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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 [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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 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: Kathryn V. Montague, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-1243; e-mail address: *montague.kathryn @epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding

the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0283 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 [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0283, 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 April 20, 2011 (76 FR 22067) (FRL- 8869-7), 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 1F7836) by Dow AgroSciences, LLC, 9330 Zionsville Road, Indianapolis, IN, 46268 . The petition requested that 40 CFR 180.576 be amended by reestablishing and making permanent tolerances for residues of the herbicide, cyhalofop-butyl, R-(+)-n-butyl-2-(4(4-cyano-2-fluorophenoxy)-phenoxy)propionate, plus cyhalofop acid, R-(+)-2-(4(4-cyano-2-fluorophenoxy)-phenoxy)propionic acid) and the di-acid metabolite, (2R)-4-[4-(1-carboxyethoxy)phenoxy]-3-fluorobenzoic acid, in or on rice, grain and rice, wild, grain at 0.35 parts per million (ppm), respectively. That notice referenced a summary of the petition prepared by Dow AgroSciences, LLC, the registrant, which is available in the

docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing. These amended tolerances are required due to recent side-by-side field trial data submitted to support a new formulation of cyhalofop-butyl, which resulted in higher than anticipated residues associated with the currently registered formulation with this active ingredient. Based upon review of the data supporting the petition, EPA has increased the proposed tolerances from 0.35 ppm to 0.40 ppm and has revised the tolerance expression. 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 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 cyhalofop-butyl

including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyhalofop-butyl 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.

Cyhalofop-butyl has low or minimal acute toxicity via the oral, dermal and inhalation routes of exposure. It is minimally irritating to the eye, nonirritating to the skin and is not a dermal sensitizer.

Kidney effects were observed after subchronic and chronic dosing of the rat and mouse as well as in the rabbit developmental and rat reproduction studies. In the 90–day rat study, lipofuscin pigment deposition in proximal tubule kidney cells was noted in both sexes in addition to hepatocyte eosinophilic granules (males only); and in the 90–day mouse study (females only), there was an increase in absolute and relative kidney weights as well as swelling of the proximal tubule cells. In the rabbit developmental study, 1/18 dams in the mid-dose group and 9/18 dams in the high-dose group died or were sacrificed in extremis after exhibiting hematuria (gross pathological examinations revealed cloudy or dark colored kidneys). Slight kidney tubular cell swelling was observed only in adult males in the rat reproductive toxicity study. In the 18–month mouse carcinogenicity study, kidney findings included tubular dilatation, chronic glomurulonephritis and hyaline casts in females (not males). In both sexes in the chronic/carcinogenicity rat study

increased deposition of kidney changes (early and increased deposition of the pigments lipofuscin and hemosiderin in the renal proximal tubular cells) was observed. In addition, in females only, renal mineralization was observed.

Non-kidney effects observed following subchronic or chronic exposure to cyhalofop-butyl included hyperplasia of the stomach mucosal epithelium (male mice only) in the 18–month mouse carcinogenicity study and brown and/or atrophied thymuses and decreased thymus weight in the 90–day dog study. The thymus effects, which could be an indication of potential immunotoxicity, were not observed in the 1–year dog study or in other species (rats, mice or rabbits) and were not seen in any tested species following chronic exposure to cyhalofop-butyl.

There was no evidence of developmental, reproductive or endocrine toxicity in the toxicology studies for cyhalofop-butyl. In the rat developmental toxicity study, there were no maternal or fetal effects observed up to the limit dose. In the rabbit developmental toxicity study, no fetal effects were observed up to the limit dose; whereas kidney effects (deaths related to hematuria and the occurrence of cloudy or dark colored kidneys on gross pathological examination) were seen in maternal animals. Slight kidney tubular cell swelling was observed in adult males in the rat reproductive toxicity study with no evidence of treatment-related effects observed in females or offspring. There were no systemic or neurotoxic effects noted at the limit dose in the gavage acute neurotoxicity study or in the 90–day feeding neurotoxicity study.

In a previous 2002 risk assessment for cyhalofop-butyl, it was not possible to assess the carcinogenic potential of cyhalofop-butyl due to insufficient dosing in the rat and mouse carcinogenicity studies. In the absence of acceptable data, EPA assumed that cyhalofop-

butyl had the same carcinogenic potential as the structural analog, diclofop-methyl, and conducted an exposure assessment to evaluate cancer risk using quantitative linear low-dose extrapolation and the Q1* for diclofop-methyl of 2.3 x 10^{-1} $(mg/kg/day)^{-1}$. Subsequently, two specific mechanistic studies (Peroxisome Proliferator Receptor-Alpha Reporter Assays) in the mouse were submitted to EPA. Review of the mechanistic data indicated that cyhalofop-butyl is not a liver toxicant/carcinogen for humans, since the rodent liver mode of action is not likely to occur in humans; and that the doses in the original long-term studies were approaching a maximum tolerated dose. In addition, there were no positive effects in the battery of mutagenic studies. Based on these findings, EPA has classified cyhalofop-butyl as ‘‘Not Likely to be Carcinogenic to Humans.’’ Specific information on the studies received and the nature of the adverse effects caused by cyhalofop-butyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* in document “Cyhalofop-butyl. Human Health Risk Assessment for Proposed Amended Tolerances on Rice and Wild Rice,” p. 8 in docket ID number EPA-HQ-OPP-2011-0283 and are also discussed in the final rule published in the **Federal Register** of April 8, 2009 (74 FR 15876) (FRL-8406-8).

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a

careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.* A summary of the toxicological endpoints for cyhalofop-butyl used for human risk assessment is shown in the Table of this unit.

Table — Summary of Toxicological Doses and Endpoints for Cyhalofop-butyl for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (All Populations)	No appropriate endpoint attributable to a single dose was available in the current database. Therefore, an acute RfD was not established for the general U.S. population or any population subgroup.		

Chronic dietary (All populations)	NOAEL= 1.0 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.010 mg/kg/day cPAD = 0.010 mg/kg/day	Carcinogenicity study in mice. LOAEL = 10.06/10.28 mg/kg/day, M/F , based on kidney effects in females including tubular dilatation, chronic glomerulonephritis, and hyaline casts
Cancer (Oral, dermal, inhalation)	Classified as "not likely to be carcinogenic to humans" in accordance with the EPA Final Guidelines for Carcinogen Risk Assessment (March 29, 2005).		

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. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to cyhalofop-butyl, EPA considered exposure under the petitioned-for tolerances as well as all existing cyhalofop-butyl tolerances in 40 CFR 180.576. EPA assessed dietary exposures from cyhalofop-butyl in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for cyhalofop-butyl; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed that all rice and wild rice commodities would be treated with cyhalofop-butyl and contain tolerance-level residues.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that cyhalofop-butyl 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 cyhalofop-butyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyhalofop-butyl. 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 Tier 1 Rice Model and Screening Concentration in Ground Water (SCI-GROW) model, the estimated drinking water concentrations (EDWCs)

of cyhalofop-butyl for chronic exposures for non-cancer assessments (the only dietary exposure scenario for which a toxicological endpoint of concern was identified) are estimated to be 21 parts per billion (ppb) for surface water and 0.152 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration value of 21 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). Cyhalofop-butyl 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 cyhalofop-butyl to share a common mechanism of toxicity with any other substances, and cyhalofop-butyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cyhalofop-butyl does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the 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*. The prenatal and postnatal toxicology data base for cyhalofop-butyl includes rat and rabbit developmental toxicity studies and a 2–generation reproduction toxicity study in rats. There were no treatment-related effects observed in fetuses or offspring in any of these studies.

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

i. The toxicity database for cyhalofop-butyl is complete except for immunotoxicity data. EPA has evaluated the available cyhalofop-butyl toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. Brown and/or atrophied thymuses and decreased thymus weight were observed in the 90–day dog study. However, these effects, which could be an indication of potential immunotoxicity, were not observed in the 1–year dog study or in other species (rats, mice or rabbits) and were not seen in any tested species following

chronic exposure to cyhalofop-butyl. Based on these considerations, EPA has concluded that the doses and endpoints selected for risk assessment (along with traditional uncertainty factors) are protective of potential immunotoxicity and an additional uncertainty factor is not needed. The required immunotoxicity study has been received by EPA and is currently being reviewed. A screening- level review of this study indicates that there are no immunotoxic effects associated with cyhalofop-butyl.

ii. There is no indication that cyhalofop-butyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

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

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

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term

risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, cyhalofop-butyl is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyhalofop-butyl from food and water will utilize 18 % of the cPAD for All Infants (< 1 year old), the population group receiving the greatest exposure. There are no residential uses for cyhalofop-butyl.

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). Cyhalofop-butyl is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to cyhalofop-butyl through food and water and will not be greater than the chronic aggregate risk.

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). Cyhalofop-butyl is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to cyhalofop-butyl through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Based on the evidence summarized in Unit III.A., cyhalofop-butyl is classified as ‘‘not likely to be carcinogenic to humans’’ and is, therefore, not expected to pose a cancer risk.

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 cyhalofop-butyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Gas Chromatography/Mass Spectrometry (GC/MS) Method GRM 99.06) 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; e-mail 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 cyhalofop-butyl.

C. Revisions to Petitioned-For Tolerances

EPA has revised the proposed tolerances levels. The petitioner requested tolerances of 0.35 ppm based on the use of the North American Free Trade Agreement (NAFTA) tolerance calculation procedures. Based on the submitted rice data using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures that were implemented in April 2011, EPA calculated that the rice, grain and wild rice, grain tolerances should be 0.40 ppm.

Also, EPA is revising the tolerance expression in order to make clear that the tolerances cover residues of the herbicide cyhalofop-butyl, including its metabolites and degradates. Compliance with the tolerance levels is to be determined by measuring cyhalofop butyl, cyhalofop acid, and the di-acid metabolite

V. Conclusion

Therefore, tolerances are established for residues of cyhalofop-butyl, including its metabolites and degradates, 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 tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In

addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 19, 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. Section 180.576 is amended by revising paragraph (a) to read as follows:

§ 180.576 Cyhalofop-butyl; tolerances for residues.

(a) *General*. Tolerances are established for residues of cyhalofop-butyl, including its metabolites and degradates, in or on the commodities listed in the table below. Compliance with the tolerance levels specified below is to be determined by measuring cyhalofop butyl [R-(+)-n-butyl-2-(4(4-cyano-2-fluorophenoxy)-phenoxy)propionate], cyhalofop acid [R-(+)-2-(4(4-cyano-2-fluorophenoxy)-phenoxy)propionic acid], and the di-acid metabolite [(2R)-4-(4-(1-carboxyethoxy)phenoxy)-3-fluorobenzoic acid].

Commodity	Parts per million
Rice, grain	0.40
Wild rice, grain	0.40

* * * * *

[FR Doc. 2011-33480 Filed 12/29/2011 at 8:45 am; Publication Date: 12/30/2011]