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).

VIII. 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


Dated: June 5, 2015.

Susan Lewis, Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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


3. In § 180.930, add alphabetically the inert ingredient to the table to read as follows:

Pesticide chemical CAS Reg. No. Limits Uses

---

Di-n-butyl carbonate ......................... 542–52–9 When ready for use, the end-use concentration is not to exceed 15,000 ppm.

---

3. In § 180.930, add alphabetically the inert ingredient to the table to read as follows:

<table>
<thead>
<tr>
<th>Inert ingredients</th>
<th>Limits</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Di-n-butyl carbonate (CAS 542–52–9)</td>
<td>Solvent.</td>
<td></td>
</tr>
</tbody>
</table>

4. In § 180.940(a), add alphabetically the inert ingredient to the table to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

(a) * * *
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?


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–2014–0161 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 August 14, 2015. 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–2014–0161, 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.
- 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 May 23, 2014 (79 FR 29729) [FR–9910–29], 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 4E8239) by Interregional Research Project Number 4 (IR–4), IR–4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.412 be amended by establishing tolerances for combined residues of the herbicide sethoxydim 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the cyclohexen-1-one moiety (calculated as the herbicide sethoxydim) in or on raw agricultural commodities (RACs): Bushburry subgroup 13–07B at 5.0 parts per million (ppm); caneberry subgroup 13–07A at 5.0 ppm; berry, low growing subgroup 13–07H, except strawberry at 2.5 ppm; fescue forage at 6.0 ppm; fescue, hay at 4.0 ppm; fruit, citrus group 10–10 at 0.5 ppm; fruit, pome group 11–10 at 0.2 ppm; fruit, small, vine climbing subgroup 13–07F, except fuzzy kiwifruit at 1.0 ppm; rapeseed subgroup 20A at 35 ppm; sunflower subgroup 20B, except safflower, seed at 7.0 ppm; cottonseed subgroup 20C at 5.0 ppm; vegetable, bulb group 3–07 at 1.0 ppm; and vegetable, fruiting group 8–10 at 4.0 ppm. That document referenced a summary of the petition prepared by BASF Corporation, 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 this comment is discussed in Unit IV.C.

Based upon review of the data submitted, the petition, EPA has made certain modifications, including revising certain petitioned-for tolerance levels, setting meal tolerances for various oilseed crop subgroups to cover potential processed commodities, and updating crop definitions as well as the tolerance expression for sethoxydim to conform to current EPA policies. 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 sethoxydim including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with sethoxydim 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.

Toxicological tests in animals (rats, mice, and dog) show that the target organ of sethoxydim toxicity is the liver. Toxic effects are characterized by increased liver weight; hypertrophy; fatty degeneration; hepatocyte swelling; increased serum bilirubin, alkaline phosphatase, aspartate...
aminotransferase, and alanine aminotransferase levels; focal granulomatous inflammation; and eosinophilic foci. Liver toxicity was observed by exposure through both the oral and inhalation routes.

Findings other than liver toxicity were also observed. In a subchronic rat study, decreased body weight, body weight gain, and food efficiency were noted at a lower dose than liver toxicity. In a chronic dog toxicity study, increased hemosiderosis in the spleen and depressed myeloid erythropoiesis in the sternal bone marrow were observed. Interstitial fibrosis and heart failure cells in lung in female rats were observed in the chronic toxicity/carcinogenicity study in rats.

In the developmental rat study, maternal toxicity was observed, as evidenced by an irregular gait, decreased activity, excessive salivation, and anogenital staining at a dose greater than half the limit dose and at the limit dose. All clinical signs reported were transient, with the exception of the anogenital staining, which did not reverse.

Developmental toxicity occurred at the same dose as maternal toxicity in rats and included decreased fetal weights, filamentous tail, and lack of tail due to the absence of sacral and/or caudal vertebrae, and delayed ossification in the hyoids, vertebra centrum and/or transverse processes, sternebrae and/or metatarsals, and pubes. No maternal toxicity was noted in rabbits at 400 milligrams per kilogram (mg/kg)/day, and developmental toxicity was noted at 400 mg/kg/day (NOAEL = 320 mg/kg/day) as an increase in the incidence of incompletely ossified 6th sternebrae. In the reproduction study, no parental or reproductive toxicity was observed at 150 mg/kg/day (highest dose tested), but offspring toxicity was noted at this dose as decreased pup weight in the F1a, F1b, and F2a generation during lactation (no-observed-adverse-effect-level (NOAEL) = 30 mg/kg/day). There is a low concern for these findings, since the selected points of departure are protective; there is low concern for pre- and/or postnatal toxicity resulting from exposure to sethoxydim.

Dermal toxicity was not observed at the limit dose in a 21-day dermal study in rabbits. Based on the lack of sensitization in treated guinea pigs, sethoxydim is not a skin sensitizer. No eye or dermal irritation were noted in rabbits. No neurotoxicity or other toxicity was observed at the highest dose tested (207 mg/kg/day) in the subchronic neurotoxicity test in rats.

There was no evidence of carcinogenicity in rats and mice, and no evidence of genotoxicity. Sethoxydim is classified as “Not Likely to Be Carcinogenic to Humans.” Specific information on the studies received and the nature of the adverse effects caused by sethoxydim, as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies, can be found at http://www.regulations.gov in document “Sethoxydim: Human Health Risk Assessment for Registration Review and to Support the Section 3 Registration of Proposed Uses on High Bush Blueberry and Fine Fescue Grasses”, dated February 3, 2015 at page 40 in docket ID number EPA–HQ–OPP–2014–0161–000x.

### Table 1—Summary of Toxicological Doses and Endpoints for Sethoxydim for Use in Human Health Risk Assessment

<table>
<thead>
<tr>
<th>Exposure/scenario</th>
<th>Point of departure and uncertainty/safety factors</th>
<th>RI(D), PAD, LOC for risk assessment</th>
<th>Study and toxicological effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dietary (females 13–49 years of age).</td>
<td>NOAEL = 180 mg/kg/day.</td>
<td>Acute RFD = aPAD = 1.8 mg/kg/day.</td>
<td>Rat Developmental Toxicity Developmental LOAEL = 650 mg/kg/day based on decreased fetal body weight, tail abnormalities, and delayed ossification Tail abnormalities were considered an acute effect.</td>
</tr>
<tr>
<td></td>
<td>UF(X) = 10x ...</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UF(II) = 10x ...</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>FQPA SF = 1x ...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute dietary (general population including infants and children).</td>
<td>NOAEL = 180 mg/kg/day.</td>
<td>Acute RFD = aPAD = 1.8 mg/kg/day.</td>
<td>Rat Developmental Toxicity Maternal LOAEL = 650 mg/kg/day based on irregular gait that was observed in 12/34 dams on the first day of dosing.</td>
</tr>
<tr>
<td></td>
<td>UF(X) = 10x ...</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UF(II) = 10x ...</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>FQPA SF = 1x ...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic dietary (all populations)</td>
<td>NOAEL = 14 mg/kg/day.</td>
<td>Chronic RFD = cPAD = 0.14 mg/kg/day.</td>
<td>Mouse Carcinogenicity Study LOAEL = 41 mg/kg/day based on liver hypertrophy and fatty degeneration.</td>
</tr>
<tr>
<td></td>
<td>UF(X) = 10x ...</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UF(II) = 10x ...</td>
<td></td>
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<tr>
<td></td>
<td>FQPA SF = 1x ...</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SETHOXYDIM FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

<table>
<thead>
<tr>
<th>Exposure/scenario</th>
<th>Point of departure and uncertainty/safety factors</th>
<th>RID, PAD, LOC for risk assessment</th>
<th>Study and toxicological effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidental oral short-term (1 to 30 days).</td>
<td>NOAEL = 180 mg/kg/day, UF = 10x; FQPA SF = 1x</td>
<td>Residential LOC for MOE = 100.</td>
<td>Rat Developmental Toxicity</td>
</tr>
<tr>
<td>Short- and Intermediate term Inhalation.</td>
<td>Inhalation study NOAEL = 0.3 mg/L, UF = 3x; FQPA SF = 1x</td>
<td>Residential LOC for MOE = 30.</td>
<td>Maternal LOAEL = 650 mg/kg/day based on irregular gait, decreased activity, excessive salivation, and anogenital staining.</td>
</tr>
<tr>
<td></td>
<td>HEC = 0.932 mg/L/day (residential handler)</td>
<td>Occupational LOC for MOE = 30.</td>
<td>Rat 28-day Inhalation Study</td>
</tr>
<tr>
<td></td>
<td>HED = 26.7 mg/kg/day (residential handler) or 39.8–138.9 mg/kg/day (occupational handler).</td>
<td></td>
<td>LOAEL = 2.4 mg/L based on increased liver weight, increased total serum bilirubin, and increased incidence of slight centrilobular hepatocyte swelling.</td>
</tr>
</tbody>
</table>

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to sethoxydim, EPA considered exposure under the petitioned-for tolerances as well as all existing sethoxydim tolerances in 40 CFR 180.412. EPA assessed dietary exposures from sethoxydim in food as follows:

   a. Acute exposure. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for sethoxydim. In conducting the acute dietary exposure assessment for sethoxydim, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM—FCID) Version 3.16. This software uses 2003–2008 food consumption data from the U.S. Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). A partially refined acute analysis was performed based on tolerance-level residues; percent crop treated (PCT) estimates for most agricultural uses of sethoxydim were applied, and DEEM™ default processing factors were applied to account for processed commodities.

   b. Chronic exposure. In conducting the chronic dietary exposure assessment for sethoxydim, EPA used DEEM—FCID Version 3.16 in which the software uses 2003–2008 food consumption data from the USDA’s NHANES/WWEIA. A partially refined chronic dietary exposure assessment was conducted, which used PCT data, but the overall dietary assessment represents high-end exposure because tolerance-level residues were used for food and bounding modeled residues for drinking water. Anticipated residues (based on maximum theoretical diets) were used for livestock commodities.

   c. Cancer. Based on the data summarized in Unit III.A., EPA has concluded that sethoxydim is not likely to pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

   d. Anticipated residue and percent crop treated (PCT) information. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances. Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

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

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

   • Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not underestimate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To
provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses. For acute dietary risk assessment for sethoxydim the following maximum PCT estimates were used: Alfalfa 2.5%; almonds 5%; apples 2.5%; apricots 10%; artichokes 2.5%; asparagus 10%; beans, green 15%; blueberries 10%; broccoli 5%; cabbage 10%; canerries 10%; canola 2.5%; cantaloupe 25%; carrots 5%; cauliflower 10%; celery 2.5%; cherries 2.5%; corn 2.5%; cotton 2.5%; cucumbers 10%; dry beans/peas 35%; eggplant 10%; fallow 2.5%; garlic 5%; grapefruit 2.5%; grapes 5%; hazelnuts 2.5%; lettuce 10%; oats 2.5%; onions 15%; oranges 5%; peaches 2.5%; peanuts 10%; pears 2.5%; peas, green 15%; peans 2.5%; peppers 15%; pistachios 2.5%; plums/prunes 2.5%; potatoes 5%; pumpkins 10%; soybeans 2.5%; spinach 2.5%; squash 10%; strawberies 10%; sugar beets 5%; sunflowers 10%; sweet corn 5%; tomatoes 5%; walnuts 1%; tobacco 10%; tomatoes 5%; walnuts 5%; watermelons 20%; wheat 2.5%.

For chronic dietary risk assessment, the following average PCT estimates for sethoxydim were used: Alfalfa 1%; almonds 2.5%; apples 1%; apricots 2.5%; artichokes 2.5%; asparagus 5%; beans, green 10%; blueberries 5%; broccoli 2.5%; cabbage 5%; canberries 5%; canola 2.5%; cantaloupes 5%; carrots 2.5%; cauliflower 5%; celery 2.5%; corn 1%; cotton 1%; cucumbers 5%; dry beans/peas 30%; eggplant 5%; fallow 1%; garlic 2.5%; grapefruit 2.5%; grapes 2.5%; hazelnuts 2.5%; lettuce 2.5%; oats 1%; onions 5%; oranges 2.5%; peaches 1%; peanuts 5%; pears 2.5%; peas, green 5%; peans 2.5%; peppers 5%; pistachios 1%; plums/prunes 1%; potatoes 2.5%; pumpkins 5%; soybeans 1%; spinach 2.5%; squash 5%; strawberries 2.5%; sugar beets 2.5%; sunflowers 5%; sweet corn 2.5%; tobacco 2.5%; walnuts 2.5%; watermelons 10%; wheat 1%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA’s computer-based model for evaluating the exposure of significant subpopulations inclusive several regional groups. Use of this consumption information in EPA’s risk assessment process ensures that EPA’s exposure estimate does not underestimate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which sethoxydim may be applied in a particular area.

2. Dietary exposure from drinking water. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for sethoxydim in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of sethoxydim. 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) Surface Water Calculator (SWCC Version 1.106), Surface Water Provisional Cranberry Model and Tier 1 mode of the Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCS) of sethoxydim for acute exposure were estimated to be 79.6 parts per billion (ppb) for surface water and 0.565 ppb for ground water.

For chronic exposures for non-cancer assessments are estimated to be 13.9 ppb for surface water and 0.51 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration value of 79.6 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 13.9 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, termicides, and flea and tick control on pets).

Sethoxydim is currently registered for the following uses that could result in residential exposure: Turf (including lawns, golf courses, recreational parks, and sod farms) and ornamentals. Short-term exposure to sethoxydim may occur via the dermal and inhalation routes for adults using sethoxydim products in residential settings. Since no dermal hazard was identified, only inhalation exposures were assessed for residential applicators. In addition, children may potentially be exposed orally in post-application turf scenarios. Intermediate- or long-term exposures are not expected due to the intermittent nature of applications by homeowners.

EPA assessed residential exposure using the following assumptions: Since no dermal hazard was identified in the toxicity database for sethoxydim, a quantitative residential post-application dermal risk assessment is not required and was not completed. Post-application inhalation exposures while performing activities in previously treated turf or ornamentals are not expected, primarily due to the very low vapor pressure (1.6 x 10^-7 mm Hg at 25 °C) and the expected dilution in outdoor air after an application has occurred. Therefore, post-application inhalation exposures were not assessed. The residential post-application assessment considers non-dietary incidental oral exposures only. Residential post-application exposures are generally considered to be intermittent and short-term in duration.

For the residential turf use scenario, post-application incidental oral exposure is assessed for children (1 to < 2 years old as the sentinel population). The turf use site assessed was a residential lawn turf as exposures from that use are expected to be higher than any potential exposures from other...
turf uses (i.e., recreational parks, golf courses, or treated sod). The assessment was conducted assuming the maximum application rate (0.47 lbs ai/acre) and used unit exposure values and estimates for area treated or amount handled. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at http://www.epa.gov/pesticides/science/residential-exposure-sop.html.

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 sethoxydim to share a common mechanism of toxicity with any other substances, and sethoxydim does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that sethoxydim 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 is evidence of increased susceptibility of the young following exposure to sethoxydim in the rat and/or rabbit developmental and reproduction studies. To further assess these effects, the EPA performed a Degree of Concern Analysis in which sethoxydim was evaluated for potential developmental effects in the rat and rabbit. Maternal toxicity included transient clinical signs (irregular gait, decreased activity, excessive salivation, and anogenital staining) in rats at 650 mg/kg/day and at the limit dose. Decreased fetal body weight, delayed ossification, and malformations (filamentous tail; lack of tail) were observed in the rat at 650 mg/kg/day and at the limit dose. Maternal toxicity was not observed in rabbits, whereas an increased incidence of incompletely ossified 6th sternebrae was noted in fetuses at the high dose (400 mg/kg/day). Decreased body weight was observed in F1, F1b, and F2 pups during lactation in the 2-generation reproduction study at 150 mg/kg/day (highest dose tested), while parental toxicity was not observed. The Agency concluded from the Degree of Concern Analysis that there was low concern because the chosen points of departure for risk assessment for each exposure scenario are protective for these effects.

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 10X. This decision is based on the following findings:

i. The toxicity database for sethoxydim is complete.

ii. There was no clear evidence of neurotoxicity or neuropathology in the available studies, which include a subchronic neurotoxicity study. The acute neurotoxicity study and developmental neurotoxicity study requirements have been waived.

iii. There is evidence that sethoxydim results in increased susceptibility in in utero exposure to sethoxydim in the rabbit developmental toxicity study and following in utero and/or pre-/post-natal exposure in the 2-generation reproduction study in rats. However, there is low concern because the chosen points of departure for risk assessment for each exposure scenario are protective for these effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary exposure estimates were partially refined by incorporation of percent of crop treated assumptions; however, tolerance-level residue in food and upper-bound drinking water estimates based on modeling were used which are conservative assumptions. 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 sethoxydim.

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. Using the exposure assumptions described in this unit for acute exposure, acute dietary risk estimates for the registered and proposed uses of sethoxydim will occupy 5.4% of the aPAD for the general U.S. population. The risk estimate for the most highly exposed subgroup, children 1–2 year old, was 8.6% of the aPAD.

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to sethoxydim from food and water will utilize 27% 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 sethoxydim 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).

Sethoxydim 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 sethoxydim. The short-term aggregate assessment for children 1–2 years old, the most exposed subpopulation group, includes post-application oral residential exposures from treated turf and chronic dietary exposure.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposure results in aggregate MOEs of 4.000 that are below the EPA’s level of concern for sethoxydim.
Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Because there is no intermediate-term exposure, sethoxydim is not expected to pose an intermediate-term risk.

Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, sethoxydim 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 sethoxydim residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate gas chromatography/flame photometric detection GC/FPD method is available (Method I in PAM Vol. II) for determining the combined residues of sethoxydim and its metabolites containing the 3-alkyl substituted pentanediolic acid moiety in plant and livestock commodities which provides a 0.05 ppm limit of quantitation (LOQ).

The method may be requested from:
Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Maps 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.

There are no Codex MRLs established for the residues of sethoxydim in/on raw agricultural or processed commodities.

C. Response to Comments

One comment was received from a private citizen objecting to establishment of petitioned-for tolerances for residues of sethoxydim and a number of other pesticides on food items as these are “dangerous chemicals” and children are disproportionately exposed to health risks from these chemicals. In addition, the commenter expressed concern about the potential for increased cancer rates in children due to pesticide exposures. The Agency understands the commenters’ concerns regarding chemicals and their potential effects on humans. Pursuant to its authority under the FFDCA, and as discussed further in this preamble, EPA conducted a comprehensive assessment of sethoxydim, which included an assessment on the carcinogenic potential of sethoxydim. Based on its assessment of the available data, EPA has found that there is a reasonable certainty of no harm to humans, with special emphases on infants and children sensitivity, from aggregate exposure to sethoxydim based on a complete toxicological database and the potential exposure levels.

D. Revisions to Petitioned-For Tolerances

The tolerance for the bushberry subgroup 13–07B is based on the residue data on blueberry, the representative crop at 4.0 ppm and not the previously established tolerances for juneberry, lingonberry, and salal at 5.0 ppm. The juneberry, lingonberry, and salal tolerances were based on the translation of caneberry data, which are no longer relevant to these crops following updated crop grouping realignment. Moreover, EPA has determined that available data support a reduction in sethoxydim residue tolerance level for these crops from 5.0 ppm to 4.0 ppm.

Based on available data and the application of the OECD calculation procedures, EPA is establishing a tolerance of 7.0 ppm for fescue, forage, rather than 6.0 ppm as requested by the petitioner. This difference stems from the conclusion that only 4 independent grass trials were conducted instead of 5 (as assumed by IR–4).

In addition, for the requested rapeseed subgroup 20A and sunflower subgroup 20B crop group conversions, each RAC could potentially be reprocessed into meal. Therefore, following the established meal tolerance of the representative crop, canola meal at 40 ppm for subgroup 20A and sunflower meal at 20 ppm for subgroup 20B, tolerances for the residues of sethoxydim are also required for translation to the following commodities: Calendula, meal at 20 ppm; castor oil plant, meal at 20 ppm; Chinese tallowtree, meal at 20 ppm; cuphea, meal at 40 ppm; echium, meal 40 ppm; euphoriba, meal at 20 ppm; evening primrose, meal at 20 ppm; flax seed, meal at 40 ppm; hare’s ear mustard, meal at 40 ppm; jojoba, meal at 20 ppm; lesquerella, meal at 40 ppm; lunaria, meal at 40 ppm; meadowfoam, meal at 40 ppm; milkweed, meal at 40 ppm; mustard, meal at 40 ppm; niger seed, meal at 20 ppm; oil radish, meal at 40 ppm; poppy seed, meal at 40 ppm; rose hip, meal at 20 ppm; sesame, meal at 40 ppm; stokes aster, meal at 20 ppm; sweet rocket, meal at 40 ppm; tallowwood, meal at 20 ppm; tea oil plant, meal at 20 ppm; and vernonia, meal at 20 ppm. Additionally, an existing borage, meal tolerance at 10 ppm is being raised to 40 ppm.

Lastly, the Agency is updating the tolerance expressions for sethoxydim as follows to reflect current EPA policies:
Tolerances are established for the herbicide sethoxydim, including its metabolites and degradates, in or on the commodities listed in the subsections.

E. Trade Considerations

Establishing a tolerance at 4.0 ppm for the expanded crop subgroup 13–07B results in reductions of the existing sethoxydim tolerance level for juneberry, lingonberry, and salal, which are each set individually at 5.0 ppm. In order to allow a reasonable interval for producers in the exporting member countries of the World Trade Organization’s Sanitary and Phytosanitary Measures Agreement to adapt to the requirements of these modified tolerances, EPA is establishing an expiration date for those higher individual tolerances (for juneberry, lingonberry, and salal) of December 15, 2015. Those tolerances will remain in place for six months after the publication of this rule and residues of sethoxydim may be present on juneberry, lingonberry, and salal at levels up to 5.0 ppm until their expiration date.
expiration date—in order to allow a reasonable interval for producers in exporting member countries to adapt to the reduced tolerances. After that 6-month period, those individual tolerances will expire, and residues of sethoxydim on juneberry, lingonberry, and salal will need to comply with the bushberry subgroup 13–07B tolerance, which includes those commodities and limits residues to 4.0 ppm.

V. Conclusion
Tolerances are established for the herbicide sethoxydim, including its metabolites and degradates, in or on the commodities listed below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of the herbicide 2-(ethylthio)butyl][5-2-(ethylthiopropyl)]-3-hydroxy-2-cyclohexen-1-one (CAS Reg. No. 74051–80–2) and its metabolites containing the 2-cyclohexen-1-one moiety, calculated as the stoichiometric equivalent of sethoxydim, in or on commodities: Berry, low growing, subgroup 13–07H, except strawberry at 2.5 ppm; borage, meal at 40 ppm; bushberry, subgroup 13–07B at 4.0 ppm; calendula, meal at 20 ppm; caneberry, subgroup 13–07A at 5.0 ppm; castor oil plant, meal at 20 ppm; Chinese tallowtree, meal at 20 ppm; cottonseed, subgroup 20C at 5.0 ppm; cuphea, meal at 40 ppm; echium, meal 40 ppm; euphorbia, meal at 20 ppm; evening primrose, meal at 20 ppm; fescue, forage at 7.0 ppm; fescue, hay at 4.0 ppm; flax seed, meal at 40 ppm; fruit, citrus, group 10–10 at 0.5 ppm; fruit, pome, group 11–10 at 0.2 ppm; fruit, small, vine climbing, subgroup 13–07F, except fuzzy kiwifruit at 1.0 ppm; hare’s ear mustard, meal at 40 ppm; jojoba, meal at 20 ppm; lesquerella, meal at 40 ppm; lunaria, meal at 40 ppm; meadowfoam, meal at 40 ppm; milkweed, meal at 40 ppm; mustard, meal at 40 ppm; niger seed, meal at 20 ppm; oil radish, meal at 40 ppm; poppy seed, meal at 40 ppm; rapeseed, subgroup 20A at 35 ppm; rose hip, meal at 20 ppm; sesame, meal at 40 ppm; stokes aster, meal at 20 ppm; sunflower subgroup 20B, except safflower at 7.0 ppm; sweet rocket, meal at 40 ppm; tallowwood, meal at 20 ppm; tea oil plant, meal at 20 ppm; vegetable, bulb, group 3–07 at 1.0 ppm; vegetable, fruiting, group 8–10 to 4.0 ppm; and vernonia, meal at 20 ppm. In addition, upon establishment of the above tolerances, remove the following entries that are superseded by this action including: Blueberry; borage, seed; caneberry, subgroup 13A; canola, seed; cotton, undelinted seed; crambe, seed; cranberry; cuphea, seed; echium, seed; flax, seed; fruit, citrus group 10; fruit, pome, group 11; gold of pleasure, seed; grape; hare’s ear mustard, seed; lesquerella, seed; lunaria, seed; meadowfoam, seed; milkweed, seed; mustard, seed; oil radish, seed; okra; poppy, seed; rapeseed, seed; sesame, seed; sunflower, seed; sweet rocket, seed; vegetable, bulb group 3; and vegetable, fruiting group 8.
Finally, the individual tolerances for juneberry, lingonberry, and salal at 5.0 ppm will expire 6 months from the date of publication of this final rule in the Federal Register.

VI. Statutory and Executive Order Reviews
This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), 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 tolerances 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(a)(4). As such, the Agency has determined that this action will not have a direct effect on States or tribal governments, or 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: June 4, 2015.

Susan Lewis,
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:


2. § 180.412 is revised to read as follows:

§ 180.412  Sethoxydim; tolerances for residues.
(a) Tolerances are established for the herbicide sethoxydim, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by
measuring only the sum of the herbicide 2-[(1-ethoxyimino)butyl]-5-[(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one (CAS Reg. No. 74051–80–2) and its metabolites containing the 2-cyclohexen-1-one moiety, calculated as the stoichiometric equivalent of sethoxydim, in or on the commodity.

Commodity | Parts per million
---|---
Alfalfa, forage | 40
Alfalfa, hay | 40
Almond, hulls | 2.0
Apricot | 0.2
Apple, wet pomace | 0.8
Asparagus | 4.0
Bean, succulent | 15
Beet, sugar, molasses | 10
Beet, sugar, tops | 3.0
Berry, low growing, subgroup 13–07H, except strawberry | 2.5
Borage, meal | 40
Buckwheat, flour | 25
Buckwheat, grain | 19
Bushberry subgroup 13–07B | 4.0
Calendula, meal | 20
Caneberry subgroup 13–07A | 5.0
Canola, meal | 40
Castor oil plant, meal | 20
Cattle, fat | 0.2
Cattle, meat byproducts | 1.0
Cherry, sweet | 0.2
Cherry, tart | 0.2
Chinese tallowtree, meal | 20
Citrus, dried pulp | 1.5
Clover, forage | 35
Clover, hay | 55
Coriander, leaves | 4.0
Corn, field, forage | 2.0
Corn, field, grain | 0.5
Corn, field, stover | 2.0
Corn, sweet, forage | 3.0
Corn, sweet, kernel plus cob with husk removed | 0.4
Corn, sweet, stover | 3.5
Cottonseed subgroup 20C | 5.0
Cowpea, forage | 15
Cowpea, hay | 50
Crambe, meal | 40
Cuphea, meal | 40
Dillweed, fresh leaves | 10
Echium, meal | 40
Egg | 
Euphorbia, meal | 2.0
Evening primrose, meal | 20
Flax seed, meal | 40
Fruit, citrus, group 10–10 | 0.5
Fruit, pome, group 11–10 | 0.2
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F | 2.0
Goat, fat | 1.0
Goat, meat | 0.2
Goat, meat byproducts | 0.2
Gold of pleasure, meal | 40
Grape, raisin | 2.0
Hare’s ear mustard, meal | 40
Hog, fat | 0.2
Hog, meat | 0.2
Hog, meat byproducts | 1.0
Horse, fat | 0.2
Horse, meat | 0.2

Compliance with the tolerance levels specified below is to be determined by measuring only the sum of the herbicide 2-[(1-ethoxyimino)butyl]-5-[(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one (CAS Reg. No. 74051–80–2) and its metabolites containing the 2-cyclohexen-1-one moiety, calculated as the stoichiometric equivalent of sethoxydim, in or on the commodity.

| Commodity | Parts per million  
---|---
Artichoke, globe | 5.0
Fescue, forage | 7.0
Fescue, hay | 4.0
Rhubarb | 0.3

(d) Indirect and inadvertent residues.
[Reserved]

BILING CODE 5650-50-P

DEPARTMENT OF DEFENSE
Defense Acquisition Regulations System
48 CFR Part 216
Types of Contracts

CFR Correction

In Title 48 of the Code of Federal Regulations, Chapter 2, Parts 200 to 299, revised as of October 1, 2014, on page 111, redesignate section 216.405–270 as section 216.405–2–70.

BILING CODE 1505-01-D

DEPARTMENT OF DEFENSE
Defense Acquisition Regulations System
48 CFR Part 217
Special Contracting Methods

CFR Correction

In Title 48 of the Code of Federal Regulations, Chapter 2, Parts 200 to 299, revised as of October 1, 2014, on page 117, in section 217.171, redesignate paragraph (c)(2)(C)(2) as paragraph (c)(2)(I).