*Consistency in Implementation:* Nationally, almost all State/EPA UIC programs intend to apply the new Class V requirements state and Indian country-wide. The remaining UIC programs nonetheless expect that all motor vehicle waste disposal wells will be either closed or permitted.

*Possible Delay of Source Water Assessment Completion:* EPA's 1999 rule states that if all four steps (*i.e.,* inventory, delineation, susceptibility analysis, and public notification) of the assessment process for all applicable public water systems (PWSs) are not completed by a state or tribe by January 1, 2004, the new requirements affecting existing motor vehicle waste disposal wells will apply throughout the relevant state or area of Indian country, absent a formal request for a one-year extension. (40 CFR 144.87(b).) Based on feedback Region 8 has received from state and tribal source water program contacts, it is unlikely that assessments will be completed for all PWSs affected by this rule. This is particularly true in Indian country because tribes are not required to complete this work under the SDWA. Therefore, Region 8 expects that the new requirements will most likely apply across all Region 8 states and areas of Indian country, consistent with today's decision.

*Reduced Owner/Operator Liability:* EPA and State UIC program inspections and environmental audits conducted by property owners, lenders, and insurers have identified motor vehicle waste disposal wells as an unnecessary and long-term environmental liability. The costs of soil and ground water cleanup have far exceeded the preventive costs of adopting alternatives such as sewer connections, holding tanks, and dry shops. Today's decision will encourage these alternative, more environmentally sound means of managing and disposing of motor vehicle waste fluids.

Dated: May 17, 2002.

**Kerrigan G. Clough,**

*Assistant Regional Administrator, Office of Partnerships and Regulatory Assistance, Region 8.*

[FR Doc. 02–13699 Filed 6–3–02; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–2002–0087; FRL–7178–5]**

## Cyhalofop-butyl; Time-Limited Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for combined residues of cyhalofop (cyhalofop-butyl plus cyhalofop-acid) and the di-acid metabolite in or on rice grain and rice straw. Dow AgroSciences, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire on June 1, 2007.

**DATES:** This regulation is effective June 4, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0087, must be received on or before August 5, 2002.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0087 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–6224; and e-mail address: miller.joanne@epamail.epa.gov

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

| Categories | NAICS codes | Examples of potentially affected entities |
|---|---|---|
| Industry | 111<br>112<br>311<br>32532 | Crop production<br>Animal production<br>Food manufacturing<br>Pesticide manufacturing |

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,''and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0087. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

### II. Background and Statutory Findings

In the **Federal Register** of April 25, 2001 (66 FR 20808) (FRL–6774–7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–

170), announcing the filing of a pesticide petition (PP 0F6089) by Dow AgroSciences, LLC, 9330 Zionsville Road, Indianapolis, IN 46268. This notice included a summary of the petition prepared by Dow AgroSciences, LLC, theregistrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for combined residues of the herbicide cyhalofop-butyl (cyhalofop-butyl, cyhalofop-acid and cyhalofop-diacid) in or on rice grain, rice hull, rice bran and polished rice at 0.03 parts per million (ppm) and rice straw at 8.0 ppm.

Section 408(b)(2)(A)(i) of the 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) 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) 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....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for combined residues of cyhalofop (cyhalofop-butyl plus cyhalofop acid) and the di-acid metabolite in or on rice grain at 0.03 ppm and rice straw at 8.0 ppm. Tolerances are not required for rice processed fractions or for animal commodities. EPA's assessment of exposures and risks associated with establishing the tolerance 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. The nature of the toxic effects caused by cyhalofop-butyl are discussed in the following Table 1 and Table 2 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—ACUTE TOXICITY OF CYHALOFOP-BUTYL TECHNICAL

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.1100 | Acute Oral (Rat) | $LD_{50}$ >5000 mg/kg (limit test)<br>There was no evidence of toxicity.<br>Toxicity Category IV |
| 870.1100 | Acute Oral (Mice) | $LD_{50}$ >5000 mg/kg (limit test)<br>There was no evidence of toxicity.<br>Toxicity Category IV |
| 870.1200 | Acute Dermal (Rat) | $LD_{50}$ >5000 mg/kg (2.5 x the limit dose)<br>Chromodacryorrhea was observed in 2/5 males on day 2 only. Delayed weight gain was observed in all rats, with the females being most affected. There was no dermal irritation.<br>Toxicity Category IV |
| 870.1300 | Acute Inhalation (Rat) | $LC_{50}$ >5.63 mg/L (2.8 x the limit concentration)<br>Bradypnea was noted in all rats with recovery within two hours following exposure. Abnormal respiratory sounds were noted in all rats after exposure with recovery by day 1. Reddish adhesive materials in the nasorostral and periocular regions were noted from all test rats after exposure with recovery by day 2. No gross abnormalities.<br>Two control rats had reddish adhesive materials in the nasorostral region after exposure with recovery within two hours.<br>Toxicity Category IV |
| 870.2400 | Primary Eye Irritation - Rabbit | Minimally irritating<br>Toxicity Category IV |
| 870.2500 | Primary Skin Irritation - Rabbit | Essentially nonirritating<br>Toxicity Category IV |
| 870.2600 | Dermal Sensitization - Guinea Pig | Not a dermal sensitizer |

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.3100 | Subchronic (4 and 13 Week) Feeding (Rat) | NOAEL (male)≥400 mg/kg/day (Highest Dose Tested [HDT] in male)<br>NOAEL (female) = 400 mg/kg/day<br>LOAEL (female) = 800 mg/kg/day<br>(HDT in female) based on perineal soiling and reduced body weights and body weight gain. |
| 870.3100 | Subchronic Feeding (Rat) | NOAEL = 60.5/65.3 mg/kg/day,M/F<br>LOAEL = 189.5/199.6 mg/kg/day, M/F (HDT) based on kidney toxicity (lipofuscin pigment deposition in proximal tubule cells) in both sexes, and possible liver toxicity (hepatocyte eosinophilic granules) in males. |
| 870.3100 | Subchronic Feeding (Mice) | NOAEL (male)≥30 mg/kg/day (HDT in male)<br>NOAEL (female)≥100 mg/kg/day (HDT in female) |
| 870.3100 | Subchronic Feeding (Mice) | NOAEL (male) ≥37.5 mg/kg/day (HDT)<br>NOAEL (female) = 4.3 mg/kg/day<br>LOAEL (female) = 14.1 mg/kg/daybased on enlarged kidneys (20% absolute and relative) accompanied by swelling of the proximal tubule cells (4/12 mice). |
| 870.3150 | Subchronic Feeding (Dog) | NOAEL = 14.7 / 15.6 mg/kg/day, M/F<br>LOAEL = 75.2 / 79.4 mg/kg/day, M/F (HDT) based on brown and/or atrophied thymuses, and decreased thymus weight. |
| 870.3200 | 21-Day Dermal (Rat) | Systemic NOAEL ≥1000 mg/kg/day (limit dose)<br>Dermal NOAEL ≥1000 mg/kg/day (limit dose) |
| 870.3700 | Gavage Developmental Toxicity (Rat) | Maternal NOAEL =1000 mg/kg/day (limit dose)<br>Developmental NOAEL ≥1000 mg/kg/day (limit dose) |
| 870.3700 | Gavage Developmental Toxicity (Rabbit) | Maternal NOAEL = 40 mg/kg/day<br>Maternal LOAEL = 200 mg/kg/day based on maternal death<br>Developmental NOAEL ≥1000 mg/kg/day (limit dose) |
| 870.3800 | Feeding Reproductive Toxicity (Rat) | Systemic NOAEL (males) = 100 ppm (4.85-13.75 mg/kg/day)<br>Systemic LOAEL (males) = 1000 ppm (50.0-138.7 mg/kg/day) based on kidney lesions (slight tubular cell swelling) in $F_0$ and $F_1$ male rats.<br>Systemic NOAEL (females) ≥1000 ppm (69.2-147.7 mg/kg/day, HDT)<br>Reproductive NOAEL ≥1000 ppm (50.1-138.7 mg/kg/day for males; 69.2-147.7 mg/kg/day for females)<br>Offspring NOAEL ≥1000 ppm (50-147.7 mg/kg/day) |
| 870.4100 | Chronic Feeding Toxicity (Dog) | NOAEL ≥46.7 / 45.9 mg/kg/day; M/F (HDT) |
| 870.4200 | Carcinogenicity Feeding (Mouse) | NOAEL = 0.99 mg/kg/day<br>LOAEL = 10.06 / 10.28 mg/kg/day, M/F (HDT) based on effects on the kidney including tubular dilatation, chronic glomerulonephritis, and hyaline casts in females, and hyperplasia of the stomach mucosal epithelium in males. There was no evidence of carcinogenic potential under the conditions of this study. Dosing was too low to elicit frank toxicity and inadequate to assess carcinogenic potential. |
| 870.4300 | Chronic Feeding Toxicity / Carcinogenicity (Rat) | NOAEL = 0.823 mg/kg/day in males and 2.475 mg/kg/day in females<br>LOAEL = 3.44 mg/kg/day (HDT in males), 24.97 mg/kg/day (HDT in females) based on the early and increased deposition of the pigments lipofuscin and hemosiderin in the renal proximal tubular cells of both sexes, and renal mineralization in female rats. There were no treatment-related increases in tumor incidence, compared to controls. Dosing was too low to elicit frank toxicity and inadequate to assess carcinogenic potential. |
| 870.5100 | Bacterial Reverse Gene Mutation Test (Ames Assay) | Negative in *Salmonella* TA strains and *E. coli* WP2 uvrA. |
| 870.5300 | Gene Mutation in Mouse | Negative |
| 870.5375 | *In Vitro* Cheomosomal Aberration in Chinese Hamster Lung | Polyploidy was induced when CHL (V79) cells were treated for 48 hours in the absence of S9, but there was no clastogenic effect on DNA. |

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.5395 | *In Vivo* Mammalian Cytogenetics - Micronucleus Assay in Mouse Bone Marrow Cells | Negative |
| 870.5550 | Unscheduled DNA Synthesis in Rat Hepatocytes | Negative |
| 870.6200 | Gavage Acute Neurotoxicity (Rat) | NOAEL ≥2000 mg/kg (limit dose) based on the absence of clinical signs, a lack of effects on FOB parameters and motor activity, and the absence of neuropathologic lesions. |
| 870.6200 | Feeding Subchronic Neurotoxicity (Rat) | NOAEL ≥75 male/ ≥250 female mg/kg/day (HDT) based on the absence of clinical signs, lack of effects on FOB parameters and motor activity, and absence of neuropathologic lesions. |
| Special Study | Pharmacology - Mice and Rabbits | Mice: A single I.P. dose of 1250 or 5000 mg/kg was lethal to all male and female mice within 24 hours. Death occurred as early as three hours at 5000 mg/kg and was preceded by behavioral and motor function abnormalities (e.g., alterations in alertness, visual placing, spontaneous activity, incoordination, decreased muscle tone, and compromised autonomic reflexes), some of which appeared as early as 30 minutes postdosing. Male and female mice responded similarly.<br>NOAEL = 78.1 mg/kg<br>LOAEL = 313 mg/kg (based on minimal effects including decreased spontaneous activity, minor alterations in muscle tone, and minor changes in autonomic functions such as slight hyperthermia, and slightly decreasedrespiratory rate).<br>LD≥1250 mg/kg<br>Rabbits: One of three rabbits gavaged at 5000 mg/kg showed decreased spontaneous activity, prostration, decreased muscle tone, compromised autonomic reflexes, and decreased respiratory and heart rate at one day after dosing, and died on Day 4. There were no clinically significant findings in the remaining rabbits of the 5000 mg/kg dose group or any lower dose groups, and no significant effects on EKGs or blood pressure in any dosed rabbits.<br>NOAEL = 2500 mg/kg<br>LOAEL = 5000 mg/kg (based on the response of one of three test subjects including decreased spontaneous activity, prostration, decreased muscle tone, compromised autonomic reflexes, decreased respiratory and heart rate at one day after dosing, and death on day 4). |
| 870.7485 | Absorption, Metabolism, and Excretion (Dog) | No treatment-related adverse effects were reported. Approximately 50% of a single gavage dose was absorbed over several hours. Bloodand plasma radioactivity peaked after 1-2 hours.<br>Clearance from plasma and blood was notespecially rapid but nearly complete at 48 hours. Over 168 hours, excretion was 42.5-43.9% in the urine, and 48.6-50.6% in the feces. Tissue distribution was not measured. The test article appears to be metabolized primarily by hydrolysis to R-(+)-2-[4-cyano-2-fluorophenoxy)phenoxy]propanoic acid which was found in both the urine and feces. Several other metabolites were also formed, each representing <5% of the administered dose. No parent compound was found in the urine, and only minimal amounts were detected in the feces. |
| 870.7485 | Metabolism and Pharmacokinetics (Rat) | Absorption of gavaged test article was 93-100%, and urinary excretion was the major route of elimination regardless of dose, label position, or gender. Over 168-hours, 84-100% of the radioactivity was eliminated in urine, with 86-90% eliminated within 24 hours. Fecal excretion was <5%. There was no elimination via expired air. Over a 24-hour period, biliary elimination accounted for 1.7 % and 20.1% of the administered dose in males and females, respectively, in the low-dose [$\alpha$-$^{14}$C]XRD–537 BE group, and 17.0% (males) and 11.6% (females) of the administered dose in the [$\beta^{14}$C]XRD–537 BE low-dose group.<br>The greatest radioactivity levels were found in liver, kidneys, plasma, whole blood, heart, lung, and stomach, with the highest tissue levels being found in the liver and kidney at 2 hours. Most tissue levels accounted for <1% of the administered dose. Due to rapid excretion,tissue/organ levels declined to near detection limits by 24 hours in all dose groups. |

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

| Guideline No. | Study Type | Results |
|---|---|---|
| | | There was a biphasic pattern for both labels with no substantial differences in pharmacokinetic indices ($C_{max}$, $t_{cmax}$, $t_{1/2}$, AUC). Time-to-maximum plasma concentration ($t_{cmax}$ of 0.5 to 4 hrs) elimination half-times ($t_{1/2}$) reflected the relatively rapid absorption. Females had somewhat shorter tcmax and lower $C_{max}$ values suggestive ofsaturated absorption processes. The acid metabolite (R-(+)-2-[4-(4-cyano-2-fluoro-phenoxy)phenoxy]propanoic acid) was the most prominent plasma fraction (~90-94% of the dose for males and ~75-81% for females regardless of dose).<br>No parent compound or other metabolites were detected. The acid metabolite was the most common product in urine and feces 71-87% (urine) and 46-75% (feces) of the administered dose. |
| 870.7600 | Dermal Penetration (Rat) | Dermal absorption was ~25-34% for the spray formulation and ~11-16% for the EF-1218 formulation following a 24 hour dermal dosing. Within 48 hours, excretion was >85% in the urine and <1% in the feces, which is consistent with metabolism to water soluble metabolites and subsequent urinary excretion.<br>Levels tested: Four Fischer 344 rats were dermally dosed for 24 hours with $^{14}$C-labeled DE-537 n-butyl ester and nonlabeled DE-537 n-butyl ester in two formulations 200 mg/mL test article in EF1218 (Clincher EDC with which DE-537 n-butyl ester is normally formulated) and a spray solution at 0.005, 1.0, or 1.8 mg/cm$^2$. |
| Special Study | Hepatocellular Proliferation in Rats | In a subchronic oral toxicity study in rats (MRID 45000413), satellite rats dosed for 4 weeks had hepatocellular hypertrophy and focal necrosis at all dose levels. Although multiple necrotic foci accompanied by inflammatory cells were graded very slight, and were not considered dose-related, this study was performed to explore these findings.<br>An initial dramatic increase in DNA synthesis during the first week of treatment was followed by hepatocellular hypertrophy at subsequent observations. This was the reason for enlarged livers observed in XRD-537nBu-treated rats.<br>Levels tested: 0, 3.0, 25, 100, or 400 mg/kg/day in the diet with sacrifices at 1, 2, 4, and 13 weeks. One week prior to sacrifice, 10 µL BrdU/hour was administered via an ALZET osmotic pump implanted subcutaneously. BrdU is a DNA stain used to quantify hepatocellular proliferation. |

*B. Toxicological Endpoints*

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x $10^{-6}$ or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer}$ = point of departure/exposures) is calculated. A summary of the toxicological endpoints for cyhalofop-butyl used for human risk assessment is shown in the following Table 3:

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYHALOFOP-BUTYL FOR USE IN HUMAN RISK ASSESSMENT

| Exposure Scenario | Dose (mg/kg/day) | Endpoint | Study |
|---|---|---|---|
| Acute Dietary | An appropriate endpoint attributable to a single dose was not identified. An acute RfD was not established. | | |

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYHALOFOP-BUTYL FOR USE IN HUMAN RISK ASSESSMENT—Continued

| Exposure Scenario | Dose (mg/kg/day) | Endpoint | Study |
|---|---|---|---|
| Chronic Dietary | NOAEL (Female) = 0.99<br>FQPA SF = 1 | Kidney effects in females including tubular dilatation, chronic glomerulonephritis, and hyaline casts at the LOAEL of 10.06 / 10.28 mg/kg/day, M/F. | Carcinogenicity in Mice<br>MRID 45000418 |
| | Chronic RfD = NOAEL/UF = 0.99 mg/kg/day/100 ≈0.01 mg/kg/day<br>Chronic PAD = cRfD/FQPA SF = 0.01 mg/kg/day/1 = 0.01 mg/kg/day | | |
| Incidental Oral, Short-Term (1–30 days) | NOAEL (Female) = 4.3<br>FQPA SF = 1 | Enlarged kidneys in females accompanied by swelling of the proximal tubule cells in 4/12 mice at the LOAEL of 14.1 mg/kg/day.<br>LOC = 100 | Subchronic Feeding in Mice<br>MRID 45014706 |
| Incidental Oral, Intermediate-Term (1–6 months) | | | |
| Dermal, Short-Term (1–30 days) | No hazard has been identified to support quantification ofrisk. No systemic effects were observed in the 21-day dermal study in therat at doses up to 1000 mg/kg/day (limit dose). In addition, nodevelopmental effects were observed in the developmental toxicity studies. | | |
| Dermal, Intermediate-Term (1–6 months) | | | |
| Dermal, Long-Term[a](>6 months) | NOAEL (Female) = 0.99<br>FQPA SF = 1 | Kidney effects in females including tubular dilatation, chronic glomerulonephritis, and hyaline casts at the LOAEL of 10.06 / 10.28 mg/kg/day, M/F.<br>LOC = 100 | Carcinogenicity in Mice<br>MRID 45000418 |
| Inhalation, Short-Term[b](1–30 days) | NOAEL (Female) = 4.3<br>FQPA SF = 1 | Enlarged kidneys in females accompanied by swelling of the proximal tubule cells in 4/12 mice at the LOAEL of 14.1 mg/kg/day.<br>LOC = 100 | Subchronic Feeding in Mice<br>MRID 45014706 |
| Inhalation, Intermediate-Term[b](1–6 months) | | | |
| Inhalation, Long-Term[b](>6 months) | NOAEL (Female) = 0.99<br>FQPA SF = 1 | Kidney effects in females including tubular dilatation, chronic glomerulonephritis, and hyaline casts at the LOAEL of 10.06 / 10.28 mg/kg/day, M/F.<br>Target MOE = 100 | Carcinogenicity in Mice<br>MRID 45000418 |
| Cancer | This herbicide has not been classified. The rat and mouse carcinogenicity studies are identified as data gaps. Since the doses tested in these studies were too low to assess the carcinogenic potential of cyhalofop-butyl, the cancer dietary risk assessment was conducted using the potency factor (Q1*) of 2.3 x $10^{-1}$ for the structural analog diclofop-methyl. | | |

[a]Since an oral endpoint was identified, a 34% dermal absorption factor should be used in route-to-route extrapolations.
[b]Since an oral endpoint was identified, a default oral: inhalation absorption factor of 1 should be used in route-to-route extrapolations.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* No tolerances have previously been established for the combined residues of cyhalofop-butyl, in or on raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from cyhalofop-butyl in food as follows:

i. *Acute exposure.* Acute dietary 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 one day or single exposure. No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies. No appropriate study available show any acute dietary effects of concern.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA insert 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Residue levels are at the recommended tolerances for rice and 100% of the crop rice is treated with cyhalofop-butyl. All sub-populations had dietary exposure values which represented <1% of the cPAD.

iii. *Cancer*. The cancer dietary risk assessment was conducted using the potency factor (Q1*) of $2.3 \times 10^{-1}$ for the structural analog diclofop-methyl since the dose levels in the rat and mouse carcinogenicity studies were too low to assess the carcinogenic potential of cyhalofop-butyl. In cancer studies with diclofop-methyl there are tumors at doses similar to those doses which caused no tumors in the cyhalofop-butyl studies. Hypothetical rat and mouse Q1* values were calculated on the assumption that tumor incidence might rapidly escalate at doses greater than those actually used in the submitted studies. When a hypothetical Q1* was calculated for cyhalofop-butyl by assigning increased tumors at doses above those actually tested, the results came out slightly less potent than the Q1* for diclofop-methyl . For risk assessment purposes the diclofop-methyl Q1* will not underestimate any possible cancer risk. A refined (Tier 3) deterministic cancer risk assessment was conducted. Inputs to the dietary exposure assessment included the anticipated residues of 0.0066 ppm for rice grain from field trials and estimates that a maximum of 17.6% of rice will be treated with cyhalofop-butyl. Based on the anticipated residue and the percent of the crop treated, the refined dietary cancer risk from residues in food is $6.2 \times 10^{-8}$.

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information in Table 4 and Table 5 as follows.

TABLE 4.—SOUTHERN STATES ESTIMATED PERCENT RICE CROP TREATED

| Year | 2002 | 2003 | 2004 | 2005 | 2006 |
|---|---|---|---|---|---|
| EPA Estimate | 2 | 4.3 | 4.3 | 5.02 | 5.6 |

TABLE 5.—CALIFORNIA ESTIMATED PERCENT RICE CROP TREATED

| Year | 2002 | 2003 | 2004 | 2005 | 2006 |
|---|---|---|---|---|---|
| EPA Estimate | 6.7 | 12.7 | 13.2 | 15.6 | 17.6 |

The Agency believes that the three conditions have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The market share was for cyhalofop-butyl on rice was projected based on current percent of crop treated with the existing alternative controls. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. More importantly, EPA has taken steps to ensure this market share projection is not exceeded by imposing, as a condition of registration for cyhalofop-butyl under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, a production limit corresponding to the projection. As to Conditions 2 and 3, regional consumption information and consumption information for significant sub-populations is taken into account through EPA's computer-based model for evaluating the exposure of significant sub-populations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant sub-population group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which cyhalofop-butyl may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for cyhalofop-butyl in drinking water. Because the Agency does not have comprehensive monitoring data,

drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of cyhalofop-butyl.

The GENEEC model is not adequate for predicting the estimated environmental concentrations (EECs) for pesticide applications to rice. The Agency developed a model using available chemical and physical property data, to calculate the EECs for the use of cyhalofop-butyl on rice. The model was based on a hypothetical rice paddy, 1 hectare in size, flooded to a depth of 10 cm, with a sediment interaction zone of 1 cm. Based on these dimensions there are one million liters of water and 100 cubic meters of active sediment in the paddy. The sediment is assumed to weigh 135,000 kg based on a bulk density of 1.35g/cc. This model was used for both dry and water seeded rice.

The peak drinking water concentrations for the Gulf Coast and California are 137 and 36 ppb, respectively. The resulting chronic EECs (annual averages in Index Reservoir) are 14.2 and 3.7 ppb, respectively. The peak drinking water concentration for the Mississippi Valley is 119 ppb, and the chronic EEC annual average is 12.4 ppb. If the (normal) release is on day 78 (90 days from seedling), the peak is 25 ppb and the annual average is 2.6 ppb.

Based on this model and the SCI-GROW model the estimated environmentalconcentrations (EECs) of for acute exposures are estimated to be: In a water-seeded paddy 36 parts per billion (ppb) , and in a dry-seeded paddy 25 ppb for surface water and 0.16 ug/L ppb for ground water. The EECs for chronic exposures are estimated to be 3.7 ppb for water-seeded rice and 2.6 ppb for dry-seeded rice.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to cyhalofop-butyl they are further discussed in the aggregate risk sections.

Because EECs calculated using the above models exceeded the DWLOC regarding potential cancer risk, EPA undertook a further analysis of this estimate. It was determined that there was not sufficient reliable data to further refine these estimates. Therefore, the Agency required that the FIFRA label for cyhalofop-butyl mandate a holding time of seven days before the treated paddy water may be released to the environment. This 7–day holding time will result in the concentration of cyhalofop-butyl, expressed as an annual average (conc/365), falling below 0.15 ppb.

3. *From non-dietary exposure*. The term ''residentialexposure'' 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 use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism oftoxicity*. Section 408(b)(2)(D)(v) 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 does not have, at this time, available data to determine whether cyhalofop-butyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, cyhalofop-butyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cyhalofop-butyl has 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 the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

### *D. Safety Factor for Infants and Children*

1.*In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants andchildren. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* or postnatal exposure.

3. *Conclusion*. There is a complete toxicity data base for cyhalofop-butyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor should be reduced to 1x in assessing the risk posed by this chemical because: (1) There is no indication of quantitative or qualitative increased susceptibility; (2) a developmental neurotoxicity study (DNT) is notrequired; (3) the dietary food and drinking water exposure assessments will not underestimate the potential exposures for infants and children; (4) there currently no registered or proposed residential (non-occupational) uses of cyhalofop-butyl, and (5) the database pertaining to threshold effects on infants and children is complete.

### *E. Aggregate Risks and Determination of Safety*

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water

exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level andquantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculatedDWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with apesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. An appropriate endpoint attributable to a single dose was not identified. Therefore, cyhalofop-butyl is not expected to pose an acute risk.

2. *Chronic risk*. For all population subgroups, the chronic DWLOC is greater than the chronic surface EEC, and there is no expectation of migration of cyhalofop-butyl residues to ground water, therefore, aggregate chronic (non cancer) exposure to cyhalofop-butyl is not expected to exceed the Agency's level of concern. There are no residential uses for cyhalofop-butyl that result in chronic residential exposure to cyhalofop-butyl. The DWLOCs for chronic risk are shown in Table 6 as follows:

TABLE 6.—CHRONIC DWLOC CALCULATIONS

| Population Subgroup[1] | Chronic Scenario | | | | | |
|---|---|---|---|---|---|---|
| | cPAD mg/kg/day | Chronic Food Exp mg/kg/day[2] | Max Chronic Water Exp mg/kg/day[3] | Ground Water EEC (*units*) | Surface Water EEC (*units*)[4] | Chronic DWLOC (µg/L)[4/5] |
| U.S. Population | 0.01 | 0.000007 | 0.009993 | | 14.2 | 350 |
| All Infants | 0.01 | 0.000028 | 0.009972 | | 14.2 | 100 |
| Children (1-6 years) | 0.01 | 0.000015 | 0.009985 | | 14.2 | 100 |
| Children (7-12 years) | 0.01 | 0.000009 | 0.009991 | | 14.2 | 100 |
| Females (13-50 years) | 0.01 | 0.000005 | 0.009995 | | 14.2 | 300 |
| Males (13-19 years) | 0.01 | 0.000005 | 0.009995 | | 14.2 | 350 |
| Males (20+ years) | 0.01 | 0.000006 | 0.009994 | | 14.2 | 350 |
| Seniors (55+ years) | 0.01 | 0.000004 | 0.009996 | | 14.2 | 350 |
| Non-hispanic/non-white/non-black | 0.01 | 0.000018 | 0.009982 | | 14.2 | 350 |

[1]The Non-hispanic/non-white/non-black population was included in this table because it has the highest adult dietary exposure level. Body weights used to calculate the DWLOCs are 70 kg for adult males; 60 kg for adult females, and 10 kg for children <12 years.

[2]The chronic food exposure levels are for rice, the sole crop being considered for registration.

[3]Maximum Chronic Water Exposure (mg/kg/day) = [Chronic PAD (mg/kg/day) - Chronic Dietary Exposure (mg/kg/day)]

[4]This table presents the surface water EECs without taking into account the further reduction achieved by the mandated holding period. Even absent the holding period the predicted levels are well within the DWLOCs.

[5]Chronic DWLOC( µg/L) = [maximum chronic water exposure (mg/kg/day) x body weight (kg)]/[water consumption (L/day)x $10^{-3}$ mg/ µg]

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Cyhalofop-butyl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Cyhalofop-butyl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Cyhalofop-butyl is not registered for use on any sites that would result in residential exposure. The cancer dietary risk assessment was conducted using the potency factor (Q1*) of 2.3 x $10^{-1}$ for the structural analog diclofop-methyl since the dose levels in the rat and mouse carcinogenicity studies were too low to assess the carcinogenic potential of cyhalofop-butyl. In cancer studies with diclofop-methyl there are tumors at doses similar to those doses which resulted in no tumors in the cyhalofop-butyl studies. Hypothetical rat and mouse Q1* values were calculated on the assumption that tumor incidence might rapidly escalate at doses greater than those actually used in the submitted studies. These hypothetical Q1*s came out slightly less potent than the Q1* for diclofop-methyl. Thus, given that no data with cyhalofop-butyl

has indicated carcinogenic potential, use of the diclofop-methyl Q1* will produce a conservative (health-protective) estimate of cancer risk. Based on the anticipated residue and the percent of the crop treated, the refined dietary cancer risk from residues in food is $6.2 \times 10^{-8}$. The cancer DWLOC for the general population is shown in the table below. With a water holding time of 7 days, the concentration of cyhalofop-butyl residues in paddy water, expressed as an annual average (concentration/365) will be less than 0.15 µg/L. Since this value is below the calculated cancer DWLOC of 0.44 µg/L, aggregate cancer risk to cyhalofop-butyl is not expected to exceed EPA's level of concern.

TABLE 7.—CANCER DWLOC CALCULATIONS

| Population | Q* | Negligible Risk Level[1] | Target Max Exposure[2] mg/kg/day | Chronic Food Exposure mg/kg/day | Max Water Exposure[3] mg/kg/day | Cancer DWLOC[4](µ/L) |
|---|---|---|---|---|---|---|
| U.S. Population | 0.23 | $3 \times 10^{-6}$ | $1.3 \times 10^{-5}$ | $3 \times 10^{-7}$ | $1.27 \times 10^{-5}$ | 0.44 |

[1]EPA has traditionally regarded risks in the range of the probability of one in one million as negligible, with risks as high as three in one million considered as falling within that range.

[2] Target Maximum Exposure (mg/kg/day) = [negligible risk/Q*]

[3] Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure - Chronic Food Exposure (Note: There are no residential uses for this chemical.)

[4] Cancer DWLOC(µg/L) = [maximum water exposure (mg/kg/day) x body weight (kg)]/[water consumption (L) x $10^{-3}$ mg/µg]² Body weight (kg) = 70

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, and to infants and children from aggregate exposure to cyhalofop-butyl residues.

**IV. Other Considerations**

*A. Analytical Enforcement Methodology*

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

*B. International Residue Limits*

There are no CODEX, Canadian, or Mexican tolerances/Maximum Residue Levelsfor cyhalofop-butyl residues. Thus, harmonization is not an issue at this time.

*C. Conditions*

The following data gaps must be fulfilled: Subacute (28-day) inhalation toxicity study, a carcinogenicity study in rats, and a carcinogenicity study in mice.

**V. Conclusion**

Therefore, time limited tolerances are established for combined residues of cyhalofop (cyhalofop-butyl plus cyhalofop-acid) and the di-acid metabolite in or on rice grain at 0.03 ppm and rice straw 8.0 ppm.

**VI. Objections and Hearing Requests**

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

*A. What Do I Need to Do to File an Objection or Request a Hearing?*

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0087 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 on or before August 5, 2002.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of theHearing Clerk is (202) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you maycontact James Tompkins by phone at (703) 305–5697, by e-mail attompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins

at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0087, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

*B. When Will the Agency Grant a Request for a Hearing?*

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

## VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one ormore Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on therelationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

## VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 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 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: May 23, 2002.

**James Jones,**

*Acting Director, 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), 346(a) and 374.

2. Part 180 is amended by adding § 180.579 to read as follows:

**§ 180.579 Cyhalofop-butyl; tolerances for residues.**

(a) *General.* Time-limited tolerances are established for combined residues of cyhalofop (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, from the application of the herbicide cyhalofop-butyl in or on the following raw agricultural commodities:

| Commodity | Parts per million | Expiration/Revocation Date |
|---|---|---|
| Rice, grain | 0.03 | 6/1/2007 |
| Rice, straw | 8.0 | 6/1/2007 |

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

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 02–13982 Filed 6–3–02; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 271

**[FRL–7223–2]**

**RIN 2050–AE77**

### Notification of States Having Interim Authorization for the Amendments to the Corrective Action Management Unit Rule

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notification of interim authorization.

**SUMMARY:** The Environmental Protection Agency (''EPA'' or ''the Agency'') is today notifying the public which States have submitted notifications to EPA under the requirements of 40 CFR 271.27 and thus have interim authorization for the Corrective Action Management Units (CAMU) amendments rule (January 22, 2002, 67 FR 2962). The CAMU amendments rule granted interim authorization to states that are authorized for the 1993 CAMU rule, and that submitted a notification letter to EPA by March 22, 2002.

**FOR FURTHER INFORMATION CONTACT:** For general information, contact the RCRA Hotline at (800) 424–9346 or TDD (hearing impaired) (800) 553–7672. In the Washington, DC metropolitan area, call (703) 412–9810 or TDD (703) 412–3323. For more detailed information on specific aspects of today's document, contact Wayne Roepe, U.S. Environmental Protection Agency (5303W), 1200 Pennsylvania Ave., NW, Washington, DC 20460, at (703) 308–8630, or e-mail *roepe.wayne@epa.gov.*

**SUPPLEMENTARY INFORMATION:** The January 22, 2002 Corrective Action Management Units (CAMU) amendments rule promulgated amendments to the regulations governing CAMUs. These amendments were promulgated under HSWA statutory authority and are generally more stringent than the previous CAMU regulations, published on February 16, 1993 (58 FR 8658). Thus, in states that are authorized for the 1993 CAMU rule, there was the potential for dual implementation of the CAMU regulations by EPA and states authorized for the 1993 rule if these states are not authorized for the amendments before they become effective.

To avoid this potential disruption in the implementation of the RCRA cleanup program caused by the regulatory authority for CAMUs being split between states and EPA, the CAMU amendments rule promulgated an authorization procedure called interim authorization-by-rule. The rule also granted interim authorization for those amendments to states that have final authorization for the 1993 CAMU rule and submitted a letter to EPA that they are willing and able to implement the amended CAMU regulations by March 22, 2002 (see 40 CFR 271.27(a)).

A total of 25 states authorized for the 1993 CAMU rule, submitted the notification letter to EPA by March 22, 2002 and met the criteria for interim authorization-by-rule. These states are: Alabama, California, Delaware, Florida, Georgia, Illinois, Indiana, Louisiana, Missouri, Nevada, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Washington, Wisconsin, and Wyoming. Thus, these states have interim authorization for the CAMU amendments rule, effective April 22, 2002.

**List of Subjects in 40 CFR Part 271**

Environmental protection, Administrative practice and procedure, Hazardous waste, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: May 28, 2002.

**Marianne Lamont Horinko,**

*Assistant Administrator, Office of Solid Waste and Emergency Response.*

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BILLING CODE 6560–50–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Reclamation

### 43 CFR Part 422

**RIN 1006–AA42**

### Law Enforcement Authority at Bureau of Reclamation Projects

**AGENCY:** Bureau of Reclamation, Interior.

**ACTION:** Final rule with request for comments.

**SUMMARY:** The Bureau of Reclamation (Reclamation) is issuing this rule to establish criteria for the use of non-Department of the Interior (Department) law enforcement personnel within a Reclamation project or on Reclamation lands. We are required by law to issue this rule in order to provide for the security of dams, facilities, and resources under our jurisdiction.

**DATES:** This rule is effective on June 4, 2002. We must receive any comments on this final rule no later than August 5, 2002.

**ADDRESSES:** Any comments on this rule should be sent to Commissioner's Office, Bureau of Reclamation, 1849 C Street NW., Washington, DC 20240, Attn: Henk Willems.

**FOR FURTHER INFORMATION CONTACT:** Larry Todd, Director, Operations, Bureau of Reclamation, 1849 C Street NW., Washington, DC 20240, telephone (202) 513–0615.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Public Law 107–69 (November 12, 2001), an Act to Amend the Reclamation Recreation Management Act of 1992 (the Act) provides for law enforcement authority at Reclamation facilities. Section 1(g) provides: ''REGULATIONS—Except for the