DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD 08–98–045]

Drawbridge Operating Regulation; Dulac Bayou, LA

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District has issued a temporary deviation from the regulation in 33 CFR 117.5 governing the operation of the SR 57 swing span drawbridge across Dulac Bayou, mile 0.6, at Dulac, Terrebonne Parish, Louisiana. This deviation allows the Lousiana Department of Transportation and Development to close the bridge from 7 a.m. until noon and from 12:30 p.m. until 3:30 p.m., on August 3, 4, 5, 10, 11, 12, 17, 18 and 19, 1998. The span will open for the passage of traffic from noon until 12:30 p.m. on each of these days. The bridge will operate normally at all other times. In the event of an approaching tropical storm or hurricane, the draw will return to normal operation within 12 hours of notification by the Coast Guard. This temporary deviation is issued to allow for cleaning and painting the swing span, an extensive but necessary maintenance operation.

DATES: This deviation is effective from 7 a.m. on August 3 until 3:30 p.m. on August 19, 1998.

FOR FURTHER INFORMATION CONTACT: Mr. Phil Johnson, Bridge Administration Branch, Commander (ob), Eighth Coast Guard District, 501 Magazine Street, New Orleans, Louisiana, 70130–3396, telephone number 504–589–2965.

SUPPLEMENTARY INFORMATION: The SR 57 swing span drawbridge across Dulac Bayou, mile 0.6, in Dulac, Terrebonne Parish, Louisiana, has a vertical clearance of 7 feet above high water in the closed-to-navigation position and unlimited clearance in the open-to-navigation position. Navigation on the waterway consists of tugs with tows, fishing vessels, sailing vessels, and other recreational craft. The Louisiana Department of Transportation and Development requested a temporary deviation from the normal operation of the bridge in order to accommodate the maintenance work. The maintenance work involves cleaning and painting of the swing span and is essential for the continued operation of the draw span.

This deviation allows the draw of the SR 57 swing span bridge across Dulac Bayou, mile 0.6, at Dulac to remain in the closed-to-navigation position between 7 a.m. and noon and from 12:30 p.m. until 3:30 p.m., on August 3, 4, 5, 10, 11, 12, 17, 18 and 19, 1998. The span will open for the passage of traffic from noon until 12:30 on each of these days. The bridge will operate normally at all other times.

This deviation will be effective from 7 a.m. on August 3 until 3:30 p.m. on August 19, 1998. Presently, the draw opens on signal at any time.

Dated July 28, 1998.

A.L. Gerfin, Jr.

Captain, U.S. Coast Guard Commander, 8th Coast Guard District.

[FR Doc. 98–20931 Filed 8–4–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300689; FRL–6018–5]

RIN 2070-AB78

Buprofezin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of buprofezin in or on cucurbits, tomatoes and tomato paste. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on cucurbits and tomatoes. This regulation establishes a maximum permissible level for residues of buprofezin in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on December 31, 1999.

DATES: This regulation is effective August 5, 1998. Objections and requests for hearings must be received by EPA on or before October 5, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300689], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300689], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP-300689]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9367, e-mail: ertman.andrew@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the insecticide buprofezin, in or on cucurbits at 0.5 parts per million (ppm), tomatoes at 0.7 ppm, and tomato paste at 1.0 ppm. These tolerances will expire and are revoked on December 31, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C.

301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. *136 et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL-5572-9).

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

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

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Buprofezin on Cucurbits and FFDCA Tolerances

Buprofezin was requested for use on cucurbits in Arizona to control whiteflies. The applicant states that the whitefly has been a major pest in Arizona since the late 1980's and has caused significant economic loss in a host of crops throughout the region. In Arizona, without efficacious control of whitefly, losses top $30 million annually to the watermelon and cantaloupe industries.

The host range for whitefly is broad and includes such commercial crops as cotton, melons and other cucurbit crops, cole crops, tomatoes, leafy vegetables, alfalfa and citrus. Urban ornamental plantings (such as lantana, hibiscus, brittlebush, rose, mints, etc.) and native vegetation (cheeseweed, mallows, etc.) are also host crops for the whitefly. The year round availability of hosts provides the foundation for an endemic population of whitefly, given the right environmental conditions and a lack of effective registered pesticides to suppress or control populations. What makes Arizona an excellent area for the commercial production of a variety of agricultural crops also makes it ideal for the annual survival of the whitefly.

Feeding whiteflies extract critical crop nutrients causing defoliation, stunting and yield losses. In addition, quality losses are common in commercial crops as the feeding whitefly excretes a ''sticky honeydew'' that promotes the development of black sooty mold. Both the mold development and the ''stickiness'' result in quality (economic) losses in addition to the economic loss inherent in reduced yields. Whiteflies are also vectors of disease, cause physiological disorders, and exacerbate a host of other production problems including increased plant stress leading to increased water and nutrient needs. The constant use of broad-spectrum insecticides for the control of this pest can lead to further damage by secondary pests such as aphids and mites. Finally, the continued and repeated use of the same or similar classes of insecticides has lead rapidly to the development of resistance in whiteflies.

Buprofezin was also requested for use on tomatoes in Florida to control the silverleaf whitefly. Tomatoes are produced and harvested year-round in Florida. Tomato seedlings are grown in planthouses and transplanted to fields. Silverleaf whitefly is a key pest on tomatoes from the seedling stage through harvest in Florida year-round in all production regions. High populations feeding on plants cause irregular ripening, reducing fruit value. Whiteflies may also transmit tomato mottle geminivirus (TMV) and tomato yellow leaf curl virus (TYLCV) during feeding. TYLCV was discovered in tomatoes in Florida in the summer of 1997 and is, therefore, a new pest-related problem. Because whitefly is such a good vector of the virus and the virus is so prevalent, only minimal infestations of whitefly are required to transmit TYLCV to tomato plants.

Alternative control practices include cultural control methods, natural enemies, and resistant varieties. Removal of alternate and overwintering host plants, use of trap crops, use of reflective mulches, and planting of windbreaks have not resulted in adequate whitefly control. Natural enemies suppress whitefly but, alone, do not provide adequate control. Buprofezin and pyriproxifen, because they are IGRs that only affect immature insect development or development of eggs, are less detrimental to natural enemies than are broad-spectrum insecticides. Resistant tomato varieties adapted to the Florida climate have not been developed.

No effective registered insecticides are available in Florida to manage Silverleaf Whitefly. In order to prevent spread of TYLCV, whitefly populations must be kept at a minimal level from transplanted seedling stage through harvest (up to 110 days). Systemic imidacloprid was very effective for controlling irregular ripening and TMV caused by whitefly before TYLCV became a problem in Florida. Because imidacloprid is only applied once and does not protect plants for the first two weeks after transplanting or for the last several weeks before harvest, it does not provide whitefly control required to prevent TYLCV infection of plants. Up to two applications each of both buprofezin and pyriproxifen will be required for protection of plants for the entire growing season. Field testing in Florida has demonstrated that whitefly has developed an unacceptable level of resistance to recommended foliar pyrethroids, methamidophos, and other registered products. EPA has authorized under FIFRA section 18 the use of buprofezin on cucurbits for control of whiteflies in Arizona and tomatoes for control of the silverleaf whitefly in Florida. After having reviewed the submissions, EPA concurs that emergency conditions exist for these states.

As part of its assessment of this emergency exemption, EPA assessed the

potential risks presented by residues of buprofezin in or on cucurbits and tomatoes. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemptions in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on cucurbits, tomatoes, and tomato paste after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether buprofezin meets EPA's registration requirements for use on cucurbits or tomatoes or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of buprofezin by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Arizona and Florida to use this pesticide on these crops under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for buprofezin, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects*. For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration*. The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the

assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased).

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (children 1-6 years old) was not regionally based.

IV. 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 buprofezin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for residues of buprofezin on cucurbits at 0.5 ppm, tomatoes at 0.7 ppm, and tomato paste at 1.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances 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 buprofezin are discussed below.

1. *Acute toxicity*. Acute RfD = 0.67 mg/kg/day; NOEL = 200 mg/kg/day. For acute dietary risk assessment, the Agency determined that the rat developmental NOEL of 200 milligrams/kilogram/day (mg/kg/day), based on decreased fetal body weight and delayed ossification, at the LOEL of 800 mg/kg/day, from the rat developmental study should be used for the acute dietary risk assessment. This risk assessment will evaluate developmental risks to females 13+ years of age. An MOE of 300 is required (a factor of 3 for FQPA considerations plus a factor of 100 to account for inter-species extrapolation and intra-species variability).

2. *Short - and intermediate - term toxicity*. The Agency determined that the maternal NOEL of 50 mg/kg/day in the rabbit developmental study based on decreases in body weight and food consumption at the LOEL of 250 mg/kg/day should be used for short and intermediate-term exposure scenarios for both dermal and inhalation exposure. MOEs of 100 are required.

3. *Chronic toxicity*. EPA has established the RfD for buprofezin at 0.006 mg/kg/day. This RfD is based on a 2-year feeding study in dogs with a NOEL of 2.0 mg/kg/day and an uncertainty factor of 300 a factor of 3 for FQPA considerations, due to inadequate reproduction study, and a factor of 100 to account for inter-species extrapolation and intra-species variability based on a increased liver weight, increased liver enzymes, and bile duct hyperplasia at the LOEL of 20.0 mg/kg/day.

4. *Carcinogenicity*. Buprofezin has not been evaluated by the OPP's Hazard ID Committee. However, buprofezin will be likely be evaluated by the OPP Cancer Peer Review Committee based on lung and liver tumors in the mouse carcinogenicity study. For the purposes of these section 18 requests, the Agency calculated the cancer risk for buprofezin. The male mouse Q_2* based on combined lung tumors is 2.747 x 10^{-3}. The female mouse Q_1* on combined tumors is 2.488 x 10^{-3}.

B. Exposures and Risks

1. *From food and feed uses*. Section 18 time limited tolerances (40 CFR 180.511) have been established for the residues of buprofezin at 1.0 ppm in or on cotton seed; 2 ppm in citrus fruit; 10 ppm in dried citrus pulp; 20 ppm in cotton gin byproducts; 0.5 ppm in meat byproducts of cattle, goats, hogs, horse, and sheep; 0.02 ppm in the meat and fat of cattle, goats, hogs, horse, and sheep; and 0.03 ppm in milk. No permanent tolerances have been established. Risk assessments were conducted by EPA to assess dietary exposures and risks from buprofezin as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The acute dietary (food only) risk assessment used the TMRC. Since for acute dietary risk assessment, the acute effect is based on decreased fetal body weight and delayed ossification, the population subgroup of concern is females 13+ years of age. For this subgroup, an MOE value of 20,000 (equivalent to 1.5% of the acute RfD) was calculated using the high-end exposure value of 0.01 mg/kg/day. This result should be viewed as a conservative risk estimate.

ii. *Chronic exposure and risk*. In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions — 100% of cucurbits and tomatoes having buprofezin tolerances will contain buprofezin residues and those residues would be at the level of the tolerance — which result in an overestimation of human dietary exposure. Thus, in making a safety determination for this tolerance, HED is taking into account this conservative exposure assessment. The existing buprofezin tolerances (published, pending, and section 18 tolerances) include anticipated residues for citrus commodities, and thus result in an Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

Population subgroup	%RfD
U.S. Population (48 States)	23.1%
U.S. Population - Summer Season	26.0%
Nursing Infants (<1 year old)	12.4%
Non-Nursing Infants (<1 year old)	47.4%
Children (1-6 years old)	48.2%
Children (7-12 years old)	34.6%
Northeast Region	24.7%
North Central Region	23.2%
Western Region	25.4%
Hispanics	25.4%
Non-Hispanic Whites	23.7%
Non-Hispanic Others	23.3%
Males (13-19 years old)	23.5%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

2. *From drinking water*. A Tier I drinking water assessment of buprofezin was conducted. This assessment utilized GENEEC and SCI-GROW screening models to provide estimates of surface and ground water contamination resulting from applications of buprofezin. The estimated environmental concentrations (EECs) using the GENEEC model ranged from a peak concentration of 2.82 parts per billion (ppb) to a 21-day average of 1.31 ppb for aerial application. For calculation of chronic DWLOCs, the higher 21-day average value (i.e., aerial) was used. Based on these screening models, maximum concentrations are not expected to exceed 3 ppb in surface water and 0.013 ppb in ground water. There are no established Maximum Contaminant Level for residues of buprofezin in drinking water. No health advisory levels for buprofezin in drinking water have been established.

Acute and chronic exposure and risk. The ''Interim Guidance for Conducting Drinking Water Exposure and Risk Assessments'' issued on 24-NOV-1997 using the GENEEC and the SCI-GROW models was used to produce estimates of buprofezin concentrations in surface and ground water respectively. The primary use of these models is to provide a coarse screen for sorting out pesticides for which OPP has a high degree of confidence that the true levels of the pesticide in drinking water will be less than the human health drinking water levels of concern (DWLOCs). The DWLOC is an upper limit above which residues in drinking water would result in an unacceptable aggregate risk.

The $DWLOC_{acute}$ is the concentration in drinking water as part of the acute aggregate exposure that occupies no more than 100% of the RfD_{acute}. The $DWLOC_{chronic}$ is the concentration in drinking water as part of the aggregate chronic exposure that occupies no more than 100% of the $RfD_{chronic}$. The Agency's default body weights and consumption values used to calculate DWLOCs are as follows: 70 kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/1L (child).

For chronic (non-cancer) exposure to buprofezin in surface and ground water, the drinking water levels of concern are 23,000 µg/L for the U.S. Population, 19800 for females (13+ years), and 6,400 µg/L for children (1-6 yrs). To calculate the DWLOC for acute exposure relative to a acute toxicity endpoint, the acute dietary food exposure (from DRES) was subtracted from the acute RfD to obtain the acceptable acute exposure to buprofezin in drinking water. To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DRES) was subtracted from the chronic RfD to obtain the acceptable chronic (non-cancer) exposure to buprofezin in drinking water. DWLOCs were then calculated using default body weights and drinking consumption figures.

Estimated average concentrations of buprofezin in surface and ground water are 0.013 ppb and 1.31 ppb, respectively. The estimated average concentrations of buprofezin in surface and ground water are less than OPP's level of concern for buprofezin in drinking water as a contribution to chronic aggregate exposure. Therefore, taking into account present uses and uses proposed in this action, OPP concludes with reasonable certainty that residues of buprofezin in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time.

3. *From non-dietary exposure*. Buprofezin is an unregistered active ingredient. Section 18 emergency exemptions have been approved for use on cotton, citrus, and tomatoes. An experimental use permit (EUP) has been granted for use on greenhouse ornamental plants. There are no registered residential uses for this chemical.

4. *Cumulative exposure to substances with 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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely

that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether buprofezin 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, 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.

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk*. For the subpopulation group of concern, females 13+ years, the acute dietary exposure to buprofezin from food will utilize 1.5 % of the acute RfD (calculated MOE is 20,000). The maximum concentrations of buprofezin in surface and ground water are less than OPP's levels of concern for buprofezin in surface and ground water as a contribution to acute aggregate risk. Therefore, the aggregate acute risk (food + water) is not expected to exceed the Agency's level of concern for acute dietary exposure.

2. *Chronic risk*. Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to buprofezin from food will utilize 23.1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to buprofezin in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to buprofezin residues.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. There are no registered residential uses for buprofezin, therefore, the potential short and intermediate-term aggregate risks are adequately addressed by the chronic aggregate dietary (food + water) assessment.

D. Aggregate Cancer Risk for U.S. Population

Based on the buprofezin Q_2*, the dietary cancer risk for the U.S. population is 2.7×10^{-7}.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of buprofezin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional 10-fold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the data base 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed effect level in the animal study appropriate to the particular risk assessment. This 100-fold uncertainty (safety) factor/MOE (safety) is designed to account for inter-species extrapolation and intra-species variability. HED believes that reliable data support using the 100-fold margin/factor, rather than the 1,000-fold margin/factor, when EPA has a complete data base under existing guidelines, and when the severity of the effect in infants or children, the potency or unusual toxic properties of a compound, or the quality of the exposure data do not raise concerns regarding the adequacy of the standard margin/factor.

ii. *Developmental toxicity studies*. In a developmental study in rats, the maternal (systemic) NOEL was 200 mg/kg/day, based on mortality, decreased pregnancy rates, and increased resorptions at the LOEL of 800 mg/kg/day. The developmental (fetal) NOEL was 200 mg/kg/day, based on increased incidence of delayed ossifications and decreased pup weight at the LOEL of 800 mg/kg/day.

In a developmental toxicity study in rabbits, the maternal (systemic) NOEL was 50 mg/kg/day, based on body weight and food consumption and possibly increased fetal loss at the LOEL of 250 mg/kg/day. The developmental (pup) NOEL was 250 mg/kg/day (highest dose tested).

iii. *Reproductive toxicity study*. The 2-generation reproductive toxicity in rats does not satisfy guideline requirements for a reproduction study and is considered a data gap.

iv. *Pre- and post-natal sensitivity*. The toxicological data base for evaluating pre- and post-natal toxicity for buprofezin is not complete with respect to current data requirements, since there is no adequate reproduction study. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies, but the Agency recommends an additional FQPA factor of 3 due to the absence of the reproduction study and the possible incomplete assessment of extra-sensitivity to infants and children.

v. *Conclusion*. Based on the above, the Agency concludes that reliable data support use of a 300-fold margin of exposure/uncertainty factor, rather than the standard 1,000-fold margin/factor, to protect infants and children for acute dietary MOE requirements and the determination of the RfD.

2. *Acute risk*. For females 13+ years, the acute dietary exposure (maternal and fetal) to buprofezin from food will utilize 1.5% of the acute RfD (calculated MOE is 20,000). These calculations are based on a developmental NOEL in rats of 200 mg/kg/day. This risk assessment assumed 100% crop treated with tolerance level residues on all treated crops consumed, resulting in a significant overestimate of dietary exposure. The maximum concentrations of buprofezin in surface and ground water are less than OPP's levels of concern for buprofezin in surface and ground water as a contribution to acute aggregate risk. Therefore, the aggregate acute risk (food + water) is not expected to exceed OPP's level of concern for acute dietary exposure.

3. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to buprofezin from food ranges from 12.4% of the RfD

for nursing infants less than 1 years old, up to 48.2% of the RfD for children 1-6 years old. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The estimated average concentrations of buprofezin in surface and ground water are less than OPP's levels of concern for buprofezin in surface and ground water as a contribution to chronic aggregate risk. Under current HED guidelines, the non-dietary uses of buprofezin do not constitute a chronic exposure scenario.

4. *Short- or intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential uses. There are no registered residential uses for buprofezin, therefore the potential short and intermediate-term aggregate risks are adequately addressed by the chronic aggregate dietary (food + water) risk assessment.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants is adequately understood for purposes of this section 18 only. Studies conducted in tomatoes, lettuce, cotton, and citrus indicate that the residue of concern is the parent buprofezin (BF1, 2-tert-butylimino-3-isopropyl-5-phenylperhydro-1,3,5-thiadizinan-4-one) only. The nature of the residue in animals (rats and fish) is consistent with that determined for crops.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography using a nitrogen-phosphorous detector) is available to enforce the proposed tolerance on cucurbits and tomatoes. The method was validated by an independent laboratory using lettuce, tomato, and cucumber as the test matrices. Samples of the test matrices were fortified with buprofezin at 0.1 ppm, 0.5 ppm, and 1.0 ppm. Recoveries were reported as 90%, 94%, and 82% for lettuce, tomato, and cucumber respectively. In addition, methodology for buprofezin and its metabolites in cottonseed and gin trash is summarized in the report ''Determination of Buprofezin and BF 12 residues in Cottonseed and Gin Trash,'' Method BF-96-01, AgrEvo Corporation, Wilmington, Delaware. The limit of detection for buprofezin is 0.01 ppm and the limit of quantitation is 0.02 ppm.

C. Magnitude of Residues

Residues of buprofezin are not expected to exceed 0.5 ppm in/on cucurbits or 0.7 ppm in/on tomatoes and 1.0 ppm in tomato paste as a result of these section 18 uses.

D. International Residue Limits

A temporary Codex MRL of 1.0 mg/kg has been established for buprofezin on tomatoes (pending additional data submission). There are no Canadian or Mexican MRLs for buprofezin on tomatoes. Therefore, compatibility problems may exist (i.e., the Codex MRL is higher than the U.S. tolerance) which will need to be addressed when a permanent section 3 tolerance for buprofezin on tomatoes is granted.

E. Rotational Crop Restrictions

The following plant-back restrictions are required: - 30 days for brassica and non-brassica leafy vegetables, small grains, and radishes - 120 days for all other crops.

VI. Conclusion

Therefore, the tolerance is established for residues of buprofezin in cucurbits at 0.5 ppm, tomatoes at 0.7 ppm, and tomato paste at 1.0 ppm.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by October 5, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300689] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically

into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(l)(6). 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). 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) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or 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 in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance acations published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. 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 the rule in the **Federal Register**. This 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: July 16, 1998.

James Jones,

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. 346a and 371.

2. Section 180.511 is amending paragraph (b) by alphabetically adding the following entries to the table to read as follows:

§ 180.511 Buprofezin; tolerances for residues

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation Date
* *	* *	*
Cucurbits	0.5	12/31/99
* *	* *	*
Tomatoes	0.7	12/31/99
Tomato paste	1.0	12/31/99

* * * * *

[FR Doc. 98–20906 Filed 8–4–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300688; FRL–6018–4]

RIN 2070–AB78

Fluroxypyr 1-Methylheptyl Ester; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for the combined residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr in or on wheat, barley, field corn, and sweet corn. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on wheat, barley, field corn, and sweet corn. This regulation establishes a maximum permissible level for residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on December 1, 1999.

DATES: This regulation is effective August 5, 1998. Objections and requests for hearings must be received by EPA on or before October 5, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300688], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300688], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.