* * * * *

[FR Doc. 03–23854 Filed 9–18–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0282; FRL–7324–6]

Butafenacil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of butafenacil (1,1-dimethyl-2-oxo-2-(2-propenyloxy)ethyl 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl] benzoate) in or on cotton and livestock commodities. Syngenta Crop Protection, Inc. requested this tolerance 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 September 19, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0282, must be received on or before November 18, 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: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *Tompkins.Jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II. 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–2003–0282. 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. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

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 February 26, 2003 (68 FR 8896) (FRL–7293–9), 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 a pesticide petition (PP 1F6309) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419–8300. That notice included a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the herbicide butafenacil, the [2+2] cycloaddition dimer of butafenacil, and CGA-293731 in or on cotton, undelinted seed at 0.5 parts per million (ppm); and in or on cotton, gin byproducts at 13.0 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 (62 FR 62961, November 26, 1997) (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 a tolerance for residues of butafenacil and CGA-293731 on cattle, kidney; goat, kidney; hog, kidney; horse, kidney; and sheep, kidney at 0.05 parts per million (ppm); in or on cattle, liver; goat, liver; hog, liver; horse, liver; and sheep, liver at 0.50 ppm; and tolerances for residues of butafenacil in or on cotton, undelinted seed at 0.50 ppm; and in or on cotton, gin byproducts at 10 ppm. EPA's assessment of exposures and risks associated with establishing these 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 butafenacil are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—ACUTE TOXICITY OF BUTAFENACIL

Guideline number	Study Type	Results	Toxicity Category
870.1100	Acute oral	Lethal dose $(LD)_{50}$ >5,000 milligrams/kilogram (mg/kg) male and female (M/F)	IV
870.1200	Acute dermal	LD_{50} >2,000 mg/kg M/F	III
870.1300	Acute inhalation	Lethal concentration $(LC)_{50}$ >5.10 milligrams per Liter (mg/L)	IV
870.2400	Primary eye irritation	Ocular irritation resolved within 96 hours	III
870.2500	Primary skin irritation	Not an irritant	IV
870.2600	Dermal sensitization	Not a sensitizer	Not Applicable (NA)

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline number	Study Type	Results
870.3100	90–Day oral (dietary) toxicity rodents (rat)	NOAEL = 300 ppm (18.8/20.6 mg/kg/day M/F) LOAEL = 1,000 ppm (62.3/69.3 mg/kg/day M/F), based on decreased body weight gains, decreased hemoglobin, hematocrit, mean corpuscular hemoglobin (MCH), mean corpuscular volume (MCV), increased red cell volume, increased bone marrow hypercellularity; increased bilirubin and urobilinogen; increased alanine aminotransferase; hepatocyte necrosis; inflammatory liver cell infiltration
870.3100	90–Day oral (dietary) toxicity in rodents (mouse)	NOAEL = 30 ppm (4.11/5.67 mg/kg/day M/F) LOAEL = 100 ppm (13.8/20.1 mg/kg/day M/F), based on hepatic histopathology: fatty change, glycogen deposition, and hypertrophy in both sexes
870.3150	90–Day oral (capsule) toxicity in non-rodents (dog)	NOAEL = 200 mg/kg/day M/F LOAEL = 1,000 mg/kg/day M/F, based on decreases in MCV and MCH in males; increases in RDW, HDW, platelets and triglycerides in males; and hemosiderosis in spleen and liver and extramedullary hematopoiesis the spleen in males
870.3200	28–Day dermal toxicity (rat)	NOAEL = 1,000 mg/kg/day LOAEL = not determined
870.3700	Prenatal developmental toxicity in rodents (rat)	Maternal NOAEL = 1,000 mg/kg/day Maternal LOAEL = not determined Developmental NOAEL = 1,000 mg/kg/day Developmental LOAEL = not determined
870.3700	Prenatal developmental toxicity in non-rodents (rabbit)	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 1,000 mg/kg/day based on decreased body weight gains and food consumption during the treatment period, and on blood-stained vaginal discharge (related to total litter loss) in two doses Developmental NOAEL = 100 mg/kg/day Developmental LOAEL = 1,000 mg/kg/day based on increased early resorptions and post-implantation loss

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline number	Study Type	Results
870.3800	2–Generation reproduction and fertility effects	Parental/systemic NOAEL = 30 ppm (2.4/2.5 mg/kg/day M/F) Parental/systemic LOAEL = 300 ppm (23.8/25.2 mg/kg/day M/F), based on decreased body weights and food consumption and on increased incidences of bile duct hyperplasia and liver necrosis in males and females of both generations Offspring NOAEL = 300 ppm (23.8/25.2 mg/kg/day M/F) Offspring LOAEL = 1,000 ppm (79.6/83.8 M/F), based on decreased pup body weight and body weight gain in both generations Reproductive NOAEL = 30 ppm (2.4/2.5 mg/kg/day M/F) Reproductive LOAEL = 300 ppm (23.8/25.2 mg/kg/day M/F) based on an increase in the number of days to mating in both generations
870.4100	1–Year chronic oral (capsule) toxicity (dog)	NOAEL = 500 mg/kg/day M/F LOAEL = 1,000 mg/kg/day M/F, based on decreased body weight gain in males, decreased MCV, MCH, and mean corpuscular hemoglobin concentration (MCHC); increased thrombocytes and red cell volume distribution width; hepatic histopathology: glycogen disposition, inclusion bodies in cytoplasm, and pigment disposition in both sexes, and focal vaculolation in females
870.4200	18–Month carcinogenicity dietary study (mouse)	NOAEL = 10 ppm (1.17/1.20 mg/kg/day M/F) LOAEL = 60 ppm (6.96/6.59 mg/kg/day M/F), based on enlarged livers with increased weights, and hepatic microscopic lesions including Kupffer cell hyperplasia, inflammatory cell infiltration, and single cell necrosis in both sexes and on deposits of lipofuscin in males No evidence of carcinogenicity
870.4300	Combined 2–Year chronic/carcinogenicity dietary study (rat)	NOAEL = 100 ppm (3.76/4.43 mg/kg/day M/F) LOAEL = 300 ppm (11.4/13.0 mg/kg/day M/F), based on minimal hepatic abnormalities in the females, including a fatty change and increased mitotic activity No evidence of carcinogenicity
870.5100	*In vitro* bacterial gene mutation	Negative in a reverse gene mutation assay in strains TA98, TA100, TA102, TA1535, TA1537 of *S. typhimurium* and strain WP2(uvrA) of *E. coli* in the presence and absence of mammalian metabolic activation
870.5300	*In vitro* mammalian cells in culture	Evidence of borderline induction of mutant colonies in presence of S9 in a mammalian cell gene mutation assay at the hypoxanthine guanine phophoribosyl transferase (HGPRT) locus of Chinese hamster V79 cells
870.5375	*In vitro* mammalian cytogenetics	Negative. No evidence of increase in chromosome aberrations over background
870.5395	*In vivo* mammalian cytogenetics - micronucleus assay (mouse)	Negative. No increase in frequency of micronucleated polychromatic erythrocytes
870.5550	Other genotoxicity - unscheduled DNA synthesis (UDS)- *in vivo/in vitro*	Negative. No evidence of induction of UDS; no indications of induction of DNA damage
870.5550	Other genotoxicity - UDS - *in vitro*	Negative. No evidence of induction of UDS; no indications of induction of DNA damage in primary rat hepatocytes in culture
870.6200	Acute neurotoxicity screening battery (rat)	NOAEL = 2,000 mg/kg LOAEL = Not determined No evidence of neurotoxicity
870.6200	Subchronic neurotoxicity screening battery (rat)	NOAEL = 300 ppm 21/24 mg/kg/day M/F LOAEL = 1,000 ppm 72/76 mg/kg/day M/F, based on liver histopathology and decreased motor activity at week 13 in the males No evidence of neurotoxicity

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline number	Study Type	Results
870.7485	Metabolism and pharmacokinetics (rat)	Overall recovery of administered radioactivity exceeded 95%, most (74–93%) of which was eliminated in the feces. Approximately 4–15% of the administered radioactivity was excreted in the urine over 168 hours while tissue residues were negligible, thereby implying limited absorption. No radioactivity was detected in expired air. Excretion of radioactivity was >90% complete by 48 hours. Up to six components were detected in the urine of rats from both dose groups, the most prevalent being an hydrolysis product, CGA-293731 which represented >90% of urinary radioactivity. Urinary elimination of metabolites was quantitatively greater in female rats than in males. Only minor amounts (near detection limits) of parent compound were detected in the urine of high-dose males. Based upon biliary elimination, ~74–79% of the dose entered the hepatobiliary pathway but was eliminated via the feces. An increase in parent compound in feces of the high-dose group was indicative of saturated absorption and/or saturated metabolism, but could not be definitively resolved due to the absence of biliary elimination studies at the high dose. Biliary elimination studies revealed that approximately 60–64% of the administered low dose was detected in 0–4 hour pooled bile samples and that the majority of fecal radioactivity could be attributed to biliary metabolites
870.7485	Mechanistic studies	Effects on enzymes of cultured mouse, rat, and/or human hepatocytes involved with heme biosynthesis
870.7485	Mechanistic studies	Effects on liver microsomal and plasma protox activity and its metabolic conversion
870.7485	Mechanistic studies	Effects on porphyrin profile in rats; treatment induced porphyria, consisting of accumulation of selected porphyrins in the liver, spleen, and plasma and increased excretion in urine and feces
870.7485	Mechanistic studies	Test substance interferes with heme biosynthesis in rats, as evidenced by dose-dependent, pronounced porphyria in the liver, spleen, and plasma; increased porphyrin excretion, and decreased activity of various isoenzymes of the hepatic microsomal cytochrome P450 system
870.7485	Mechanistic studies	Test substance interferes with heme biosynthesis in mice, as evidenced by dose-dependent, pronounced porphyria in the liver, spleen, and plasma; increased porphyrin excretion, and decreased activity of various isoenzymes of the hepatic microsomal cytochrome P450 system
870.7485	Mechanistic studies	Effects on porphyrin profile in mice; treatment induced porphyria, consisting of accumulation of selected porphyrins in the tissue and plasma, and increased excretion of heme precursors

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the margin of exposure (MOE). 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. A UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety 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 level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

A summary of the toxicological endpoints for butafenacil used for human risk assessment is shown in Table 3 of this unit:

TABLE 3.—TOXICOLOGICAL DOSE AND ENDPOINTS FOR BUTAFENACIL

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	None	NA	An endpoint attributable to a single dose is not available in the data base
Chronic dietary (All populations)	NOAEL= 1.2 mg/kg/day UF = 100 Chronic RfD = 0.012 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD Special FQPA SF = 0.012 mg/kg/day	Mouse oncogenicity study The LOAEL is 6.96 mg/kg/day, based on enlarged livers with increased weights, and hepatic microscopic lesions including Kupffer cell hyperplasia, inflammatory cell infiltration, and single cell necrosis in both sexes and on deposits of lipofuscin in males
Short-term inhalation (1 to 30 days)	Oral NOAEL = 18.8 mg/kg/day	Residential LOC for MOE = 100 Occupational = 100	90–day rat feeding study The LOAEL for this study is 62.3 mg/kg/day based on decreased hemoglobin, hematocrit, mean corpuscular hemoglobin, mean corpuscular volume, increased red cell volume distribution width, and increased incidence of bone marrow hypercellularity
Short-term incidental oral (1 to 30 days)	NOAEL = 18.8 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	90–day rat feeding study The LOAEL for this study is 62.3 mg/kg/day, based on decreased hemoglobin, hematocrit, mean corpuscular hemoglobin, mean corpuscular volume, increased red cell volume distribution width, and increased incidence of bone marrow hypercellularity
Intermediate-term incidental oral (1–6 months)	NOAEL = 18.8 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	90–day rat feeding study The LOAEL for this study is 62.3 mg/kg/day, based on decreased hemoglobin, hematocrit, mean corpuscular hemoglobin, mean corpuscular volume, increased red cell volume distribution width, and increased incidence of bone marrow hypercellularity
Dermal (All durations)	NA	NA	Quantification of dermal risk assessment is not required due to lack of concern for dermal, systemic or developmental toxicity
Short-term inhalation (1 to 30 days)	Oral NOAEL = 18.8 mg/kg/day	Residential LOC for MOE = 100 Occupational = 100	90–day rat feeding study The LOAEL for this study is 62.3 mg/kg/day based on decreased hemoglobin, hematocrit, mean corpuscular hemoglobin, mean corpuscular volume, increased red cell volume distribution width, and increased incidence of bone marrow hypercellularity
Intermediate-term inhalation (1 to 6 months)	Oral NOAEL = 18.8 mg/kg/day	Residential LOC for MOE = 100 Occupational = 100	90–day rat feeding study The LOAEL for this study is 62.3 mg/kg/day, based on decreased hemoglobin, hematocrit, mean corpuscular hemoglobin, mean corpuscular volume, increased red cell volume distribution width, and increased incidence of bone marrow hypercellularity

TABLE 3.—TOXICOLOGICAL DOSE AND ENDPOINTS FOR BUTAFENACIL—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Long-term inhalation (>6 months)	Oral NOAEL = 1.2 mg/kg/day	Residential LOC for MOE = 100 Occupational = 100	Mouse oncogenicity study The LOAEL is 6.96 mg/kg/day, based on enlarged livers with increased weights, and hepatic microscopic lesions including Kupffer cell hyperplasia, inflammatory cell infiltration, and single cell necrosis in both sexes and on deposits of lipofuscin in males
Cancer (oral, dermal, inhalation)	NA	NA	Classified as ''not likely to be carcinogenic to humans''

* The reference to the Special 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*. No tolerances have previously been established for butafenacil. Risk assessments were conducted by EPA to assess dietary exposures from butafenacil in food as follows:

i. *Acute exposure*. Quantitative 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. No appropriate endpoint attributable to a single exposure was identified for butafenacil in either the general population or to the subpopulation of females 13–50 years old, therefore no acute exposure assessment was performed.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment, the Dietary Exposure Evaluation Model Food Commodity Intake Database (DEEM-FCID®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996, and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The dietary exposure analysis assumed 100% crop treated and tolerance level residues or maximum field trial residues. Based on total food exposure for butafenacil, all population subgroups are below 1% cPAD.

iii. *Cancer*. Butafenacil showed no evidence of carcinogenicity in animal tests in two different species, and therefore, a quantitative cancer risk assessment was not performed.

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

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/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. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health LOC.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to butafenacil they are further discussed in Unit III.E.

Based on the FIRST and SCI-GROW models, the EECs of butafenacil for chronic exposures are estimated to be 0.049 parts per billion (ppb) for surface water and 0.00095 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Butafenacil is not proposed for registration for use on any sites that would result in residential exposure.

4. *Cumulative effects from 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 butafenacil 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 butafenacil and any other substances

and butafenacil 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 butafenacil 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 margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There are no residual concerns regarding prenatal or postnatal toxicity or completeness of the toxicity or exposure data base.

3. *Conclusion*. There is a complete toxicity data base for butafenacil 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 could be reduced to 1X. The FQPA factor was reduced because:

- There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies or to *in utero* and postnatal exposure to rats in the 2–generation reproduction study.
- There are no residential uncertainties for prenatal or postnatal toxicity.
- The toxicological data base is complete for the assessment of toxicity and susceptibility following prenatal and/or postnatal exposures. No clinical signs of neurotoxicity or neuropathology were observed in the data base, and the developmental neurotoxicity study was not required.
- There are no residual concerns regarding prenatal or postnatal toxicity or completeness of the toxicity or exposure data base.
- The dietary food exposure assessment is Tier I, screening level, which is based on tolerance level residues or maximum field trial residues and assumes 100% of all crops will be treated with chemical. By using these screening level assessments, actual exposures/risks will not be underestimated.
- The dietary drinking water assessment utilizes water concentration values generated by health protective, high-end estimates of water concentrations which will not likely be exceeded.
- There are currently no registered residential uses of butafenacil.
- These assessments will not underestimate the exposure/risks posed by current or proposed uses of butafenacil.

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 chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA's Office of Water are used to calculate DWLOCs: 2 L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. No acute risk from exposure to butafenacil is expected because there were no toxic effects of concern attributable to a single dose identified in available data.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to butafenacil from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for infants ages 1–2, and <1% of the cPAD for children ages 3–5. There are no proposed residential uses for butafenacil that result in chronic residential exposure to butafenacil. In addition, there is potential for chronic dietary exposure to butafenacil 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 Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO BUTAFENACIL

Population	cPAD (mg/kg/day)	% cPAD (mg/kg/day)	Chronic Food Exposure[1] (mg/kg/day)	Ground Water EEC[2] (ppb)	Surface Water EEC[2] (ppb)	Chronic DWLOC[3] (ppb)
General U.S. population	0.012	<1%	0.000041	0.00095	0.049	420
All infants (< 1 year old)	0.012	<1%	0.000014	0.00095	0.049	120
Children (1–2 years old)	0.012	<1%	0.000097	0.00095	0.049	120
Children (3–5 years old)	0.012	<1%	0.000104	0.00095	0.049	120
Children (6–12 years old)	0.012	<1%	0.000069	0.00095	0.049	120
Youth (13–19 years old)	0.012	<1%	0.000036	0.00095	0.049	360
Adults (20–49 years old)	0.012	<1%	0.000033	0.00095	0.049	420
Females (13–49 years old)	0.012	<1%	0.000030	0.00095	0.049	360
Adults (50+ years old)	0.012	<1%	0.000031	0.00095	0.049	420

[1] Maximum chronic water exposure (mg/kg/day) = cPAD (mg/kg/day) - chronic food exposure from DEEM (mg/kg/day); no res. exp.
[2] Parent plus CGA-293731; cotton application scenario - 1 x 0.141 lb ai/acre; maximum proposed rate
[3] DWLOC(µg/L) = (allowable water exposure (mg/kg/day) x body weight (kg) x 1,000 µg/mg) ÷ (water consumption (liters)) Consumption = 1 L/day for populations <13 years old and 2 L/day for populations ≥ 13 years old. Default body weights = 70 kg for general U.S. population and adult males, 60 kg for youth and females ≥ 13 years old, and 10 kg for all others.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Butafenacil is not proposed for registrations for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Butafenacil is not proposed for registrations for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population*. Butafenacil is not expected to pose a cancer risk because no evidence of carcinogenicity was found in adequate animal tests in two different species, therefore no aggregate cancer risk assessment was performed.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Syngenta Crop Protection, Inc. proposed Syngenta Method 131–99 for enforcement of the proposed cotton tolerances (adequate validation, independent laboratory validation (ILV), and radiovalidation data have been submitted). The petitioner did not propose ruminant liver and kidney tolerances and therefore did not propose a method for enforcement of the recommended ruminant liver and kidney tolerances. The petitioner has and will submit an enforcement method, adequate validation, ILV, and radiovalidation for enforcement of the ruminant liver and kidney tolerances as a condition of registration.

B. International Residue Limits

Canada, Codex, and Mexico do not have maximum residue limits for residues of butafenacil in/on cotton. Therefore, harmonization is not an issue.

C. Conditions

As a condition of registration, the petitioner must submit:

1. A ruminant liver and kidney enforcement method and submit adequate validation, ILV, and radiovalidation data.

2. Submit confirmatory data on the frozen storage stability of residues of butafenacil in or on cottonseed, cotton gin byproduct, cotton hull, cotton meal, and cotton oil.

3. Submit a ruminant feeding study to confirm the Agency's estimate of maximum residues of butafenacil from the goat metabolism study.

V. Conclusion

Therefore, the tolerance is established for residues of butafenacil, in or on cattle, kidney; goat, kidney; hog, kidney; horse, kidney; and sheep, kidney at 0.05 ppm; in or on cattle, liver; goat, liver; hog, liver; horse, liver; and sheep, liver at 0.50 ppm; in or on cotton, undelinted seed at 0.50 ppm; and in or on cotton, gin byproducts at 10 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–2003–0282 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 18, 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–2003–0282, 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. Statutory 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: September 10, 2003.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.592 is added to read as follows:

§ 180.592 Butafenacil; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide butafenacil, (1,1-dimethyl-2-oxo-2-(2-propenyloxy)ethyl 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl] benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Cotton, gin byproducts	10
Cotton, undelinted seed	0.50

(2) Tolerances are established for residues of the herbicide butafenacil, (1,1-dimethyl-2-oxo-2-(2-propenyloxy)ethyl 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl] benzoate) and its metabolite CGA-293731 (1-carboxy-1-methylethyl 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl] benzoate), in or on the following livestock commodities:

Commodity	Parts per million
Cattle, kidney	0.05
Cattle, liver	0.50
Goats, kidney	0.05
Goats, liver	0.50
Hog, kidney	0.05
Hog, liver	0.50
Horse, kidney	0.05
Horse, liver	0.50
Sheep, kidney	0.05
Sheep, liver	0.50

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

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

(d) *Indirect and inadvertant residues.* [Reserved]

[FR Doc. 03–23853 Filed 9–18–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0300; FRL–7324–9]

S-Metolachlor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of the herbicide S-metolachlor and its metabolites in or on asparagus; carrot, roots; horseradish; onion, green; rhubarb; and swiss chard. The 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 (FQPA) of 1996.

DATES: This regulation is effective September 19, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0300, must be received on or before November 18, 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: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–9368; e-mail address:jamerson.hoyt@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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