Commodity	Parts per million
Rye, straw	0.05
Wheat, forage	0.05
Wheat, grain	0.01
Wheat, hay	0.05
Wheat, straw	0.05

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

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

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

[FR Doc. E7–19219 Filed 9–27–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0072; FRL–8148–2]

Tembotrione; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of tembotrione, 2-[2-chloro-4-(methyl sulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-1,3-cyclohexanedione and its metabolite (M5); 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-4,6-dihydroxy-1,3-cyclohexanedione in or on corn (field, sweet and pop) and livestock commodities. Bayer CropScience requested those tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 28, 2007. Objections and requests for hearings must be received on or before November 27, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006-0072. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Eugene Wilson, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305-6103; e-mail address: *wilson.eugene@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006-0072 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 as required by 40 CFR part 178 on or before November 27, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2006-0072, by one of the following methods:

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

II. Petition for Tolerance

In the **Federal Register** of April 26, 2006 (71 FR 24690 - 24692) (FRL–8063-6), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F7009) by Bayer CropScience, 2 TW Alexander Drive, P.O. Box 12014, RTP, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for combined residues of the herbicide AE 0172747 (tembotrione), 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-1,3-cyclohexanedione, and metabolite (M5), AE 1417268 (2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-4,6-dihydroxy-1,3-cyclohexanedione (expressed as tembotrione equivalents in or on corn, field, grain at 0.02 ppm; corn, field, forage at 0.5 ppm; corn, field, stover at 0.5 ppm; corn, sweet, kernel plus cob with husks removed at 0.03 ppm; corn, sweet, forage at 1.0 ppm; corn sweet, stover at 1.0 ppm; popcorn, grain at 0.01 ppm; Popcorn, stover, 0.25 ppm; cattle, liver at 0.5 ppm; cattle, meat byproducts, except liver at 0.07 ppm; goat, liver at 0.5 ppm; goat, kidney at 0.07 ppm; Hog Liver at 0.5; Hog, Kidney at 0.07 ppm, sheep, kidney at 0.07 ppm; sheep, meat byproducts at 0.5 ppm ; horse, kidney at 0.07 ppm; horse, meat byproducts at 0.5 ppm. There were no comments received in response to the notice of filing.

Based on the aggregate exposure from food and feed commodities resulting from the use-patterns proposed in the petition, the proposed tolerances were revised to account for both tembotrione and its metabolite M5, expressed as tembotrione equilivants. The aggregate risk assessment is discussed in Unit III, below. The reasons for these changes are also explained in Unit V.

III. Aggregate Risk Assessment and Determination of Safety

For tembotrione, aggregate exposure risk assessments were performed for the following scenarios: acute aggregate exposure (food and drinking water), and chronic aggregate exposure (food and drinking water). Short- and intermediate-term assessments were not performed because there are no registered or proposed residential non-food uses. The chronic Reference Dose (cRfD) will be protective of cancer and non-cancer effects, because tembotrione is classified as ''Suggestive Evidence of Carcinogenicity'' and EPA's Cancer Assessment Review Committee (CARC) recommended that a separate quantification of cancer risks is not required, while noting that the progression of non-neoplastic related lesions in rats was biologically plausible by non-genotoxic modes of action for the corneal tumors.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for combined residues of tembotrione, 2-[2-chloro-4-(methyl sulfonyl)-3-[(2,2,2-trifluoro ethoxy]methyl]benzoyl]-1,3-cyclo hexanedione and metabolite (M5), 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-4,6-dihydroxy-1,3-cyclohexanedione, in or on corn, field, grain at 0.02 ppm; corn, field, forage at 0.60 ppm; corn, field, stover at 0.45 ppm; corn, sweet, kernel plus cob with husks removed at 0.04 ppm; corn, sweet, forage at 1.0 ppm; corn, sweet, stover at 1.2 ppm; corn, pop, grain at 0.02 ppm; corn, pop, stover at 0.35 ppm; cattle, liver at 0.40 ppm; cattle, meat byproducts, except liver 0.07 ppm; goat, liver at 0.40 ppm; goat, meat byproducts, except liver at 0.07 ppm; horse, liver at 0.40 ppm; horse, meat byproducts except liver at 0.07 ppm; sheep, liver at 0.40 ppm; sheep, meat byproducts, except liver at 0.07 ppm; poultry, liver at 0.07 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by tembotrione, 2-[2-chloro-4-(methyl sulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-1,3-cyclohexanedione as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA–HQ–OPP–2006–0072 in that docket.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account 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. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are

considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

A summary of the toxicological endpoints for tembotrione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-1,3-cyclohexanedione used for human risk assessment is shown in Table 1 of this unit.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TEMBOTRIONE, 2-[2-CHLORO-4-(METHYLSULFONYL)-3-[(2,2,2-TRIFLUOROETHOXY)METHYL]BENZOYL]-1,3-CYCLOHEXANEDIONE FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional FQPA, SF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children) and Females 13 to 49	LOAEL = 0.8 (mg/kg/day) SF = 1000 UF_A = 10X UF_H = 10X FQPA SF = 10X(includes UF_L = 10X) Acute reference dose (RfD) = 0.0008 mg/kg	Special FQPA SF = 1 aPAD = acute RfD ÷ Special FQPA SF = 0.0008 mg/kg	Developmental Neurotoxicity Study: Offspring NOAEL was not established.Offspring LOAEL = 0.8 mg/kg/day based on decreased acoustic startle response on PND 60 (males), and brain morphometric changes on PND 75 (males and females).
Chronic dietary(All populations)	NOAEL= .04 mg/kg/day SF = 100 UF_A = 10X UF_H = 10X FQPA SF = 1X Chronic RfD = 0.0004 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD Special FQPA SF = 0.0004 mg/kg/day	Chronic/Carcinogenicity Study LOAEL = 0.79 mg/kg/day based on neovascularization and edema of the cornea and snow flake-like corneal opacity, unilateral or bilateral keratitis of the eye, decreased mean body weight and mean body-weight gain, increased total cholesterol, higher ketone levels and lower pH values, higher protein levels, increased kidney weight, kidney to body weight and kidney to brain weight ratios, chronic nephropathy and atrophy of the sciatic nerve.
Short-term dermal (1 to 30 days) (Residential)	Oral study LOAEL= 0.8 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 10X (includes UFL = 10X) (dermal absorption rate = 15 %)	LOC for MOE =1000	Developmental neurotoxicity Study Offspring NOAEL was not established.Offspring LOAEL = 0.8 mg/kg/day based on decreased acoustic startle response on PND 60 (males), and brain morphometric changes on PND 75 (males and females).
Intermediate-term dermal (1 to 6 months) (Residential)	Oral study LOAEL= 0.8 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 10X (includes UFL = 10X) (dermal absorption rate = 15 %)	LOC for MOE = 1000 (Residential)	Developmental neurotoxicity Study Offspring NOAEL was not established.Offspring LOAEL = 0.8 mg/kg/day based on decreased acoustic startle response on PND 60 (males), and brain morphometric changes on PND 75 (males and females).

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TEMBOTRIONE, 2-[2-CHLORO-4-(METHYLSULFONYL)-3-[(2,2,2-TRIFLUOROETHOXY)METHYL]BENZOYL]-1,3-CYCLOHEXANEDIONE FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional FQPA, SF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Long-term dermal (>6 months to lifetime) (Residential)	Oral study NOAEL= 0.04 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X (dermal absorption rate = 15 % when appropriate)	LOC for MOE = 100 (Residential)	Chronic/Carcinogenicity Study LOAEL = 0.79 mg/kg/day based on neovascularization and edema of the cornea and snow flake-like corneal opacity, unilateral or bilateral keratitis of the eye, decreased mean body weight and mean body-weight gain, increased total cholesterol, higher ketone levels and lower pH values, higher protein levels, increased kidney weight, kidney to body weight and kidney to brain weight ratios, chronic nephropathy and atrophy of the sciatic nerve.
Short-term inhalation (1 to 30 days) (Residential)	Oral study LOAEL= 0.8 UF_L = 10X) (inhalation absorption rate = 100%)	LOC for MOE = 1000 (Residential)	Developmental neurotoxicity Study Offspring NOAEL was not established. Offspring LOAEL = 0.8 mg/kg/day based on decreased acoustic startle response on PND 60 (males), and brain morphometric changes on PND 75 (males and females).
Intermediate-term inhalation (1 to 6 months) (Residential)	Oral study LOAEL= 0.8 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 10X (includes UF_L = 10X) (inhalation absorption rate = 100%)	LOC for MOE = 1000 (Residential)	Developmental neurotoxicity Study] Offspring NOAEL was not established.Offspring LOAEL = 0.8 mg/kg/day based on decreased acoustic startle response on PND 60 (males), and brain morphometric changes on PND 75 (males and females).
Long-term inhalation (>6 months) (Residential)	Oral study NOAEL= 0.04 mg/kg/day UF_H = 10X FQPA SF = 1X (inhalation absorption rate = 100%)	LOC for MOE = 100 Residential	Chronic/Carcinogenicity Study LOAEL = 0.79 mg/kg/day based on neovascularization and edema of the cornea and snow flake-like corneal opacity, unilateral or bilateral keratitis of the eye, decreased mean body weight and mean body-weight gain, increased total cholesterol, higher ketone levels and lower pH values, higher protein levels, increased kidney weight, kidney to body weight and kidney to brain weight ratios, chronic nephropathy and atrophy of the sciatic nerve.
Cancer (Oral, dermal, inhalation)	Classification: ''Suggestive Evidence of Carcinogenic Potential'' based on the observance of squamous cell carcinomas in a rat carcinogenicity study. Quantification of cancer risk is not required.		

UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tembotrione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-1,3-cyclohexanedione, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from tembotrione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-tri

fluoroethoxy)methyl]benzoyl]-1,3-cyclohexanedione in food as follows:

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

Effects were identified in the toxicological studies for tembotrione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-1,3-cyclohexanedione; therefore, a quantitative acute dietary exposure assessment was necessary. The acute analysis assumed 100% crop treated (CT), Dietary Exposure Evaluation Model (DEEM(™)) 7.81 default processing factors, and tolerance-level residues for all foods. For drinking water, the entire distribution of estimated daily exposure values from the Pesticide Root Zone Modeling-Exposure Evaluation Analysis Modeling System (PRZM-EXAMS) run was incorporated in the acute probabilistic exposure analyses. The resulting acute dietary (food + water) risk estimates were <32% of the aPAD for the general U.S. population and <77% of the aPAD for all infants (<1 year old, the most highly-exposed population subgroup) at the 95th percentile; less than HED's LOC (100% aPAD). Even though the entire distribution of estimated daily drinking water exposure values was incorporated, this analysis is still conservative since tolerance-level residues, DEEM(™) 7.81 default processing factors, and 100% CT were assumed. Also, the distribution of estimated daily drinking water exposure still assumes 100% CT and the maximum application rate.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA, 1994–1996, and 1998 Continuing Survey of Food Intake by Individuals. As to residue levels in food, EPA assumed all foods for which there are proposed tolerances were treated and contain tolerance-level residues. A conservative chronic dietary assessment assuming tolerance-level residues, DEEM(™) 7.81 default processing factors, and 100% CT was also conducted. The highest estimate of chronic surface water exposure (1.05 parts per billion (ppb)) was used for drinking water in this analysis.

iii. *Cancer*. There was only suggestive evidence of carcinogenic potential based on the observance of squamous cell carcinomas in a rat carcinogenicity study. Quantification of cancer risk is not required. Dietary cancer risk concerns due to long-term consumption of tembotrione residues are adequately addressed by the chronic exposure analysis using the cPAD.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for tembotrione, 2-[2-chloro-4-(methyl sulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-1,3-cyclohexanedione 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 environmental fate characteristics of tembotrione, 2-[2-chloro-4-(methyl sulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-1,3-cyclohexanedione. Further, information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the PRZM/EXAMS and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of tembotrione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-1,3-cyclohexanedione for acute exposures are estimated to be 5.84 parts per billion (ppb) for surface water and 0.0139 ppb for ground water. The EECs for chronic exposures are estimated to be 1.05 ppb for surface water and 0.0139 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 5.84 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 1.05 ppb was used to access the contribution to drinking 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).

Tembotrione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-1,3-cyclohexanedione is not registered 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 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.''

Tembotrione, belongs to a class of herbicides (including mesotrione, pyrasulfotole, isoxaflutole and topramezone) that inhibit the liver enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD). As discussed above, EPA has concluded that the ocular effects caused by these herbicides has limited relevance to humans. Nonetheless, as a worst case scenario, EPA has assessed aggregate exposure to tembotrione based on ocular effects in rats. For similar reasons, a semi-quantitative screening cumulative assessment was conducted using the rat ocular effects and 100% crop treated information. The results of this screening analysis did not indicate a concern. In the future, assessments of HPPD-inhibiting herbicides will consider more appropriate models and cross species extrapolation methods.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1.*In general*. Section 408 of FFDCA provides that EPA shall apply an additional (''10X'') tenfold 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is evidence of increased susceptibility in rabbit and rat fetuses to *in utero* exposure to tembotrione compared to the doses for the effects found in maternal animals. In a developmental toxicity study in rabbits, the NOAEL of 1 milligram per kilogram of body weight per day (mg/kg bw/day) was based on decreased growth and/or delayed development of the skeleton

and increased incidences of skeletal variations and anomalies in fetuses seen at a LOAEL of 10 mg/kg/day. This LOAEL is ten-fold lower than the dose resulting in maternal toxicity (100 mg/kg/day, few or no feces, late abortion, decreased body weight and food consumption). In a rat developmental toxicity study, increased skeletal variations (e.g., delayed ossifications) and other fetal effects (decreased fetal body weights and an increased number of runts) occurred at a dose of 25 mg/kg/day (the lowest dose tested), which is lower than the 125 mg/kg bw dose that caused marginal maternal toxicity (decreased body-weight gains and food consumption). In a rat developmental neurotoxicity study (DNT), decreased post-weaning body weight (males), decreased acoustic startle response and brain morphometric changes were seen in rat fetuses at a dose of 0.8 mg/kg/day (the lowest dose tested) which was lower than the dose of 16.3 mg/kg/day at which maternal toxicity occurred (cornel opacity during lactation).

Although, these studies provide evidence of increased susceptibility following pre- and post-natal exposures, the concern for increased susceptibility is low for several reasons. First, a well characterized NOAEL (with a sufficient margin from the LOAEL) protecting fetuses has been established in the rabbit prenatal study. Also, the prenatal developmental NOAELs or LOAELs for both the rabbit and rat studies are approximately 12 to 30-fold higher than the LOAEL used for the acute RfD. Although there were some marginal effects reported in the offspring in the rat 2-generation reproduction study at 1.4 mg/kg/day (the lowest dose tested), these parameters (ocular, decreased absolute brain weight, preputial separation) were also evaluated at the lower dose in the rat DNT study but were not found at the low dose tested (0.8 mg/kg/day). Therefore, a NOAEL has been identified for these effects. Other effects indicative of neurotoxicity (altered brain morphometrics, decrease in auditory startle response) were seen in the rat developmental neurotoxicity study at the lowest dose tested. The response for brain morphometrics seen at termination is considered to be marginal or equivocal since the changes were small and no clear dose response was observed. The decreased acoustic startle response was not found in young pups (post-natal day 22) but only observed in adult rats (post-natal day 60) and was statistically significant at the mid and high dose but not at the lowest dose tested.

3. *Conclusion*. Given the above-described data on pre- and post-natal effects, the only significant uncertainty concerns the acute RfD due to the failure to identify a NOAEL for the brain morphometric alterations found in the rat DNT. The LOAEL in the DNT is lower than the NOAEL and the LOAEL from the rabbit and rat developmental studies, and thus is the lowest dose reflective of potential acute effects. Because of the uncertainty as to the NOAEL for the acute effects (brain morphometric alterations) seen at 0.8 mg/kg/day in the DNT, EPA has retained the additional 10X FQPA safety factor in calculating the acute RfD. This is a conservative step given the equivocal nature of the brain morphometric alterations seen at the LOAEL in the DNT.

EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X for assessing chronic risk. That decision is based on the following findings:

i. For the reasons described in Unit III.D.2., the toxicity database for tembotrione, 2-[2-chloro-4-(methyl sulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-1,3-cyclohexanedione is adequate to assess chronic risk.

ii. Despite evidence of sensitivity in pre- and post-natal studies, as detailed in Unit III.D.2., the chronic RfD based on an adult animal study (chronic rat study) is considered to be protective of the chronic offspring toxicity found in the rat DNT and 2-generation reproduction studies. The 2-generation reproduction study did not identify a NOAEL for the chronic effects seen on brain weight and preputial separation but a NOAEL can be characterized from the DNT, as discussed above, at 0.8 mg/kg/day. The NOAEL used to set the chronic RfD is 20-fold lower than this 0.8 mg/kg/day dose and is not based on an effect as to which the data have raised sensitivity concerns. Similarly, the chronic rat study and the NOAEL from that study are protective of the chronic effects seen in the DNT study and the other chronic effects found in the 2-generation reproduction study. The endpoints of concern for the chronic RfD are based on ocular toxicity, body weight decreases, kidney toxicity, and changes in the clinical chemistry parameters. Target organ toxicity such as ocular toxicity, kidney toxicity, body weight changes and nervous system effects were assessed in the young through pre- and post-natal exposure to tembotrione in the 2-generation reproduction study and the DNT study. In those studies, these effects were observed at higher doses in the young than in the adults in the chronic rat study. Therefore, the chronic RfD is considered to be protective of effects in the young. As noted, the NOAEL (0.04 mg/kg/day) selected for the chronic RfD is 20-fold lower than the dose at which developmental and neurological effects were observed in any study; it is also 20-fold lower than the NOAEL for other chronic effects seen in the young.

iii. There are no residual uncertainties identified in the exposure data bases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues of tembotrione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-1,3-cyclohexanedione.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to tembotrione, 2-[2-chloro-4-(methyl sulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-1,3-cyclo hexanedione will occupy 77% of the aPAD for the population group (infants (<1 year old) receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to tembotrione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-1,3-cyclohexanedione from food and water will utilize 48% of the cPAD for the population group (children 3 to 5 years old). There are no residential uses for tembotrione, 2-[2-chloro-4-(methyl sulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-1,3-cyclohexanedione that result in chronic residential exposure to tembotrione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-1,3-cyclohexanedione.

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).

Tembotrione, 2-[2-chloro-4-(methyl sulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-1,3-cyclohexanedione is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which does not exceed the Agency's level of concern.

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

Tembotrione, 2-[2-chloro-4-(methyl sulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-1,3-cyclo hexanedione is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which does not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Dietary cancer risk concerns due to long-term consumption of tembotrione residues are adequately addressed by the chronic exposure analysis using the cPAD.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to tembotrione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-1,3-cyclohexanedione residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

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

B. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican limits for residues of tembotrione and its metabolites in or on crops or livestock commodities.

C. Response to Comments

There were no comments received on the Notice of Filing of the pesticide petition.

V. Conclusion

Therefore, the tolerance is established for combined residues or residues of tembotrione, 2-[2-chloro-4-(methyl sulfonyl)-3-[(2,2,2-(trifluoro ethoxy)methyl]benzoyl]-1,3-cyclohexanedione, metabolite; 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluorethoxy)methyl]benzoyl]-4,6-dihydroxycyclohexanedione, in or on corn, field, grain at 0.02 ppm; corn, field, forage at 0.60 ppm; corn, field, stover at 0.45 ppm; corn, sweet, kernel plus cob with husks removed at 0.04 ppm; corn, sweet, forage at 1.0 ppm; corn sweet, stover at 1.2 ppm; corn, pop, grain at 0.02 ppm; corn, pop, stover at 0.35 ppm; cattle, liver at 0.40 ppm; cattle, meat byproducts, except liver 0.07 ppm; goat, liver at 0.40 ppm; goat, meat byproducts, except liver at 0.07 ppm; horse, liver at 0.40 ppm; horse, meat byproducts except liver at 0.07 ppm; sheep, liver at 0.40 ppm; sheep, meat byproducts, except liver at 0.07 ppm; poultry, liver at 0.07 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 23, 2007.

Debra Edwards,

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), 346a and 371.

■ 2. Section 180.634 is added to subpart C to read as follows:

§180.634 Tembotrione; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, tembotrione, 2-[2-chloro-4-(methyl sulfonyl)-3-[(2,2,2-trifluoro ethoxy)methyl]benzoyl]-1,3-cyclo hexanedione and its metabolite 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl]-4,6-dihydroxycyclohexane-1,3-dione in or on the following commodities:

Commodity	Parts per million
Cattle, liver	0.40
Cattle, meat byproducts, except liver	0.07
Corn, field, forage	0.60
Corn, field, grain	0.02
Corn, field, stover	0.45
Corn, pop, grain	0.02
Corn, pop, stover	0.35
Corn, sweet, forage	1.0
Corn, sweet, kernel plus cob with husks removed	0.04
Corn, sweet, stover	1.2
Goat, liver	0.40
Goat, meat byproducts, except liver	0.07
Horse, liver	0.40
Horse, meat byproducts, except liver	0.07
Poultry, liver	0.07
Sheep, liver	0.40
Sheep, meat byproducts, except liver	0.07

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

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

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

[FR Doc. E7–19230 Filed 9–27–07; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1545–CN]

42 CFR Part 409

RIN 0938–AM46

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Corrections

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction notice.

SUMMARY: This document corrects technical errors that appeared in the August 3, 2007 **Federal Register**, entitled ''Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2008; Final Rule.''

DATES: *Effective Date:* This correction is effective October 1, 2007.

FOR FURTHER INFORMATION CONTACT: Bill Ullman, (410) 786–5667.

SUPPLEMENTARY INFORMATION:

I. Background

FR Doc. 07–3784 of August 3, 2007 (72 FR 43412) contained technical errors that this notice serves to identify and correct. The first involves the construction of the 2004 skilled nursing facility (SNF) market basket update. In the SNF prospective payment system (PPS) proposed rule for fiscal year (FY) 2008 (72 FR 25552, May 4, 2007), we proposed to discontinue the previous, 1997-based market basket's use of the Producer Price Index (PPI) for Industrial Chemicals, in favor of using a blended PPI composed of the PPIs for soap and other detergent manufacturing (North American Industrial Classification System (NAICS) 325611), polish and other sanitation good manufacturing (NAICS 325612), and all other miscellaneous chemical product and preparation manufacturing (NAICS 325998) in the 2004-based market basket, which we believed would better reflect SNF purchasing patterns. In the FY 2008 SNF PPS final rule, we finalized this proposal ''* * * to revise the market basket to reflect more appropriate, industry-specific price proxies (such as the blended compensation and chemical price proxies)'' (72 FR 43426, 43436).

However, in performing the actual calculations in the final rule, we inadvertently proxied the chemicals cost weight by the PPI for Industrial Chemicals rather than by the appropriate blended chemical price proxy. We note that this error did not affect the final market basket update factor of 3.3 percent, but did affect the labor-related share. The corrected labor-related share is 70.249, which is slightly higher than the 70.152 figure published in the FY 2008 SNF PPS final rule. Accordingly, in this notice, we are republishing corrected versions of Tables 6, 7, 10, 13, and 14 (as well as revising the corresponding portions of the final rule's preamble text) in order to reflect the final, corrected labor-related share.

In addition, we have determined that in the process of developing the most recent hospital wage index, two inpatient hospital providers with wage data that belonged in the Hartford–West Hartford–East Hartford, CT core-based statistical area (CBSA) were inadvertently included in rural Connecticut instead. Accordingly, in Table 8, we are revising the wage index value for CBSA Code 25540 (Hartford–West Hartford–East Hartford, CT) from 1.0937 to the corrected value of 1.0930. Similarly, in Table 9, we are revising the wage index value for CBSA Code 7 (rural Connecticut) from 1.1283 to the corrected value of 1.1711. As we are revising only a single entry in each of these two tables, we are not republishing Tables 8 and 9 in their entirety in this notice; however, we note that the corrected versions of both tables are available online on the SNF PPS Web site, at *http://www.cms.hhs.gov/SNFPPS/04_WageIndex.asp*. Moreover, we note that the corrected version of Table 14 that we are republishing in this notice also reflects these corrected values. We are also correcting a typographical error in the final rule's version of that table, which had inadvertently displayed the wage data update for rural New England incorrectly as a negative value.

II. Correction of Errors

In FR Doc. 07–3784 (72 FR 43412), make the following corrections:

1. On page 43421, Table 6 is corrected to read as follows: