(b) *Section 18 emergency exemptions.* [Reserved]

* * * * *

[FR Doc. E9–7966 Filed 4–7–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0361; FRL–8406–8]

Cyhalofop-butyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of cyhalofop-butyl, cyhalofop acid and the di-acid metabolite in or on rice, grain and rice, wild, grain. Interregional Research Project Number 4 (IR-4) and Dow AgroSciences, LLC, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also removes the expired, time-limited tolerances for residues of cyhalofop-butyl, cyhalofop acid and the di-acid metabolite in or on on rice, grain and rice, straw.

DATES: This regulation is effective April 8, 2009. Objections and requests for hearings must be received on or before June 8, 2009, 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–2008–0361. 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; e-mail 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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0361 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before June 8, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0361, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Registers** of June 4, 2008 (73 FR 31862) (FRL–8365–3) and August 29, 2008 (73 FR 50963) (FRL–8379–2), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7341) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ, 08540; and a pesticide petition (PP 8F7403) by Dow AgroSciences, LLC, 9330 Zionsville Rd., Indianapolis, IN 46268, respectively. The petitions requested that 40 CFR 180.576 be amended by establishing tolerances for combined 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 (PP 8F7403) and rice, wild, grain (PP 8E7341) at 0.03 parts per million (ppm);

and in or on rice, straw at 8.0 ppm (8F7403). The notices referenced summaries of the petitions prepared by Dow AgroSciences, LLC, the registrant, which are available to the public in the dockets established for each action (PP 8E7341: Docket ID number EPA–HQ–OPP–2008–0361; and PP 8F7403: Docket ID number EPA–HQ–OPP–2008–0600) at *http://www.regulations.gov*. Comments were received on the notice of filing of PP 8F7403 (rice, grain). EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting these petitions and current Agency policy, EPA has determined that the proposed tolerance on rice, straw is unnecessary and should not be established. The reason for this change is 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 the petitioned-for tolerances for combined residues of cyhalofop-butyl, cyhalofop acid and the di-acid metabolite on rice, grain and rice, wild, grain at 0.03 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Cyhalofop-butyl has low or minimal acute toxicity via the oral, dermal and inhalation routes of exposure. It is minimally irritating to the eye, non-irritating 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 glomerulonephritis 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 asssessment to evaluate cancer risk using quantitative linear low-dose extrapolation and the Q1* for diclofop-methyl of 2.3×10^{-1} (mg/kg/day)$^{-1}$. Subsequently, two specific mechanistic studies (Peroxisome Proliferator Receptor-Alpha Reporter Assays (PPARά)) 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 PPARά 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 the document *Cyhalofop-butyl: Human Health Risk Assessment for Proposed Uses on Wild Rice and A Proposed Amended Labeling for Clincher® SF Herbicide,* page 30 in docket ID number EPA–HQ–OPP–2008–0361.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for

derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles, EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for cyhalofop-butyl used for human risk assessment can be found at *http://www.regulations.gov* in the document *Cyhalofop-butyl: Human Health Risk Assessment for Proposed Uses on Wild Rice and A Proposed Amended Labeling for Clincher® SF Herbicide*, page 16 in docket ID number EPA–HQ–OPP–2008–0361.

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. There are no other tolerances in effect for cyhalofop-butyl. 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 United States Department of Agriculture 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 results of carcinogenicity studies in rats and mice, and mechanistic studies in mice, EPA classified cyhalofop-butyl as ''Not Likely to be Carcinogenic To Humans;'' therefore, an exposure assessment for evaluating cancer risk is not needed for this chemical.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue or PCT information in the dietary assessment for cyhalofop-butyl. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for 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 I 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 database 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, and EPA has determined that an additional uncertainty factor is not required to account for potential immunotoxicity. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement is relatively new, these data are not yet available for cyhalofop-butyl. In the absence of specific immunotoxicity studies, 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.

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 offspring in the 2–generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed assuming 100 PCT 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. 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 15% of the cPAD for infants, less than 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*. 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

There are no CODEX, Canadian or Mexican maximum residue limits (MRLS) established for cyhalofop-butyl on the commodities associated with these petitions.

C. Response to Comments

An anonymous citizen objected to the presence of any pesticide residues on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) contemplates that tolerances greater than zero may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-For Tolerances

Dow AgroSciences proposed a tolerance for residues of cyhalofop-butyl on rice, straw. EPA recently concluded that rice straw is not a significant livestock feed item. Insignificant livestock feed items are considered covered by the tolerance for the raw agricultural commodity with which they are associated (62 FR 66020; December 17, 1997). Therefore, the proposed tolerance on rice, straw is unnecessary and is not being established.

V. Conclusion

Therefore, tolerances are established for combined residues of cyhalofop-

butyl, R-(+)-n-butyl-2-(4(4-cyano-2-fluorophenoxy)-phenoxy)propionate, plus cyhalopfop 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 0.03 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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: March 27, 2009.

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 the table in paragraph (a) to read as follows:

§ 180.576 Cyhalofop-butyl; tolerances for residues.

(a) * * *

Commodity	Parts per million
Rice, grain	0.03
Rice, wild, grain	0.03

* * * * *

[FR Doc. E9–7990 Filed 4–7–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0272; FRL–8406–6]

Spiromesifen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the combined residues of spiromesifen (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate) and its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents, in or on pop corn grain and stover. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, this regulation establishes tolerances for sweet corn, kernel, stover, and forage; and berry, lowgrowing, subgroup 13G. Interregional Research Project No. 4 (IR-4) requested these tolerances under the FFDCA. Additionally, the existing tolerance for strawberry is being deleted because it is superseded by the tolerances established for low growing berry subgroup 13–07G. Also, the tolerances for milk fat and meat byproducts of cattle, goats, horses, and sheep are being increased.In addition, this action establishes time-limited tolerances for the combined residues of spiromesifen (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate) and its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents, in or on soybean commodities in response to the approval of a specific exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing the use of spiromesifen on soybeans to control spider mites. The time-limited tolerances expire and are revoked on December 31, 2011.

DATES: This regulation is effective April 8, 2009. Objections and requests for hearings must be received on or before June 8, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION)**.