Executive Order 12866 (58 FR 51735, October 4, 1993);

• Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

• Are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Are not subject to the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Do not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. section 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. section 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 28, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Oxides of nitrogen, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: December 16, 2011.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.282 is amended by adding paragraph (d) to read as follows:

§ 52.282 Control strategy and regulations: Ozone.

* * * * *

(d) *Determinations that Certain Areas Did Not Attain the 1-Hour Ozone NAAQS.* EPA has determined that the Los Angeles-South Coast Air Basin Area and the San Joaquin Valley Area extreme 1-hour ozone nonattainment areas did not attain the 1-hour ozone NAAQS by the applicable attainment date of November 15, 2010 and that the Southeast Desert Modified Air Quality Maintenance Area severe-17 1-hour ozone nonattainment area did not attain the 1-hour ozone NAAQS by the applicable attainment date of November 15, 2007. These determinations bear on the areas' obligations with respect to the one-hour ozone standard anti-backsliding requirements whose implementation is triggered by a determination of failure to attain by the applicable attainment date: section 172(c)(9) contingency measures for failure to attain and sections 182(d)(3) and 185 major stationary source fee programs.

[FR Doc. 2011–33475 Filed 12–29–11; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0865; FRL–9330–2]

Tepraloxydim; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tepraloxydim in or on the imported commodities ''Pea and bean, dried shelled, except soybean, subgroup 6C'' and ''Sunflower subgroup 20B''. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also removes established tolerances for residues of tepraloxydim on ''Lentil, seed'' and ''Pea, dry, seed,'' as residues on these commodities will be covered by the new tolerance on the pea and bean subgroup (6C).

DATES: This regulation is effective December 30, 2011. Objections and requests for hearings must be received on or before February 28, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0865. 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; email address: *stanton.susan@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.* To access the harmonized test guidelines referenced in this document electronically, please go *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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–2010–0865 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 February 28, 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–2010–0865, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 15, 2010 (75 FR 78240) (FRL–8853–1), 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 0E7788) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.573 be amended by establishing tolerances for residues of the herbicide tepraloxydim, 2-[1-[[[(2E)-3-chloro-2-propen-1-yl]oxy]imino]propyl]-3-hydroxy-5-(tetrahydro-2H-pyran-4-yl)-2-cyclohexen-1-one and its metabolites convertible to GP (3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid) and OH–GP (3-hydroxy-3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim, in or on Pea and bean, dried shelled, except soybean, subgroup 6C and Sunflower subgroup 20B at 0.10 parts per million (ppm) and 0.25 ppm, respectively. That notice referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available 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 reduced the proposed tolerance for Sunflower subgroup 20B from 0.25 ppm to 0.20 ppm. The reason for this change 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 tepraloxydim including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tepraloxydim 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.

Tepraloxydim has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It produces minimal

eye irritation, is a slight dermal irritant, and is not a dermal sensitizer.

In subchronic and chronic toxicity studies, the main target organs for tepraloxydim toxicity were the liver, the spleen/hematopoietic system and reproductive system. Liver findings were reported in all subchronic and chronic toxicity/carcinogenicity feeding studies and included increased incidences of hepatocellular foci, abnormal liver function parameters, increased relative liver weight, hepatocyte hypertrophy, and increased hepatocellular neoplasms in the mouse and rat carcinogenicity studies. Tepraloxydim also affected the hematopoietic system. In dogs, hemolytic anemia was demonstrated by depressed hematocrit, hemoglobin, and red blood cells (RBCs). These changes were accompanied by compensatory responses, including splenic hematopoiesis, femoral and sternal bone marrow hyperplasia, increased erythroid precursors and hemosiderin-laden macrophages, and splenic hemosiderosis. The reproductive system was affected by tepraloxydim at relatively high doses (in excess of LOAELs (lowest observed adverse effect levels) established in repeat-dose mouse, rat and dog studies). Reproductive effects included morphological microscopic changes indicative of reduced secretory activity in the seminal vesicles and preputial glands in male mice; increased uterine sclerosis, decreased corpora lutea, and decreased follicles in female mice; increased incidences of focal calcification of the testes in the high dose group in the rat carcinogenicity feeding study; and effects on male sex organs at high doses in dogs.

In the rat developmental toxicity study, fetal effects (reduced fetal body weights, delayed ossification and the occurrence of hydroureter) were seen at a dose threefold lower than the dose resulting in maternal toxicity (reduced body weight and body weight gain). Additional developmental anomalies or malformations (dilatation of both heart ventricles and filiform tails that were observed externally and corresponded to absent caudal and sacral vertebrae) were observed at the maternal LOAEL in the study. The results indicate potential increased quantitative and qualitative susceptibility of fetuses to tepraloxydim exposure. In contrast, no developmental effects were seen in the rabbit developmental toxicity study up to the highest tested dose, the LOAEL for maternal toxicity (reduced body weight and food consumption). In the multi-generation rat reproduction study, there were no effects on any of the measured reproductive parameters up to and including the highest tested dose and no evidence of quantitative or qualitative susceptibility of the offspring.

In both the acute and subchronic rat neurotoxicity studies, there were mild changes in motor activity and grip strength indices. On day 0 of the acute oral neurotoxicity study in rats, motor activity was decreased in all treated female groups, while forelimb grip strength was slightly increased in all treated females. In the rat subchronic neurotoxicity study, motor activity was increased in the high dose females at day 50 and in both sexes on day 85 at the highest dose tested. None of the studies, including both neurotoxicity studies, reported treatment-related effects on brain weight or gross/microscopic lesions in the tissues of the nervous system.

In cancer studies conducted in rats and mice, there was weak and/or conflicting evidence of carcinogenicity. In rats, there was some evidence of carcinogenicity in the females based on an increased incidence of liver tumors at the high dose only in the carcinogenicity phase of the study, but this finding was not supported by the results of the chronic phase in the same strain and sex of rats. In mice, liver tumors were seen in females at an excessively toxic dose. EPA's concern for carcinogenicity is low, and the Agency has determined that the chronic population-adjusted dose (cPAD) of 0.05 milligrams/kilogram/day (mg/kg/day) will adequately account for all chronic effects, including carcinogenicity, likely to result from exposure to tepraloxydim. This determination is based on the following considerations:

- The liver tumors in female rats were seen only at the high dose (*i.e.,* lack of dose response);
- The incidences of these tumors were within the ranges for the historical controls;
- The rat liver tumors observed in one study were not seen in a parallel study conducted at the same dose and duration (*i.e.,* tumorogenic potential not replicated);
- In mice, liver tumors were seen only at excessive doses (*i.e.,* greater than the Limit Dose of 1,000 mg/kg/day) which may have resulted in indirect effects that may not occur at lower doses;
- The liver tumors did not result in reduced latency in either species;
- There is no concern for mutagenicity/genotoxicity; and
- The NOAEL (no observed adverse effect level) of 5 mg/kg/day used for deriving the chronic reference dose (cRfD) is approximately 55-fold lower than the lowest dose (272 mg/kg/day) that induced liver tumors in rats.

Specific information on the studies received and the nature of the adverse effects caused by tepraloxydim 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 the document *''Amended: Tepraloxydim: Human Health Risk Assessment for New Tolerances on Imported Dry Bean and Dry Pea Subgroup 6C and Sunflower Subgroup 20B''* at page 31 in docket ID number EPA–HQ–OPP–2010–0865.

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 point of departure (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 PAD or a 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 tepraloxydim used for human risk assessment is shown in the following Table .

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk asssessment	Study and toxicological effects
Acute dietary (General population including infants and children).	LOAEL = 500 (mg/kg/day) UF_A = 10× UF_H = 10× FQPA SF retained as UF_L = 10×.	Acute RfD = 0.5 mg/kg/day aPAD = 0.5 mg/kg/day	Acute neurotoxicity screening battery LOAEL = 500 mg/kg/day based on decreased motor activity in females. (The NOAEL is not identified.)
Acute dietary ..... (Females 13–49 years of age).	NOAEL = 40 mg/kg/day UF_A = 10× UF_H = 10× FQPA SF = 1×	Chronic RfD = 0.4 mg/kg/day. cPAD = 0.4 mg/kg/day	Rat developmental toxicity LOAEL = 120 mg/kg/day based on findings of reduced ossification indicative of delayed maturation, and the occurrence of hydroureter.
Chronic dietary (All populations).	NOAEL = 5 mg/kg/day UF_A = 10× UF_H = 10× FQPA SF = 1×	Chronic RfD = 0.05 mg/kg/day. cPAD = 0.05 mg/kg/day	Rat carcinogenicity study LOAEL = 30 mg/kg/day based on male liver microscopic lesions (eosinophilic foci).
Cancer ..... (Oral, dermal, inhalation)	Weak and/or conflicting evidence of carcinogenicity in the rat and mouse; the chronic population-adjusted dose of 0.05 mg/kg/day will adequately account for all chronic effects, including carcinogenicity.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tepraloxydim, EPA considered exposure under the petitioned-for tolerances as well as all existing tepraloxydim tolerances in 40 CFR 180.573. EPA assessed dietary exposures from tepraloxydim 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. Such effects were identified for tepraloxydim. As shown in the Table above, EPA identified different points of departure for assessing acute dietary exposure for the general population (including infants and children) and women of childbearing age (13 to 49).

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 assumed that residues are present in all commodities at the tolerance level and that 100% of commodities are treated with tepraloxydim.

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 assumed that residues are present in all commodities at the tolerance level and that 100% of commodities are treated with tepraloxydim.

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

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for tepraloxydim in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tepraloxydim. 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 tepraloxydim for acute exposures are estimated to be 1.4 parts per billion (ppb) for surface water and 0.002 ppb for ground water. EDWCs for chronic exposures for non-cancer assessments are estimated to be 0.7 ppb for surface water and 0.002 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 1.4 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.7 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). Tepraloxydim is not registered for any specific use patterns that would result in 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 tepraloxydim to share a common mechanism of toxicity with any other substances, and tepraloxydim does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that tepraloxydim 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 (10×) 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 10×, 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.* As discussed in Unit III.A, there was evidence of increased qualitative and quantitative susceptibility of fetuses in the rat developmental toxicity study. There was no evidence of increased susceptibility seen in the rabbit developmental toxicity study or multi-generation rat reproduction study. The degree of concern is low for the increased susceptibility seen in the developmental study in rats (prenatal exposure), since a clear NOAEL/LOAEL was established for developmental toxicity and the endpoints of concern are used to assess exposure for the most sensitive population of concern (*i.e.,* Females 13to 49). There is no residual uncertainty for prenatal and/or postnatal toxicity.

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 1× for all exposure scenarios, except acute dietary exposure of the general population.

A 10× FQPA Safety Factor in the form of a UF_L is retained for assessing acute dietary risk for the general population, including infants and children, to account for the uncertainty resulting from using a LOAEL, rather than a NOAEL, as the POD (*i.e.,* a NOAEL was not identified in the critical study). The critical effect (decreased motor activity in females) observed at the LOAEL of 500 mg/kg/day in the acute neurotoxicity study was neither severe nor irreversible; and the dose-responsive decrease in motor activity was observed in females on Day 0 in the absence of any other treatment-related clinical signs (including functional observation battery) or neurohistopathological effects. The dose-response relationship of tepraloxydim indicates that an uncertainty factor of 10× is sufficiently protective against the critical effect and any other adverse effects at the aRfD.

The decision to reduce the FQPA SF to 1× for all other exposure scenarios is based on the following findings:

i. The toxicity database is complete except for immunotoxicity testing (OPPTS Guideline 870.7800). Recent changes to 40 CFR part 158 make this testing required for pesticide registration. In the absence of specific immunotoxicity studies, EPA has evaluated the available tepraloxydim toxicity database to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. No evidence of immunotoxicity was found. Treatment-related effects seen in the spleen (splenic hematopoiesis) and bone marrow (hyperplasia) are compensatory responses to tepraloxydim-induced hemolytic anemia.

Considering the lack of evidence of immunotoxicity in the database for tepraloxydim, EPA does not believe that conducting an immunotoxicity study will result in a NOAEL less than that (5 mg/kg/day) used to derive the current cRfD. Consequently, the EPA believes the existing data are sufficient for endpoint selection for exposure/risk assessment purposes and for evaluation of the requirements under the FQPA, and an additional database uncertainty factor is unnecessary.

ii. In both the acute and subchronic rat neurotoxicity studies, there were mild changes in motor activity and grip strength indices. However, EPA has concluded that there is no need for a developmental neurotoxicity (DNT) study or additional UFs to account for neurotoxicity, based on the following considerations:

- Neurotoxic effects were seen at high doses of 500 mg/kg (¼ of the limit dose), 1,000 mg/kg, and 2,000 mg/kg following bolus (gavage) dosing in the acute neurotoxicity study and at 428 mg/kg/day in males and 513 mg/kg/day in females following dietary administration in the subchronic neurotoxicity study.
- In the two-generation reproduction study, no clinical signs indicative of neurotoxicity were seen in the parental animals or offspring; nor was there evidence for increased susceptibility of offspring.
- Because a DNT study would necessarily be conducted at high doses in order to elicit neurotoxicity, it would not yield a POD lower than those currently used for acute (40 mg/kg [aPAD = 0.40 mg/kg] and 500 mg/kg [cPAD = 0.5 mg/kg]) and chronic (5 mg/kg/day) risk assessments.

iii. Although there was evidence of increased qualitative and quantitative susceptibility of fetuses in the rat developmental toxicity study, the concern for the increased susceptibility is low, and EPA did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of tepraloxydim.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated (CT) and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to tepraloxydim in drinking water. These assessments will not underestimate the exposure and risks posed by tepraloxydim.

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 aPAD and 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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to tepraloxydim will occupy 2.2% of the aPAD for children, 1 to 2 years old, the population group receiving the greatest exposure. The acute dietary exposure from food and water to tepraloxydim will occupy 1.0% or less of the aPAD for all other population subgroups, including females 13 to 49 years old.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tepraloxydim from food and water will utilize 9.6% of the cPAD for children, 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for tepraloxydim.

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). A short-term adverse effect was identified; however, tepraloxydim is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-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 short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for tepraloxydim.

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, tepraloxydim 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 tepraloxydim.

5. *Aggregate cancer risk for U.S. population.* Based on the results of two adequate rodent carcinogenicity studies and the explanation given in Unit III.A, tepraloxydim 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 tepraloxydim residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography/mass spectrometry (GC/MS) BASF Analytical Method D9701/1) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. 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 tepraloxydim.

C. Revisions to Petitioned-For Tolerances

EPA has reduced the proposed tolerance for Sunflower subgroup 20B from 0.25 ppm to 0.20 ppm to harmonize with the established MRL in Canada. Since the highest average field trial residue and maximum field trial residue for sunflower seed were 0.14 ppm and 0.18 ppm, respectively, EPA has determined that the Canadian level is adequate to cover expected residues on commodities in subgroup 20B.

EPA is also revising the introductory text of § 180.573(a)(1), (a)(2) and (c), which contain the tolerance expression for the existing and new tolerances, to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be determined. Tolerances for plant commodities are currently expressed in terms of the combined residues tepraloxydim, 2-[1-[[[(2E)-3-chloro-2-propen-1-yl]oxy]imino]propyl]-3-hydroxy-5-(tetrahydro-2H-pyran-4-yl)-2-cyclohexen-1-one, and its metabolites convertible to GP (3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid) and OH–GP (3-hydroxy-3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim. Livestock tolerances are currently expressed in terms of the combined residues of tepraloxydim and its metabolites convertible to GP, OH–GP, and GL (3-(2-oyotetrahydropyran-4-yl)-1,5-dioic acid), calculated as tepraloxydim. The tolerance expression for plants is being revised to make clear that the tolerances cover residues of tepraloxydim, including its metabolites and degradates, but that compliance with the tolerances is to be determined by measuring only the combined residues of tepraloxydim and its metabolites convertible to GP and OH–GP, calculated as tepraloxydim. Similarly, the tolerance expression for livestock commodities is being revised to clarify that the tolerances cover residues of tepraloxydim, including its metabolites and degradates, but that compliance with the tolerance levels will be determined by measuring only the combined residues of tepraloxydim and its metabolites convertible to GP, OH–GP, and GL, calculated as tepraloxydim. EPA has determined that it is reasonable to make these changes final without prior proposal and opportunity for comment, because public comment is not necessary, in that the changes have no substantive effect on the tolerances, but rather are merely intended to clarify the existing tolerance expressions.

Finally, EPA is removing established tolerances for residues of tepraloxydim on ''Lentil, seed'' and ''Pea, dry, seed'' because residues on these commodities are covered by the new tolerances for residues of tepraloxydim on the pea and bean subgroup 6C.

V. Conclusion

Therefore, the established tolerances for residues of tepraloxydim on ''Lentil, seed'' and ''Pea, dry, seed'' are removed, and new tolerances are established for residues of tepraloxydim, including its metabolites and degradates, in or on ''Pea and bean, dried shelled, except soybean, subgroup 6C'' and ''Sunflower subgroup 20B'' as set forth in the regulatory text.

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 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 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: December 14, 2011.

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. Amend § 180.573 as follows:

■ a. Revise the introductory text in paragraphs (a)(1), (a)(2), and (c);

■ b. Remove the commodities ''Lentil, seed'' and ''Pea, dry, seed'' from the table in paragraph (a)(1);

■ c. Add alphabetically the commodities ''Pea and bean, dried shelled, except soybean, subgroup 6C'' and ''Sunflower subgroup 20B'' and add footnote 1 to the table in paragraph (a)(1).

The revised and added text read as follows:

§ 180.573 Tepraloxydim; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of tepraloxydim, 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 combined residues of tepraloxydim, (2-[1-[[[(2*E*)-3-chloro-2-propen-1-yl]oxy]imino]propyl]-3-hydroxy-5-(tetrahydro-2*H*-pyran-4-yl)-2-cyclohexen-1-one) and its metabolites convertible to GP (3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid) and OH–GP (3-hydroxy-3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim, in or on the commodities.

Commodity	Parts per million
* * *	*
Pea and bean, dried shelled, except soybean, subgroup 6C [1]	0.10
* * *	*
Sunflower subgroup 20B [1]	0.20
* * *	*

[1] There are no U.S. registrations for commodities in this subgroup.

(2) Tolerances are established for residues of tepraloxydim, 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 combined residues of tepraloxydim (2-[1-[[[(2*E*)-3-chloro-2-propen-1-yl]oxy]imino]propyl]-3-hydroxy-5-(tetrahydro-2*H*-pyran-4-yl)-2-cyclohexen-1-one) and its metabolites convertible to GP (3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid), OH–GP (3-hydroxy-3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid), and GL (3-(2-oxotetrahydropyran-4-yl)-1,5-dioic acid), calculated as tepraloxydim, in or on the commodities.

* * * * *

(c) *Tolerances with regional registrations.* A tolerance with regional registration, as defined in § 180.1(l), is established for residues of tepraloxydim, 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 combined residues of tepraloxydim (2-[1-[[[(2*E*)-3-chloro-2-propen-1-yl]oxy]imino]propyl]-3-hydroxy-5-(tetrahydro-2*H*-pyran-4-yl)-2-cyclohexen-1-one) and its metabolites convertible to GP (3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid) and OH–GP (3-hydroxy-3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim, in or on the commodities.

* * * * *

[FR Doc. 2011–33477 Filed 12–29–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0283; FRL–9330–1]

Cyhalofop-butyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends tolerances for residues of cyhalofop-butyl in or on rice, grain and rice, wild, grain. Dow AgroSciences, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 30, 2011. Objections and requests for hearings must be received on or before February 28, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2011–0283. All documents in the