

Point and partly bare at low water. This part of the reef is not covered at low water and lies on the northeast side of a true northwest-and-southeast line that is located 300 feet true southwest from the center of the concrete pier of Lewis Reef Light (Approx. Long. 131°44' 1/2' W, Lat. 55°22' 25" N).

(N) Lyman Point and Clarence Strait are shown on the U.S. Coast and Geodetic Survey, Chart No. 8076—Sheet No. 8. The reference location is marked as 73 south, 86 east, CRM, SEC 13, on a map labeled as USS 2174 TRC. It begins at a point at the low-water mark. The aforementioned point is 300 feet in a direct line easterly from Lyman Point light; thence due south 300 feet; thence due west to a low-water mark 400 feet, more or less; thence following the winding of the low-water mark to place of beginning (Approx. Long. 132°18' W, Lat. 35°35' N).

(O) Narrow Point, Clarence Strait, and Prince of Wales Island are shown on the U.S. Coast and Geodetic Survey Chart No. 8100—Sheet No. 9. The reference location is marked as 70 south, 84 east, CRM, on a map labeled as USS 1628. The point begins at a point on a low-water line about 1 nautical mile southerly from Narrow Point Light, from which point a left tangent to a high-water line of an islet about 500 yards in diameter and about 300 yards off shore, bears south 30° true East; thence north 30° W, true 7,600 feet; thence N 60° E, 3,200 feet, more or less to an intersection with a low-water line; thence southeasterly, southerly, and southwesterly, following the winding of the low-water line to the point of the beginning. The map includes all adjacent rocks not covered at low water (Approx. Long. 132°28' W, Lat. 55°47' 1/2' N).

(P) Niblack Point, Cleveland Peninsula, and Clarence Strait, Alaska, are shown on the U.S. coast and Geodetic Survey Chart No. 8102—Sheet No. 6, which is the same sheet used for Caamano Point. The location begins at a point on a low-water line from which Niblack Point Beacon, a tripod anchored to three concrete piers, bears southeasterly and is 1,520 feet in a direct line; thence true northeast 1,520 feet; thence true southeast 3,040 feet; thence true southwest at 600 feet, more or less, to an intersection with a low-water line; thence northwesterly following the windings of the low-water line to the point of the beginning (Approx. Long. 132°07' W, Lat. 55°33' N).

(Q) Rosa Reef and Tongass Narrows are shown on the U.S. Coast and Geodetic Survey Chart No. 8094—Sheet No. 71. The reference location is marked

as 74 south, 90 east, CRM, SEC 31. That part of the reef is not covered at low water and lies east of a true north-and-south line, located 600 feet true west from the center of the concrete pier of Rosa Reef Light. The reef is covered at high water (Approx. Long. 131°48' W, Lat. 55°24' 15" N).

(R) Ship Island and Clarence Strait are shown on the U.S. Coast and Geodetic Survey Chart No. 8100—Sheet No. 9. The reference location is marked as south, 8 east, CRM, SEC 27. The point begins as a small island on the northwesterly side of the Clarence Strait, about 10 nautical miles northwesterly from Caamano Point and 1/4 mile off the shore of Cleveland Peninsula. The sheet includes all adjacent islets and rocks not connected to the main shore and not covered at low water (Approx. Long. 132°12' W, Lat. 55°36' N).

(S) Spire Island Reef and Revillagigedo Channel are shown on the U.S. Coast and Geodetic Survey Chart No. 8075—Sheet No. 3. The reference location is marked as 76 south, 92 east, CRM, SEC 19. The detached reef, covered at high water and partly bare at low water, is located northeast of Spire Island. Spire Island Light is located on the reef and consists of small houses and lanterns surmounting a concrete pier. See chart for "Angle Pt." (Approx. Long. 131°30' W, Lat. 55°16' N).

(T) Surprise Point and Nakat Inlet are shown on the U.S. Coast and Geodetic Survey Chart No. 8051—Sheet No. 1. The reference location is marked as 80 south, 89 east, CRM. This point lies north of a true east-and-west line. The true east-and-west line lies 3,040 feet true south from the northernmost extremity of the point together with adjacent rocks and islets (Approx. Long. 130°44' W, Lat. 54°49' N).

(U) Caamano Point, Cleveland Peninsula, and Clarence Strait, Alaska, are shown on the U.S. Coast and Geodetic Survey Chart No. 8102—Sheet No. 6. Location consists of everything apart of the extreme south end of the Cleveland Peninsula lying on a south side of a true east-and-west line that is drawn across the point at a distance of 800 feet true north from the southernmost point of the low-water line. This includes off-lying rocks and islets that are not covered at low water (Approx. Long. 131°59' W, Lat. 55°30' N).

(V) Meyers Chuck and Clarence Strait, Alaska, are shown on the U.S. and Geodetic Survey Chart No. 8124—Sheet No. 26. The small island is about 150 yards in diameter and located about 200 yards northwest of Meyers Island

(Approx. Long. 132°16' W, Lat. 55°44' 1/2' N).

(W) Round Island and Cordova Bay, Alaska, are shown on the U.S. coast and Geodetic Survey Chart No. 8145—Sheet No. 36. The Southwestern Island of the group is about 700 yards long, including off-lying rocks and reefs that are not covered at low water (Approx. Long. 132°30' 1/2' W, Lat. 54°46' 1/2' N).

(X) Mary Island begins at a point that is placed at a low-water mark. The aforementioned point is southward 500 feet from a crosscut on the side of a large rock on the second point below Point Winslow and Mary Island; thence due west 3/4 mile, statute; thence due north to a low-water mark; thence following the winding of the low water to the place of the beginning (Approx. Long. 131°11' 00" W, Lat. 55°05' 55" N).

(Y) Tree Point starts a point of a low-water mark. The aforementioned point is southerly 1/2 mile from extreme westerly point of a low-water mark on Tree Point, on the Alaska Mainland; thence due true east, 3/4 mile; thence due north 1 mile; thence due west to a low-water mark; thence following the winding of the low-water mark to the place of the beginning (Approx. Long. 130°57' 44" W, Lat. 54°48' 27" N).

* * * * *

Dated: April 20, 2018.

David E. Schmid,

Acting Regional Forester, USDA—Forest Service.

Dated: May 15, 2018.

David L. Bernhardt,

Deputy Secretary, Fish and Wildlife Service.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0035; FRL–9977–13]

Clopyralid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clopyralid in or on multiple commodities which are identified and discussed later in this document. In addition, it removes certain previously established tolerances that are superseded by this final rule. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 23, 2018. Objections and requests for hearings must be received on or before July 23, 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-2017-0035, 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, 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: RDFFRNotices@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-2017-0035 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 23, 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-2017-0035, 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 June 8, 2017 (82 FR 26641) (FRL-9961-14), 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 6E8528) by IR-4 Project Headquarters, 500 College Road East, Suite 201W, Princeton, New Jersey 08540. The petition requested that 40

CFR part 180 be amended by establishing tolerances for residues of the herbicide, clopyralid, (3,6-dichloro-2-pyridinecarboxylic acid), in or on berry, low growing, subgroup 13-07G at 4.0 parts per million (ppm); berry, low growing, except strawberry, subgroup 13-07H at 4.0 ppm; *brassica*, leafy greens, subgroup 4-16B at 5.0 ppm; fruit, pome, group 11-10 at 0.05 ppm; fruit, stone, group 12-12 at 0.5 ppm; radish, roots at 0.3 ppm; stalk and stem vegetable subgroup 22A at 1.0 ppm; vegetable, *brassica*, head and stem, group 5-16 at 2.0 ppm; and vegetable, leaves of root and tuber, group 2 at 5.0 ppm. Additionally, upon establishment of the above new tolerances, the petitioner requests to amend 40 CFR 180.431 by removing the established tolerances for clopyralid in or on apple at 0.05 ppm, asparagus at 1.0 ppm, beet, garden, tops at 3.0 ppm, beet, sugar, tops at 3.0 ppm, *brassica*, head and stem, subgroup 5A at 2.0 ppm, *brassica*, leafy greens, subgroup 5B at 5.0 ppm, canola, seed at 3.0 ppm, cranberry at 4.0 ppm, fruit, stone, group 12 at 0.5 ppm, strawberry at 4.0 ppm, and turnip, greens at 4.0 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to that comment is discussed in Unit IV.C.

Consistent with the authority in FFDCA 408(d)(4)(A)(i), EPA is issuing tolerances that vary from what the petitioner sought. The reasons for these changes are explained in Unit IV.D.

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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.

Clopyralid has low acute toxicity via the dermal, oral, and inhalation routes of exposure. It is not a dermal irritant or sensitizer, but it is a severe eye irritant in its acid form.

Toxicity was observed in the mouse after subchronic and chronic exposure and the rat and dog after chronic exposure, but consistent target organs were not identified. In dogs, reductions in red blood cell parameters, increased liver weight, and vacuolated adrenal cortical cells were observed, with skin lesions and clinical chemistry changes at the highest dose. In rats, stomach lesions were observed at the lowest-observed-adverse-effects level (LOAEL), and decreased body weight was observed at the high dose. In mice, the only observed effects were decreased body weight/body weight gain. No systemic toxicity was seen in a rabbit

21-day dermal toxicity study. The available toxicology studies did not indicate the potential for neurotoxicity, immunotoxicity or reproductive toxicity.

The available database does not show evidence of increased qualitative or quantitative pre- and/or post-natal susceptibility in the available developmental or 2-generation reproduction toxicity studies. No developmental toxicity was observed in the rat at doses that caused maternal mortality. In the developmental study in the rabbit, decreased fetal body weight and hydrocephalus were observed, but only at a dose that caused significant maternal toxicity, including mortality, clinical signs of toxicity, and gastric mucosal lesions. Reproductive toxicity was not observed in the rat, but mean pup weights (day 28) were reduced, and relative pup liver weights were increased at doses that caused parental toxicity (decreased body weight/weight gain and food consumption; gastric lesions).

There were no direct clinical or histopathological indications of neurotoxicity in the available studies at doses up to or exceeding the limit dose. Hydrocephalus was observed in the young in the rabbit developmental study, but only in the presence of significant maternal toxicity, including a high rate of mortality.

Clopyralid is classified as “not likely to be carcinogenic to humans,” based on the lack of treatment-related tumors in the rat and mouse carcinogenicity studies, and negative results of the genotoxicity assays.

Specific information on the studies received and the nature of the adverse effects caused by clopyralid as well as the no-observed-adverse-effect-level (NOAEL) and LOAEL from the toxicity studies can be found at <http://www.regulations.gov> in document

SUBJECT: Clopyralid. Aggregate Human Health Risk Assessment to Support Proposed New Uses on Pome Fruit Group 11–10 and Radish Roots, Along with Various Crop Group/Subgroup Conversions and Expansions at pages 31–35 in docket ID number EPA–HQ–OPP–2017–0035.

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 the NOAEL and the LOAEL are identified. 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 clopyralid used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CLOPYRALID FOR USE IN HUMAN HEALTH RISK ASSESSMENT

| Exposure/scenario | Point of departure and uncertainty/safety factors | RfD, PAD, LOC for risk assessment | Study and toxicological effects |
|---|---|---|---|
| Chronic dietary (All populations) | NOAEL= 15 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x | Chronic RfD = 0.15 mg/kg/day cPAD = 0.15 mg/kg/day | 2-Year Combined Chronic Toxicity-Carcinogenicity (oral)—rat. LOAEL = 150 mg/kg/day, based on increased epithelial hyperplasia and thickening of the limiting ridge of the stomach in both sexes. |
| Incidental oral short-term (1 to 30 days) | NOAEL= 75 mg/kg/day | Residential LOC for MOE = <100. | Developmental Toxicity (oral)—rat. Maternal LOAEL = 250 mg/kg/day, based on mortality. |

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CLOPYRALID FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

| Exposure/scenario | Point of departure and uncertainty/safety factors | RfD, PAD, LOC for risk assessment | Study and toxicological effects |
|--|---|-----------------------------------|---|
| Inhalation short-term (1 to 30 days) | Inhalation (or oral) study NOAEL = 75 mg/kg/day (inhalation absorption rate = 100%). UF _A = 10x UF _H = 10x FQPA SF = 1x | Residential LOC for MOE = <100. | Developmental Toxicity (oral)—rat. Maternal LOAEL = 250 mg/kg/day, based on mortality. |
| Cancer (Oral, dermal, inhalation) routes | "Not likely to be carcinogenic to humans." | | |

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to clopyralid, EPA considered exposure under the petitioned-for tolerances as well as all existing clopyralid tolerances in 40 CFR 180.431. EPA assessed dietary exposures from clopyralid 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 clopyralid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) which incorporates consumption data from the United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA) conducted from 2003 to 2008. As to residue levels in food, the chronic dietary exposure assessment was based on tolerance-level residues, and assumed that 100 percent (PCT) of all crops were treated.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that clopyralid 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.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for clopyralid. Tolerance level residues

and 100 PCT 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 clopyralid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of clopyralid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Pesticide Water Calculator Version 1.52 (PWC) model, the estimated drinking water concentrations (EDWCs) of clopyralid for chronic exposures for non-cancer assessments are estimated to be 5.43 parts per billion (ppb) for surface water and 38.1 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 value of 38.1 ppb was used to assess the contribution from 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).

Clopyralid is currently registered for the following uses that could result in residential exposures: Weed control on lawns, turf and ornamentals in residential and public areas. EPA assessed residential exposure using the following assumptions: Residential handler exposures are not expected since the residential uses require that handlers wear specific clothing (e.g., long-sleeved shirt and long pants; shoes

plus socks) and/or personal protective equipment (e.g., gloves). As a result, a residential handler assessment was not conducted. Short-term post-application exposure is anticipated for children from incidental oral contact with treated turf (hand-to-mouth, object-to-mouth and soil ingestion). Post-application dermal exposure is also anticipated from residential use of clopyralid. However, systemic toxicity via the dermal route of exposure is not expected for clopyralid. Therefore, dermal risks were not quantitatively assessed for residential exposure.

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 clopyralid to share a common mechanism of toxicity with any other substances, and clopyralid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that clopyralid does not have a common mechanism of toxicity with other substances.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of

safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased qualitative or quantitative sensitivity/susceptibility in the developing or young animal. In the rat developmental toxicity study, no developmental toxicity was observed at a maternally toxic dose. In the rat 2-generation reproductive toxicity study, decreased pup weight (post-natal day 28), and increased relative liver weights were observed at the parental LOAEL. Hydrocephalus and decreased mean fetal weight were observed in the rabbit developmental study, but at a dose that also caused significant maternal toxicity, including mortality; therefore, quantitative or qualitative developmental susceptibility was not observed for clopyralid.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the Food Quality Protection Act Safety Factor Safety Factor (FQPA SF) were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for clopyralid is considered complete and no additional studies are required at this time.

ii. There are no clinical or micropathological indications of neurotoxicity in the available subchronic and chronic studies in multiple species. Hydrocephalus was observed in fetuses in the rabbit developmental study, but only at a high dose that resulted in significant maternal toxicity, including mortality. There is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no evidence that clopyralid results in increased susceptibility *in utero* in 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 dietary and residential exposure databases. EPA conducted the

chronic dietary food exposure assessment based on 100 PCT, tolerance-level residues of clopyralid, and default processing factors, where applicable. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to clopyralid 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 clopyralid.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, clopyralid 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 clopyralid from food and water will utilize 26% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of clopyralid is not expected.

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). Several clopyralid products are 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 clopyralid.

Using the exposure assumptions described in this unit for short-term exposures and data results from a most recent previous EPA assessment of

residential exposure, the Agency combined food, water, and short-term residential exposures result in aggregate MOEs of 1600 for children. Because EPA's level of concern (LOC) for clopyralid is an 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). An intermediate-term adverse effect was identified; however, clopyralid is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk aggregate 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 clopyralid.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, clopyralid 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 clopyralid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The Pesticide Analytical Manual Volume II (PAM II) lists a method utilizing gas chromatography with electron capture detection (GC/ECD) for determination of clopyralid residues in plant commodities (Method I or Method ACR 75.6).

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 clopyralid residues on any commodities for which tolerances are established in this rule.

C. Response to Comments

One comment to the Notice of Filing was received from an anonymous commenter that stated, in part, that no clopyralid (pesticide) residue should be allowed on food crops.

EPA's Response: The Agency recognizes that some individuals believe that pesticides should not be allowed on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) 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. This commenter's statements appear to be directed at the underlying statute and not EPA's implementation of it; the commenter has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-For Tolerances

EPA is establishing individual tolerances in kohlrabi and broccoli, chinese as they were part of subgroup 5A, but not included in expansion crop group 5–16 for which a tolerance is being established by this action.

EPA is not establishing the petitioned-for tolerance for Berry, low growing, except strawberry, subgroup 13–07H because it is not necessary. All commodities in subgroup 13–07H, plus strawberry, are included in subgroup 13–07G.

In accordance with its standard practice to provide greater precision about the levels of residues that are permitted by a tolerance, EPA is adding an additional significant figure to the

petitioned-for tolerance values for the following commodities: Fruit, stone, group 12–12 from 0.5 to 0.50 ppm and radish, roots from 0.3 to 0.30. This is to avoid the situation where residues may be higher than the tolerance level, but as a result of rounding would be considered non-violative (for example, radish, roots proposed at 0.3 ppm was established at 0.30 ppm, to avoid an observed hypothetical tolerance at 0.34 ppm being rounded to 0.3 ppm).

V. Conclusion

Therefore, tolerances are established for residues of clopyralid, (3,6-dichloro-2-pyridinecarboxylic acid), in or on Berry, low growing, subgroup 13–07G at 4.0 ppm; *Brassica*, leafy greens, subgroup 4–16B at 5.0 ppm; broccoli, Chinese at 2.0 ppm; fruit, pome, group 11–10 at 0.05 ppm; fruit, stone, group 12–12 at 0.50 ppm; kohlrabi at 2.0 ppm; radish, roots at 0.30 ppm; stalk and stem vegetable subgroup 22A at 1.0 ppm; vegetable, *Brassica*, head and stem, group 5–16 at 2.0 ppm; and vegetable, leaves of root and tuber, group 2 at 5.0 ppm. In addition, established tolerances in or on “apple”; “asparagus”; “beet, garden, tops”; “beet, sugar, tops”; “*Brassica*, head and stem, subgroup 5A”; “*Brassica*, leafy greens, subgroup 5B”; “canola, seed”; “cranberry”; “fruit, stone, group 12”; “strawberry”; and “turnip, greens” are removed as they are superseded by this final tolerance rule.

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); 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: April 30, 2018.

Daniel Rosenblatt,

Acting 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. Amend the table in § 180.431(a) as follows:

■ a. Add alphabetically the entries for “Berry, low growing, subgroup 13–07G”; “*Brassica*, leafy greens, subgroup 4–16B”; “Broccoli, Chinese”; “Fruit, pome, group 11–10”; “Fruit, stone, group 12–12”; “Kohlrabi”; “Radish, roots”; “Stalk and stem vegetable subgroup 22A”; “Vegetable, *Brassica*, head and stem, group 5–16”; and “Vegetable, leaves of root and tuber, group 2”.

■ b. Remove the entries for “Apple”; “Asparagus”; “Beet, garden, tops”; “Beet, sugar, tops”; “*Brassica*, head and stem, subgroup 5A”; “*Brassica*, leafy greens, subgroup 5B”; “Canola, seed”; “Cranberry”; “Fruit, stone, group 12”; “Strawberry”; and “Turnip, greens”.

The additions read as follows:

§ 180.431 Clopyralid; Tolerances for residues.

(a) * * *

| Commodity | Parts per million |
|--|-------------------|
| Berry, low growing, subgroup 13–07G | 4.0 |
| <i>Brassica</i> , leafy greens, subgroup 4–16B | 5.0 |
| Broccoli, Chinese | 2.0 |
| Fruit, pome, group 11–10 | 0.05 |
| Fruit, stone, group 12–12 | 0.50 |
| Kohlrabi | 2.0 |
| Radish, roots | 0.30 |
| Stalk and stem vegetable subgroup 22A | 1.0 |

| Commodity | Parts per million |
|--|-------------------|
| Vegetable, <i>Brassica</i> , head and stem, group 5–16 | 2.0 |
| Vegetable, leaves of root and tuber, group 2 | 5.0 |

[FR Doc. 2018–10693 Filed 5–22–18; 8:45 am]
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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 120919470–3513–02]

RIN 0648–XG231

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Shrimp Fishery Off the Southern Atlantic States; Reopening of the Penaeid Shrimp Fishery Off Georgia

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reopening.

SUMMARY: NMFS reopens the exclusive economic zone (EEZ) off Georgia in the South Atlantic to trawling for penaeid shrimp, *i.e.*, for brown, pink, and white shrimp. NMFS previously closed penaeid shrimp trawling in the EEZ off Georgia on January 24, 2018. The reopening is intended to maximize harvest benefits while protecting the penaeid shrimp resource.

DATES: The reopening is effective at 12:01 a.m., local time, May 18, 2018, until the effective date of a notification of a closure which will be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Frank Helies, 727–824–5305; email: Frank.Helies@noaa.gov.

SUPPLEMENTARY INFORMATION: Penaeid shrimp in the South Atlantic are managed under the Fishery Management Plan for the Shrimp Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council (Council) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

Under 50 CFR 622.206(a), NMFS may close the EEZ adjacent to South Atlantic states that have closed their waters to the harvest of brown, pink, and white shrimp to protect the white shrimp spawning stock that has been severely depleted by cold weather or when applicable state water temperatures are 9 °C (48 °F), or less, for at least 7 consecutive days. Consistent with those procedures and criteria, after determining that unusually cold temperatures resulted in water temperatures of 9 °C (48 °F), or less, for at least 7 consecutive days in its state waters, the state of Georgia closed its waters on January 15, 2018, to the harvest of brown, pink, and white shrimp. Georgia subsequently requested that NMFS implement a concurrent closure of the EEZ off Georgia.

NMFS determined that Georgia’s request for an EEZ closure conformed with the procedures and criteria specified in the FMP and the Magnuson-Stevens Act, and, therefore, implemented the concurrent EEZ closure effective as of January 24, 2018 (83 FR 3404, January 25, 2018).

During the closure, as specified in 50 CFR 622.206(a)(2), no person could: (1) Trawl for brown, pink, or white shrimp in the EEZ off Georgia; (2) possess on board a fishing vessel brown, pink, or white shrimp in or from the EEZ off Georgia unless the vessel is in transit through the area and all nets with a mesh size of less than 4 inches (10.2 cm) are stowed below deck; or (3) for a vessel trawling within 25 nautical miles of the baseline from which the territorial sea is measured, use or have on board a trawl net with a mesh size less than 4 inches (10.2 cm), as measured between the centers of opposite knots when pulled taut.

The FMP and implementing regulations at 50 CFR 622.206(a) state that: (1) The closure will be effective until the ending date of the closure in the state waters, but may be ended earlier based on the state’s request; and (2) if the closure is ended through a state’s request, NMFS will terminate the closure of the EEZ by filing a notification to that effect with the Office of the Federal Register. On May 16, 2018, the state of Georgia requested the EEZ be reopened as soon as possible, based on their biological sampling. The state of Georgia is continuing its monitoring of both water conditions and the penaeid shrimp population in state waters but has not yet determined when the state waters reopening will occur. Therefore, NMFS publishes this notification to reopen the EEZ off Georgia to the harvest of brown, pink,