Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have made a preliminary determination that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore we believe this rule should be categorically excluded, under figure 2–1, paragraph 34 (g) from further environmental documentation. This temporary rule establishes a regulated navigation area and as such is covered by this paragraph.

A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES.** Comments on this section will be considered before we make the final decision on whether the rule should be categorically excluded from further environmental review.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09.102 to read as follows:

§ 165.T09.102 Temporary Regulated Navigation Area between mile markers 296.1 and 296.7 of the Chicago Sanitary and Ship Canal located near Romeoville, IL.

(a) *Location.* The following is a Regulated Navigation Area: All waters of the Chicago Sanitary and Ship Canal, Romeoville, IL beginning at the north side of Romeo Road Bridge Mile Marker 296.1, and ending at the south side of the Aerial Pipeline Mile Marker 296.7.

(b) *Effective period:* This rule is effective from 12 p.m. (local) June 30, 2005 through 12 p.m. (local) December 31, 2005.

(c) *Regulations.* (1) The general regulations contained in 33 CFR 165.13 apply.

(2) All vessels are prohibited from loitering in the regulated navigation area. Vessels may enter this section of the waterway with the sole purpose of transiting to the other side, and must maintain headway throughout the transit. All personnel on open decks must wear a Coast Guard approved Type I personal flotation device while in the regulated navigation area until subsequent field testing determines the waters in this area do not pose significant risk to human life. Vessels may not moor or lay up on the right or left descending banks. Towboats may not make or break tows. Vessels may not pass (meet or overtake) in the regulated navigation area and must make a SECURITE call when approaching the barrier to announce intentions and work out passing arrangements on either side. Commercial tows transiting the barrier must be made up with wire rope to ensure electrical connectivity between all segments of the tow.

(3) All persons and vessels shall comply with this rule and any additional instructions of the Ninth Coast Guard District Commander, or his designated representative.

Dated: June 30, 2005.

R.J. Papp, Jr.,

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 05–15781 Filed 8–9–05; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0156; FRL–7726–9]

Topramezone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of topramezone in or on field corn, pop corn, sweet corn, kidney, and liver. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 10, 2005. Objections and requests for hearings must be received on or before October 11, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0156. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either

electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 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 provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of June 11, 2003 (68 FR 34950) (FRL–7310–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F6568) by BASF Corporation, 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-isoxazol-3-yl)-4-methanesulfonyl-2-methylphenyl)-(5-hydroxyl-1-methyl-1H-pyrazol-4-yl)methanone, in or on corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet, kernal plus cob with husks removed; corn, sweet, stover; cattle, kidney; cattle, liver; goat, kidney; goat, liver; hog, kidney; hog, liver; horse, kidney; horse, liver; sheep, kidney; and sheep, liver at 0.05; 0.01; 0.05; 0.01; 0.05; 0.05; 0.01; 0.05; 0.02; 0.70; 0.20; 0.70; 0.20; 0.70; 0.20; 0.70; 0.20; and 0.70 parts per million (ppm), respectively. That notice included a summary of the petition prepared by BASF Corporation, the registrant. There were no comments received in response to the notice of filing.

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....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of topramezone on cattle, kidney at 0.05 ppm; cattle, liver at 0.15 ppm; corn, field, forage at 0.05 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.05 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 0.05 ppm; corn, sweet, forage at 0.05 ppm; corn, sweet, kernal plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 0.05 ppm; goat, kidney at 0.05 ppm; goat, liver at 0.15 ppm; horse, kidney at 0.05 ppm; horse, liver at 0.15 ppm; sheep, kidney at 0.05 ppm; and sheep, liver at 0.15 ppm, respectively.

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 toxic effects caused by topramezone are discussed in Table 1. of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed .

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity--rodents (rat)	NOAEL = 1.1 milligrams/kilogram/day (mg/kg/day) males (M) and 2.1 mg/kg/day females (F) LOAEL = 2.1 mg/kg/day for males based on diffuse degeneration in the pancreas and was not established for females
870.3100	90-Day oral toxicity--rodents (mouse)	NOAEL = 2,289/3,010 mg/kg/day (M/F) LOAEL = was not established
870.3150	90-Day oral toxicity--nonrodents (dog)	NOAEL = 535/1,712 mg/kg/day (M/F) LOAEL = 1,511 mg/kg/day for males based on decreased body-weight gain, impaired food efficiency, and inflammation of the urinary bladder and was not established for females
870.3200	28-Day dermal toxicity (rat)	NOAEL = 100/300 mg/kg/day (M/F) LOAEL = 300 mg/kg/day males based on thyroid follicular cell hypertrophy and 1,000 mg/kg/day females based on thyroid follicular cell hypertrophy
870.3700	Prenatal developmental--rodents (rat)	Maternal NOAEL = not established Maternal LOAEL = 100 mg/kg/day based on decreased body-weight gains Developmental NOAEL = not established Developmental LOAEL = 100 mg/kg/day based on decreased fetal body weight and increased incidences of skeletal variation
870.3700	Prenatal developmental--nonrodents (rabbit)	Maternal NOAEL = not established Maternal LOAEL = 0.5 mg/kg/day based on increased serum tyrosine level Developmental NOAEL = 0.5 mg/kg/day Developmental LOAEL = 5 mg/kg/day based on alterations in skeletal ossification sites and increased number of pairs of ribs
870.3700	Prenatal developmental--nonrodents (rabbit)	Maternal NOAEL = not established Maternal LOAEL = 1.5 mg/kg/day based on increased serum tyrosine level Developmental NOAEL = not established Developmental LOAEL = 1.5 mg/kg/day based on an increased incidence of absent kidney and ureter and increased incidences of supernumerary thoracic vertebrae and supernumerary 13th rib
870.3700	Prenatal developmental--nonrodents (rabbit)	Maternal NOAEL = 5.0 mg/kg/day Maternal LOAEL = was not established Developmental NOAEL = not established Developmental LOAEL = 1.5 mg/kg/day for N33 and N17/CFR 1–2 based on increased presence of supernumerary thoracic vertebrae and supernumerary 13th rib. No effect was observed for N17/CFR 3 at 0.5 mg/kg/day (the only dose tested)
870.3700	Prenatal developmental--nonrodents (rabbit)	Maternal NOAEL = 450 mg/kg/day Maternal LOAEL = not established Developmental NOAEL = not established Developmental LOAEL = 5 mg/kg/day based on visceral findings (fluid-filled abdomen, pale liver, and dark content of the stomach and intestines) and alterations in skeletal development (i.e. incomplete ossification of the vertebrae and talus, and supernumerary thoracic vertebrae and 13th rib)
870.3700	Prenatal developmental--nonrodents (rabbit)	Maternal NOAEL = 150 mg/kg/day Maternal LOAEL = 450 mg/kg/day based on decreased body-weight, body-weight gains, food consumption, and increased incidences of abortion and lack of defecation Developmental NOAEL = not established Developmental LOAEL = 50 mg/kg/day based on decreased fetal weight and increased incidence of visceral malformations, and skeletal malformations, variations, and unclassified abnormalities
870.3700	Prenatal developmental--nonrodents (rabbit)	Maternal NOAEL = 450 mg/kg/day Maternal LOAEL = not established Developmental NOAEL = 0.5 mg/kg/day Developmental LOAEL = 5 mg/kg/day based on increased presence of 27 pre-sacral vertebrae and increased an incidence of full supernumerary 13th rib

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3700	Prenatal developmental--nonrodents (rabbit)	Maternal NOAEL = 450 mg/kg/day Maternal LOAEL = not established Developmental NOAEL = not established Developmental LOAEL = 50 mg/kg/day based on an increased incidence of extra sternebral ossification sites and supernumerary 13th rib
870.3700	Prenatal developmental--nonrodents (mouse)	Maternal NOAEL = not established Maternal LOAEL = 30 mg/kg/day based on increased serum tyrosine level Developmental NOAEL = 1,000 mg/kg/day Developmental LOAEL = not established
870.3800	Reproduction and fertility effects (rat)	Parental/Systemic NOAEL = 0.4/0.5 mg/kg/day (M/F) Parental/Systemic LOAEL = 4.2/4.6 mg/kg/day (M/F) 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 Reproductive NOAEL = 426.8/471.9 mg/kg/day (M/F) Reproductive LOAEL = not established Offspring NOAEL = 0.4/0.5 mg/kg/day (M/F) Offspring LOAEL = 4.2/4.6 mg/kg/day (M/F) based on decreased pup weight and weight gain in F_2 male and female pups and increased time to preputial separation in the F_1 males
870.4100	Chronic toxicity--rodents (rat)	NOAEL = 0.4/0.5 mg/kg/day (M/F) LOAEL = 3.9/5.3 mg/kg/day (M/F) based on corneal opacity and pannus and chronic keratitis in both sexes, and thyroid hypertrophy in males
870.4100	Chronic toxicity--dogs	NOAEL = 2.9/15.4 (M/F) mg/kg/day LOAEL = 15.3 mg/kg/day (M) based on increased incidence of thyroid C-cell hyperplasia and 92 mg/kg/day (F) based on decreased body-weight, body-weight gain, and food efficiency
870.4200	Carcinogenicity--rats	NOAEL = 0.4/0.5 mg/kg/day (M/F) LOAEL = 3.6/4.7 mg/kg/day (M/F) based on increased incidences of corneal opacity, decreased body-weight and body-weight gains (males only) and histopathological evaluations in the thyroids, pancreas, and eyes of both sexes Neoplastic pathology showed increased incidences of follicular cell adenomas in the thyroid glands of both sexes
870.4300	Carcinogenicity--mice	NOAEL = not established LOAEL = 19/26 mg/kg/day (M/F) based on decreased body-weight and body-weight gains in males No evidence of carcinogenicity
870.5100	Gene mutation	No indication of a mutagenic response in any strain at any level up to cytotoxic concentrations either with or without S9 activation
870.5100	Gene mutation	Based on these considerations, it was concluded that there was confirmed evidence of a mutagenic response in S. typhimurium TA98 in the nonactivated portion of both the plate incorporation and preincubation assays. The effect was, however, observed at high concentrations (≥ 3,000 μg/plate-plate incorporation and ≥ 2,500 μg/plate-preincubation). It was further concluded that the mutagenic effect was likely due to impurities in the test article because: 1) The response was seen at high concentrations including and exceeding the limit dose, 2) bacterial gene mutation assays conducted with other lots of the test material were negative up to the limit dose (see Master Record Identification (MRID) Nos. 45902225 through 45902227, and 3) the active ingredient (a.i.) used in the current study has the lowest percentage of purity (95.8% versus 97.7 to 99.3% a.i. for the other lots)
870.5300	*In vitro* mammalian cell gene mutation	No indication that topramezone induced a mutagenic response, either in the presence of absence of S9 activation
870.5375	*In vitro* mammalian chromosome aberration	Topramezone-induced a clastogenic response in the presence of S9 activation with significant effects recorded only at an insoluble limit concentration
870.5395	*In vivo* mouse bone morrow micronucleus	No evidence that topramezone was clastogenic or aneugenic
870.5550	Unscheduled DNA synthesis (UDS)	No evidence that topramezone-induced UDS, as determined by radioactive tracer procedures (nuclear silver grain counts) at any concentration tested

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.6200	Acute neurotoxicity screening battery (rat)	NOAEL= 2,000 mg/kg/day, no neurotoxicity observed
870.6200	Subchronic neurotoxicity (rat)	No neurotoxicity observed Systemic NOAEL = not established LOAEL = 4.2/5/0 mg/kg/day (M/F) based on elevated levels of granular casts and transitional epithelial cells in the urinary sediment of the males, increased incidences of corneal clouding in females, minimal diffuse degeneration of the pancreas (both sexes), and slight to moderate flaky colloid in the thyroid of the males
870.6300	Developmental neurotoxicity (rat)	Maternal NOAEL = not established Maternal LOAEL = 8 mg/kg/day based on corneal opacities Offspring NOAEL = not established Offspring LOAEL = 8 mg/kg/day based on decreased auditory startle reflex response
870.7485	Metabolism and pharmacokinetics	Absorption of [^{14}C]-topramezone following a single oral dose was rapid but limited, with the highest plasma concentrations observed at 1 hour (first time point measured). Oral absorption is estimated to be approximately 20% of the administered dose. The majority of the dose was recovered within 48 hours in the feces (73–91% dose) and urine (8–29% dose)
870.7600	Dermal penetration	The majority of the applied dose for each group was not absorbed (91.0–98.3% dose), with the greatest amount of the non-absorbed material being recovered from the skin wash (90.8–96.0% dose). Absorbed radioactivity was low and accounted for 0.16–2.60% of the dose for all groups for all exposures

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' in which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for topramezone used for human risk assessment is shown in Table 2. of this unit:

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

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–50 years of age)	NOAEL = 0.5 mg/kg/day UF = 100 Acute RfD = 0.005 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD ÷ Special FQPA SF = 0.005 mg/kg/day	Developmental Toxicity Study in Rabbits LOAEL = 5 mg/kg/day based on alterations in skeletal ossification sites and increased number of pairs of ribs
Acute Dietary (General population including infants and children)	An endpoint of concern for the general population attributable to a single dose was not identified in the hazard database		
Chronic Dietary (All populations)	NOAEL= 0.4 mg/kg/day UF = 100 Chronic RfD = 0.004 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD ÷ Special FQPA SF = 0.004 mg/kg/day	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 thyroid, pancreas, and eyes of both sexes
Cancer (oral, dermal, inhalation)	In accordance with the EPA Final Guidelines for Carcinogen Risk Assessment (March 29, 2005), EPA classified topramezone as ''not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis.'' EPA determined that quantification of human cancer risk is not required since the NOAEL (0.4 mg/kg/day) for non-cancer risk assessment is not expected to alter thyroid hormone homeostasis nor result in thyroid tumor formation		

Topramezone inhibits the 4-hydroxyphenylpyruvate dioxygenase (4-HPPD) enzyme in the metabolism of tyrosine. Inhibition of this enzyme results in increased serum tyrosine levels and eventually in adverse effects in the animal with increased incidences of corneal opacity, decreased body-weight, and body-weight gains. The petitioner conducted eight rabbit studies to determine the NOAEL for increased serum tyrosine levels as well as determine the NOAELs for systemic maternal and fetal developmental toxicity endpoints that are not based on tyrosine measurements.

There are well established NOAELs and LOAELs for the standard endpoints for maternal and developmental toxicity in rabbits. Currently, it is not known what level of inhibition of the 4-HPPD enzyme results in an adverse effect. Therefore, the observation of enzyme inhibition in the absence of systemic toxicity in maternal animals or soft tissue or skeletal alterations in pups/offspring are being considered to be a biomarker of exposure, not an adverse effect. None of the data in the submitted studies permit a determination of the percentage of increased tyrosine levels that result in detrimental or adverse effects.

The lowest maternal LOAEL observed in the numerous rabbit developmental toxicity studies was 0.5 mg/kg/day. It is not clear, however, that this value is actually a LOAEL because it is based on increased serum tyrosine levels. In this study it could not be determined what dose would not induce increased serum tyrosine levels. In fact, in no study could a ''no effect'' level be determined for increased serum tyrosine levels in dams. However, a maternal NOAEL of 5 mg/kg/day was observed in another study based on systemic toxicity; in this study tyrosine measurements were not performed. This study has the lowest maternal NOAEL for systemic toxicity among the eight rabbit developmental toxicity studies. Tyrosine levels were not measured for fetuses in any of the rabbit developmental studies. There was a clear developmental toxicity NOAEL of 0.5 mg/kg/day, based on skeletal variations observed at 5 mg/kg/day.

The acute RfD for females 13–49 years of age is based on a NOAEL of 0.5 mg/kg/day for alterations in skeletal ossification sites in rabbits. The chronic RfD is based on the NOAEL of 0.4 mg/kg/day in the carcinogenicity study in rats. In this study the LOAEL was based on increased incidence of corneal opacities, decrease in body weight gain, liver, pancreas, and thyroid effects seen at 3.6 mg/kg/day.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* No tolerances have been established (40 CFR 180.612) previously for the residues of topramezone. Risk assessments were conducted by EPA to assess 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 one-day or single exposure.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: For the acute analyses, tolerance-level residues were assumed for all food commodities with proposed topramezone tolerances, and it was assumed that all of the crops included in the analysis were treated. Percent crop treated (PCT) and/or anticipated residues were not used in the acute risk assessment.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for

the chronic exposure assessments: For the chronic analyses, tolerance-level residues were assumed for all food commodities with current or proposed topramezone tolerances, and it was assumed that all of the crops included in the analysis were treated. PCT and/or anticipated residues were not used in the chronic risk assessment.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for topramezone in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of topramezone.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of topramezone for acute exposures are estimated to be 0.77 parts per billion (ppb) for surface water and 0.0671 ppb for ground water. The EECs for chronic exposures are estimated to be 0.14 ppb for surface water and 0.0671 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Topramezone 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 the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to topramezone and any other substances and topramezone does not appear to produce a toxic metabolite produced by other substances. However, EPA is aware of other herbicides that inhibit the 4-HPPD enzyme (i.e. mesotrione and isoxaflutole). Topramezone, isoxaflutole and mesotrione are known to cause tyrosinemia. To ensure that the potential cumulative effects from these pesticides are not of concern EPA examined three factors:

- The extent to which the uses of these pesticides overlap.
- The exposure assumptions used in the risk assessments for each of the pesticides.
- The risk characterization for each pesticide.

As explained Unit III.C.4.i.,ii., and iii., this analysis suggests both that the individual risk characterizations for each pesticide are highly overstated and that cumulative exposure to these pesticides, even if they are later determined to share a common mechanism, is unlikely to pose a risk of concern.

i. *Pesticide uses*. Topramezone, mesotrione, and isoxaflutole are broad-spectrum herbicides used to control grassy and broadleaf weeds in corn (the mesotrione label does not list grasses on the label). All three active ingredients are in the phenylpyrazolyl ketone class of chemicals and share the same mode of herbicidal action. They inhibit the 4-HPPD enzyme and thereby impair caroteniod biosynthesis in the chlorophyll synthesis pathway, leading to the breakdown in chloroplasts. Therefore no more than one of these active ingredients would be applied to the same field in the same growing season. Topramezone is used post-emergent, mesotrione is used pre- and post-emergent, and isoxaflutole is used pre-plant and pre-emergent. The current PCT information for field corn indicates a 5–10% PCT for isoxaflutole and 10–15% PCT for mesotrione. Sweet corn PCT is < 2.5 for both chemicals. Maximum PCT projections for topramezone on field corn and sweet corn, made by assuming that it will surely not overtake the current leader(s) among herbicides on those crops (i.e. atrazine), are 68 and 60, respectively.

ii. *Exposure assumptions*. Highly-conservative assumptions were used for the aggregate (food + water) risk assessments for each individual assessment. First, it was assumed that 100% of the corn crop was treated with all three of the pesticides. Second, each of the exposure assessments assumed all corn in the diet would have residues present at the tolerance level. In fact, residue data indicates that very low levels of residues were detected in the grain for all three pesticides.

iii. *Risk characterization*. Even with the highly-conservative assumptions, the individual aggregate risk for each of the active ingredients is as follows:

- The topramezone chronic dietary risk estimates (food + water) were < 1% of the cPAD for the U.S. population and 1.2% of the cPAD for the most highly exposed population subgroup (children 3–5 years old).
- The mesotrione chronic dietary risk estimates (food + water) were 15% of the cPAD for the U.S. population and 45% of the cPAD for the most highly-exposed population subgroup (all infants (< 1 year old)).
- The chronic dietary risk estimates (food + water) for residues of the 4-HPPD inhibitors (isoxaflutole + RPA 202248) were 18% of the cPAD for the U.S. population and 40% of the cPAD for the most highly-exposed population subgroup (children 3–5 years old).

In fact, even if one were to calculate the chronic dietary risk for all three herbicides by combining the individual exposures and using the most sensitive endpoint, the risk would not exceed the level of concern. These pesticides do not share a common acute adverse effect.

Accordingly, because the use patterns, exposure assumptions, and risk characterizations for the three pesticides do not suggest that any potential cumulative effect would be at a level of concern, EPA concludes it has adequately considered the potential cumulative effects of topramezone and the pesticides for which it may possibly share a common mechanism of toxicity.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In 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 safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Increased sensitivity of the young*. There is a potential of increased quantitative susceptibility following *in utero* and/or pre-/post-natal exposure in the developmental toxicity and developmental neurotoxicity studies in rats because a NOAEL for parental or offspring systemic toxicity was not established. However, the current NOAEL of 0.5 mg/kg/day for an acute RfD would provide a 200-fold lower dose based on the most sensitive endpoint. In a developmental neurotoxicity (DNT) study in rats, decreased auditory startle reflex was seen at the LOAEL of 8 mg/kg/day in the presence of maternal toxicity manifested as corneal opacity. Therefore, the susceptibility in this study could not be assessed. However, the NOAEL for the chronic RfD is 0.4 mg/kg/day based on the most critical tyrosine-mediated effects which is 20-fold lower than the LOAEL for the DNT study. There is no evidence of increased susceptibility following pre-/post-natal exposure to rats in the two-generation reproduction study.

3. *Conclusion*. There is a complete toxicity data base for topramezone and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Although there is the potential for increased quantitative sensitivity in the young from exposure to topramezone, the RfDs selected for evaluating the safety of exposure provide a wide margin of safety for the effects seen in the young. Accordingly, the additional 10X factor for the protection of infants and children is removed.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and drinking water to topramezone will occupy 1.4 % of the aPAD for females 13 years and older.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to topramezone from food and drinking water will utilize 0.6 % of the cPAD for the U.S. population, 0.9 % of the cPAD for all infants (< 1 year old), and 1.2 % of the cPAD for children 3–5 years old.

Topramezone 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 do not exceed the Agency's level of concern.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

A proposed enforcement methodology (liquid chromatography (LC)/mass spectrometry (MS)) 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 are currently no established Codex, Canadian, or Mexican maximum residue limits (MRLs) for topramezone.

V. Conclusion

Therefore, the tolerance is established for residues of topramezone, [3-(4,5-dihydro-3-isoxazolyl)-2-methyl-4-(methylsulfonyl)phenyl](5-hydroxy-1-methyl-1H-pyrazol-4-yl)methanone, in or on cattle, kidney at 0.05 ppm; cattle, liver at 0.15 ppm; corn, field, forage at 0.05 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.05 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 0.05 ppm; corn, sweet, forage at 0.05 ppm; corn, sweet, kernal plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 0.05 ppm; goat, kidney at 0.05 ppm; goat, liver at 0.15 ppm; horse, kidney at 0.05 ppm; horse, liver at 0.15 ppm; sheep, kidney at 0.05 ppm; and sheep, liver at 0.15 ppm, respectively.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0156 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 11, 2005.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the

grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0156, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risk* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a

copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: July 26, 2005.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 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 added to read as follows:

§ 180.612 Topramezone; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide topramezone, [3-(4,5-dihydro-3-isoxazolyl)-2-methyl-4-(methylsulfonyl)phenyl](5-hydroxy-1-methyl-1H-pyrazol-4-yl)methanone, in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, kidney	0.05
Cattle, liver	0.15
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
Goat, kidney	0.05
Goat, liver	0.15
Horse, kidney	0.05
Horse, liver	0.15
Sheep, kidney	0.05
Sheep, liver	0.15

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

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

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

[FR Doc. 05–15604 Filed 8–9–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0139; FRL–7724–8]

Aminopyralid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for free and conjugated residues of aminopyralid in or on grass and wheat commodities; and residues of aminopyralid in or meat; fat and meat byproducts, excluding kidney; of cattle, goat, and sheep, and milk. Dow AgroSciences, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 10, 2005. Objections and requests for hearings must be received on or before October 11, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number OPP–2004–0139. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: JoanneMiller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 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 provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at*http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of June 2, 2004 (69 FR 31106–31110) (FRL–7359–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C.