appropriate circuit by November 19, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 30, 2001.

Sally Seymour,

Acting Regional Administrator, Region IX.

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

PART 52—[AMENDED]

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

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

Subpart D—Arizona

2. Section 52.120 is amended by adding paragraph (c)(97) to read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

(97) New and amended rules for the Arizona Department of Environmental Quality were submitted on March 26, 2001, by the Governor's designee.

(i) *Incorporation by reference.*

(A) Rules R18–2–310 and R18–2–310.01 effective on February 15, 2001.

[FR Doc. 01–23001 Filed 9–17–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301175; FRL–6803–2]

RIN 2070–AB78

Bispyribac-Sodium; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of bispyribac-sodium in or on rice. Valent U.S.A. Corporation (as agent for K-I Chemical U.S.A., Inc.) requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 18, 2001. Objections and requests for hearings, identified by docket control number OPP–301175, must be received by EPA on or before November 19, 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 VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301175 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: 703–305–5697; and e-mail address: *tompkins.jim@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	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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 homepage at *http://www.epa.gov/*. To access this document, on the homepage 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*. 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.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301175. 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 September 20, 2000 (65 FR 56901) (FRL–6742–7), 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) for tolerance by Valent U.S.A. Corporation (as agent for K-I Chemical U.S.A., Inc.), 1333 North California Blvd., Suite 600, Walnut Creek, CA 94569. This notice included a summary of the petition prepared by Valent U.S.A. Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the herbicide bispyribac-sodium, sodium 2,6-bis[(4,6-dimethoxy-pyrimidin-2-yl)oxy]benzoate, in or on rice, grain and rice, straw at 0.02 part per million (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 residues of bispyribac-sodium on rice at 0.02 ppm. 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 bispyribac-sodium are discussed in the following Table 1 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.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents (rat)	NOAEL = 71.9/79.9 mg/kg/day (M/F) LOAEL = 724.0/790.8 mg/kg/day (M/F), based on decreased body weight gain, increased absolute and relative liver weights, increased alkaline phosphatase and gamma-GTP, and increased incidence of grossly dilated bile duct lumen in males, and microscopic lesions in the liver, biliary system and urinary bladder in both sexes.
870.3100	90–Day oral toxicity rodents (mouse)	NOAEL = 68.6/79.0 mg/kg/day (M/F) LOAEL = 699.1/806.1 mg/kg/day (M/F), based on liver cell swelling and slight liver cell granulation in females
870.3150	90–Day oral toxicity in nonrodents (dog)	NOAEL = 100 mg/kg/day LOAEL = 600 mg/kg/day (M/F), based on increased salivation and slight proliferation of intrahepatic bile duct
870.3200	21/28-Day dermal toxicity (rat)	NOAEL = 1,000 mg/kg/day (M/F) LOAEL >1,000 mg/kg/day (M/F). No systemic toxicity or dermal irritation noted.
870.3700	Prenatal developmental in rodents (rat)	*Maternal* NOAEL = 1,000 mg/kg/day LOAEL = >1,000 mg/kg/day *Developmental* NOAEL = 1,000 mg/kg/day LOAEL = >1,000 mg/kg/day
870.3700	Prenatal developmental in nonrodents (rabbit)	*Maternal* NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day, based on lethargy, diarrhea, and decreased body weight gain in the range finding study *Developmental* NOAEL = 300 mg/kg/day LOAEL was not established

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3800	Reproduction and fertility effects (rats)	*Parental/Systemic* NOAEL = 1.5 mg/kg/day LOAEL = 75.7 mg/kg/day (M/F), based on trace to mild choledocus *Reproductive* NOAEL = 759.0 mg/kg/day LOAEL = >759 mg/kg/day *Offspring* NOAEL = 75.7 mg/kg/day LOAEL = 759 mg/kg/day (M/F), based on decreased body weights, body weight gains, and liver weights, and increased incidence of consolidation and circumscribed areas in the liver
870.4100	Chronic toxicity (dogs)	NOAEL = 10 mg/kg/day LOAEL = 100 mg/kg/day (M/F), based on dose-related increase in intrahepatic bile duct hyperplasia and liver granulation in females
870.4300	Combined chronic toxicity/carcinogenicity rodents (rat)	NOAEL = 10.9 mg/kg/day LOAEL = 194.5 mg/kg/day (M), based on macrosopic (yellowish liver, dilated choledochus lumen), microscopic (cellular infiltration, vacuolic changes in the bile ducts), and clinical signs (morbundity, wasting, piloerection, subnormal temperature, and decreased spontaneous motor activity. No evidence of carcinogenicity
870.4300	Carcinogenicity (mice)	NOAEL = 14.1/17.4 (M/F) mg/kg/day LOAEL = 353.0/447.8 mg/kg/day (M/F), based on decreased body weight gain, and food efficiency, and increased incidence of microscopic lesions in the liver and gall bladder (M) No evidence of carcinogenicity
870.5100	Gene mutation - reverse gene mutation assay in bacteria	There was no evidence of induced mutant colonies over background
870.5375	Cytogenetics - *in vitro* mammalian cytogenetic assay	Not clastogenic with or without S9 activation, at any dose tested
870.5395	Other effects - *in vivo* mammalian cytogenetic assay	Did not induce micronucleated polychromatic erythrocytes (PMCEs) in bone marrow at any dose
870.5500	Other genotoxic effects - bacterial DNA damage and repair test	No zones of inhibition and the differential killing index suggesting potential DNA damage
870.5550	Other genotoxic effects - UDS synthesis in mammalian cell culture	Did not induce UDS at any dose
870.7485	Metabolism and pharmacokinetics (rat)	A series of rat metabolism studies with ^{14}CPy-bispyribac-sodium and ^{14}C-Bn-bispyribac-sodium indicated that pretreatment, dose level, sex and position of the radiolabel made little effect on the absorption, distribution, elimination and metabolism. It was readily absorbed by male and female rats following intravenous or oral dosing. The total recovery of the administered radioactivity was 95.8 - 101.6% for all treatment groups. Most of the dose (>43%) of the administered dose was excreted in feces within 48 hours and essentially complete within 5 days. Less than 2% of the administered dose remained in the carcass and tissues and <0.1% of the dose was recovered in air. Parent and 5 metabolites were identified in the excreta of male and females following administered of ^{14}Cpy-bispyribac-sodium and Parent and 3 metabolites identified with of ^{14}C-Bn-bispyribac-sodium administration. The parent compound, bispyribac-sodium, was the major component identified in the feces (37 - 69% of the dose) and urine (5 - 41% of the dose), in both sexes. Metabolites identified in the excreta constituted 8.3 - 14.6% and unknown metabolites constituted 0.7 - 5.2% of the dose.
Non-guideline	Serum bile acids (mice)	Bile acids increased 115% and slight cecal enlargement in 9/10 treated mice
Non-guideline	Reversibility (mice)	Bispyribac-sodium was associated with liver lesions, bile duct hyperplasia and dilated gall bladders in subchronic and oncogenicity studies were not replicated in this reversibility study

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
Non-guideline	Serum bile acids (rat)	Total bile acids increased 1,072% (12-fold). The concentration of glycocholic acid, taurocholic acid, deoxycholic acid increased 2,127%, 2,991% and 138%, respectively, where as chenodeoxy cholic acid levels were similar to controls. Hyodeoxycholic acid was reduced from 34.0% to 3.3 of the total bile acids. Treatment altered the degree of conjugation; hyodeoxycholic acid increased 84% and deoxycholic acid increased 1,133%.
Non-guideline	Reversibility (rat)	Bispyribac-sodium was associated with urinary bladder epithelial hyperplasia in subchronic study and bile duct hyperplasia, enlarged bile ducts, and liver cell hypertrophy and fibrosis in chronic study. Upon removal of bispyribac-sodium from the diet, resulted complete recovery in liver enzymes, food consumption, food efficiency, body weights, however, muscular hypertrophy of choledocus was still evident. The study did not duplicate urinary bladder lesions noted in the subchronic study.
870.5100	Gene mutation - reverse gene mutation assay in bacteria	Metabolite DesMe-2023 did not induce mutantcolonies over background
870.5100	Gene mutation - reverse gene mutation assay in bacteria	Metabolite 2,4-dihydroxy-6-mehtoxy pyrimidine did not induce mutant colonies over background
870.5100	Gene mutation - reverse gene mutation assay in bacteria	Metabolite KIH-2023-M-8-Na did not induce mutant colonies over background
870.5100	Gene mutation - reverse gene mutation assay in bacteria	Metabolite KIH-2023-M-9-Na did not induce mutant colonies over background
870.5100	Gene mutation - reverse gene mutation assay in bacteria	Metabolite BIX-180 did not induce mutant colonies over background
870.5100	Gene mutation - reverse gene mutation assay in bacteria	Metabolite Me2BA did not induce mutant colonies over background
870.5100	Gene mutation - reverse gene mutation assay in bacteria	Metabolite KIH-2023-I-1 did not induce mutant colonies over background
870.5100	Gene mutation - reverse gene mutation assay in bacteria	Metabolite KIH-2023-I-2 did not induce mutant colonies over background
870.5100	Gene mutation - reverse gene mutation assay in bacteria	Metabolite KIH-2023-I-4 did not induce mutant colonies over background

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 intraspecies 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 bispyribac-sodium used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR BISPYRIBAC-SODIUM 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
Chronic dietary (all populations)	NOAEL = 10 mg/kg/day UF = 100 Chronic RfD = 0.1 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD ÷ FQPA SF = 0.1 mg/kg/day	Chronic toxicity study - dog LOAEL = 100 mg/kg/day based on dose-related increases in hyperplasia of the intrahepatic bile ducts in males and females and granulation of the liver in the females.
Short-term incidental oral (1-30 days) (residential)	NOAEL = 100 mg/kg/day	LOC for MOE = 100 (residential, includes the FQPA SF)	Developmental toxicity study - rabbit Maternal LOAEL = 300 mg/kg/day based on lethargy, diarrhea and decreased body weight gain in the range finding study
Intermediate-term incidental oral (1-6 months) (residential)	NOAEL = 100 mg/kg/day	LOC for MOE = 100 (residential, includes the FQPA SF)	90-Day feeding study - dog LOAEL = 600 mg/kg/day based upon salivation and slight proliferation of intrahepatic bile duct
Short-term inhalation (1-30 days) (occupational/residential)	Oral study NOAEL = 100 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (occupational) LOC for MOE = 100 (residential, includes the FQPA SF)	Developmental toxicity study - rabbit Maternal LOAEL = 300 mg/kg/day based on lethargy, diarrhea and decreased body weight gain.
Intermediate-term inhalation (1-6 months) (occupational/residential)	Oral study NOAEL = 100 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (residential, includes the FQPA SF)	90-Day feeding study - dog LOAEL = 600 mg/kg/day based upon salivation and slight proliferation of intrahepatic bile duct
Long-term inhalation (<6 months) (occupational/residential)	Oral study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (occupational) LOC for MOE = 100 (residential, includes the FQPA SF)	Chronic toxicity study - dog LOAEL = 100 mg/kg/day based on dose-related increases in hyperplasia of the intrahepatic bile ducts in males and females and granulation of the liver in the females.
Cancer (oral, dermal, inhalation)	''not likely''	Not applicable	No evidence of carcinogenic or mutagenic potential. A cancer risk assessment is not required.

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* No previous tolerances have been established for the residues of bispyribac-sodium. Risk assessments were conducted by EPA to assess dietary exposures from bispyribac-sodium 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 1 day or single exposure. Acute doses and endpoints were not selected for the general U.S. population (including infants and children) or the females 13–50 years old population subgroup for bispyribac-sodium; therefore, an acute dietary exposure analysis was not performed.

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: A conservative, deterministic chronic dietary exposure analysis for bispyribac-sodium was performed for the general U.S. population and all population subgroups using proposed tolerance level residues and 100% crop treated information for all rice commodities. The results of the analysis indicate that the estimated chronic dietary risks associated with the proposed use of bispyribac-sodium do not exceed HED's level of concern for the general U.S. population or any population subgroups.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a

comprehensive dietary exposure analysis and risk assessment for bispyribac-sodium 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 bispyribac-sodium. The SCI-GROW model is used to predict pesticide concentrations in ground water. Because the Agency currently has no official model for calculating the estimated environmental concentrations (EECs) in surface water due to rice culture, a screening calculation method was developed; thus, the resulting EECs are provisional only. Estimates were done for each of the three major rice growing regions in the United States, the Gulf Coast of Louisiana and Texas, the Mississippi Valley including parts of northern Louisiana, Mississippi, Arkansas, and southern Missouri, and California in the Sacramento River Basin. The surface water EEC is a point estimate representing only peak or acute concentrations. However, as no attempt has been made to determine chronic exposure and the chronic exposure should be less than the acute estimate, the resulting EECs can be used for both acute and chronic risk assessments. Since acute risk assessment is not required due to the lack of an acute dietary endpoint for bispyribac-sodium, the resulting EECs will be used for chronic risk assessment.

None of these models or screening calculation methods 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 and calculation methods used are considered to be screening tools in the risk assessment process, the Agency does not use 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 bispyribac-sodium, they are further discussed in the aggregate risk sections below.

Based on the screening calculation method described above and SCI-GROW model the EECs of bispyribac-sodium for acute exposures are estimated to be 0.317 parts per billion (ppb) for surface water and 0.0072 ppb for ground water. The EECs for chronic exposures are estimated to be 0.317 ppb for surface water and 0.0072 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).

Bispyribac-sodium 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 bispyribac-sodium 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, bispyribac-sodium 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 bispyribac-sodium 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).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *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.

ii. *Prenatal and postnatal sensitivity.* Based on the lack of developmental and offspring effects in both the developmental studies in rats and rabbits and the reproduction study in rats, the data for bispyribac-sodium demonstrate no indication of quantitative or qualitative increased susceptibility to bispyribac-sodium from prenatal or postnatal exposures.

iii. *Conclusion.* The toxicological data base for bispyribac-sodium is essentially complete with the exception of a 28–day inhalation toxicity study and an *in vitro* mammalian cell gene mutation assay. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed based on the following factors. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* or postnatal exposure. In addition, a developmental neurotoxicity study (DNT) with bispyribac-sodium is not required. The dietary food and drinking water exposure assessments will not underestimate the potential exposures for infants and children. Finally, there are currently no registered or proposed residential (non-occupational) uses of bispyribac-sodium.

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 and screening calculation 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 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, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA 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 acute aggregate risk assessment was not performed because an acute dietary endpoint was not selected.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to bispyribac-sodium from food will utilize less than 1% of the cPAD for the U.S. population and all population subgroups. There are no residential uses for bispyribac-sodium that result in chronic residential exposure to bispyribac-sodium. In addition, there is potential for chronic dietary exposure to bispyribac-sodium in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO BISPYRIBAC-SODIUM

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.1	<1	0.317	0.0072	3,500
All infants (<1 year old)	0.1	<1	0.317	0.0072	1,000
Children (1-6 years old)	0.1	<1	0.317	0.0072	1,000
Children (7-12 years old)	0.1	<1	0.317	0.0072	1,000
Females (13-50 years old)	0.1	<1	0.317	0.0072	3,000
Males (13-19 years old)	0.1	<1	0.317	0.0072	3,500
Males (20+ years old)	0.1	<1	0.317	0.0072	3,500
Seniors (55+ years old)	0.1	<1	0.317	0.0072	3,500

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). Bispyribac-sodium 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). Bispyribac-sodium 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*. A cancer aggregate risk assessment was not performed because bispyribac-sodium was negative for carcinogenicity and classified as ''not likely human carcinogen.''

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 bispyribac-sodium residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has proposed gas chromatography (GC) method RM-35R-2 for the enforcement of tolerances on rice grain and straw. The reported method limits of detection and quatitation for residues of bispyribac-sodium are 0.01 ppm and 0.02 ppm, respectively, in/on rice grain and straw. Adequate radiovalidation and independent laboratory validation data have been submitted for this method. The GC method RM-35R-2 has been forwarded to the EPA's Analytical Chemistry Branch of the Biological Economic Analysis Division for validation. The method includes procedures for confirmation of residues (analysis using a different GC column, and/or analysis by GC with mass selective detection).

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 are currently no established Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of bispyribac-sodium in/on plant or livestock commodities.

C. Conditions

Registration of bispyribac-sodium on rice is conditional on the acceptable submission of storage stability data for the benzene-labeled rice metabolism study, a poultry feeding study, a 28–day inhalation toxicity study, and an *in vitro* mammalian cell gene mutation assay.

V. Conclusion

Therefore, the tolerance is established for residues of bispyribac-sodium, sodium 2,6-bis[(4,6-dimethoxy-pyrimidin-2-yl)oxy]benzoate, in or on rice, grain and rice, straw at 0.02 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 control number OPP–301175 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 19, 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 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 control number OPP–301175, 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 tolerances 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 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 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 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.

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: September 7, 2001.

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 371.

2. Section 180.577 is added to read as follows:

§ 180.577 Bispyribac-sodium; tolerances for residues.

(a) *General.* Tolerances are established for residues of bispyribac-sodium, sodium 2,6-bis[(4,6-dimethoxy-pyrimidin-2-yl)oxy]benzoate, in or on the following raw agricultural commodities:

Commodity	Parts per million
Rice, grain	0.02
Rice, straw	0.02

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

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

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

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