safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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 action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 15, 2008. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: October 1, 2008.

J.I. Palmer, Jr.,

Regional Administrator, Region 4.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart B—Alabama

■ 2. Section 52.50(c) is amended by revising the entry for ''Section 335–3–4.01'' to read as follows:

§ 52.50 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED ALABAMA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
Chapter 335–3–4 Control of Particulate Emissions				
Section 335–3–4–.01	Visible Emissions	9/30/2008	10/15/2008 [Insert citation of publication].	
*	*	*	*	*

* * * * *

[FR Doc. E8–24031 Filed 10–14–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0132; FRL–8382–7]

Thiencarbazone-methyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of thiencarbazone-methyl [methyl 4-[[[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl)-carbonyl]amino]sulfonyl]-5-methyl-3-thiophenecarboxylate], *per se*, in or on field corn, pop corn, sweet corn, and wheat; combined residues of thiencarbazone-methyl and its metabolite BYH 18636-MMT [5-methoxy-4-methyl-2,4-dihydro-3*H*-1,2,4-triazol-3-one], calculated as the parent compound, in or on livestock commodities; and 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 soybeans. 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–2008–0132. All documents in the docket are listed in the docket index available at *http://www.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: Jim Tompkins, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–305–5697; e-mail address: *tompkins.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to 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 electronically available documents 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, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0132 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–2008–0132, 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 Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of April 16, 2008 (73 FR 20633) (FRL–8359–1), 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 7F7208) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition proposed tolerances be established for residues of the herbicide thiencarbazone-methyl, *per se*, in or corn, field, grain at 0.01 parts per million (ppm); corn, sweet, kernels at 0.01 ppm; wheat, grain at 0.01 ppm; and soybean, seed at 0.01 ppm; thiencarbazone-methyl and its metabolites BYH 18636-MMT-glucoside and BYN 18636-N-desmethyl [methyl 4-((([(3-methoxy-5-oxo-4,5-dihydro-1*H*-1,2,4-triazol-1-yl)carbonyl]amino)sulfonyl)-5-methylthiophene-3-carboxylate], calculated as the parent compound, in or on corn, field, forage at 0.03 ppm; corn, sweet, forage at 0.15 ppm; corn, field, stover at 0.04 ppm; corn, sweet stover at 0.04 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; wheat, hay at 0.02 ppm; wheat, straw at 0.02 ppm; wheat, forage at 0.09 ppm; soybean, forage at 0.04 ppm; soybean, hay at 0.15 ppm, and cotton gin by-products at 0.15 ppm; and thiencarbazone-methyl and its metabolite BYH 18636-MMT, calculated as the parent compound, in or on milk at 0.01 ppm; cattle, meat at 0.01 ppm; cattle, fat at 0.01 ppm; cattle, liver at 0.05 ppm; cattle, kidney at 0.02 ppm; goat, meat at 0.01 ppm; goat, fat at 0.01 ppm; goat, liver at 0.05 ppm; goat, kidney at 0.02 ppm; hog, meat at 0.01 ppm; hog, fat at 0.01 ppm; hog, liver at 0.05 ppm; hog, kidney at 0.02 ppm; horse, meat at 0.01 ppm; horse, liver at 0.05 ppm; horse, kidney at 0.02 ppm; sheep, meat at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, liver at 0.05 ppm; and sheep, kidney at 0.02 ppm. There were no comments received in response to the notice of filing.

Tolerance levels and commodity expressions have been revised for corn, field, forage; corn, field, stover; corn, sweet, forage; corn, sweet, stover; wheat, forage; wheat, hay; wheat, straw; cotton gin byproducts; soybean, seed; and livestock commodities as a result of the review of the actual residue data and so that the listed commodities agree with current EPA commodity terms. Therefore, EPA is establishing tolerances for residues of thiencarbazone-methyl, *per se*, in or on corn, field, forage at 0.04 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.02 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 0.01 ppm; corn, sweet, forage at 0.05 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 0.05 ppm; wheat, forage at 0.10 ppm; wheat, grain at 0.01 ppm; wheat, hay at 0.01 ppm; and wheat, straw at 0.01 ppm; combined residues of thiencarbazone-methyl and its metabolite BYH 18636-MMT, calculated as the parent compound, in or on cattle, meat at 0.02 ppm; cattle, meat byproducts at 0.02 ppm; goat, meat at

0.02 ppm; goat, meat byproducts at 0.02 ppm; horse, meat at 0.02 ppm; horse, meat byproducts at 0.02 ppm; milk at 0.02 ppm; sheep, meat at 0.02 ppm; and sheep, meat byproducts at 0.02 ppm; and indirect or inadvertent combined residues of thiencarbazone-methyl and its metabolite BYH 18636-MMT-glucoside, calculated as the parent compound, in or on soybean, forage at 0.04 ppm and soybean, hay at 0.15 ppm. 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 thiencarbazone-methyl, *per se*, in or on corn, field, forage at 0.04 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.02 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 0.01 ppm; corn, sweet, forage at 0.05 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 0.05 ppm; wheat, forage at 0.10 ppm; wheat, grain at 0.01 ppm; wheat, hay at 0.01 ppm; and wheat, straw at 0.01 ppm; combined residues of thiencarbazone-methyl and its metabolite BYH 18636-MMT, calculated as the parent compound, in or on cattle, meat at 0.02 ppm; cattle, meat byproducts at 0.02 ppm; goat, meat at 0.02 ppm; goat, meat byproducts at 0.02 ppm; horse, meat at 0.02 ppm; horse, meat byproducts at 0.02 ppm; milk at 0.02 ppm; sheep, meat at 0.02 ppm; and sheep, meat byproducts at 0.02 ppm; and indirect or inadvertent combined residues of thiencarbazone-methyl and its metabolite BYH 18636-MMT-glucoside, calculated as the parent compound, in or on soybean, forage at 0.04 ppm and soybean, hay at 0.15 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.

Thiencarbazone-methyl has low toxicity in acute toxicity and irritation assessments and is not a skin sensitizer. In subchronic and chronic oral toxicity studies, the critical target organ for thiencarbazone-methyl is the urinary tract including the kidney, bladder and ureters. Toxicity in these structures from the formation of calculi that are formed by the deposition of the parent and are associated with the sulfonamide structure and these are evident in the dog, considered the most sensitive species at 179 milligrams/kilograms/day (mg/kg/day) in the chronic study. In mice, at 599 mg/kg/day in males and 758 mg/kg/day in females, doses where there was formation of calculi in the urothelial system, thiencarbazone-methyl was associated with transitional cell epithelium tumors in the urinary bladder in one male and three females and in the prostatic urethra in one male. The battery of mutagenicity/genetic toxicity studies did not indicate a mutagenicity concern. Since the neoplasia occurred only in the high dose group, thiencarbazone-methyl was classified as ''Not likely to be a carcinogen to humans at doses that do not cause urothelial cytotoxicity.''

Specific information on the studies received and the nature of the adverse effects caused by thiencarbazone-methyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document Human Health Risk Assessment at pages 56–59 in docket ID number EPA–HQ–OPP–2008–0132.

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 thiencarbazone-methyl used for human risk assessment can be found at *http://www.regulations.gov* in document Human Health Risk Assessment at pages 25–26 in docket ID number EPA–HQ–OPP–2008–0132.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to thiencarbazone-methyl, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from 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 thiencarbazone-methyl; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the dietary model Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID). The modeled exposure estimates for the chronic assessment are based on tolerance level residues, assuming 100% of the crops are treated, and include the highest modeled estimated drinking water concentrations (EDWCs).

iii. *Cancer*. Thiencarbazone-methyl is not likely to be carcinogenic to humans at doses that do not cause urothelium cytotoxicity. The chronic reference dose (cRfD) of 117 mg/kg/day is adequately protective of any cancer or pre-cancerous effects seen in carcinogenicity studies in rats and mice. The formation of the low incidence of the transitional cell tumors of the bladder in both sexes and urethra/prostrate in males that develop at 599 mg/kg/day in males and 758 mg/kg/day in females in mice is considered to be related to secondary effect of the urothelial toxicity (irritation) and regenerative proliferation associated with the formation of urinary tract crystals/calculi. This is commonly seen for bladder carcinogensis in rodents for non-genotoxic chemicals of the sulfonamide class. No tumors were seen in rats.

iv. *Anticipated residue and percent crop treated (PCT) information*. 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 thiencarbazone-methyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of thiencarbazone-methyl. 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 EDWCs of thiencarbazone-methyl for chronic exposures are estimated to be 0.36 parts per billion (ppb) for surface water and 0.00079 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 0.36 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).

Thiencarbazone-methyl is currently pending registration for the following uses that could result in residential exposures: Application to residential turfgrass and recreational sites. EPA assessed residential exposure using the following assumptions: Residential handlers may receive short-term dermal and inhalation exposure when mixing, loading, and applying the herbicide. Residential post-application exposure via the inhalation route is expected to be negligible; however, dermal exposure is likely for adults and children entering treated lawns. Toddlers may also experience exposure via incidental non-dietary ingestion during post-application activities on treated turf. Residential short-term dermal, inhalation, and incidental oral exposures were assessed using the same NOAEL (159 mg/kg/day). One hundred percent absorption via the dermal and inhalation exposure routes was assumed, resulting in very conservative estimates of risk (MOEs).

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 thiencarbazone-methyl 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 thiencarbazone-methyl such that cumulative risk assessment based on chemicals with a common mechanism is necessary for thiencarbazone-methyl and other sulfonamides. With thiencarbazone-methyl, the formation of calculi in the urinary tract results from the precipitation of thiencarbazone-methyl once it reaches saturation in the animal's system. Precipitation of thiencarbazon-methyl is a physical/chemical process and not a mechanism of toxicity. Exposures to thiencarbazone-methyl and other sulfonamides, 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*. There is no indication of increased susceptibility of rat or rabbit offspring to thiencarbazone-methyl as indicated by the rat and rabbit developmental toxicity studies and the rat reproduction study. There is no concern for increased susceptibility to offspring.

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 thiencarbazone-methyl 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 thiencarbazone-methyl. In the absence of specific immunotoxicity studies, EPA has evaluated the available toxicity data for thiencarbazone-methyl 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. EPA considered the entire toxicity database for thiencarbazone-methyl for adverse effects on the thymus and spleen for possible indications of immunotoxicity and determined that there were no changes in these structures indicative of immunotoxicity. There were also no changes in leucocytes or differential leucocyte counts to suggest an effect on the immune system.

b. Thiencarbazone-methyl does not belong to a class of chemicals that would be expected to be immunotoxic.

c. Therefore, based on the above considerations, EPA does not believe that conducting immunotoxicity testing will result in a NOAEL less than the NOAEL of 117 mg//kg/day already established for thiencarbazone-methyl, and an additional factor (UFDB) for database uncertainties is not needed to account for potential immunotoxicity.

ii. There is no indication that thiencarbazone-methyl 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 thiencarbazone-methyl 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 based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to thiencarbazone-methyl 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 thiencarbazone-methyl.

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 and no acute dietary endpoint was selected. Therefore, thiencarbazone-methyl 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 thiencarbazone-methyl from food and water will utilize 0.1% of the cPAD for children 1–2 yrs. and children 3–5 yrs. and <0.1% for all other population subgroups.

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

Thiencarbazone-methyl is currently pending registration 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 thiencarbazone-methyl.

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 18,700 to adults and 13,500 to children.

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

Although intermediate-term residential exposure could result from the use of thiencarbazone-methyl, no toxicological effects resulting from intermediate-term dosing were observed. Therefore, the aggregate risk is the sum of the risk from food and water and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population*. Thiencarbazone-methyl is not likely to be carcinogenic to humans. The cRfD of 117 mg/kg/day is adequately protective of any cancer or pre-cancerous effects seen in carcinogenicity studies in rats and mice and as the chronic risk assessment shows estimated exposure to thiencarbazone-methyl is well below the cRfD.

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 thiencarbazone-methyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

A high performance liquid chromotography/mass spectrometry/mass spectrometry (HPLC/MS/MS) method was submitted for the determination of residues of thiencarbazone-methyl and two metabolites in/on samples of crop commodities. The validated limit of quantification (LOQ) is 0.01 ppm for each analyte in each matrix. A HPLC/MS/MS method was submitted for the determination of residues of thiencarbazone-methyl in livestock commodities. The LOQ is 0.01 ppm.

Adequate enforcement methodology 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

EPA established tolerances are harmonized with Maximum Residue Limits (MRLs) established in Canda, except for tolerances on livestock commodities, livestock feedstuffs, and soybeans (as a rotational crop).

C. Revisions to Petitioned-For Tolerances

Tolerance levels and commodity expressions have been revised for corn, field, forage; corn, field, stover; corn, sweet, forage; corn, sweet, stover; wheat, forage; wheat, hay; wheat, straw; and livestock commodities as a result of the

review of the actual residue data and so that the listed commodities agree with current EPA commodity terms. EPA concluded that there is no need to establish indirect or inadvertent tolerance levels in or on cotton gin byproducts or soybean, seed because the submitted field rotational crop data demonstrated that residues were not likely to be found on these commodities when the plant back intervals specified on the product labels are followed. EPA determined that the residue(s) of concern for both risk assessment and tolerance expression is thiencarbazone-methyl for corn and wheat commodities, thiencarbazone-methyl and BYH 18636-MMT-glucoside for soybean rotational crop commodities, and thiencarbazone-methyl and BYH 18636-MMT for livestock commodities.

V. Conclusion

Therefore EPA is establishing tolerances for residues of thiencarbazone-methyl, in or on corn, field, forage at 0.04 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.02 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 0.01 ppm; corn, sweet, forage at 0.05 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 0.05 ppm; wheat, forage at 0.10 ppm; wheat, grain at 0.01 ppm; wheat, hay at 0.01 ppm; and wheat, straw at 0.01 ppm; combined residues of thiencarbazone-methyl and its metabolite BYH 18636-MMT, calculated as the parent compound, in or on cattle, meat at 0.02 ppm; cattle, meat byproducts at 0.02 ppm; goat, meat at 0.02 ppm; goat, meat byproducts at 0.02 ppm; horse, meat at 0.02 ppm; horse, meat byproducts at 0.02 ppm; milk at 0.02 ppm; sheep, meat at 0.02 ppm; and sheep, meat byproducts at 0.02 ppm; and indirect or inadvertent combined residues of thiencarbazone-methyl and its metabolite BYH 18636-MMT-glucoside, calculated as the parent compound, in or on soybean, forage at 0.04 ppm and soybean, hay at 0.15 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, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under 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 180.645 is added to read as follows:

§ 180.645 Thiencarbazone-methyl; tolerances for residues

(a) *General.* (1) Tolerances are established for residues of thiencarbazone-methyl [methyl 4-[[[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl)-carbonyl]amino]sulfonyl]-5-methyl-3-thiophenecarboxylate], *per se*, in or on the following food and feed commodities:

Commodity	Parts per million
Corn, field, forage	0.04
Corn, field, grain	0.01
Corn, field, stover	0.02
Corn, pop, grain	0.01
Corn, pop, stover	0.01
Corn, sweet, forage	0.05
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.05
Wheat, forage	0.10
Wheat, grain	0.01
Wheat, hay	0.01
Wheat, straw	0.01

(2) Tolerances are established for combined residues of thiencarbazone-methyl and its metabolite BYH 18636-MMT [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 of animal origin:

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.