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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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 FIFRA section 18 exemption under FFDCA section 408, 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).

IX. 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: September 11, 2001.

Peter Caulkins,

Acting 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), 346(a) and 371.

2. Section 180.442 is amended by alphabetically adding the following commodity to the table in paragraph (a) to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

(a)* * *

Commodity	Parts per million	Expiration/ Revocation Date
* *	*	* *
Sweet potato	0.05	12/31/03
* *	*	* *

* * * * *

[FR Doc. 01–24199 Filed 9–26–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301167; FRL–6800–2]

RIN 2070–AB78

Cyhalofop-butyl; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of cyhalofop-butyl plus the cyhalofop-acid and di-acid metabolites in or on rice grain and rice straw. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on rice. This regulation establishes a maximum permissible level for residues of cyhalofop-butyl plus the cyhalofop-acid and di-acid metabolites in this food commodity. These tolerances will expire and are revoked on June 30, 2002.

DATES: This regulation is effective September 27, 2001. Objections and requests for hearings, identified by docket control number OPP–301167, must be received by EPA on or before November 26, 2001.

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 VII. of the **SUPPLEMENTARY INFORMATION:** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301167 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone

number: (703) 305–6463; and e-mail address: madden.barbara@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 categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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/. 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 control number OPP–301167. 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, 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

EPA, on its own initiative, in accordance with sections 408(e) and 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for combined residues of the herbicide cyhalofop-butyl, 2-[4-(4-cyano-2-fluorophenoxy)phenoxyl]-propanoic acid, butyl ester (R) plus the cyhalofop-acid and di-acid metabolites, in or on rice grain at 0.03 part per million (ppm) and rice straw at 8.0 ppm. These tolerances will expire and are revoked on June 30, 2002. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . .''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Cyhalofop-butyl on Rice and FFDCA Tolerances

Weeds cause economic damage by competing with rice plants for soil, nutrients and sunlight, and by interfering with harvesting equipment. Bearded sprangletop is one of the most important grass weeds in California rice. The California Rice Research Board surveyed growers in 1999, and found that more than half reported an increasing trend in sprangletop infestation, while only 4% thought the weed was decreasing. The remainder called the weed populations ''variable'' or ''stable.''

As for impacts on yield, the University of California Cooperative Extension Service in 1999 conducted trials to investigate a link between sprangletop infestations and yield loss. The UC found that a 50% sprangletop cover results in yield losses ranging from 20% to as high as 60%.

In 2000, Rice Researchers, Inc. measured yield impacts of sprangletop at levels of infestation ranging from 1–3 plants per square meter to 25–30 plants per square meter. In three replications it was shown that yields were impacted as much as 25%.

The following conditions give rise to sprangletop infestations in California leading to yield losses: (1) thiobencarb cannot be applied to soils with Delayed Phytotoxicity Syndrome (DPS); (2) water management practices (BMPs) necessary for the protection or promotion of the rice that incidentally lead to heavier weed infestations; and (3) the lack of

suitable herbicides that are effective under all conditions.

EPA has authorized under FIFRA section 18 the use of cyhalofop-butyl on rice for control of Bearded sprangletop in California. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of cyhalofop-butyl in or on rice. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on June 30, 2002, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on rice grain or rice straw after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether cyhalofop-butyl meets EPA's registration requirements for use on rice or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of cyhalofop-butyl by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for cyhalofop-butyl, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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).

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 cyhalofop-butyl and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of cyhalofop-butyl plus the cyhalofop-acid and di-acid metabolites in or on rice grain at 0.03 ppm and rice straw at 8.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. 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 endpoint. 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 level of concern (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 1×10^{-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 1.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYHALOFOP-BUTYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary females 13–50 years of age and the general population including infants and children	None	None	An appropriate endpoint attributable to a single exposure (dose) was not identified in any study including the acute neurotoxicity study or developmental toxicity studies. No systemic effects were observed in the acute neurotoxicity study in rats at 2,000 mg/kg (limit dose), and no developmental effects were observed in the developmental toxicity studies.
Chronic dietary all populations	NOAEL = 0.99 mg/kg/day UF = 100 Chronic RfD = 0.01 mg/kg/day	FQPA SF = 10 cPAD = chronic RfD ÷ FQPA SF = 0.001 mg/kg/day	Carcinogenicity in mice LOAEL = 10.06 mg/kg/day based on kidney effects in females including tubular dilatation, chronic glomerulonephritis, and hyaline casts.
Short-term dermal (1 to 30 days) and intermediate-term dermal (1–6 months) (residential)	None	None	No hazard has been identified to support quantification of risk. No systemic effects were observed in the 21–day dermal study in the rat at doses up to 1,000 mg/kg/day (limit dose). In addition, no developmental effects were observed in the developmental studies.
Long-term dermal (greater than 6 months) (residential)	oral study NOAEL= 0.99 mg/kg/day (dermal absorption rate = 34% when appropriate)	LOC for MOE = 1,000 (residential)	Carcinogenicity in mice LOAEL = 10.06 mg/kg/day based on kidney effects in females including tubular dilatation, chronic glomerulonephritis, and hyaline casts.
Short-term inhalation (1 to 30 days) and intermediate-term inhalation (1–6 months) (residential)	inhalation (or oral) study NOAEL= 4.3 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (residential)	Subchronic feeding study in mice LOAEL = 14.1 mg/kg/day based on enlarged kidneys in females accompanied by swelling of the proximal tubule cells.
Long-term inhalation (greater than 6 months) (residential) Inhalation (or oral) study NOAEL = 1.0 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (residential)	Carcinogenicity in mice LOAEL = 10.06 mg/kg/day based on kidney effects in females including tubular dilatation, chronic glomerulonephritis, and hyaline casts.	
Cancer (oral, dermal, inhalation)	None	None	At the doses tested, there were no treatment-related increase in tumor incidence when compared to controls.

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Cyhalofop-butyl is a new chemical, this is the first tolerance established for the combined residues of cyhalofop-butyl plus the cyhalofop-acid and di-acid metabolites, in or on a raw agricultural commodity (rice grain and rice straw). 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. An appropriate endpoint attributable to a single exposure (dose) was not identified in any study including the acute neurotoxicity study or developmental toxicity studies. Therefore, acute dietary risk assessments were not conducted.

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 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: Use of 100% crop treated and tolerance level residues.

iii. *Cancer*. The Agency has not yet classified cyhalofop-butyl for cancer. A combined chronic toxicity/carcinogenicity study in rats and a carcinogenicity study in mice were conducted to assess the carcinogenic potential of cyhalofop-butyl. At the doses tested, there was no treatment-related increase in tumor incidence when compared to controls.

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 Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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 below.

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of cyhalofop-butyl for chronic exposures are estimated to be 4 parts per billion (ppb) for surface water and 0.016 ppb for ground 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 use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. 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).

C. 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 and children. 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. *Developmental toxicity studies*. In a developmental toxicity study in rats the maternal toxicity NOAEL is 1,000 mg/kg/day (limit dose). At the 1,000 mg/kg/day treatment level, the liver to body weight ratio and the liver to adjusted body weight ratio were both increased (106–107% of controls; $p < 0.01$), and there were slight, non-statistical increases in the mean absolute liver weights of all treated groups; however, these increases can be attributed to enzyme induction as an adaptive response to a xenobiotic agent rather than a treatment-related adverse effect. There were no treatment-related effects observed at 25 and 250 mg/kg/day. The developmental toxicity NOAEL is greater than or equal to 1,000 mg/kg/day (limit dose).

In a developmental toxicity study in rabbits the maternal LOAEL is 200 mg/kg/day based on maternal death. The maternal NOAEL is 40 mg/kg/day. The developmental NOAEL is greater than or equal to 1,000 mg/kg/day (limit test).

3. *Reproductive toxicity study*. In a 2–generation reproduction study in rats no treatment-related deaths, clinical signs, body weight changes, or food consumption differences were observed for parental male or female rats in either generation administered any dose of the test material. No effects were observed for F0 or F1 females during gestation or lactation. The Reproductive NOAEL is greater than or equal to 1,000 ppm (50.1–138.7 mg/kg/day for males; 69.2–147.7 mg/kg/day for females, highest dose tested (HDT)) and the Offspring NOAEL is greater than or equal to 1,000 ppm (50–147.7 mg/kg/day, HDT).

4. *Neurotoxicity studies.* In an acute neurotoxicity study in rats the NOAEL is greater than or equal to 2,000 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 following gavage dosing.

In a subchronic neurotoxicity study in rats the NOAEL is greater than or equal to 75 mg/kg/day HDT in males and greater than or equal to 250 mg/kg/day (HDT) in females based on the absence of clinical signs, lack of effects on FOB parameters and motor activity, and absence of neuropathologic lesions.

5. *Conclusion*. There is no evidence of quantitatively or qualitatively increased susceptibility in the developmental toxicity studies in rats and rabbits, or in the two generation reproductive toxicity study in rats. However, cyhalofop-butyl has not been evaluated by the Agency's FQPA Safety Factor Committee. Therefore, for the purposes of this emergency exemption, the FQPA safety factor of 10X, to protect infants and children has been retained for all dietary and residential risk assessments.

D. 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 + chronic non-dietary, non-occupational 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 and quantitative 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 ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to cyhalofop-butyl 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 a pesticide'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 cyhalofop-butyl on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. An appropriate endpoint attributable to a single exposure (dose) was not identified in any study including the acute neurotoxicity study or developmental toxicity studies. Therefore, acute dietary risk assessments were not conducted.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cyhalofop-butyl from food will utilize less than 1% of the cPAD for the U.S. population, 4% of the cPAD for non-nursing infants (infant subpopulation at greatest exposure) and 2% of the cPAD for children 1–6 years old (children subpopulation at greatest exposure. There are no residential uses for cyhalofop-butyl. In addition, despite the potential for chronic dietary exposure to cyhalofop-butyl in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of cyhalofop-butyl in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2. —AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CYHALOFOP-BUTYL

Population subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.001	1%	4	0.016	35
Children 1–6 years old	0.001	2%	4	0.016	5
Non-nursing infants	0.001	4%	4	0.016	5

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 were previously addressed.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account non-dietary, non-occupational 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 were previously addressed.

5. *Aggregate cancer risk for U.S. population*. The Agency has not yet classified cyhalofop-butyl for cancer. A combined chronic toxicity/carcinogenicity study in rats and a carcinogenicity study in mice were conducted to assess the carcinogenic potential of cyhalofop-butyl. At the doses tested, there was no treatment-related increase in tumor incidence when compared to controls. Therefore, a risk assessment to estimate risk from cancer was not conducted.

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.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance

expression. The method may be requested from: Calvin Furlow, PRRIB, 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 is neither a Codex proposal, nor Canadian or Mexican limits, for residues of cyhalofop-butyl and its metabolite in or on rice. Therefore, harmonization is not an issue for this use.

VI. Conclusion

Therefore, the tolerance is established for combined residues of cyhalofop-butyl, 2-[4-(4-cyano-2-fluorophenoxy)phenoxyl]propanoic acid, butyl ester (R) plus the cyhalofop-acid and di-acid metabolites in or on rice grain at 0.03 ppm and rice straw at 8.0 ppm.

VII. 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 control number OPP–301167 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 November 26, 2001.

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 the Hearing 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 may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.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 VII.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 the docket control number OPP–301167, 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).

VIII. Regulatory Assessment Requirements

This final rule establishes time-limited tolerances under FFDCA section 408. 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 other 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 FIFRA section 18 exemption under FFDCA section 408, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 or more 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 the relationship 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.

IX. 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: August 29, 2001.

Anne E. Lindsey,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[ADDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

§ 180.576 Cyhalofop-butyl, tolerances for residues.

2. Section 180.576 is added to read as follows:

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of cyhalofop-butyl, 2-[4-(4-cyano-2-fluorophenoxy)phenoxyl]propanoic acid, butyl ester (R), plus the cyhalofop-acid and di-acid metabolites in connection with use of the pesticide under section 18 emergency exemptions granted by the EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
*	* * * * *	
Rice, grain	0.03	6/30/02
Rice, straw	8.0	6/30/02

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

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

[FR Doc. 01-24198 Filed 9–26–01; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Office of Procurement and Property Management

48 CFR Parts 419 and 452

[AGAR Case 2000–01]

RIN 0599–AA09

Agriculture Acquisition Regulation; North American Industrial Classification System

AGENCY: Office of Procurement and Property Management, USDA.

ACTION: Direct final rule.

SUMMARY: This direct final rule amends the Agriculture Acquisition Regulation (AGAR) by replacing references to Standard Industrial Classification (SIC) Codes with references to North American Industrial Classification System (NAICS) codes. On July 26, 2000, the Federal Acquisition Regulation (FAR) was amended to employ NAICS codes for small business size determinations and other purposes in lieu of SIC codes. Since the AGAR supplements the FAR, USDA is amending the AGAR to reflect the FAR's adoption of NAICS codes.

DATES: This rule is effective November 26, 2001 without further action, unless we receive written adverse comments or written notice of intent to submit adverse comments on or before October 29, 2001. If we receive adverse comments, the Office of Procurement and Property Management will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: Please submit any adverse comments, or a notice of intent to submit adverse comments, in writing to U.S. Department of Agriculture, Office of Procurement and Property Management, Procurement Policy Division, Stop 9303, 1400 Independence Avenue SW, Washington, DC 20250–9303. You may submit comments or request additional information via electronic mail (E-mail) to *joe.daragan@usda.gov* or via fax at (202) 720–8972.

FOR FURTHER INFORMATION CONTACT: Joseph J. Daragan, (202) 720–5729.

SUPPLEMENTARY INFORMATION:

I. Background
II. Procedural Requirements
A. Executive Orders Nos. 12866 and 12988
B. Regulatory Flexibility Act
C. Paperwork Reduction Act
D. Small Business Regulatory Enforcement Fairness Act
E. Unfunded Mandates Reform Act
F. Executive Order 13132: Federalism
G. Executive Order 13084: Consultation and Coordination With Indian Tribal governments

I. Background

The AGAR implements the FAR (48 CFR chapter 1) where further implementation is needed, and supplements the FAR when coverage is needed for subject matter not covered by the FAR. On July 26, 2000, the FAR was amended to employ NAICS codes for small business size determinations and other purposes in lieu of SIC codes (65 FR 46055–46063). AGAR 452.219–70, a solicitation provision prescribed for use by AGAR 419.508, informs prospective offerors which small business size standards will be used in determining whether an offeror is a large business or a small business. The provision sets out size standards by SIC code. We are amending this provision and prescription to use NAICS codes to identify business classifications and applicable size standards. In this rulemaking document, USDA is amending the AGAR as a direct final rule, since the changes are non-controversial and unlikely to generate adverse comment.

Rules that an agency believes are noncontroversial and unlikely to result in adverse comments may be published in the **Federal Register** as direct final rules. The Office of Procurement and Property Management published a policy statement in the **Federal Register** (63 FR 9158, Feb. 24, 1998) notifying the public of its intent to use direct final rulemaking in appropriate circumstances.

This rule makes the following changes to the AGAR:

(a) In parts 419 and 452, we substitute the term ''North American Industrial Classification System'' and its acronym ''NAICS'' for the term ''Standard Industrial Classification'' and its acronym ''SIC'.

(b) In part 452, we change the date of the solicitation provision at AGAR 452.219–70, because the provision is amended by this direct final rule.

II. Procedural Requirements

A. Executive Orders Nos. 12866 and 12988

USDA prepared a work plan for this regulation and submitted it to the Office of Management and Budget (OMB) pursuant to Executive Order No. 12866. OMB determined that the rule was not significant for the purposes of Executive Order No. 12866. Therefore, the rule has not been reviewed by OMB. USDA has reviewed this rule in accordance with Executive Order No. 12988, Civil Justice Reform. The proposed rule meets the applicable standards in section 3 of Executive Order No. 12988.

B. Regulatory Flexibility Act

USDA reviewed this rule under the Regulatory Flexibility Act, 5 U.S.C. 601–611, which requires preparation of a regulatory flexibility analysis for any rule which is likely to have significant economic impact on a substantial number of small entities. USDA certifies that this rule will not have a significant economic effect on a substantial number of small entities, and, therefore, no regulatory flexibility analysis has been prepared. However, comments from small entities concerning the effects of the rule will be considered. Such comments must be submitted separately and cite 5 U.S.C. 609 (AGAR Case 2000–01) in correspondence.

C. Paperwork Reduction Act

No information collection or recordkeeping requirements are imposed on the public by this rule. Accordingly no OMB clearance is required by the Paperwork Reduction Act, 44 U.S.C. chapter 35, or OMB's implementing regulations at 5 CFR Part 1320.

D. Small Business Regulatory Enforcement Fairness Act

A report on this rule has been submitted to each House of Congress and the Comptroller General in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801–808. This rule is not a major rule for purposes of the Act.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. USDA has determined that this direct final rule does not contain a Federal mandate as defined in 2 U.S.C. 658(a). USDA has also determined that this direct final rule does not significantly or uniquely affect small governments. Accordingly, this rule is not subject to the requirements of Title II of UMRA.