FIRE SUPPRESSION AND EXPLOSION PROTECTION SECTOR—ACCEPTABLE SUBJECT TO NARROWED USE LIMITS

End-Use	Substitute	Decision	Conditions	Further information
Streaming	C7 Fluoroketone as a substitute for Halon 1211.	Acceptable subject to narrowed use limits.	For use only in non-residential applications.	Use of this agent should be in accordance with the latest edition of NFPA Standard 10 for Portable Fire Extinguishers. For operations that fill canisters to be used in streaming applications, EPA recommends the following: —Adequate ventilation should be in place; —All spills should be cleaned up immediately in accordance with good industrial hygiene practices; and —Training for safe handling procedures should be provided to all employees that would be likely to handle containers of the agent or extinguishing units filled with the agent. See additional comments 1, 2, 3, 4.

Additional comments:
1—Should conform to relevant OSHA requirements, including 29 CFR 1910, Subpart L, Sections 1910.160 and 1910.162.
2—Per OSHA requirements, protective gear (SCBA) should be available in the event personnel should reenter the area.
3—The agent should be recovered from the fire protection system in conjunction with testing or servicing, and recycled for later use or destroyed.
4—EPA has no intention of duplicating or displacing OSHA coverage related to the use of personal protective equipment (e.g., respiratory protection), fire protection, hazard communication, worker training or any other occupational safety and health standard with respect to halon substitutes.

[FR Doc. 2012–23138 Filed 9–18–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0569; FRL–9361–5]

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. This regulation additionally removes several established individual tolerances, as they will be superseded by inclusion in subgroup tolerances. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 19, 2012. Objections and requests for hearings must be received on or before November 19, 2012, 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–2011–0569, is available at *http://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, 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: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; email address: *Nollen.Laura@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. 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. 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://ecfr.gpoaccess.gov/cgi/t/text/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–2011–0569 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 November 19, 2012. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0569, 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

Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 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.htm.*

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 Tolerances

In the **Federal Register** of August 26, 2011 (76 FR 53372) (FRL–8884–9), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7882) by IR–4, 500 College Road East, Suite 201W., Princeton, NJ 08540. The petition requested that 40 CFR 180.431 be amended by establishing tolerances for residues of the herbicide clopyralid, (3,6-dichloro-2-pyridinecarboxylic acid), in or on apple at 0.05 parts per million (ppm); brassica, leafy greens, subgroup 5B at 5.0 ppm; rapeseed subgroup 20A, except gold of pleasure, seed at 3.0 ppm; rapeseed subgroup 20A, except gold of pleasure, meal at 6.0 ppm; and rapeseed subgroup 20A, except gold of pleasure, forage at 3.0 ppm. That notice referenced a summary of the petition prepared on behalf of IR–4 by Dow AgroSciences, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Additionally, in the **Federal Register** of July 25, 2012 (77 FR 43562) (FRL–9353–6), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8013) by IR–4. The petition requested that 40 CFR 180.431 be amended by establishing tolerances for residues of the herbicide clopyralid, (3,6-dichloro-2-pyridinecarboxylic acid), in or on teff, forage at 9.0 ppm; teff, grain at 3.0 ppm; teff, straw at 9.0 ppm; and teff, hay at 9.0 ppm. That notice referenced a summary of the petition prepared on behalf of IR–4 by Dow AgroSciences, the registrant, which is available in docket ID number EPA–HQ–OPP–2012–0309, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has determined that the proposed tolerance on rapeseed subgroup 20A, except gold of pleasure, forage is not necessary. Additionally, EPA has determined that several established tolerances should be removed. Finally, the Agency determined that the proposed tolerance on rapeseed subgroup 20A, except gold of pleasure, meal should be established as a tolerance on rapeseed, meal. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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 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.

Clopyralid has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not a dermal irritant or sensitizer, but it is a severe eye irritant in its acid form. No consistent mammalian target organ was identified in the clopyralid toxicological studies submitted to the Agency. Effects were noted in various organs and systems in different species, including increases in liver weight, changes in clinical chemistry and blood cell parameters, skin lesions, and decreases in body weight gain.

In subchronic mouse studies, decreased body weights were observed in males and females. Following chronic exposure, effects in dogs included reductions in red blood cell parameters, increased liver weight (males), and vacuolated adrenal cortical cells (females). Additionally, skin lesions and clinical chemistry changes (decreased serum glucose, protein, and albumin) were observed at the highest dose tested. In the rat, epithelial hyperplasia, thickening of the limiting ridge of the stomach, and decreased body weight were observed following chronic exposure. There were no clinical indications of neurotoxicity or immunotoxicity in the subchronic or chronic toxicity studies.

No developmental toxicity was observed in the rat at doses that caused maternal mortality and decreased body weight gains. In the rabbit developmental toxicity study, decreased fetal body weights and hydrocephalus were observed at a dose that caused severe maternal toxicity including a high rate of mortality, clinical signs of toxicity, decreased body weight gains, and gastric mucosal lesions. Reproductive toxicity was not observed in the rat, but mean pup weight reductions and relative liver weight increases were observed at doses that caused parental toxicity (decreased body weight/weight gain and food consumption and gastric lesions).

There was no evidence of carcinogenic potential in the rat and mouse 2-year carcinogenicity studies. Further, there were no positive findings for mutagenicity or clastogenicity observed in a battery of mutagenicity studies (including bacterial reverse gene mutation, *in vitro* and *in vivo* host-mediated assays in *Salmonella* and *Saccharomyces, in vivo* chromosomal aberrations, unscheduled DNA synthesis, and dominant lethal activity studies). Based on the results of these studies, EPA has determined that clopyralid is ''not likely to be carcinogenic to humans.''

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 the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document, ''Clopyralid. Human Health Risk Assessment for New Uses on Apples, Teff, Brassica Leafy Greens, and Rapeseed'' at pages 32–35 in docket ID number EPA–HQ–OPP–2011–0569.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for clopyralid used for human risk assessment is shown in Table 1 of this unit. EPA notes that in the last final rule for clopyralid, published in the **Federal Register** of March 24, 2010 (75 FR 14086) (FRL–8814–2), the Agency identified an acute dietary toxicological POD based on decreased maternal body weight in the rat developmental toxicity study. However, upon reevaluation of the toxicological database for clopyralid, EPA determined that the effect is not the result of a single dose, and is not appropriate for an acute dietary endpoint. Additionally, while the last final rule included endpoints and points of departure for intermediate-term residential scenarios, including postapplication incidental oral exposure for children, the Agency has reevaluated this scenario and has determined that for clopyralid, residential exposure to children on turf is not likely to occur over an intermediate-term duration (i.e., 1 month to 6 months). Further, intermediate-term exposures are not expected for residential handlers, based on the use pattern.

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
Acute dietary (Females 13–50 years of age and general population, including infants and children).	An appropriate endpoint for a single exposure was not identified.		
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 UF_A = 10x. UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity (oral)—rat LOAEL = 250 mg/kg/day based on decreased body weight gain and food consumption during gestation days 6–9.
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	LOC for MOE = 100	Developmental Toxicity (oral)—rat LOAEL = 250 mg/kg/day based on decreased body weight gain and food consumption during gestation days 6–9.
Cancer (Oral, dermal, inhalation).	''Not likely to be carcinogenic to humans.'' Cancer risk is not of concern.		

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 the food consumption data from the USDA 1994–1996 and 1998 Continuing Surveys of Food Intakes by

Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues, 100 percent crop treated (PCT) estimates, and DEEM™ ver. 7.81 default processing factors.

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 percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for clopyralid. Tolerance level residues or 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://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST) model, the estimated drinking water concentration (EDWC) of clopyralid for chronic exposures is estimated to be 11.9 parts per billion (ppb) for surface water. The Agency also considered available monitoring data from the United States Geological Survey (USGS) National Water Quality Assessment Data Warehouse (*http://water.usgs.gov/nawqa/*) for clopyralid. For ground water monitoring data, the peak observed value for detectable levels of clopyralid was 0.5288 ppb (Oregon) with a nationwide mean value of 0.065 ppb. Therefore, the EDWC of clopyralid for chronic exposures is estimated to be 0.5288 ppb for ground water.

For chronic dietary risk assessment, the water concentration of value 11.9 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).

Clopyralid is currently registered for use on lawns, turf, and ornamentals in residential and public areas, which could result in residential exposures. EPA assessed residential exposure using the following assumptions: Short-term inhalation exposure for adult residential handlers and short-term postapplication exposure for children from incidental oral contact with treated turf (hand-to-mouth, object-to-mouth and soil ingestion). Although dermal exposure is anticipated from residential use of clopyralid, risks via the dermal route of exposure are not of concern 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://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

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

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 prenatal and/or postnatal qualitative or quantitative susceptibility in the available studies in the toxicology database, including the rat and rabbit developmental toxicity studies and a 2-generation reproduction toxicity study in rats. In the developmental rat study, no developmental effects were seen at doses that caused maternal toxicity. In the rabbit developmental study, hydrocephalus and decreased mean fetal weight were observed at a dose that caused severe maternal toxicity, including mortality. In the 2-generation reproduction study, decreased pup weights and increased relative liver weights were observed at the same level that resulted in parental toxicity (decreased body weights, body weight gains and food consumption and slight focal hyperkeratotic changes in the gastric squamous mucosa).

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 clopyralid is complete. EPA has waived the requirement of a 28-day inhalation toxicity study in rats (OCSPP Guideline 870.3465) based on the low volatility and low acute inhalation toxicity for clopyralid, as well as the selection of conservative and adequately protective points of departure from oral studies for clopyralid. As the 28-day inhalation toxicity study was not required, oral studies were considered for use with route-to-route extrapolation for the short-term adult handler inhalation exposure assessment. For short-term inhalation exposure, the maternal toxicity NOAEL of 75 mg/kg/day from the rat developmental toxicity study was selected based on mortality, decreased maternal body weight gain, and decreased food consumption at the LOAEL of 250 mg/kg/day. This study was chosen because it was of the appropriate duration and route, and it provided the most sensitive NOAEL. This endpoint is protective of potential pre- and postnatal toxicity because developmental toxicity in the rabbit was only seen in the presence of significant maternal toxicity (maternal/developmental NOAEL = 250 mg/kg/day), and developmental toxicity in the rat was not observed up to a maternally toxic dose. As such, it is considered to be a conservative endpoint for this exposure scenario.

ii. In the rabbit developmental toxicity study, neuropathology (hydrocephalus) was observed at the highest dose tested. However, the concern for this effect is considered low because it occurred at a dose that caused severe maternal toxicity, including a

high rate of mortality and decreased body weight gain and food consumption. Further, there was no evidence of neurotoxicity in the rat developmental or reproduction studies or in the available subchronic or chronic studies; therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that clopyralid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment was performed based on 100 PCT and tolerance-level residues. 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 postapplication 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 25% 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). Clopyralid 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 clopyralid.

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 5,300 for the general population and 1,700 for children 1–2 years old. Because EPA's level of concern for clopyralid 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). 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 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 following adequate enforcement methodology is available in *The Pesticide Analytical Manual Vol. II* to enforce the tolerance expression for plant commodities: a gas chromatography/electron-capture detection (GC/ECD) method.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for clopyralid in or on the commodities associated with these petitions.

C. Revisions to Petitioned-for Tolerances

Based on the data supporting the petitions, EPA has determined that the proposed tolerance on rapeseed subgroup 20A, except gold of pleasure, forage at 3.0 ppm is not necessary because the commodity is not a significant livestock feed item. Additionally, the Agency has determined that the established tolerances in or on crambe, seed; flax, seed; mustard, seed; and rapeseed, seed should be removed because they are superseded by inclusion in rapeseed, subgroup 20A, except gold of pleasure at 3.0 ppm. EPA is also removing the established tolerance on mustard greens, as it is superseded by inclusion in brassica, leafy greens, subgroup 5B. Finally, the Agency determined that the proposed tolerance on rapeseed subgroup 20A, except gold of pleasure, meal at 6.0 ppm should be established on rapeseed, meal at 6.0 ppm. The EPA may establish an individual tolerance on a processed commodity that is a member of rapeseed subgroup 20A. However, the Agency will not establish a subgroup tolerance for processed foods prepared from crops covered by a group tolerance, as outlined in 40 CFR 180.40, paragraph (f). Therefore, a separate tolerance for the processed commodity is appropriate.

V. Conclusion

Therefore, tolerances are established for residues of clopyralid, (3,6-dichloro-

2-pyridinecarboxylic acid), in or on apple at 0.05 ppm; brassica, leafy greens, subgroup 5B at 5.0 ppm; rapeseed, subgroup 20A, except gold of pleasure at 3.0 ppm; rapeseed, meal at 6.0 ppm; teff, forage at 9.0 ppm; teff, grain at 3.0 ppm; teff, hay at 9.0 ppm; and teff, straw at 9.0 ppm. This regulation additionally removes established tolerances in or on crambe, seed; flax, seed; mustard greens; mustard, seed; and rapeseed, seed.

VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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 of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: September 10, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.431, paragraph (a) is amended by removing the commodities ''Crambe, seed''; ''Flax, seed''; ''Mustard greens''; ''Mustard, seed''; and ''Rapeseed, seed'' from the table and by adding, alphabetically, the following commodities to the table to read as follows:

§ 180.431 [Amended]

(a) * * *

Commodity	Parts per million
Apple	0.05
* * * * *	
Brassica, leafy greens, subgroup 5B	5.0
* * * * *	
Rapeseed, meal	6.0
Rapeseed, subgroup 20A, except gold of pleasure	3.0
* * * * *	
Teff, forage	9.0
Teff, grain	3.0
Teff, hay	9.0
Teff, straw	9.0
* * * * *	

* * * * *

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 32

Refuge-Specific Hunting and Sport Fishing Regulations

CFR Correction

§ 32.29 [Corrected]

■ In Title 50 of the Code of Federal Regulations, parts 18 to 199, revised as of October 1, 2011, on page 320, in § 32.29, under Savannah National Wildlife Refuge, the second paragraph A.1. is removed.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 32

Refuge-Specific Hunting and Sport Fishing Regulations

CFR Correction

§ 32.37 [Corrected]

■ In Title 50 of the Code of Federal Regulations, Parts 18 to 199, revised as of October 1, 2011, on page 345, in § 32.37, under Black Bayou Lake National Wildlife Refuge, the second paragraph B.1. and the second paragraph C.1. are removed.

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