§ 180.474 [Amended]

■ 8. In § 180.474, in the table to paragraph (b), amend the entries for barley, grain; barley, hay; barley, straw; wheat, hay; and wheat, straw by revising the expiration/revocation date ''12/31/03'' to read ''6/30/05'' and amend the entry for garlic by revising the expiration/revocation date ''12/31/03'' to read. ''12/31/05''

§ 180.475 [Amended]

■ 9. In § 180.475, in the table to paragraph (b), amend the entry for corn, sweet, kernel plus cob with husks removed; corn, sweet, forage; and, corn, sweet, stover by revising the expiration/revocation date ''12/31/03'' to read ''12/31/05.''

§ 180.480 [Amended]

■ 10. In § 180.480, in the table to paragraph (b), amend the entries for cattle, fat; cattle, meat byproducts; cattle, meat; goat, fat; goat, meat byproducts; goat, meat; grapefruit; grapefruit, dried pulp; grapefruit, oil; hog, fat; hog, meat byproducts; hog, meat; horse, fat; horse, meat byproducts; horse, meat; sheep, fat; sheep, meat byproducts; sheep, meat by revising the expiration/revocation date ''12/31/03'' to read. ''12/31/05.''

§ 180.510 [Amended]

■ 11. In § 180.510, in the table to paragraph (b), amend the entry for bean, succulent by revising the expiration/revocation date ''6/30/03'' to read ''6/30/05.''

§ 180.515 [Amended]

■ 12. In § 180.515, in the table to paragraph (b), amend the entry for hop, dried cone by revising the expiration/revocation date ''6/30/03'' to read ''6/30/05.''

§ 180.516 [Amended]

■ 12. In § 180.516, in the table to paragraph (b), amend the entry for pomegrante by revising the expiration/revocation date ''6/30/03'' to read ''6/30/06.''

§ 180.544 [Amended]

■ 13. In § 180.544, in the table to paragraph (b), amend the entries for soybean, aspirated grain fractions; soybean, forage; soybean, hay; soybean, refined oil; soybean, seed by revising the expiration/revocation date ''12/31/03'' to read ''12/31/05.''

§ 180.557 [Amended]

■ 14. In § 180.515, in the table to paragraph (b), amend the entries for beet, sugar, dried pulp; beet, sugar, molasses; beet, sugar, roots; beet, sugar, tops; cattle, fat; cattle, kidney; cattle, liver; cattle, meat; cattle, meat byproducts, except kidney and liver; and milk by revising the expiration/revocation date ''12/31/03'' to read ''12/31/05.''

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0136; FRL–7310–7]

Buprofezin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of buprofezin in or on bean, snap, succulent; logan; lychee; pistachio; pulasan; rambutan;, and spanish lime. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective June 25, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0136, must be received on or before August 25, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7050C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov@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, and pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

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 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 Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification ID number OPP–2003–0136. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html,* a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of March 26, 2003 (68 FR 14619) (FRL–7295–8), EPA issued a notice pursuant to section 408

of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (2E6369, 2E6455, and 2E6493) by IR-4, 681 U.S. Highway #1 South, New Brunswick, NJ 08902–3390. That notice included a summary of the petition prepared by Nichino American Inc., the registrant.

The petition requested that 40 CFR 180.511 be amended by establishing tolerances for residues of the insecticide buprofezin, buprofezin (2-[(1,1-dimethylethyl)imino]tetrahydro-3(1-methylethyl)-5-phenyl-4H-1,3,5-thiadiazin-4-one), in or on bean, snap, succulent at 0.02 parts per million (ppm); logan at 0.30 ppm; lychee at 0.30 ppm; pistachio at 0.05 ppm; pulasan at 0.30 ppm; rambutan at 0.30 ppm; and spanish lime at 0.30 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) of the 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 the 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. . . .''

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 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances November 26, 1997 (62 FR 62961) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the 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, consistent with section 408(b)(2) of the FFDCA, for tolerances for residues of buprofezin on bean, snap, succulent at 0.02 ppm; logan at 0.30 ppm; lychee at 0.30 ppm; pistachio at 0.05 ppm; pulasan at 0.30 ppm; rambutan at 0.30 ppm;, and spanish lime at 0.30 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follow.

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 buprofezin is discussed in Unit III.A. of the Final Rule on Buprofezin Pesticide Tolerance published in the **Federal Register** on September 5, 2001 (66 FR 46381) (FRL–6796–6).

B. Toxicological Endpoints

The dose at which no observed adverse effects (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 observed 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 (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factors (SF) 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 SF.

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 1×10^{-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 buprofezin used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR BUPROFEZIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years of age)	NOAEL = 200 milligrams/kilogram/day (mg/kg/day) UF = 100 aRfD = 2.0 mg/kg/day	FQPA SF = 1X aPAD = aRfD FQPA SF = 2.0 mg/kg/day	Developmental toxicity study-rats LOAEL = 800 mg/kg/day based on incomplete ossification and reduced pup weight

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR BUPROFEZIN FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population including infants and children)	N/A	N/A	N/A
Chronic dietary (all populations)	NOAEL= 1.0 mg/kg/day UF = 100 Chronic RfD = 0.01 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD FQPA SF = 0.01 mg/kg/day	2–year chronic/feeding study - rat LOAEL = 8.7 mg/kg/day based on increased incidence of follicular cell hyperplasia and hypertrophy in the thyroid in males
Short-term dermal (1 to 30 days) (Residential)	Dermal study NOAEL = 300 mg/kg/day	LOC for MOE = <100 (Residential) Adults <1,000 (Residential) Infants/children	24–day dermal toxicity study - rat LOAEL = 1,000 mg/kg/day based on inflammatory infiltrate of the liver in females and an increase in acanthosis and hyperkeratosis of the skin in females
Intermediate-term dermal (1 week to 6 months) (Residential)	Dermal study NOAEL = 300 mg/kg/day	LOC for MOE = <100 (Residential) Adults <1,000 (Residential) Infants/children	24–day dermal toxicity study - rat LOAEL = 1,000 mg/kg/day based on inflammatory infiltrate of the liver in females and an increase in acanthosis and hyperkeratosis of the skin in females
Long-term dermal (several months to lifetime) (Residential)	Oral study NOAEL = 1.0 mg/kg/day	LOC for MOE = < 100 (Residential) Adults <1,000 (Residential) Infants/children	2–year chronic/feeding study - rat LOAEL = 8.7 mg/kg/day based on increased incidence of follicular cell hyperplasia and hypertrophy in the thyroid in males
Short-term inhalation (1 to 30 days) (Residential)	Oral study NOAEL = 13.0 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = < 100 (Residential) Adults <1,000 (Residential) Infants/children	90–day oral toxicity study - rat LOAEL = 68.6 mg/kg/day based on organ weight changes and microscopic findings in the liver and thyroid of both males and females and in the kidney of males
Intermediate-term inhalation (1 week to 6 months) (Residential)	Oral study NOAEL = 13.0 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = <100 (Residential) Adults <1,000 (Residential) Infants/children	90–day oral toxicity study - rat LOAEL = 68.6 mg/kg/day based on organ weight changes and microscopic findings in the liver and thyroid of both males and females and in the kidney of males
Cancer (oral, dermal, inhalation)		N/A	2–year carcinogenicity study in mice Liver tumors observed in female mice The Agency Cancer Assessment Review Committee recommends that no quantification of cancer risk is required.

*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.511 for the residues of buprofezin, in or on the following raw agricultural commodities: Almond, banana, citrus fruits, cotton, cucumber, grape, lettuce (head and leaf), tomato, melon (cantaloupe, honeydew, watermelon, muskmelon), pumpkin, and squash with tolerances for residues of buprofezin ranging from 0.05 to 60 ppm. Tolerances have also been established for residues of buprofezin in/on ruminant fat, liver, and meat byproducts at 0.05 ppm. Risk assessments were conducted by EPA to assess dietary exposures from buprofezin 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. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (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 acute exposure assessments: The acute dietary analysis assumed tolerance level residues, DEEM™ (ver. 7.76) default processing factors, and 100% crop treated for all registered and proposed commodities (Tier I).

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment, the (DEEM™-FCID) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996, 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure assumed 100% crop treated and DEEM™-FCID (ver. 1.30) default processing factors for all registered/proposed commodities and tolerance level residues for all registered/proposed commodities excluding banana, orange, and tomato processed and unprocessed commodities where average field trial residues were assumed (Tier II).

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for buprofezin 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 buprofezin.

The Agency uses the FQPA Index Reservoir Screening Tool or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water, EPA will use FIRST (a Tier I model) before using PRZM/EXAMS (a Tier II model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and include a percent crop (PC) area factor as an adjustment to account for the maximum PC 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 population adjusted dose (%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 buprofezin, they are further discussed in the aggregate risk section under Unit III.E.

Based on the FIRST and SCI-GROW models, the EECs of buprofezin for acute exposures are estimated to be 102 parts per billion (ppb) for surface water and 0.08 ppb for ground water. The EECs for chronic surface water and ground water exposures are estimated to be 34 ppb, and 0.08 ppb, respectively.

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).

Buprofezin 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) of the 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 does not have, at this time, available data to determine whether buprofezin has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to buprofezin and any other substances and buprofezin 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 buprofezin 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold MOS 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 MOS will be safe for infants and children. MOS are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using UF (safety) in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. The Agency concluded that the available studies provided no indication of increased susceptibility of rats or rabbits following *in utero* exposure or of rats following prenatal/postnatal exposure to buprofezin.

3. *Conclusion*. There is a complete toxicity data base for buprofezin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be reduced. The FQPA factor is reduced to 1X based on toxicological considerations and based on the conservative residue assumptions used in the dietary risk assessment (currently no residential exposures) and the completeness of the toxicity, residue chemistry and environmental fate data base (evaluated by EPA).

E. Aggregate Risks and Determination of Safety

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

available for exposure through drinking water e.g., allowable water exposure (mg/kg/day) = PAD - (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 EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female and youth), 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*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to buprofezin will occupy 1% of the aPAD for the females 13–49 years old. No effect that could be attributed to a single exposure was observed, (no endpoint was chosen) for the general U.S. population (including infants and children). In addition, there is potential for acute dietary exposure to buprofezin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO BUPROFEZIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females (13–49 years old)	2.0	1	102	0.08	59,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to buprofezin from food will utilize 32% of the cPAD for the U.S. population, 18% of the cPAD for infants <1 year old, and 63% of the cPAD for children 1–2 years old. There are no residential uses for buprofezin that result in chronic residential exposure to buprofezin. In addition, there is potential for chronic dietary exposure to buprofezin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water 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 BUPROFEZIN

Population Subgroup	cPAD mg/kg/day	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.01	32	34	0.08	240
All infants (<1 year old)	0.01	18	34	0.08	83
Children (1–2 years old)	0.01	63	34	0.08	37
Females (13–years old)	0.01	30	34	0.08	210

3. *Aggregate cancer risk for U.S. population*. In accordance with the EPA Guidelines for Carcinogen Risk Assessment, the Carcinogen Assessment Review Commission classified buprofezin as having ''suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential'' based on liver tumors in female mice. The Committee further recommended no quantification of cancer risk.

4. *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 buprofezin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology gas chromotography using nitrogen phosphorus detection is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755– 5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

Canada, Codex, and Mexico do not have maximum residue limits for residues of buprofezin in/on the proposed crops. Therefore, harmonization is not an issue.

V. Conclusion

Therefore, the tolerances are established for residues of buprofezin, [(2-[(1,1-dimethylethyl)imino]tetrahydro-3(1-methylethyl)-5-phenyl-4H-1,3,5-

thiadiazin-4-one)], in or on bean, snap, succulent at 0.02 ppm; logan at 0.30 ppm; lychee at 0.30 ppm; pistachio at 0.05 ppm; pulasan at 0.30 ppm; rambutan at 0.30 ppm; spanish lime at 0.30 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0136 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 25, 2003.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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 20460–0001.

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 20460–0001.

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.1. Mail your copies, identified by docket ID number OPP–2003–0136, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. 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. Statuatory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any

technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the 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. 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 section 408(n)(4) of the FFDCA. 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. Congressional Review Act

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: June 6, 2003.

Debra Edwards,

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 180.511 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.511 Tolerances are established for residues of buprofezin in or on the following food commodities.

(a) * * *

Commodity	Parts per million	Expiration/Revocation Date
* * * * * * *		
Bean, snap, succulent	0.02	None
* * * * * * *		
Logan	0.30	None
Lychee	0.30	None
* * * * * * *		
Pistachio	0.05	None
Pulasan	0.30	None
Rambutan	0.30	None
* * * * * * *		
Spanish lime	0.30	None
* * * * * * *		

* * * * *

[FR Doc. 03–15767 Filed 6–24–03; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket 98–21; FCC 02–110]

Policies and Rules for the Direct Broadcast Satellite Service; Correction

AGENCY: Federal Communications Commission.

ACTION: Correcting amendments.

SUMMARY: This document contains a correction to final regulations which were published Wednesday, August 7, 2002 (67 FR 51110). The regulations relates to Policy and Rules for the Direct Broadcast Satellite Service.

DATES: Effective June 25, 2003.

FOR FURTHER INFORMATION CONTACT: Selina Y. Khan, Attorney Advisor, Satellite Division, International Bureau, telephone (202) 418–7282 or via the Internet at *skhan@fcc.gov.*

SUPPLEMENTARY INFORMATION:

Background

The final rule document published on Wednesday, August 7, 2002 publishes 47 CFR 25.114 by adding paragraph (c)(22) instead of paragraph (c)(23).

Need for Correction

As published, the final regulations contain an error which may prove to be misleading and are in need of clarification.

List of Subjects in 47 CFR Part 25

Satellites.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

■ Accordingly, 47 CFR part 25 is corrected by making the following correcting amendments:

PART 25—SATELLITE COMMUNICATIONS

■ 1. The authority citation for part 25 continues to read as follows:

Authority: U.S.C. 701744. Interprets or applies 47 U.S.C. 51, 154, 302, 303, and 307, unless otherwise noted.

§ 25.114 [Amended]

■ 2. Amend § 25.114 by redesignating the second paragraph (c)(22) as paragraph (c)(23).

[FR Doc. 03–15963 Filed 6–24–03; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 030617153–3153–01; I.D. 061203E]

RIN 0648–AR29

Atlantic Highly Migratory Species (HMS) Fisheries; Vessel Monitoring Systems (VMS)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Final rule; amendment of effective date.

SUMMARY: This document amends the effective date for the requirement to have a NOAA-approved, VMS unit installed and operating on any vessel leaving port to fish for HMS with pelagic longline gear on board to September 1, 2003.

DATES: Effective September 1, 2003.

ADDRESSES: To obtain copies of the list of NOAA-approved VMS mobile transmitting units and NOAA-approved VMS communications service providers, write to NMFS Office for Law Enforcement (OLE), 8484 Georgia Avenue, Suite 415, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: For information regarding the requirement contact Chris Rilling, Highly Migratory Species Management Division (F/SF1), Office of Sustainable Fisheries, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910, phone 301–713–2347. For current listing of approved VMS units contact Mark Oswell, Outreach Specialist, phone 301–427–2300, fax 301–427–2055. For questions regarding VMS installation and activation checklists, contact Jonathan Pinkerton, National VMS Program Manager, phone 301–427–2300, fax 301–427–2055.

The public may acquire this notice, installation checklist, and relevant updates via the ''fax-back'' service, or at the OLE website *http://www.nmfs.noaa.gov/ole/vms.html.*

SUPPLEMENTARY INFORMATION: On May 28, 1999, NMFS issued a regulation (64 FR 29090) codified at 50 CFR 635.69(a), requiring all commercial pelagic longline vessels fishing for Atlantic HMS to install a NMFS-approved VMS unit. Due to litigation, the requirement was stayed indefinitely on October 1, 2000 (66 FR 1907, January 10, 2001). On October 15, 2002, the U.S. District Court for the District of Columbia issued a final order upholding the VMS regulation. Following the favorable court ruling, NMFS began working to reinstate the VMS requirement.

On March 11, 2003, NMFS published a notice in the **Federal Register** (68 FR 11534) and corrected it on March 27, 2003 (68 FR 14949), to provide a list of the NMFS-approved VMS units for use by pelagic longline vessels in the Atlantic Highly Migratory Species (HMS) Fisheries and set forth relevant features of each VMS. The notification was issued to update and replace the approval notice published on September 9, 1999. An additional type approval notice was published on May 1, 2003 (68 FR 23285).

NMFS also submitted a request to the Office of Management and Budget (OMB) to reinstate approval for VMS information collection under the provisions of the Paperwork Reduction Act. A notice regarding this collection was published in the **Federal Register** on November 18, 2002 (67 FR 69506). The second notice of OMB review was published in the **Federal Register** on March 19, 2003 (68 FR 13280). OMB approved the VMS information collection request on May 10, 2003.

The placement of VMS units on fishing vessels in this fishery will enable NMFS to determine vessel locations and will complement the Agency's efforts to monitor and enforce compliance with applicable regulations. Because fishermen need time to purchase and install VMS, the VMS rule will be effective September 1, 2003, which provides approximately 60 days for affected fishermen to come into compliance.

Classification

This action is published under the authority of the Magnuson-Stevens Fishery Conservation and Management Act. The Assistant Administrator (AA) has determined that implementation of a VMS program in the pelagic longline fishery is necessary to monitor and enforce closed areas implemented to reduce bycatch. The AA finds that good cause exists to waive the requirement to provide prior notice and the opportunity for comment, pursuant to authority set forth at 5 U.S.C. 553(b)(B), as such procedures would be unnecessary and contrary to the public interest. This amendment establishes a new effective date for the HMS VMS rule, which had been suspended due to litigation. NMFS provided for prior notice and comment before promulgating the HMS VMS rule in 1999, then provided for additional