for cyprodinil in or on berries and other small fruits (except grapes) at 10 ppm, based on U.S. raspberry residue data reflecting foliar applications. These Codex MRLs are different than the tolerance being established for residues of cyprodinil in the United States because the U.S. tolerance for residues in/on cranberry at 0.4 ppm is based on newly submitted cranberry field trial data that reflects a longer 30-day PHI, whereas the Codex MRL is based on a 0-day PHI. Because the use pattern is different resulting in significantly different residue levels, the U.S. tolerance will not be harmonized with the existing Codex MRLs.

V. Conclusion

Therefore, a tolerance is established for residues of cyprodinil, including its metabolites and degradates, in or on the raw agricultural commodity cranberry at 0.4 ppm.

Additionally, EPA is making a housekeeping correction to a separate tolerance provision. In 2010, the tolerance expression in the introductory paragraph of 40 CFR 180.582, which contains tolerances for pyraclostrobin, was erroneously revised to refer to "pyradostrobin" as the pesticide chemical, instead of "pyraclostrobin". *See* 75 FR 42324 (July 21, 2010). Up until that date, the rule had always referred to "pyraclostrobin", since that is the correct name of the pesticide chemical that is the subject of that rulemaking, and all preambles to subsequent rulemakings revising §180.582, have referred to "pyraclostrobin". The misnomer was a result of a typographical error, which EPA is correcting at this time. Since this change has no substantive effect, it can be accomplished without further notice and comment.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.).

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 (CRA)

This action is subject to the CRA (5 U.S.C. 801 *et seq*.), and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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: February 10, 2025.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

2. Section 180.532 is amended by adding in alphabetical order to table 1 to paragraph (a) the entry “Cranberry”.

The addition reads as follows:

§ 180.532 Cyprodinil; tolerances for residues.

(a) * * *

(1) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * * * *	
Cranberry	0.4
* * * * * * *	

* * * * *

3. Section 180.582 is amended by removing “pyradostrobin” and adding in its place “pyraclostrobin” in paragraph (a)(1) introductory text.

* * * * *

[FR Doc. 2025-03001 Filed: 2/25/2025 8:45 am; Publication Date: 2/26/2025]