

Dated: March 11, 2010.

**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 §180.910, in the table add alphabetically the following inert ingredient to read as follows:

**§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

| Inert ingredients                                                                                                                                                                                                        | Limits | Uses       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|------------|
| * * *                                                                                                                                                                                                                    | * *    | * *        |
| Ammonium salts of fatty acids (C <sub>8</sub> -C <sub>18</sub> saturated) (CAS Reg. No. 5972-76-9, 63718-65-0, 16530-70-4, 32582-95-9, 2437-23-2, 191799-95-8, 16530-71-5, 93917-76-1, 5297-93-8, 94266-36-1, 1002-89-7) | * *    | Surfactant |
| * * *                                                                                                                                                                                                                    | * *    | * *        |

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2009-0092; FRL-8814-2]

**Clopyralid; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of clopyralid in or on Swiss chard and bushberry subgroup 13-07B. This regulation additionally amends an existing tolerance in or on strawberry. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective March 24, 2010. Objections and requests

for hearings must be received on or before May 24, 2010, 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:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0092. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**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; e-mail address: [nollen.laura@epa.gov](mailto: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 cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/oppts> and select "Test Methods and Guidelines."

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 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-2009-0092 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before May 24, 2010.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2009-0092, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays).

Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## II. Petition for Tolerance

In the **Federal Register** of April 8, 2009 (74 FR 15971) (FRL-8407-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7481) 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 combined residues of the herbicide clopyralid, (3,6-dichloro-2-pyridinecarboxylic acid), in or on Swiss chard at 5.0 parts per million (ppm) and bushberry subgroup 13-07B at 6.0 ppm. This petition additionally requested that EPA establish a tolerance with regional restrictions in or on strawberry, annual at 4.0 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Dow AgroSciences, the registrant, which is available to the public in the docket, <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 revised the proposed tolerance levels on Swiss chard and bushberry subgroup 13-07B. The reason for these changes is 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 the petitioned-for tolerances for residues of clopyralid on Swiss chard at 3.0 ppm; bushberry subgroup 13-07B at 0.50 ppm; and strawberry at 4.0 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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 (HDT). 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 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 the document: "Human Health Risk Assessment to Evaluate New Uses on Swiss Chard, Bushberry Subgroup (13-07B), and Strawberry (Regional Restriction)," at pages 26-30 in docket ID number EPA-HQ-OPP-2009-0092.

### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a benchmark dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by

dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

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 greater than that 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 can be found at <http://www.regulations.gov> in the document: "Human Health Risk Assessment to Evaluate New Uses on Swiss Chard, Bushberry Subgroup (13-07B), and Strawberry (Regional Restriction)," at pages 16–18 in docket ID number EPA–HQ–OPP–2009–0092.

### 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.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance-level residues, Dietary Exposure Evaluation Model (DEEM) default processing factors, and 100 percent crop treated (PCT) for all proposed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance-level residues, DEEM default processing factors, and 100 PCT for all proposed commodities.

iii. *Cancer.* Based on the evidence discussed in Unit III.A., EPA has determined that clopyralid is "not likely to be carcinogenic to humans." Therefore, a quantitative exposure assessment to evaluate 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://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of clopyralid for surface water are estimated to be 45.0 parts per billion (ppb) for acute exposures and 11.9 ppb for chronic exposures. For ground water, the EDWC is estimated to be 0.39 ppb for both acute exposures and chronic exposures for non-cancer assessments.

The Agency also considered available surface and ground water monitoring data from the United States Geological Survey (USGS) National Water Quality Assessment Data Warehouse (<http://water.usgs.gov/nawqa/>) for clopyralid. Groundwater concentrations as high as 13 ppb have been detected in Alabama and surface water concentrations of up to 42 ppb have been detected in North Carolina, Illinois, and Ohio. Clopyralid is a persistent chemical that partitions to water. Degradation is driven by aerobic aquatic metabolism, though this pathway is not directly characterized through a guideline study. The degradation behavior for clopyralid best fits second-order kinetics, though first-order kinetics are used to derive and parameterize FIRST and SCIGROW models. In this case, second-order kinetics provide a substantially larger half-life estimate than first-order kinetics. These modeling limitations likely account for the higher concentrations in groundwater from the monitoring data versus the groundwater EDWCs. Peak surface water concentrations from monitoring data are

slightly below the EDWC (45.0 ppb) used to estimate the contribution to drinking water for the acute dietary risk assessment. Therefore, EPA believes 45.0 ppb is a reasonable, high end estimate to be used in risk assessment.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 45.0 ppb was used to assess the contribution to drinking water. The EDWC of 11.9 ppb was used to assess the contribution to drinking water for chronic dietary risk assessment.

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 residential turf, which could result in residential exposures. EPA assessed residential exposure using the following assumptions: Short-term inhalation exposure for adults applying clopyralid to residential turf by push-type spreaders, low-pressure hand sprayers, and garden hose end sprayers; short-term postapplication exposure for toddlers from incidental oral contact with treated turf (hand-to-mouth exposure); short-term postapplication incidental oral ingestion of granules from treated turf; and intermediate-term postapplication exposure for toddlers from incidental oral contact with treated turf (hand-to-mouth exposure). 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.

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 website 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 Food Quality Protection Act safety factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There 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 except for immunotoxicity, acute neurotoxicity, and subchronic neurotoxicity testing. Recent changes to 40 CFR part 158 require acute and subchronic neurotoxicity testing (OPPTS Guideline 870.6200), and immunotoxicity testing (OPPTS Guideline 870.7800) for pesticide registration; however, the existing data are sufficient for endpoint selection for

exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. There are no clinical or micropathological indications of neurotoxicity or immunotoxicity in the available subchronic and chronic studies in multiple species. Although hydrocephalus was observed in the rabbit developmental toxicity study, it was only observed at a dose that also caused severe maternal toxicity, including mortality. The endpoints selected for risk assessment are considered adequately protective of prenatal and/or postnatal toxicity; therefore, an additional database uncertainty factor is not needed to account for potential immunotoxicity or neurotoxicity.

ii. In the rabbit developmental toxicity study, neuropathology (hydrocephalus) was observed at the HDT. However, the concern for this effect is considered low because it occurred at a dose that caused severe maternal toxicity, including 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 from *in utero* exposure to rats or rabbits in the prenatal developmental studies or exposure to young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residue data. Based on both modeling and monitoring data, EPA made reasonable (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 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by

all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to clopyralid will occupy 9% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

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 23% of the cPAD for children 1 to 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. While there is potential for toddlers to ingest granular formulations of clopyralid directly from treated turf, due to the episodic nature of granule ingestion, this source of exposure was not included in the short-term aggregate assessment. Therefore, 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 5,500 for adult handlers from inhalation exposure and 1,700 for children 1 to 2 years old from incidental oral (hand-to-mouth) exposure. The LOC is for MOEs lower than 100. Therefore, the aggregate MOEs for short-term exposure are not of concern to EPA.

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).

Clopyralid is currently registered for uses that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure to clopyralid through food and water with intermediate-term exposures for clopyralid. Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 390 for children 1 to 2 years old from incidental oral (hand-to-mouth) exposure. The LOC is for MOEs lower than 100. Therefore, the aggregate MOE for intermediate-term exposure is not of concern to EPA.

5. *Aggregate cancer risk for U.S. population.* Based on the adequate cancer studies in rats and mice, EPA has concluded that 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

There are no Codex or Mexican maximum residue limits (MRLs) for residues of clopyralid in or on the requested commodities. There are Canadian MRLs for residues of clopyralid at 1.0 ppm on strawberry and 0.1 ppm on blueberry. While the Canadian MRL for strawberry harmonizes with the existing U.S. tolerance for strawberry at 1.0 ppm, the revised U.S. tolerance on strawberry at 4.0 ppm cannot be harmonized with the Canadian MRL because the residue field trial data supporting the revised tolerance resulted in residues that were higher than 1.0 ppm. Additionally, the U.S. tolerance on bushberry subgroup 13-07B (at 0.50 ppm) cannot be harmonized with the Canadian MRL on blueberry (at 0.1 ppm) because residue field trial data supporting the U.S.

tolerance resulted in residues that were higher than 0.1 ppm.

##### C. Revisions to Petitioned-For Tolerances

Based on analysis of the residue field trial data supporting the petition, EPA revised the proposed tolerances on Swiss chard from 5.0 ppm to 3.0 ppm and bushberry subgroup 13-07B from 6.0 ppm to 0.50 ppm. The Agency revised the tolerance levels based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*. Additionally, EPA revised the introductory text in paragraph (a) to clarify in the tolerance expression (1) that, as provided in FFDCa section 408(a)(3), the tolerance covers metabolites and degradates of clopyralid not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

#### V. Conclusion

Therefore, tolerances are established for residues of clopyralid, (3,6-dichloro-2-pyridinecarboxylic acid), in or on Swiss chard at 3.0 ppm; bushberry subgroup 13-07B at 0.50; and strawberry at 4.0 ppm.

#### VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCa 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 section 408(d) of FFDCa, 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 section 408(n)(4) of FFDCa. 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) (Pub. L. 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: March 12, 2010.

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 as follows:

i. Revise the introductory text.

ii. In the table, revise the entry for “Strawberry”, and add alphabetically “Bushberry subgroup 13-07B” and “Swiss chard” to read as follows:

**§ 180.431 Clopyralid; tolerances for residues.**

(a) *General.* Tolerances are established for residues of the herbicide clopyralid, including its metabolites and degradates, in or on the commodities in the table below from its application in the acid form or in the form of its salts. Compliance with the tolerance levels specified below is to be determined by measuring only clopyralid, (3,6-dichloro-2-pyridinecarboxylic acid), in or on the following commodities:

| Commodity                       | Parts per million |
|---------------------------------|-------------------|
| * * *                           | * *               |
| Bushberry subgroup 13-07B ..... | 0.50              |
| * * *                           | * *               |
| Strawberry .....                | 4.0               |
| Swiss chard .....               | 3.0               |
| * * *                           | * *               |

\* \* \* \* \*

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BILLING CODE 6560-50-S

**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**44 CFR Part 67**

[Docket ID FEMA-2010-0003]

**Final Flood Elevation Determinations**

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

**SUMMARY:** Base (1% annual-chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

**DATES:** The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated in the table below.

**ADDRESSES:** The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Kevin C. Long, Acting Chief, Engineering Management Branch, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2820, or (e-mail) [kevin.long@dhs.gov](mailto:kevin.long@dhs.gov).

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Federal Insurance and Mitigation Administrator has resolved any appeals resulting from this notification.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community. The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

*National Environmental Policy Act.* This final rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

*Regulatory Flexibility Act.* As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601-612, a regulatory flexibility analysis is not required.

*Regulatory Classification.* This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

*Executive Order 13132, Federalism.* This final rule involves no policies that have federalism implications under Executive Order 13132.

*Executive Order 12988, Civil Justice Reform.* This final rule meets the applicable standards of Executive Order 12988.

**List of Subjects in 44 CFR Part 67**

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is amended as follows:

**PART 67—[AMENDED]**

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

**§ 67.11 [Amended]**

2. The tables published under the authority of § 67.11 are amended as follows: