

specified below is to be determined by measuring only the sum of sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its metabolite HMS (*N*-[2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl]methanesulfonamide), calculated as the stoichiometric equivalent of sulfentrazone in or on the following commodities.

(2) Tolerances are established for the combined residues of the free and conjugated forms of sulfentrazone, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its metabolites HMS (*N*-[2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl]methanesulfonamide) and

DMS (*N*-[2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl]methanesulfonamide), calculated as the stoichiometric equivalent of sulfentrazone in or on the following commodities.

Commodity	Parts per million
* * * * *	*
Brassica, head and stem, subgroup 5A .....	0.20
Brassica, leafy greens, subgroup 5B .....	0.40
* * * * *	*
Flax .....	0.15
* * * * *	*
Melon, subgroup 9A .....	0.15
Pea, succulent .....	0.15
* * * * *	*
Strawberry .....	0.15
* * * * *	*
Vegetable, fruiting, group 8–10 ..	0.15
Vegetable, tuberous and corm, subgroup 1C .....	0.15

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the free and conjugated forms of sulfentrazone, including its metabolites and degradates, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its metabolites HMS (*N*-[2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl]methanesulfonamide) and DMS (*N*-[2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl]methanesulfonamide), calculated as the stoichiometric equivalent of sulfentrazone in or on the following commodities. These tolerances expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Flax, seed .....	0.20	12/31/13
Strawberry .....	0.60	12/31/13

(d) *Indirect or inadvertent residues.* Tolerances are established for inadvertent and indirect combined residues of the free and conjugated forms of sulfentrazone, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its metabolites HMS (*N*-[2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl]methanesulfonamide) and DMS (*N*-[2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl]methanesulfonamide), calculated as the stoichiometric equivalent of sulfentrazone in or on the following commodities when present

therein as a result of the application of sulfentrazone to growing crops.

\* \* \* \* \*

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**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2009-0796; FRL-8860-2]

**Bispyribac-sodium; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of bispyribac-sodium in or on fish, freshwater. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective February 2, 2011. Objections and requests for hearings must be received on or before April 4, 2011, and must be filed in accordance with the instructions

provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0796. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:**  
Hope Johnson, Registration Division,  
Office of Pesticide Programs,  
Environmental Protection Agency, 1200  
Pennsylvania Ave., NW., Washington,  
DC 20460-0001; telephone number:  
(703) 305-5410; e-mail address:  
[johnson.hope@epa.gov](mailto:johnson.hope@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this action apply to me?*

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

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

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

*B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>. To access the harmonized test guidelines referenced in this document electronically, please go <http://www.epa.gov/ocsp> and select "Test Methods and Guidelines."

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0796 in the subject line on

the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 4, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-0796, by one of the following methods:

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

**II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of January 6, 2010 (75 FR 864) (FRL-8801-5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F7509) by Valent U.S.A Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596. The petition requested that 40 CFR 180.577 be amended by establishing tolerances for residues of the herbicide bispyribac-sodium, sodium, 2,6-bis[(4,6-dimethoxy-pyrimidin-2-yl)oxy]benzoate, in or on fish, freshwater at 0.01 parts per million (ppm). That notice referenced a summary of the petition prepared by Valent U.S.A Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised

the proposed tolerance expression. The reason for this change is explained in Unit IV.C.

**III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. \* \* \*"

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for bispyribac-sodium including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with bispyribac-sodium 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 toxicological database for bispyribac-sodium is complete with the exception of immunotoxicity, acute neurotoxicity, and subchronic neurotoxicity studies, as well as a 28-day inhalation study. Bispyribac-sodium has a low acute toxicity profile and is not a dermal sensitizer. The liver and bile duct were identified as the target organs in the subchronic and chronic toxicity studies in rats, mice, and dogs, and the reproductive toxicity

study in rats. Repeated dermal applications at the limit dose did not elicit systemic toxicity or dermal irritation. Bispyribac-sodium was negative for carcinogenicity in feeding studies in rats and mice and is classified as a “not likely human carcinogen” and mutagenicity studies conducted with the parent and three major metabolites were negative. There was no evidence of fetal toxicity or offspring susceptibility in the developmental toxicity studies in rats and rabbits or in the reproductive toxicity study in rats. Bispyribac-sodium has shown no indications of central or peripheral nervous system toxicity in any study and does not appear to be structurally related to any other chemical that causes adverse nervous system effects.

Acute and subchronic neurotoxicity studies are not available for bispyribac-sodium. There were clinical signs of potential neurotoxicity (i.e., piloerection, subnormal temperature, and decreased spontaneous motor activity) in the combined rat chronic/carcinogenicity study. However, these clinical signs occurred at a low incidence in the high dose group and

were not dose-dependent. The primary effects of the study were based on macro- and microscopic changes in the liver and choldedochus, decreased body weights, and decreased food efficiency. There are no other signs of neurotoxicity in the database.

Specific information on the studies received and the nature of the adverse effects caused by bispyribac-sodium as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document “Bispyribac-sodium; Human-Health Risk Assessment for New Product Registration for Aquatic Uses on Freshwater Fish” at page 28 in docket ID number EPA-HQ-OPP-2009-0796.

*B. Toxicological Points of Departure/ Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological

POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>. A summary of the toxicological endpoints for Bispyribac-sodium used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BISPYRIBAC-SODIUM FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure scenario	Dose used in risk assessment, UF	FQPA SF and LOC for risk assessment	Study and toxicological effects
Acute Dietary <i>all populations</i> .	No appropriate endpoint attributable to a single exposure was identified.		
Chronic Dietary <i>all populations</i> .	NOAEL = 10 mg/kg/day ..... UF = 100	FQPA SF = 1X ..... cPAD = cRfD = 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 (includes FQPA SF = 1X).	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 (includes FQPA SF = 1X).	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 = 1X).	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 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 = 1X).	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 = 1X).	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 to be carcinogenic to humans.		

UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>L</sub> = use of a LOAEL to extrapolate a NOAEL. UF<sub>S</sub> = use of a short-term study for long-term risk assessment. UF<sub>DB</sub> = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to bispyribac-sodium, EPA considered exposure under the petitioned-for tolerances as well as all existing bispyribac-sodium tolerances in 40 CFR 180.577. EPA assessed dietary exposures from bispyribac-sodium in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for bispyribac-sodium; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues (for all registered and proposed new uses), default processing factors, and 100% crop treated (CT).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that bispyribac-sodium does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

2. *Dietary exposure from drinking water.* Because currently used Tier 1 aquatic exposure models are used to simulate agricultural uses and are not appropriate for determining estimated drinking water concentrations (EDWCs) for aquatic uses of pesticides applied directly to surface water bodies, the Agency used the maximum annual label target rate of 180 ppb for subsurface injection of bispyribac-sodium into water. This value represents the maximum cumulative concentration in water based on four applications, at unspecified intervals, needed to achieve a 45-ppb level of bispyribac-sodium in the water column. Because bispyribac-sodium is only moderately persistent and will undergo degradation in the environment between applications, this value can be considered conservative.

For chronic dietary risk assessment, the water concentration of value 180

ppb was used to assess the contribution to drinking water and was incorporated directly into the dietary assessment.

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 currently registered for the following uses that could result in residential exposures: golf courses and sod farms. EPA assessed residential exposure using the following assumptions: No residential handler exposure is expected from the proposed and registered uses of bispyribac-sodium. Residential postapplication exposure following use of bispyribac-sodium on golf courses and sod farms is possible. A dermal postapplication assessment was not performed since there is no short-term dermal point of departure. For the proposed aquatic use, there is a potential for exposure to recreational users (*i.e.*, swimmers) in these water bodies. Postapplication exposure and risks were developed for the non-competitive adult and child swimmer. Exposure is expected to be short-term; however, since the short- and intermediate-term points of departure are the same, the short-term assessment is protective of intermediate-term exposures. Only oral postapplication exposure to recreational swimmers was assessed.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found bispyribac-sodium to share a common mechanism of toxicity with any other substances, and bispyribac-sodium does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that bispyribac-sodium does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such

chemicals, see EPA’s Web site at <http://www.epa.gov/pesticides/cumulative>.

### D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* or postnatal exposure to bispyribac-sodium. In the rat prenatal developmental toxicity study in rats, no toxicity was observed in the dams or the fetuses up to the highest dose tested (1000 mg/kg/day). In the rabbit prenatal developmental toxicity study, the dams were more susceptible than the fetuses. Maternal toxicity at the LOAEL of 300 mg/kg/day included lethargy, diarrhea, and decreased body weight gain. There were no fetal effects. In the 2-generation reproduction study, the parents were more susceptible than the offspring. At the parental LOAEL of 75.7 mg/, effects observed included mild choledocus (bile duct) hyperplasia. There were no reproductive effects. At the offspring LOAEL of 759 mg/kg/day, effects observed were decreased body weights and body-weight gains, liver weights, and increased incidence of consolidation and circumscribed areas in the liver.

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

i. The toxicity database for bispyribac-sodium is complete with the exception of immunotoxicity, acute neurotoxicity, subchronic neurotoxicity and a 28-day inhalation study.

The concern for neurotoxicity is low and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. There are no indications in any of the studies available that the nervous system is a target for

bispyribac-sodium. Although there were clinical signs potentially indicative of neurotoxicity (e.g., piloerection, subnormal temperature, and decreased spontaneous motor activity) in the combined rat chronic/carcinogenicity study, these effects were considered secondary to the critical effects (macro- and microscopic changes in the liver and choldedochus, decreased body weights, and decreased food efficiency). Additionally, treatment-related clinical signs only occurred at the highest dose tested (404 mg/kg/day) and were not dose-dependent. These effects are therefore attributed to general, systemic toxicity, not neurotoxicity. Although acute and subchronic neurotoxicity studies are now required as part of the revisions to 40 CFR part 158, the Agency does not believe that conducting these studies will result in a lower point of departure (POD) than that currently used for overall risk assessment, and therefore, a database uncertainty factor (UF<sub>DB</sub>) is not needed to account for lack of these studies. The toxicology database for bispyribac-sodium does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system. An immunotoxicity study is required as a part of new data requirements in the 40 CFR part 158 for conventional pesticide registration; however, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower point of departure than that currently used for overall risk assessment, and therefore, a database uncertainty factor (UF<sub>DB</sub>) is not needed to account for lack of this study. A 28-day inhalation study is not available; however, the Agency has determined that the additional FQPA SF is not needed. Based on the very low vapor pressure of bispyribac-sodium ( $3.79 \times 10^{-11}$  at 25°C) and because the residential use pattern is limited to golf courses and swimming areas, minimal potential for inhalation exposure is expected. Therefore, the risk estimate is conservative and is considered protective and the additional FQPA SF is not needed.

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

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

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to bispyribac-sodium in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by bispyribac-sodium.

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

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to bispyribac-sodium from food and water will utilize 12.5% of the cPAD for infants (<1 year old) the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of bispyribac-sodium is not expected.

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

Bispyribac-sodium is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to bispyribac-sodium.

Using the exposure assumptions described in this unit for short-term

exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 25,000 for the U.S. general population, 26,000 for adults 50+ years old, and 7,700 for all infants (<1 year old). Because EPA's level of concern for bispyribac-sodium is a MOE of 100 or below, these MOEs are not of concern.

#### *4. Intermediate-term risk.*

Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, bispyribac-sodium is not expected to pose an intermediate-term risk. However, since the short- and intermediate-term points of departure are the same, the short-term aggregate assessment is protective of intermediate-term exposures.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, bispyribac-sodium is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to bispyribac-sodium residues.

## **IV. Other Considerations**

### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (high-performance liquid chromatography (HPLC) with tandem mass spectroscopy detection (MS/MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety

standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for bispyribac-sodium.

C. Revisions to Petitioned-For Tolerances

EPA is revising the requested tolerance expression for bispyribac-sodium. The revised tolerance expression makes clear that the tolerances cover residues of the herbicide bispyribac-sodium, including its metabolites and degradates, but that compliance with the tolerance levels is to be determined by measuring only bispyribac-sodium, (2,6-bis[(4,6-dimethoxy-2-pyrimidinyl)oxy]benzoic acid, sodium salt), in or on the commodity. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of bispyribac-sodium, including its metabolites and degradates, in or on fish, freshwater at 0.01 ppm. Compliance with the tolerance level is to be determined by measuring only bispyribac-sodium, (2,6-bis[(4,6-dimethoxy-2-pyrimidinyl)oxy]benzoic acid, sodium salt), in or on the commodity.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork

Reduction Act (PRA), 44 U.S.C. 3501 et seq., nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4).

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

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the

Federal Register. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: January 18, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.577 is amended by revising paragraph (a) introductory text and alphabetically adding the following commodity to the table in paragraph (a) to read as follows:

§ 180.577 Bispyribac-sodium; tolerances for residues.

(a) General. Tolerances are established for residues of the herbicide bispyribac-sodium, including its metabolites and degradates, in or on the commodity listed below. Compliance with the tolerance level specified below is to be determined by measuring only bispyribac-sodium, (2,6-bis[(4,6-dimethoxy-2-pyrimidinyl)oxy]benzoic acid, sodium salt), in or on the following raw agricultural commodities:

Commodity	Parts per million
Fish, freshwater .....	0.01
* * * * *	*

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