Commodity	Parts per million
Cattle, meat	0.02
Cattle, meat byproducts	0.02
Goat, meat	0.02
Goat, meat byproducts	0.02
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.02

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

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

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent combined residues of thiencarbazone-methyl and its metabolite BYH 18636-MMT-glucoside [2-hexopyranosyl-5-methoxy-4-methyl-2,4-dihydro-3*H*-1,2,4-triazol-3-one], calculated as the parent compound, in or on the following food commodities:

Commodity	Parts per million
Soybean, forage	0.04
Soybean, hay	0.15

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BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0042; FRL–8377–4]

Cyprosulfamide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the herbicide safener cyprosulfamide in or on corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; and corn, sweet, stover; and for combined residues of cyprosulfamide and its metabolite 4-(aminosulfonyl)-*N*-cyclopropylbenzamide, calculated as cyprosulfamide, in or on cattle, meat byproducts; goat, meat byproducts; horse, meat byproducts and sheep, meat byproducts. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 15, 2008. Objections and requests for hearings must be received on or before December 15, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0042. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

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

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0042 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before December 15, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0042, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of June 13, 2008 (73 FR 33814) (FRL–8367–3), 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 7E7206) by Bayer CropScience, 2 TW Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by adding a section for the herbicide safener cyprosulfamide and establishing tolerances therein for residues of cyprosulfamide (parent) in or on the raw agricultural commodities field corn grain at 0.01 parts per million (ppm); sweet corn kernels at 0.01 ppm; sweet corn (k+cwhr) at 0.01 ppm; pop corn grain at 0.01 ppm; milk at 0.01ppm; cattle, meat at 0.01 ppm; cattle, fat at 0.01 ppm; cattle, liver at 0.02 ppm; cattle, kidney at 0.05 ppm; goat, meat at 0.01 ppm; goat, fat at 0.01 ppm; goat, liver at 0.02 ppm; goat, kidney at 0.05 ppm; hog, meat at 0.01 ppm; hog, fat at 0.01 ppm; hog, liver at 0.02 ppm; hog, kidney at 0.05 ppm; horse, meat at 0.01 ppm; horse, fat at 0.01 ppm; horse, liver at 0.02 ppm; horse, kidney at 0.05 ppm; sheep, meat at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, liver at 0.02 ppm; and sheep, kidney at 0.05 ppm; and for residues of parent cyprosulfamide and its metabolites AE 0001789-sulfonamide-alanine, AE 0001789-sulfonamide-lactate, and AE 0001789-N-cyclopropyl-4-sulfamoylbenzamide in or on the raw agricultural commodity field corn forage at 0.15 ppm, sweet corn forage at 0.40 ppm, field corn stover at 0.60 ppm, sweet corn stover at 0.60 ppm, and pop corn stover at 0.60 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public 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 modified the metabolites to be included in the tolerance expression for livestock, corn forage and corn stover commodities; modified tolerance levels for corn stover commodities and field corn forage; and revised the livestock commodities for which tolerances are needed as well as the livestock commodity tolerance levels. 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 section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for the petitioned-for tolerances for residues of the herbicide safener cyprosulfamide in or on corn, field, forage at 0.20 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.20 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 0.20 ppm; corn, sweet, forage at 0.40 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; and corn, sweet, stover at 0.35 ppm; and for combined residues of cyprosulfamide and its metabolite 4-(aminosulfonyl)-*N*-cyclopropylbenzamide, calculated as cyprosulfamide, in or on cattle, meat byproducts at 0.02 ppm; goat, meat byproducts at 0.02 ppm; horse, meat byproducts at 0.02 ppm; and sheep, meat byproducts at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Cyprosulfamide has low toxicity in acute toxicity and irritation studies and is not a skin sensitizer. In subchronic and chronic oral toxicity studies, the critical target organ for cyprosulfamide is the urinary tract including the kidney, bladder and ureters. Toxic effects in these organs include inflammation and irritation resulting from the formation of calculi caused by deposition of the parent compound at high doses.

In the rat chronic toxicity/carcinogenicity study, at doses associated with mortality due to nephropathy, there were treatment-related transitional cell carcinomas in the kidney of one male and a transitional cell carcinoma in the urinary bladder of one female. In mice, at a dose where there was formation of calculi in the urothelial system, cyprosulfamide was associated with two incidents of transitional cell papilloma in the urinary bladder. Since the neoplasms occurred only at high doses that also demonstrated calculi formation, cyprosulfamide was classified as ''Not likely to be a Carcinogen to Humans at doses that do not cause urothelial cytotoxicity.'' None of the battery of mutagenicity or genetic toxicity studies indicated a positive result for cyprosulfamide.

There is no evidence of developmental toxicity in the prenatal developmental toxicity studies in the rat and rabbit and no evidence of increased qualitative or quantitative susceptibility of fetuses in these studies or of offspring in the 2–generation reproduction study in rats. Specific neurotoxicity was not identified in the rat, mouse or dog subchronic or chronic studies or in the rat acute and subchronic neurotoxicity screen studies.

Specific information on the studies received and the nature of the adverse effects caused by cyprosulfamide 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 the document *Cyprosulfamide: Human Health Risk Assessment for Proposed Uses on Corn (Field, Sweet, and Pop), Sorghum (Seed Treatment), Residential Turf and*

Ornamentals, page 55 in docket ID number EPA–HQ–OPP–2008–0042.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the LOAEL or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 cyprosulfamide used for human risk assessment can be found at *http://www.regulations.gov* in the document *Cyprosulfamide: Human Health Risk Assessment for Proposed Uses on Corn (Field, Sweet, and Pop), Sorghum (Seed Treatment), Residential Turf and Ornamentals* in docket ID number EPA–HQ–OPP–2008–0042.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyprosulfamide, EPA considered exposure under the petitioned-for tolerances. No other tolerances have been established for cyprosulfamide. EPA assessed dietary exposures from cyprosulfamide 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. No such effects were identified in the toxicological studies for cyprosulfamide; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed that 100% of crops with requested uses of cyprosulfamide are treated and that all treated crops contain residues at the tolerance level.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA classified cyprosulfamide as ''Not likely to be a Carcinogen to Humans at doses that do not cause urothelial cytotoxicity ''; therefore, a cancer exposure assessment is unnecessary for this chemical.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue or PCT information in the dietary assessment for cyprosulfamide. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for cyprosulfamide in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyprosulfamide. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of cyprosulfamide for chronic exposures for non-cancer assessments are estimated to be 2.4 parts per billion (ppb) for surface water and 0.14 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 2.4 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).

Cyprosulfamide is proposed for registration on the following use sites that could result in residential exposures: Residential turfgrass, ornamentals and recreational sites. EPA assessed residential exposure using the following assumptions: Homeowners who apply cyprosulfamide to ornamentals and turfgrass may be exposed for short-term durations via the dermal and inhalation routes. Short-term dermal and inhalation exposures were assessed for residential handlers who mix, load and apply liquid cyprosulfamide products using low-pressure hand wands and garden hose-end sprayers.

There is also potential for short-term postapplication dermal exposure of adults and children and incidental oral exposure of children following application of cyprosulfamide to turf (e.g. home lawns). EPA assessed adult and toddler postapplication dermal exposures as well as incidental oral exposure of toddlers from hand-to-mouth, object-to-mouth and incidental soil ingestion activities.

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.''

Although cyprosulfamide has in common with other sulfonamide chemicals the ability to cause urinary tract calculi and in some cases tumors in the urinary tract at high doses, EPA has not made a common mechanism finding for cyprosulfamide such that cumulative risk assessment based on chemicals with a common mechanism is necessary for cyprosulfamide and other sulfonamides. With cyprosulfamide, the formation of calculi in the urinary tract results from the precipitation of cyprosulfamide once it reaches saturation in the animal's system. Precipitation of cyprosulfamide is a physical/chemical process and not a mechanism of toxicity. Exposures to cyprosulfamide and other sulfonamides, such as thiencarbazone-methyl, are not

additive with regard to the formation of urinary tract calculi at anticipated exposure levels. At higher doses, each sulfonamide will form calculi independently of the other by a separate physical/chemical process. At lower doses, near the anticipated exposure levels, calculi will not form even if there is exposure to multiple sulfonamides because sulfonamides will not influence the formation of precipitates by each other. It would be appropriate to add exposures in assessing precipitate formation only if the sulfonamides interacted somehow during crystal formation. 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(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 safety factor (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*. The prenatal and postnatal toxicity database for cyprosulfamide includes rat and rabbit developmental toxicity studies and a 2–generation reproduction toxicity study in rats. There was no evidence of increased susceptibility of *in utero* rats or rabbits in the prenatal developmental studies or of young rats in the 2–generation reproduction study.

No fetal effects were seen in the rat developmental toxicity study at doses that produced maternal toxicity (weight gain effects and indications of kidney effects in one animal). There are two rabbit developmental studies available for cyprosulfamide. A second study was conducted due to excess maternal toxicity (including deaths) in the first study. As in the rat study, no fetal effects were seen in either rabbit study at doses that resulted in maternal toxicity (body weight decrease, reduced food consumption, and kidney effects in both studies; as well as deaths in the first study).

In the rat reproduction study, effects in the pups occurred at doses that also resulted in maternal toxicity. Mid-dose effects included organ weight changes in the spleen and urinary tract in the dams and body weight changes in the pups. At the high dose, there was mortality among the dams associated with poor physical condition and severe renal lesion; effects in pups at the high dose included decreased pup weight, delayed vaginal opening (apparently related to the decreased pup weight), reduced viability (3 total litter loss in the F1 generation), reduced lactation index and clinical findings (paleness, cold to touch, missing milk spot and thin appearance). No increase in sensitivity of the pups was indicated.

3. *Conclusion*. 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. That decision is based on the following findings:

i. The toxicity database for cyprosulfamide is complete, except for immunotoxicity studies. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since the requirement went into effect well after this tolerance petition was submitted, these studies are not yet available for cyprosulfamide. In the absence of specific immunotoxicity studies, EPA has evaluated the available toxicity data for cyprosulfamide and determined that an additional database uncertainty factor is not needed to account for potential immunotoxicity. EPA's determination is based on the following considerations.

a. There was some indication of possible immunotoxicity in the form of increased severity of lymphocytolysis in the subchronic mouse study in females, but only at a high dose of about 1,300 mg/kg/day. Although minimal lymphocytolysis was seen in the control animals, lymphocytolysis to a slightly greater degree was observed in some of the high dose animals. This minor difference in severity is not of concern because:

(1) The marginal change in severity between control and dosed animals was only noted at a very high dose and may not constitute an adverse effect.

(2) No similar effect was seen in the carcinogenicity study in the mouse at about 600 mg/kg/day or in other species.

b. EPA considered the entire toxicity database for cyprosulfamide for potential adverse effects on the thymus and spleen as indications of potential immunotoxicity. Although changes in thymus weight and shape and brown pigment in the spleen were noted, these were determined to be non-specific changes not indicative of immunotoxicity.

c. Cyprosulfamide does not belong to a class of chemicals that would be expected to be immunotoxic.

Therefore, based the considerations in this Unit, EPA does not believe that conducting immunotoxicity testing will result in a NOAEL less than the NOAEL of 39 mg/kg/day already established for cyprosulfamide, and an additional factor (UFDB) for database uncertainties is not needed to account for potential immunotoxicity.

ii. There is no indication that cyprosulfamide is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that cyprosulfamide results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed assuming 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyprosulfamide in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by cyprosulfamide.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the

product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified in the toxicology studies for cyprosulfamide and no acute dietary endpoint was selected. Therefore, cyprosulfamide is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyprosulfamide from food and water will utilize less than 1% of the cPAD for the U.S. population and all population subgroups, including infants and children. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of cyprosulfamide is not expected.

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

Cyprosulfamide is currently registered for 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 cyprosulfamide. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of 6,900 for adults and 5,300 for children (toddlers). The aggregate MOE for adults is based on the residential turf scenario and includes combined food, drinking water, dermal and inhalation exposures for residential handlers as well as post-application dermal exposures from activities on treated turf. The aggregate MOE for children includes food, drinking water and post-application dermal and incidental oral exposures (hand-to-mouth, object-to-mouth and soil ingestion) from activities on turf areas previously treated with cyprosulfamide.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure through food and water (considered to be a background exposure level). Cyprosulfamide is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to cyprosulfamide through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population*. EPA classified cyprosulfamide as ''Not likely to be a Carcinogen to Humans at doses that do not cause urothelial cytotoxicity. '' Cyprosulfamide is not expected to pose a cancer risk.

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 cyprosulfamide residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression in plants (High Pressure Liquid Chromatography/Mass Spectrometry/Mass Spectromety (HPLC/MS/MS) Method UB–008–P06–01) and livestock commodities (HPLC/MS/MS Method UB–008–P06–01/02). The methods 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 no Codex, Canadian or Mexican maximum residue limits (MRLs) established for residues of cyprosulfamide in crop or livestock commodities. However, the U.S. is working with Canada and the United Kingdom to achieve MRL harmonization for corn grain.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA has modified the metabolites to be included in the tolerance expression for livestock, corn forage and corn stover commodities; modified tolerance levels for corn stover commodities and field corn forage; and revised the livestock commodities for which tolerances are needed as well as the livestock commodity tolerance levels.

The petitioner proposed tolerances for residues of cyprosulfamide and three metabolites (AE 0001789-sulfonamide-alanine, AE 0001789-sulfonamide-lactate, and AE 0001789-*N*-cyclopropyl-4-sulfamoylbenzamide) on corn forage and stover commodities as follows: Field corn forage at 0.15 ppm; field corn stover at 0.60 ppm; pop corn stover at 0.60 ppm; sweet corn forage at 0.40 ppm; and sweet corn stover at 0.60 ppm. Based on limited toxicity data for AE 0001789-*N*-cyclopropyl-4-sulfamoylbenzamide, this metabolite cannot be excluded as a residue of concern based on hazard considerations. The other two metabolites (AE 0001789-sulfonamide-alanine, AE 0001789-sulfonamide-lactate) are expected to be less toxic than the parent compound based on structure activity relationship (SAR) analysis and can thus be excluded as residues of concern based on hazard considerations. In corn field trials, residues of all four compounds were low (most below the limit of quantitation of 0.01 ppm), with parent cyprosulfamide levels being the highest of the four. Based on the lack of hazard concern for two of the metabolites and the low levels of all three, EPA concluded that parent cyprosulfamide is the residue of concern to be included in the tolerance expression for corn commodities, including forage and stover. The results of the field trials support tolerances for residues of cyprosulfamide, *per se*, of 0.20 ppm in/on field corn forage and stover; 0.20 ppm in/on popcorn stover; 0.40 ppm in/on sweet corn forage; and 0.35 ppm in/on sweet corn stover.

The petitioner proposed tolerances for residues of cyprosulfamide, *per se*, on meat (0.01 ppm), fat (0.01 ppm), liver (0.02 ppm) and kidney (0.05 ppm) of cattle, goat, hog, horse and sheep; and milk (0.01 ppm). As noted in this Unit, EPA concluded that the metabolite AE 0001789-*N*-cyclopropyl-4-sulfamoylbenzamide (4-(aminosulfonyl)-*N*-cyclopropylbenzamide) cannot be excluded as a residue of concern based on hazard considerations. The data from the submitted cattle feeding study indicate that no quantifiable residues of cyprosulfamide or this metabolite are expected in milk, meat or fat. However, quantifiable residues of cyprosulfamide and its metabolite may occur in meat byproducts (kidney and liver) of cattle, goat, horse and sheep. Based on the calculated dietary burden of swine, there is no reasonable expectation of residues of cyprosulfamide or its metabolite in swine (hog) commodities. Therefore, EPA determined that tolerances are needed only for residues of cyprosulfamide and its metabolite (4-(aminosulfonyl)-*N*-cyclopropylbenzamide) in/on the meat byproducts of cattle, goat, horse and sheep. The submitted data and calculated dietary burden for ruminants

indicate that a tolerance level of 0.02 ppm in these commodities is appropriate.

V. Conclusion

Therefore, tolerances are established for residues of the herbicide safener cyprosulfamide (*N*-[[4-[(cyclopropylamino)carbonyl] phenyl]sulfonyl]-2-methoxybenzamide) in or on corn, field, forage at 0.20 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.20 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 0.20 ppm; corn, sweet, forage at 0.40 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; and corn, sweet, stover at 0.35 ppm; and for combined residues of cyprosulfamide and its metabolite, 4-(aminosulfonyl)-*N*-cyclopropylbenzamide, calculated as cyprosulfamide, in or on cattle, meat byproducts at 0.02 ppm; goat, meat byproducts at 0.02 ppm; horse, meat byproducts at 0.02 ppm; and sheep, meat byproducts at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 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) (Public Law 104–4).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: September 29, 2008.

Debra Edwards,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.644 is added to read as follows:

§ 180.644 Cyprosulfamide; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide safener cyprosulfamide, *N*-[[4-[(cyclopropylamino)carbonyl] phenyl]sulfonyl]-2-methoxybenzamide, in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field, forage	0.20
Corn, field, grain	0.01
Corn, field, stover	0.20
Corn, pop, grain	0.01
Corn, pop, stover	0.20
Corn, sweet, forage	0.40
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.35

(2) Tolerances are established for residues of the herbicide safener cyprosulfamide, *N*-[[4-[(cyclopropylamino)carbonyl] phenyl]sulfonyl]-2-methoxybenzamide, and its metabolite 4-(aminosulfonyl)-*N*-cyclopropylbenzamide, calculated as cyprosulfamide, in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, meat byproducts	0.02
Goat, meat byproducts	0.02
Horse, meat byproducts	0.02
Sheep, meat byproducts	0.02

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

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

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

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 08–2148; MB Docket No. 08–133; RM–11465]

Television Broadcasting Services; Greenville, NC

AGENCY: Federal Communications Commission.