zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have Tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or Tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishing a temporary safety zone for navigable waters in Corpus Christi Bay lasting approximately four hours on one day. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created during a U.S. Army jump training exercise. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T08–0376 to read as follows:

§ 165.T08–0376 Safety Zones; Corpus Christi Bay, Corpus Christi, TX.

(a) *Location.* The following area is a safety zone: All waters of Corpus Christi Bay, from surface to bottom, encompassed by a line connecting the following points: Point 1 at 27°48′57.76″ N, 97°23′19.17″ W; thence to Point 2 at 27°48′50.75″ N, 97°23′16.62″ W; thence to Point 3 at 27°48′54.34″ N, 97°23′5.73″ W; thence to Point 4 at 27°49′0.15″ N, 97°23′11.33″ W; thence returning to Point 1. These coordinates are based on World Geodetic System (WGS) 84.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Corpus Christi (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by on Channel 16 VHF–FM (156.8 MHz) or by telephone at (361) 939–0450. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 7 a.m. through 11 a.m. on June 7, 2025.

Dated: May 19, 2025.

Torrey H. Bertheau,

Captain, U.S. Coast Guard, Captain of the Port Sector Corpus Christi.

[FR Doc. 2025–09677 Filed 5–28–25; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0449; FRL–12713–01–OCSPP]

Florylpicoxamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of florylpicoxamid in or on multiple commodities which are identified and discussed later in this document. Corteva Agriscience, LLC requested

these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective on May 29, 2025. Objections and requests for hearings must be received on or before July 28, 2025, 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–2020–0449, is available 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, 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. Executive Summary

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 action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is EPA's authority for taking this action?

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(b)(2)(A)(i) 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.'' FFDCA section 408(b)(2)(A)(ii) 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. FFDCA section 408(b)(2)(C) 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 . . .''

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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 the docket ID number EPA–HQ–OPP–2020–0449 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 July 28, 2025.

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.*

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 at *https://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. If you wish to include CBI in your request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 27, 2020 (85 FR 68030 (FRL–10015–86–OCSPP)), 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 0F8836) by Dow AgroSciences LLC (currently Corteva Agriscience, LLC), 9330 Zionsville Road, Indianapolis, IN. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide florylpicoxamid, (1S)-2,2-bis(4-fluorophenyl)-1-methylethyl N-[[3-(acetyloxy)-4-methoxy-2-pyridinyl]carbonyl]-L-alaninate in or on barley, bran at 0.2 parts per million (ppm); barley, grain at 0.05 ppm; barley, hay at 2.0 ppm; barley, straw at 0.9 ppm; beans, dried shelled (except soybean), straw at 0.9 ppm; beet, sugar, dried pulp at 0.4 ppm; beet, sugar, roots at 0.05 ppm; beet, sugar, tops at 0.3 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.02 ppm; pea, dried shelled, hay at 8.0 ppm; pea, dried shelled, vines at 3.0 ppm; rapeseed subgroup 20A, fodder/straw at 2.0 ppm; rapeseed subgroup 20A, seed at 0.04 ppm; wheat, aspirated grain fractions at 0.1 ppm; wheat, bran at 0.05 ppm; wheat, forage at 2.0 ppm; wheat, grain at 0.02 ppm; wheat, hay at 4.0 ppm; wheat, straw at 0.3 ppm; and in or on the raw agricultural commodity cattle, fat at 0.02 ppm; cattle, meat at 0.02 ppm; cattle, meat byproducts at 0.02 ppm; egg at 0.02 ppm; goat, fat at 0.02 ppm; goat, meat at 0.02 ppm; goat, meat byproducts at 0.02 ppm; hog, fat at 0.02 ppm; hog, meat at 0.02 ppm; hog, meat byproduct at 0.02 ppm; horse, fat at 0.02 ppm; horse, meat at 0.02 ppm; horse, meat byproduct at 0.02 ppm; milk at 0.02 ppm; poultry, fat at 0.02 ppm;

poultry, liver at 0.02 ppm; poultry, muscle at 0.02 ppm; sheep, fat at 0.02 ppm; sheep, meat at 0.02 ppm; sheep, meat byproducts at 0.02 ppm. The Agency's notice of filing document referenced a summary of the petition prepared by Corteva Agriscience, LLC, the registrant, which is available in the docket. Two comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified several tolerance expressions, the tolerances, and commodity definitions. The reasons for these changes are explained in this document.

III. Aggregate Risk Assessment and Determination of Safety

A. EPA's Safety Determination

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 florylpicoxamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with florylpicoxamid follows.

B. 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. Florylpicoxamid is a picolinamide fungicide that inhibits the quinone oxidase enzyme of Complex III in the mitochondrial electron transport chain, leading to disruption of cellular respiration. A mammalian mode of action is not known. The studies available in the toxicity database indicate that toxicity is low for florylpicoxamid and are protective of toxicity from mammalian metabolites of florylpicoxamid. The only adverse effects were observed in a 90-day oral study in dogs, a developmental study in rabbits, and a combined chronic/carcinogenicity study in rats. In the other studies, effects were not observed at the highest doses tested, ranging from 123 mg/kg/day to the limit dose of 1000 mg/kg/day. The systemic effect of decreased body weight, an effect common to the picolinamide chemical class, was the most consistent seen throughout the database.

Adaptive liver effects including increased liver weights and very slight to slight hepatocellular hypertrophy were among the most common observations in the florylpicoxamid database. In the absence of corroborating toxic effects such as clinical chemistry (*e.g.,* liver enzymes) or other histopathological changes (*e.g.,* hepatocellular necrosis and inflammation), these effects are considered an adaptive response of the liver as it activates to metabolize the xenobiotic, rather than being adverse.

No increased fetal or offspring susceptibility was observed in developmental toxicity studies in rats and rabbits or in reproductive and fertility effects studies in rats. The only effect of note in those studies was late abortions seen in two maternal rabbits.

No evidence of neurotoxicity or immunotoxicity was seen throughout the toxicity database for florylpicoxamid, and a non-guideline 90-day oral study in rats that evaluated these systems did not reveal treatment-related effects up to the highest dose tested (185 mg/kg/day). No toxicity was seen up to the limit dose in a 28-day dermal study. Florylpicoxamid has low acute oral, inhalation, and dermal toxicity, and is not a skin or eye irritant (Toxicity Category IV, except for oral and dermal Toxicity Categories of III), or a skin sensitizer.

Specific information on the studies received and the nature of the adverse effects caused by florylpicoxamid 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 ''Florylpicoxamid: Human Health Risk Assessment for the New Active Ingredient'' at pages 20–23 in docket ID number EPA–HQ–OPP–2020–0449.

C. 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 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 *https://www.epa.gov/pesticide-science-andassessing-pesticide-risks/assessinghuman-health-risk-pesticides.*

For more detailed information on the toxicological endpoints for florylpicoxamid used for human risk assessment can be found in the document ''Florylpicoxamid Human Health Risk Assessment for the New Active Ingredient'' in docket ID number EPA–HQ–OPP–2020–0449.

D. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to florylpicoxamid, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from florylpicoxamid 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 florylpicoxamid; 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 United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America (USDA 2005–2010 NHANES/WWEIA). As to residue levels in food, EPA conducted a partially refined chronic aggregate dietary (food and drinking water) exposure and risk assessment and incorporated 100% crop treated (PCT) for all commodities. The chronic dietary exposure analysis incorporated recommended tolerances for livestock commodities, as the residues of concern for both tolerance enforcement and risk assessment are the same in livestock. While the residue of concern for tolerance enforcement in plants is parent florylpicoxamid only, the residues of concern for risk assessment are florylpicoxamid and

metabolite X12485649. Therefore, to account for the residues of concern for risk assessment, the chronic dietary exposure analysis incorporated average field trial residues of florylpicoxamid and metabolite X12485649 for all plant commodities (raw and processed) in this action.

The analysis incorporated default processing factors. Additionally, the submitted wheat and barley residue data demonstrate that residues of X12485649 concentrate in wheat bran and barley bran. Therefore, anticipated residues of 0.054 ppm and 0.051 ppm based on the residues of concern for risk assessment were used for barley bran and wheat bran, respectively.

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

iv. *Anticipated residue and PCT information.* EPA did not use PCT information in the dietary assessment for florylpicoxamid. Tolerance level residues were assumed for all livestock commodities. 100 PCT was assumed for all crop commodities.

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.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for florylpicoxamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of florylpicoxamid. 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 in Water Calculator model (PWC Version 2.001), which utilizes the Pesticide Root Zone Model (PRZM5) and the Variable Volume Water Model (VVWM), the estimated drinking water concentrations (EDWCs) of florylpicoxamid residues of concern for acute exposures are estimated to be 37.5 parts per billion (ppb) for surface water and 318 ppb for ground water. EDWCs for chronic exposures for non-cancer assessments are estimated to be 32 ppb for surface water and 212 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 212 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).

Florylpicoxamid is not currently registered for any specific use patterns that would result in residential handler exposure, but there are residential post-application exposures expected from contact with previously treated turf on golf courses. There is the potential for dermal post-application exposure for youth (11 to <16 years old) and adults exposed as a result of golfing on treated turf. Residential post-application exposure is expected to be short-term in duration. Intermediate-term exposures are not likely. Dermal exposures only are anticipated while golfing on treated turf; however, there is no dermal endpoint selected for children. Therefore, only dermal exposures for adults and youths (11 to <16 years old) have been quantitatively assessed and there are no additional routes to combine.

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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to florylpicoxamid and any other substances. For the purposes of this tolerance action, therefore, EPA has assumed that florylpicoxamid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework.*

E. 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.* No increased prenatal or postnatal susceptibility was detected in developmental or reproductive studies in rats and rabbits, as no fetal or offspring effects were observed in either study. The late abortions observed in rabbit are considered a maternal effect only.

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 florylpicoxamid is complete.

ii. There is no indication that florylpicoxamid is a neurotoxic chemical, and there is no need for a developmental neurotoxicity study or additional Uncertainty Factors to account for neurotoxicity.

iii. There is no evidence that florylpicoxamid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The partially refined chronic dietary assessment utilized tolerance-level residues for livestock commodities, field trial residue data for all plant commodities (raw and processed) to account for residues of concern for risk assessment, 100 PCT, and default processing factors. EPA made conservative (protective) assumptions in

the ground and surface water modeling used to assess exposure to florylpicoxamid in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by florylpicoxamid.

F. 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. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, florylpicoxamid 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 florylpicoxamid from food and water will utilize 4.3% of the cPAD for females 13–49 years old the population group with the highest risk estimate. The population subgroup with the highest dietary exposure is all infants (<1 year old), with an exposure of 0.016275 mg/kg/day at 3.5% of the cPAD. As there are no anticipated long-term residential exposures based on the explanation in Unit III.C.3., the chronic aggregate assessment is equivalent to the chronic dietary assessment.

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

Florylpicoxamid is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to florylpicoxamid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 2,200 for adults and 2,900 for youth (11 to <16 years). Dermal exposures only are anticipated while golfing on treated turf. Because EPA's level of concern for florylpicoxamid is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there are no residential exposure scenarios which are expected to be intermediate-term, florylpicoxamid is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, florylpicoxamid is not expected to pose a cancer risk to humans.

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 florylpicoxamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has proposed a multi-residue method (quick, easy, cheap, effective, rugged and safe; QuEChERS; JRFA Method No. AU298R0) for the determination of florylpicoxamid in plant and livestock commodities.

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 MRLs for florylpicoxamid.

C. Response to Comments

Two comments were received in response to the October 27, 2020, notice of filing. One comment was from Sheryl Kunickis, Ph.D., Director at the United States Department of Agriculture in support of the petition, discussing reported efficacy of florylpicoxamid, describing it as having ''excellent foliar uptake and redistribution properties on dicot and monocot plants, as well as excellent curative reachback activity'' and being ''highly active against a broad spectrum of diseases''. Dr. Kunickis discussed the benefits of florylpicoxamid as a novel mode of action with no cross resistance and states ''[b]ased on its reported efficacy and novel mode of action, USDA believes that florylpicoximide [*sic*] demonstrates potential to serve as a beneficial new tool for U.S. growers.'' The Agency appreciates the supportive comments from Dr. Kunickis, and one additional Anonymous commenter, and is moving forward with issuing the tolerance.

D. Revisions to Petitioned-For Tolerances

Based on EPA's review of the data supporting the petition, EPA is establishing tolerances that vary from what the petitioner requested under its authority in FFDCA section 408(d)(4)(A)(i). Some commodity terms are altered to be consistent with Agency nomenclature and to reflect the crop group definition updates from 2022. EPA is not establishing tolerances on barley, bran; beet, sugar, dried pulp; wheat, aspirated grain fractions; and wheat, bran. The Agency determined that the residue of concern is parent only and parent did not concentrate in these processed commodities. Therefore, separate tolerances are not required as they are covered by the tolerances on the associated raw agricultural commodities.

EPA is removing the plant metabolite X12485649 as a residue of concern for tolerance enforcement for plants. Both parent and metabolite X12485649 were the major residues in plant metabolism studies, and both were found in quantifiable amounts in magnitude of the residue for crops. Residues of parent florylpicoxamid would be sufficient to detect misuse and serve as the residue

of concern for tolerance enforcement for plants. Therefore, the tolerance expression for plant commodities is parent only.

To support the updated 2022 crop group definitions, EPA updated the crop commodity definitions by changing pea and bean, dried shelled, except soybean, subgroup 6C to vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E and vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F; and pea, dried shelled, vines and pea, dried shelled, hay to vegetable, legume, forage and hay, except soybean, subgroup 7–22A. EPA also corrected the commodity definitions by changing poultry, muscle to poultry, meat, and beet, sugar, tops to beet, sugar, leaves. To align with the labeled uses, the Agency is not establishing tolerances on the full rapeseed subgroup 20A and is instead establishing a tolerance only on canola.

EPA is establishing tolerance levels lower than what the petitioner requested for barley, grain corrected to 0.03 ppm, barley, hay to 1.5 ppm, barley, straw to 0.5 ppm, beet, sugar, leaves to 0.1 ppm, beet, sugar, roots to 0.01 ppm, vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E to 0.01 ppm, vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F to 0.01 ppm, vegetable, legume, forage and hay, except soybean, subgroup 7–22A to 6 ppm, rapeseed subgroup 20A to 0.015 ppm, wheat, forage to 1.5 ppm, wheat, grain to 0.01 ppm, wheat, hay to 3 ppm, and wheat, straw to 0.05 ppm. This corrects for the plant residue of concern for tolerance expression being the florylpicoxamid parent compound only.

V. Conclusion

Therefore, tolerances are established for residues of florylpicoxamid, (1*S*)-2,2-bis(4-fluorophenyl)-1-methylethyl *N*-[[3-(acetyloxy)-4-methoxy-2-pyridinyl]carbonyl]-L-alaninate, in or on barley, grain at 0.03; barley, hay at 1.5; barley, straw at 0.5; beet, sugar, leaves at 0.1; beet, sugar, roots at 0.01; vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E at 0.01; vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F at 0.01; vegetable, legume, forage and hay, except soybean, subgroup 7–22A at 6; canola at 0.015; wheat, forage at 1.5; wheat, grain at 0.01; wheat, hay at 3; wheat, straw at 0.05 ppm. Tolerances are established for residues of florylpicoxamid, (1*S*)-2,2-bis(4-fluorophenyl)-1-methylethyl *N*-[[3-(acetyloxy)-4-methoxy-2-pyridinyl]carbonyl]-L-alaninate, and its metabolite, (2*S*)-1,1-bis(4-fluorophenyl)propan-2-yl *N*-[(3-hydroxy-4-methoxypyridin-2-yl)carbonyl]-L-alaninate, in or on cattle, fat at 0.02; cattle, meat at 0.02; cattle, meat byproducts at 0.02; egg at 0.02; goat, fat at 0.02; goat, meat at 0.02; goat, meat byproducts at 0.02; hog, fat at 0.02; hog, meat at 0.02; hog, meat byproducts at 0.02; horse, fat at 0.02; horse, meat at 0.02; horse, meat byproducts at 0.02; milk at 0.02; poultry, fat at 0.02; poultry, liver at 0.02; poultry, meat at 0.02; sheep, fat at 0.02; sheep, meat at 0.02; sheep, meat byproducts at 0.02 ppm.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/regulations/and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 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.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.,* because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

Since tolerance actions 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 RFA, 5 U.S.C. 601 *et seq.,* do not apply to this action.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or on the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because tolerance actions like this one are exempt from review under Executive Order 12866.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. 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: May 22, 2025.

Edward Messina,

Office Director, Office of Pesticide Programs.

For the reasons set forth 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. Add § 180.727 to subpart C to read as follows:

§ 180.727 Florylpicoxamid; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of florylpicoxamid, including its metabolites and degradates, in or on the commodities in table 1 to this paragraph (a)(1). Compliance with the tolerance levels specified in table 1 is to be determined by measuring only florylpicoxamid ((1*S*)-2,2-bis(4-fluorophenyl)-1-methylethyl *N*-[[3-(acetyloxy)-4-methoxy-2-pyridinyl]carbonyl]-L-alaninate) in or on the commodity.

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Barley, grain	0.03
Barley, hay	1.5
Barley, straw	0.5
Beet, sugar, leaves	0.1
Beet, sugar, roots	0.01
Canola	0.015
Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E	0.01
Vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F	0.01
Vegetable, legume, forage and hay, except soybean, subgroup 7–22A	6
Wheat, forage	1.5
Wheat, grain	0.01
Wheat, hay	3
Wheat, straw	0.05

(2) Tolerances are established for residues of florylpicoxamid, including its metabolites and degradates, in or on the commodities in table 2 to this paragraph (a)(2). Compliance with the tolerance levels specified in table 2 is to be determined by measuring only the sum of florylpicoxamid ((1*S*)-2,2-bis(4-fluorophenyl)-1-methylethyl *N*-[[3-(acetyloxy)-4-methoxy-2-pyridinyl]carbonyl]-L-alaninate) and its metabolite (2*S*)-1,1-bis(4-fluorophenyl)propan-2-yl *N*-[(3-hydroxy-4-methoxypyridin-2-yl)carbonyl]-L-alaninate, calculated as the stoichiometric equivalent of florylpicoxamid, in or on the commodity.

TABLE 2 TO PARAGRAPH (a)(2)

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat	0.02
Cattle, meat byproducts	0.02
Egg	0.02
Goat, fat	0.02
Goat, meat	0.02
Goat, meat byproducts	0.02
Hog, fat	0.02
Hog, meat	0.02
Hog, meat byproducts	0.02
Horse, fat	0.02
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.02
Poultry, fat	0.02
Poultry, liver	0.02
Poultry, meat	0.02
Sheep, fat	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.02

(b)–(d) [Reserved]

[FR Doc. 2025–09679 Filed 5–28–25; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 460

[CMS–4208–CN]

RIN 0938–AV40

Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule; correction.

SUMMARY: This document corrects technical errors in the final rule that appeared in the April 15, 2025 **Federal Register**, titled ''Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.''

DATES: *Effective date:* This correcting document is effective May 29, 2025.

FOR FURTHER INFORMATION CONTACT: Lucia Patrone, (410) 786–8621—General Questions.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2025–06008 of April 15, 2025 (90 FR 15792), there were a few technical and typographical errors that are identified and corrected in this correcting document. The corrections in this correcting document are applicable to the effective date beginning June 3, 2025, as if they had been included in the document that appeared in the April 15, 2025, **Federal Register**.

II. Summary of Errors

On page 15899, we made an error in the CMS identification number of a collection of information request.

On page 15903, we made errors in Table 11 which provides the summary of the transfers and costs for the final rule. For the entry regarding costs, we made errors in the first year and year range of the costs.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Specifically, 5 U.S.C. 553 requires the agency to publish a notice of the proposed rule in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Further, 5 U.S.C. 553 requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment on a proposed rule. Similarly, section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment for rulemaking to carry out the administration of the Medicare program under title XVIII of the Act. In addition, section 553(d) of the APA, and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date APA requirements. In cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act also provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process are impracticable, unnecessary, or contrary to the public interest. In addition, both section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in the effective date where such delay is contrary to the public interest and an agency includes a statement of support.

We believe that this correcting document does not constitute a rule that would be subject to the notice and comment or delayed effective date requirements of the APA or section 1871 of the Act. This correcting document corrects typographical and technical errors in the preamble of the final rule but does not make substantive changes to the policies that were adopted in the final rule. As a result, this correcting document is intended to ensure that the information in the final rule accurately reflects the policies adopted in that final rule.

In addition, even if this were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the regulatory text correction in this document into the final rule or delaying the effective date would be unnecessary, as we are not altering our policies or regulatory changes, but rather, we are simply implementing the policies and regulatory changes that we previously proposed, requested comment on, and subsequently finalized.

This final rule correcting document is intended solely to ensure that the final rule accurately reflects policies and regulatory changes that have been adopted through rulemaking. Furthermore, such notice and comment procedures would be contrary to the public interest because it is in the public's interest to ensure that the final rule accurately reflects our policies. Therefore, we believe we have good cause to waive the notice and comment and effective date requirements.

IV. Correction of Errors

In FR Doc. 2025–06008 of April 15, 2025 (90 FR 15792), make the following corrections:

1. On page 15899, second column, third full paragraph, lines 4 and 5, the parenthetical reference ''(CMS–10662)'' is corrected to read ''(CMS–10062)''.

2. On page 15903, top half of the page, in the table titled ''Table 11—Summary of the Transfers and Costs of the Final Rule by Provision and Year'', the fourth row (COSTS),

a. Second column, the year ''2026'' is corrected to read ''2025''.

b. Last column, the years ''2026–2035'' are corrected to read ''2025–2034''.

Cortney L. McCormick,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2025–09695 Filed 5–28–25; 8:45 am]

BILLING CODE 4120–01–P