§ 721.10690 Benzenedicarboxylic acid, polymer with substituted alkanediol, dodecanedioic acid, 1,2-ethanediol, alkanedioic acid, alkanediol,.alpha.-hydro-.omega.-hydroxypoly[oxyalkanediyl], 1,3-isobenzofurandione, methylene diphenyl diisocyanate, 2-oxepanone, 2,2'-oxybis[ethanol] and polymethylene polyphenylene isocyanate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as benzenedicarboxylic acid, polymer with substituted alkanediol, dodecanedioic acid, 1,2-ethanediol, alkanedioic acid, alkanediol,.alpha.-hydro-.omega.-hydroxypoly[oxyalkanediyl], 1,3-isobenzofurandione, methylene diphenyl diisocyanate, 2-oxepanone, 2,2'-oxybis[ethanol] and polymethylene polyphenylene isocyanate (PMN P–13–232) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (o) and (y)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 24. Add § 721.10691 to subpart E to read as follows:

§ 721.10691 Fatty acid amide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fatty acid amide (PMN P–13–267) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 25. Add § 721.10692 to subpart E to read as follows:

§ 721.10692 Fluorinated alkyl dianiline (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as fluorinated alkyl dianiline (PMN P–13–288) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 26. Add § 721.10693 to subpart E to read as follows:

§ 721.10693 Diphenylmethane diisocyanate polymer with alkanoic diacid and alkanediol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as diphenylmethane diisocyanate polymer with alkanoic diacid and alkanediol (PMN P–13–338) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (o) and (y)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[FR Doc. 2013–18982 Filed 8–6–13; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0262; FRL–9388–9]

Topramezone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of topramezone in or on multiple commodities which are identified and discussed later in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 7, 2013. Objections and requests for hearings must be received on or before October 7, 2013, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0262, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers

determine whether this document applies to them. Potentially affected entities may include:

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR Part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR Part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0262 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 7, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR Part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR Part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0262, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 23, 2012 (77 FR 30481) (FRL–9347–8), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F7997) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.612 be amended by establishing tolerances for residues of the herbicide topramezone ([3-(4,5-dihydro-3-isoxazolyl)-2-methyl-4-(methylsulfonyl)phenyl](5-hydroxy-1-methyl-1*H*-pyrazol-4-yl)methanone), in or on fish and shellfish at 0.05 parts per million (ppm). That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed commodity definitions and established tolerances for livestock meat by-products, which are needed as a result of the increased livestock dietary burden associated with the proposed use for topramezone. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with 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 topramezone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with topramezone 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. Topramezone is a member of the class of herbicides known as HPPD inhibitors. Inhibition of the enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD) results in decreased carotenoid synthesis and ultimately bleaching of target plants. In mammals, HPPD is involved in the catabolism of the amino acid tyrosine, and its inhibition causes blood levels of tyrosine to rise; a condition known as tyrosinemia. Some of the toxicities resulting from tyrosinemia in laboratory animals include ocular, developmental, liver, and kidney effects. Topramezone exhibits a mammalian toxicity profile that is consistent with HPPD inhibition.

The primary target organs affected following oral administration of topramezone in animal toxicity studies were the eyes, thyroid, pancreas, and liver. The most sensitive species was the rat, and in rats and dogs, males were more sensitive than females. The effects on the eyes in chronic toxicity studies consisted of pannus (vascularization) and keratitis (cloudiness) of the cornea in both sexes. Hypertrophy and hyperplasia of the thyroid, hypertrophy and focal necrosis in the liver, and degeneration of the pancreas were among the histopathology findings reported across different subchronic and chronic studies in rats and dogs. Results of chronic toxicity studies in dogs, mice, and rats also suggest decrements in body weights, body-weight gains, and food utilization (dogs only).

There was evidence for increased susceptibility following *in utero* exposure to topramezone in rats and rabbits. In rabbits, fetal abnormalities

including supernumerary thoracic vertebrae and supernumerary 13th rib were observed in the presence of maternal toxicity in six of eight developmental toxicity studies conducted in two different strains. In rats, developmental effects consisting of skeletal variations occurred in the presence of maternal toxicity. Increased maternal serum levels of tyrosine were reported in several developmental toxicity studies (several in rabbits and one in mice), consistent with the proposed mode of action for topramezone involving HPPD inhibition. In the rat 2-generation reproductive toxicity study, there was no evidence of increased pre- or post-natal susceptibility; offspring effects occurred in the presence of maternal effects. The offspring effects consisted of decreased pup body weight/body-weight gain in F_2 (both sexes) and increased time to preputial separation (F_1 males). Maternal effects were consistent with HPPD inhibition (decreased body weights, decreased body-weight gains, increased thyroid and kidney weights, and microscopic findings in the eyes, kidneys, and thyroid). No reproductive effects were reported.

Topramezone did not show any evidence of neurotoxicity in the acute (ACN) or subchronic (SCN) neurotoxicity studies, but in a rat developmental neurotoxicity (DNT) study, where dosing with topramezone took place during the prenatal as well as postnatal time periods, there was evidence for increased qualitative susceptibility. In the maternal animals, toxicity was limited to corneal opacity, whereas effects in the offspring included neurobehavioral and neuropathological changes. Offspring neurobehavioral effects consisted of a decreased auditory startle reflex at postnatal day 24 in both sexes (20–30%) and at postnatal day 60 for males (55%). There were also mild decreases in offspring absolute brain weights and neuropathological effects involving decreased brain morphometric measurements (e.g., hippocampus, and parietal cortex).

Topramezone is classified as ''not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis.'' EPA has determined that the thyroid tumors arise through a non-linear mode of action, and the chronic reference dose (cRfD) is expected to be protective of alterations in hormone homeostasis that may result in thyroid tumor formation. Mutagenicity studies conducted on technical topramezone and its major metabolites did not demonstrate any mutagenic potential.

Specific information on the studies received and the nature of the adverse effects caused by topramezone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document ''Topramezone: Human-Health Risk Assessment for (1) New Uses in Non-Crop Aquatic Sites and (2) Increased Maximum Application Rate for Currently Registered Terrestrial Uses in the Maintenance of Bare Grounds (Roadsides, Utility and Railroad Rights-of-Ways, Industrial Sites, and Tank Farms),'' pages 36–39 in docket ID number EPA–HQ–OPP–2012–0262.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for topramezone used for human risk assessment is shown in the Table of this unit.

SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TOPRAMEZONE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute Dietary (General population including infants and children).	LOAEL = 8 mg/kg bw.	UF = 100X (for inter- and intra-species extrapolation). FQPA SF = 10X aRfD = 0.008 mg/kg bw aPAD = 0.008 mg/kg bw	Developmental Neurotoxicity Study in Rats. Offspring LOAEL = 8 mg/kg bw based on decreased maximum auditory startle reflex response, decreased brain weights, and changes in brain morphology.
Acute Dietary (Females 13–49 years old).	NOAEL = 0.5 mg/kg/day.	UF = 100X (for inter- and intra-species extrapolation). FQPA SF = 1X aRfD = 0.005 mg/kg/day aPAD = 0.005 mg/kg/day	Developmental Toxicity Study in Rabbits. Developmental LOAEL = 5 mg/kg/day based on alterations in skeletal ossification sites and increased number of pairs of ribs.

SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TOPRAMEZONE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Chronic Dietary (All populations).	NOAEL= 0.4 mg/kg/day.	UF = 100X (for inter- and intra-species extrapolation). FQPA SF = 1X cRfD = 0.004 mg/kg/day cPAD = 0.004 mg/kg/day.	Chronic toxicity/Carcinogenicity Study in Rats. LOAEL = 3.6 mg/kg/day based on increased incidences of corneal opacity, decreased body weight and body-weight gains in males and histopathological evaluations in the eyes, thyroid and pancreas of both sexes.
Incidental Oral (Short- and Intermediate-Term).	NOAEL = 0.4 mg/kg/day.	Residential LOC for MOE = 100.	Two-Generation Reproduction Study in Rats. Offspring LOAEL = 4.2 mg/kg/day based decreases in body weights and body-weight gains in the F_2 generation offspring and increased time to preputial separation in the F_1 male offspring.
Short- and Intermediate-Term, Dermal.	Oral NOAEL = 0.4 mg/kg/day. (DAF = 2.6%)	Residential LOC for MOE = 100.	Two-Generation Reproduction Study in Rats. Parental LOAEL = 4.2 mg/kg/day based on decreased body weight, body-weight gain in males, increased thyroid and kidney weights of both sexes, and microscopic findings in eyes, kidney and thyroid of both sexes.
Short- and Intermediate-Term Inhalation.	Oral NOAEL= 0.4 mg/kg/day (inhalation absorption = 100%).	Residential LOC for MOE = 100.	Two Generation Reproduction Study in Rats. Parental LOAEL = 4.2 mg/kg/day based on decreased body weight, body-weight gain in males, increased thyroid and kidney weights of both sexes, and microscopic findings in eyes, kidney and thyroid of both sexes.
Cancer (Oral, dermal, inhalation).	In accordance with the 2005 EPA Guidelines for Carcinogen Risk assessment, topramezone was classified as ''not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis.'' EPA has determined that the thyroid tumors arise through a non-linear mode of action and that the NOAEL (0.4 mg/kg/day) for deriving the cRfD will be protective of thyroid hormone alterations and thyroid tumor formation.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to topramezone, EPA considered exposure under the petitioned-for tolerances as well as all existing topramezone tolerances in 40 CFR 180.612. EPA assessed dietary exposures from topramezone 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. Such effects were identified for topramezone.

In estimating acute dietary exposure for both the general U.S. population (including infants and children) and for females 13–49 years of age, EPA used food consumption information from the U.S. Department of Agriculture's *National Health and Nutrition Examination Survey, What We Eat in America,* (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT), Dietary Exposure Evaluation Model (DEEM) 7.81 default processing factors, and tolerance-level residues.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the same food consumption data and assumptions of tolerance-level residues, 100 PCT and DEEM 7.81 default processing factors.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that topramezone does not pose a cancer risk to humans at levels that do not alter rat thyroid hormone homeostasis, and doses at or below the cRfD are not expected to alter thyroid homeostasis. Therefore, a dietary exposure assessment beyond the chronic assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for topramezone. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The highest drinking water concentrations are expected to result from the direct aquatic applications. Estimates of drinking water exposure levels were based on label instructions (i.e., proposed application rates, duration, and water concentration of direct aquatic applications at potable surface water intakes). For acute and chronic dietary risk assessment, the water concentration value of 45 parts per billion (ppb) was used to assess 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). Topramezone is currently registered for turf and golf course uses that could result in residential exposures. Topramezone is also proposed for use in direct aquatic applications that could result in exposure during recreational swimming activities. EPA assessed

residential exposure using the following assumptions: For adults, short-term aggregate assessment considered the post-application exposure resulting from the physical activities on turf. For children, short-term aggregate assessment considered combined dermal and incidental oral (hand-to-mouth) post-application exposures to children 1 < 2 years old resulting from the registered turf use. These post-application exposure estimates from the turf use are protective of post-application exposure for older children more likely to engage in recreational swimming activities. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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

Topramezone belongs to a class of herbicides that inhibit the liver enzyme HPPD, which is involved in the catabolism (metabolic breakdown) of tyrosine (an amino acid derived from proteins in the diet). Inhibition of HPPD can result in elevated tyrosine levels in the blood, a condition known as tyrosinemia. HPPD-inhibiting herbicides have been found to cause a number of toxicities in laboratory animal studies including ocular, developmental, liver, and kidney effects. Of these toxicities, the ocular effect (corneal opacity) is highly correlated with the elevated blood tyrosine levels. In fact, rats dosed with tyrosine alone show ocular opacities similar to those seen with HPPD inhibitors. Although the other toxicities may be associated with chemically induced tyrosinemia, other mechanisms may also be involved. There are marked differences among species in the ocular toxicity associated with HPPD inhibition. For example, treatments with HPPD inhibitor herbicides result in ocular effects in the rat, but not the mouse or monkey. The explanation of this species-specific response is related to the species differences in the clearance of tyrosine. Some species (such as the mouse and monkey) have a metabolic pathway that exists to remove tyrosine from the blood. This pathway involves a liver enzyme called tyrosine aminotransferase (TAT). Unlike rats, mice and humans have a highly effective metabolic process for handling excess tyrosine and are unlikely to achieve the levels necessary to produce ocular opacities. In fact, HPPD inhibitors (e.g. nitisinone) are used as an effective therapeutic agent to treat human patients suffering from rare genetic diseases of tyrosine catabolism. The human experience indicates that a therapeutic dose (1 mg/kg/day dose) has an excellent safety record in infants, children, and adults and that serious adverse health outcomes have not been observed in a population followed for approximately a decade. Rarely, ocular effects are seen in patients with high plasma tyrosine levels; however, these effects are transient and can be readily reversed upon adherence to a restricted protein diet. This indicates that HPPD inhibitor in it of itself cannot easily overwhelm the tyrosine-clearance mechanism in humans.

Therefore, exposure to environmental residues of HPPD-inhibiting herbicides are unlikely to result in the high blood levels of tyrosine and ocular toxicity in humans due to an efficient metabolic process to handle excess tyrosine. EPA has therefore not conducted cumulative risk assessment with other HPPD inhibitors for purposes of this assessment of topramezone for aquatic uses.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* In the prenatal developmental toxicity study with rats, there was evidence for increased qualitative, but not quantitative, susceptibility in the offspring. Qualitative susceptibility was demonstrated by the occurrence of decreased fetal body weight and increased incidences of skeletal variations in the presence of decreased body weight gain in the maternal animals.

In six of eight rabbit studies, there was evidence for increased qualitative susceptibility. In the does, maternal toxicity was characterized as decreases in body weight, body weight gain, and food consumption, all in the presence of increased serum levels of tyrosine. In the fetuses, developmental toxicity was manifested as increased incidences of visceral findings (i.e., absent kidney and ureter) and/or multiple skeletal variations (i.e., delayed ossification, supernumerary 13th rib and/or 27th presacral vertebrae). In two studies, skeletal variations were observed at high doses in the absence of any maternal toxicity.

In the 2-generation reproduction study with rats, there was no evidence of increased susceptibility. Offspring toxicity was characterized as decreased pup weight and weight gain in F_2 male and female pups and increased time to preputial separation in the F_1 males. These effects were observed in the presence of parental/systemic toxicity that included: Decreased body weight, decreased body-weight gain in males, increased thyroid and kidney weights of both sexes, and microscopic findings in the eyes, kidney, and thyroid of both sexes.

In the developmental neurotoxicity (DNT) study, there was evidence for qualitative susceptibility. In the maternal animals, toxicity was limited to corneal opacity whereas effects in the offspring manifested as: Neurobehavioral changes (decreased auditory startle reflex), decreases in absolute brain weight, and decreases in brain morphometric measurements (e.g., hippocampus, and parietal cortex).

3. *Conclusion.* While EPA is retaining the 10X FQPA safety factor for the acute dietary risk assessment for the U.S. general population including infants and children, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for the acute dietary risk assessment for females of child-bearing age (i.e., 13–49 years old), the chronic dietary risk assessment for the U.S. general population, and all non-dietary exposure scenarios. That decision is based on the following findings:

i. The toxicity database for topramezone is complete, except for an immunotoxicity study. A database uncertainty factor (UF_{DB}) is not required for the lack of an immunotoxicity study since the PODs used for overall risk assessments are based on effects seen in target organs (e.g., eyes, thyroid, and liver) consistent with the actions of this chemical as an HPPD inhibitor. An immunotoxicity study is not likely to

yield a lower POD and the preliminary results of the retrospective analyses provide strong support for not retaining the UF_{DB} as no immunotoxicity study available thus far has provided sensitive endpoints for use in deriving points of departure.

ii. There is some indication that topramezone is a neurotoxic chemical for developing animals. While there was no evidence of neurotoxicity or neuropathology to the adult nervous system following a single oral administration to rats at the limit dose in the ACN study or following repeated dietary administration to rats in the SCN study or in the maternal animals of the DNT study, there were neurobehavioral as well as neuropathological effects observed in the offspring of the DNT study as described above.

The LOAEL of 8 mg/kg/day of the DNT study is based on decreased auditory startle reflex, decreases in brain weight, and brain morphometric parameters at the lowest dose tested. A NOAEL was not established. Nevertheless, the LOAEL (8 mg/kg/day) was employed as the point of departure in assessing the risk for the general U.S. population, including infants and children, since the offspring were exposed to topramezone both *in utero* and during the lactation period. The 10X FQPA safety factor is retained as a UF_L (i.e., use of a LOAEL to extrapolate a NOAEL.)

iii. As discussed in Unit III.D.2., there is evidence that topramezone results in increased susceptibility in the prenatal developmental studies in rats and rabbits. But the degree of concern for the effects seen in those studies is low because there were clear NOAELs for the offspring effects and EPA selected points of departure that are protective of those effects. As explained in Unit III.D.3.ii., EPA is retaining the 10X FQPA safety factor for the lack of a NOAEL in the DNT study and believes that doing so will be protective of infants and children.

iv. There are no residual uncertainties in the exposure database. The dietary and residential exposure analyses are conservative in nature. The dietary exposure assessment uses tolerance-level residues and assumes 100 PCT. EPA used similarly conservative assumptions to assess post-application exposure to children/adults. The residential exposure assessment uses chemical-specific turf transferable residue data and the 2012 Residential Standard Operating Procedures (SOPs) and is considered health-protective. These assessments will not underestimate the exposure and risks posed by topramezone.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* Acute aggregate risk is made up only of dietary sources; therefore, the acute exposure estimates provided in the acute dietary exposure analysis represent acute aggregate exposures. EPA has concluded that acute exposure to topramezone from food and drinking water will utilize 98% of the aPAD for the most highly exposed population subgroup (all infants <1 year old) and 50% of the aPAD for females 13–49 years of age. The acute dietary assessment did not result in exposure estimates above EPA's level of concern.

2. *Chronic risk:* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to topramezone from food and water will utilize 62% of the cPAD for all infants (<1 year old), the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of topramezone is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Topramezone is currently registered for residential turf uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to topramezone.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 220 for the general U.S. population and 120 for children 1–2 years old (a subgroup predicted to have the highest dietary burden as well as the highest residential exposure. Because EPA's level of concern for topramezone is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Topramezone is currently registered for turf uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to topramezone for children that are 1–2 years old that may ingest soil on treated turf.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 270. Because EPA's level of concern for topramezone is a MOE of 100 or below, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* As noted in Unit III.C.1.iii., EPA has concluded that topramezone does not pose a cancer risk of concern at exposure levels that do not alter thyroid hormone homeostasis. The chronic aggregate assessment, which utilized a cRfD that is protective of those effects did not indicate a chronic risk above the Agency's level of concern; therefore, topramezone is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (BASF method D0104) 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; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the

international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. There are no Codex maximum residue limits (MRLs) in/on fish/shellfish.

C. Revisions to Petitioned-For Tolerances

The proposed tolerance definition, ''fish'' is being revised to ''fish-freshwater finfish'' and ''fish-saltwater finfish.'' The proposed tolerance definition, ''shellfish'' is being revised to ''fish-shellfish, crustacean'' and ''fish-shellfish, mollusk.'' EPA is also establishing meat byproduct tolerances for cattle, goat, horse, sheep (0.80 ppm), hog (0.40 ppm), and poultry (0.02 ppm) as a result of the additional dietary burden resulting from the consumption of treated water by livestock since consumption of treated water by livestock is not restricted on the proposed labeling for aquatic uses. With the establishment of these tolerances, the currently established kidney (cattle, goat, horse, and sheep) and liver (cattle, goat, horse, and sheep) tolerances are being removed as it is now general policy to establish meat byproduct tolerances rather than separate liver and kidney tolerances (Chemistry Science Advisory Council (ChemSAC); min_494.12-Jan-2011).

Finally, EPA has revised the tolerance expression to clarify that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of topramezone not specifically mentioned; and that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of topramezone, including its metabolites and degradates, in or on fish-freshwater, finfish; fish-saltwater, finfish; fish-shellfish, crustacean; and fish-shellfish, mollusk at 0.05 ppm. To account for additional dietary burden to livestock from residues in drinking water for the proposed aquatic use, tolerances are being established for cattle, goat, horse, and sheep meat byproducts at 0.80 ppm; hog meat byproducts at 0.40 ppm and poultry meat byproducts at 0.02 ppm. Compliance with the following tolerance levels is to be determined by measuring only topramezone ([3-(4,5-dihydro-3-isoxazolyl)-2-methyl-4-(methylsulfonyl)phenyl](5-hydroxy-1-methyl-1*H*-pyrazol-4-yl)methanone) in or on the commodities.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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 FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

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) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: July 29, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.612 is revised to read as follows:

§ 180.612 Topramezone; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide topramezone, including its metabolites and degradates, in or on the following commodities. Compliance with the following tolerance levels is to be determined by measuring only topramezone ([3-(4,5-dihydro-3-isoxazolyl)-2-methyl-4-(methylsulfonyl)phenyl](5-hydroxy-1-

methyl-1*H*-pyrazol-4-yl)methanone) in or on the following commodities:

Commodity	Parts per million
Cattle, meat byproducts	0.80
Corn, field, forage	0.05
Corn, field, grain	0.01
Corn, field, stover	0.05
Corn, pop, grain	0.01
Corn, pop, stover	0.05
Corn, sweet, forage	0.05
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.05
Fish-freshwater finfish	0.05
Fish-saltwater finfish	0.05
Fish-shellfish, crustacean	0.05
Fish-shellfish, mollusk	0.05
Goat, meat byproducts	0.80
Hog, meat byproducts	0.40
Horse, meat byproducts	0.80
Poultry, meat byproducts	0.02
Sheep, meat byproducts	0.80

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

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

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

[FR Doc. 2013–18975 Filed 8–6–13; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 121107617–3628–03]

RIN 0648–XC351

Western Pacific Fisheries; 2013 Annual Catch Limits and Accountability Measures; Correcting Amendment

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

ACTION: Final specifications; correcting amendment.

SUMMARY: This document makes a technical correction to the final 2013 annual catch limit specifications for western Pacific fisheries that were published in the **Federal Register** on March 13, 2013.

DATES: Effective August 7, 2013 and is applicable beginning April 12, 2013.

FOR FURTHER INFORMATION CONTACT: Jarad Makaiau, Sustainable Fisheries, NMFS Pacific Islands Region, 808–944–2108.

SUPPLEMENTARY INFORMATION: At its 155th meeting held from October 29 through November 1, 2012, the Western Pacific Fishery Management Council (Council) recommended annual catch limits for western Pacific fisheries for the 2013 fishing year, including an annual catch limit of 140,000 lb for the Hawaii non-Deep 7 bottomfish.

NMFS published the proposed 2013 specifications and request for public comments in the **Federal Register** on January 31, 2013 (78 FR 6798). NMFS published the final specifications in the **Federal Register** on March 13, 2013 (78 FR 15885). Table 4 in each of those documents contained a typographical error. The limit for Hawaii non-Deep 7 bottomfish was inadvertently described as 145,000 lb, rather than the 140,000 lb recommended by the Council. This notice corrects the error.

NMFS assessed the potential environmental impacts of specifying an annual catch limit of 140,000 lb for Hawaii non-Deep 7 bottomfish for the 2013 fishing year. Consistent with National Standard 1 of the Magnuson-Stevens Fishery Conservation and Management Act, NMFS estimated that a catch limit of 140,000 lb—which is approximately 73% of the estimated overfishing limit proxy of 192,000 lb—is associated with a 26 percent chance of overfishing. National Standard 1 provides that the probability that overfishing will occur cannot exceed 50 percent, and should be a lower value. Accordingly, based on the analyses contained in the environmental assessment, NMFS determined that establishing the catch limit at this level would have no significant effect on the quality of the human environment.

NMFS did not receive public comments on the catch limit for non-Deep 7 bottomfish. The corrected catch limit of 140,000 lb is only 3.5% lower than the published limit that contained the error. The non-Deep 7 bottomfish fishery is not subject to in-season closure or other in-season accountability measures upon attainment of the annual catch limit. Accordingly, in the unlikely event that the annual catch limit is reached, the Council and NMFS would address any overage in the subsequent fishing year. For these reasons, NMFS does not anticipate that fishermen will be adversely affected by the correction.

Correction

Accordingly, in the final specifications published on March 13, 2013 (78 FR 15885), on page 15887, in Table 4—Hawaii, the entry for Non-Deep 7 Bottomfish is revised to read 140,000 lb (63,503 kg).

Dated: August 1, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2013–19069 Filed 8–6–13; 8:45 am]

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