retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: June 5, 2018.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.470,

■ i. Add alphabetically the entries ''Alfalfa, forage''; ''Alfalfa, hay''; ''Cattle, fat''; ''Cattle, kidney''; ''Cattle, meat''; ''Cattle, meat byproducts, except kidney''; ''Goat, fat''; ''Goat, kidney''; ''Goat, meat''; ''Goat, meat byproducts, except kidney''; ''Hog, kidney''; ''Horse, fat''; ''Horse, kidney''; ''Horse, meat''; ''Horse, meat byproducts, except kidney''; ''Milk''; ''Sheep, fat''; ''Sheep, kidney''; ''Sheep, meat''; ''Sheep, meat byproducts, except kidney''; to the table in paragraph (a) and

■ ii. Revise the commodities ''Animal feed, nongrass, group 18, except alfalfa, forage'', and ''Animal feed, nongrass, group 18, except alfalfa, hay'' in the table in paragraph (d).

The additions and revisions read as follows:

§ 180.470 Acetochlor; tolerances for residues.

(a) * * *

Commodity	Parts per million
Alfalfa, forage	8.0
Alfalfa, hay	20
* * * * *	
Cattle, fat	0.02
Cattle, kidney	0.03
Cattle, meat	0.02
Cattle, meat byproducts, except kidney	0.02
* * * * *	
Goat, fat	0.02
Goat, kidney	0.03
Goat, meat	0.02
Goat, meat byproducts, except kidney	0.02
Hog, kidney	0.02
Horse, fat	0.02
Horse, kidney	0.03
Horse, meat	0.02
Horse, meat byproducts, except kidney	0.02
Milk	0.02
* * * * *	
Sheep, fat	0.02
Sheep, kidney	0.03
Sheep, meat	0.02
Sheep, meat byproducts, except kidney	0.02
* * * * *	

* * * * *

(d) * * *

Commodity	Parts per million
Animal feed, nongrass, group 18, except alfalfa, forage	1.3
Animal feed, nongrass, group 18, except alfalfa, hay	3.5
* * * * *	

[FR Doc. 2018–13459 Filed 6–21–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0448; FRL–9978–50]

Thiencarbazone-methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of thiencarbazone-methyl in or on wheat forage. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 22, 2018. Objections and requests for hearings must be received on or before August 21, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0448, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial

Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0448 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 21, 2018. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2017–0448, by one of the following methods:

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

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 6, 2018 (83 FR 9471) (FRL–9973–27), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F8583) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that the existing wheat, forage tolerance in 40 CFR 180.645 for residues of the herbicide thiencarbazone-methyl, methyl 4-[[[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1H–1,2,4-triazol-1-yl)carbonyl] amino]sulfonyl]-5-methyl-3-thiophenecarboxylate, be amended from 0.10 parts per million (ppm) to 0.15 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov.* No comments related to this tolerance action were received on the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for thiencarbazone-methyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with thiencarbazone-methyl 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 acute toxicity via the oral, dermal, and inhalation routes of exposure. Thiencarbazone-methyl is not an eye nor a skin irritant and it is not a skin sensitizer.

The most toxicologically significant effect of thiencarbazone-methyl occurs in the urothelial system including the kidney, bladder, and urinary tract. Across species, the dog is more sensitive than the rat or the mouse. Common effects observed throughout the database included sulfonamide crystals in the urine, eosinophilic urolithiasis (kidney, ureter and bladder stones), pelvic dilation, thickening of the kidney, bladder, or ureter, collecting duct hyperplasia, urothelial hyperplasia, submucosal inflammatory cell infiltration, bladder hemorrhage, inflammation, and ulceration.

There is no evidence of susceptibility in the thiencarbazone-methyl database. Offspring effects occurred at the same doses as those which caused maternal toxicity. In rats, maternal toxicity was indicated by decreased body and placenta weight and yellowish sediment in the urinary bladder. Developmental toxicity was indicated by delayed ossification of several locations. In rabbits, maternal toxicity consisted of decreased body weight, deaths, reduced food consumption and sediment in the kidney and urinary bladder. Developmental toxicity consisted of more runt fetuses and lower body weight in female offspring. There were no effects on reproductive parameters in either males or females in a reproductive study in rats. Systemically, there were effects on the urothelial system at the high dose in the parents and decreases in body weight in females

toward the end of lactation. There was also evidence of reduced absolute and relative liver weight in males in the high dose F1 group. The pups also demonstrated evidence of urothelial effects as indicated by the presence of stones in the kidneys and urinary bladder in a few F2 weanlings at the highest dose tested.

There is no evidence of immunotoxicity, neurotoxicity, or mutagenicity in the thiencarbazone-methyl database. There were no treatment-related increases in neoplasia in the rat carcinogenicity study. In mice, calculi in the urothelial system as well as transitional cell epithelium tumors in the urinary bladder (1 male/3 females) and in the prostatic urethra (1 male) were observed at the highest dose tested (599 mg/kg/day in males and 758 mg/kg/day in females). 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.'' The formation of the tumors is considered to be related to the secondary effects of the urothelial toxicity (irritation) and regenerative proliferation associated with the formation of urinary tract crystals/calculi.

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, Thiencarbazone-methyl Human Health Risk Assessment, at pages 39–42 in docket ID number EPA–HQ–OPP–2017–0448.

B. Toxicological Points of Departure/Levels of Concern

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

A summary of the toxicological endpoints for thiencarbazone-methyl used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THIENCARBAZONE-METHYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations) ..	No selection because no indication of significant toxicity following a single dose.		
Chronic dietary (All populations)	NOAEL= 117 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 1.17 mg/kg/day. cPAD = 1.17 mg/kg/day.	Dog chronic feeding. LOAEL = 117 mg/kg/day based on urothelial effects.
Oral short-term (adult and incidental oral for children) (1 to 30 days).	NOAEL= 159 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential MOE = 100.	Dog subchronic study. LOAEL = 335 mg/kg/day in males and 351 mg/kg/day in females based on urothelial effects.
Dermal short-term (1 to 30 days).	NOAEL = 159 mg/kg/day. DAF = 100% UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential MOE = 100.	Dog subchronic study. LOAEL = 335 mg/kg/day in males and 351 mg/kh/day in females based on urothelial effects.
Inhalation short-term (1 to 30 days).	NOAEL= 159 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential MOE = 100.	Dog subchronic study. LOAEL = 335 mg/kg/day in males and 351 mg/kg/day in females based on urothelial effects.
Cancer (oral, dermal, inhalation).	Classification ''not likely to be carcinogenic to humans at doses that do not cause urothelium cytotoxicity.''		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). DAF= dermal absorption factor.

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 as well as all existing thiencarbazone-methyl tolerances in 40 CFR 180.180.645. EPA assessed dietary exposures from thiencarbazone-methyl 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 and assume 100% of the crops are treated.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to thiencarbazone-methyl because the chronic reference dose is protective of any cancer or pre-cancerous effect observed in carcinogenicity studies. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure.*

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for thiencarbazone-methyl. Tolerance-level residues and/or 100% CT 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 estimated drinking water concentrations (EDWCs) of thiencarbazone-methyl for chronic exposures for non-cancer assessments are estimated to be 0.36 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 registered for the following uses that could result in residential exposures: Application to residential turfgrass and ornamentals. EPA assessed residential exposure using the following assumptions:

- Residential handler exposure is expected to be short-term in duration. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners. There is a potential for inhalation and dermal exposure for adult handlers.
- Post-application exposure is expected to be short-term in nature. There is a potential for dermal exposure to adults and children and incidental oral exposure to children ages 1 <2 years old through contact with treated areas after treatment.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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

EPA has not found thiencarbazone-methyl to share a common mechanism of toxicity with any other substances, and thiencarbazone-methyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that thiencarbazone-methyl does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(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 evidence of increased qualitative or quantitative susceptibility in the young. Offspring effects occurred at the same doses as those which caused maternal toxicity.

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 considered complete. There are available developmental studies in rats and rabbits, a reproductions study in rats, and acute and subchronic neurotoxicity battery studies. The requirement for a subchronic inhalation study was waived because thiencarbazone-methyl has low volatility, low acute inhalation toxicity and the use of a POD from an oral study to estimate inhalation exposures results in MOEs that are >100 times higher than the MOEs of concern.

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% CT and

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from 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 less than 1% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure.

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 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 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 result in aggregate MOEs of 9,200 to adults, 140,000 for children 11–16 years old, 13,000 for children 6–11 years old, and 7,500 for children 1–2 years old. Because EPA's level of concern for thiencarbazone-methyl is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, thiencarbazone-methyl is not expected to pose a intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* As explained in section III.A., thiencarbazone-methyl is considered ''not likely to be carcinogenic to humans at doses that do not cause urothelial cytotoxicity.'' Because the Agency is regulating exposure to thiencarbazone-methyl to ensure that the U.S. population will not be exposed to levels that cause urothelial cytotoxicity, EPA concludes that thiencarbazone-methyl will not pose an aggregate 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 thiencarbazone-methyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (LC/MS/MS) is available to enforce the tolerance expression.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for thiencarbazone-methyl.

V. Conclusion

Therefore, the tolerance is amended for residues of thiencarbazone-methyl, methyl 4-[[[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1H–1,2,4-triazol-1-yl)carbonyl] amino]sulfonyl]-5-methyl-3-thiophenecarboxylate, in or on wheat forage at 0.15 ppm. In addition, EPA is revising the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of thiencarbazone-methyl not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

VI. Statutory and Executive Order Reviews

This action amends a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action 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), nor is it considered a regulatory action subject to Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not

require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: June 1, 2018.

Daniel J. Rosenblatt,

Deputy Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.645,
■ a. Revise paragraph (a)(1) introductory text;
■ b. Revise the entry for ''wheat, forage'' in the table in paragraph (a)(1);
■ c. Revise paragraph (a)(2) introductory text; and
■ d. Revise paragraph (d) introductory text.

The revisions read as follows:

§ 180.645 Thiencarbazone-methyl; tolerances for residues.

(a)(1) *General.* Tolerances are established for residues of the thiencarbazone-methyl, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only only 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] in or on the following food and feed commodities.

Commodity	Parts per million
* * * * *	
Wheat, forage	0.15
* * * * *	

(2) Tolerances are established for residues of thiencarbazone-methyl, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum 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] and its metabolite BYH 18636–MMT [5-methoxy-4-methyl-2,4-dihydro-3*H*-1,2,4-triazol-3-one], calculated as the stoichiometric equivalent of thiencarbazone-methyl, in or on the following food commodities of animal origin:

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of thiencarbazone-methyl, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum 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] 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 stoichiometric equivalent of thiencarbazone-methyl, in or on the following food commodities:

* * * * *

[FR Doc. 2018–13453 Filed 6–21–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0167; FRL–9977–94]

Benzovindiflupyr; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In response to a petition filed by Syngenta Crop Protection, LLC under the Federal Food, Drug, and Cosmetic Act (FFDCA), this regulation establishes tolerances for residues of benzovindiflupyr in or on bluegrass, forage at 0.15 parts per million (ppm), bluegrass, hay at 7.0 ppm, bluegrass, straw at 6.0 ppm, bromegrass, forage at 0.15 ppm, bromegrass, hay at 7.0 ppm, bromegrass, straw at 6.0 ppm, fescue, forage at 0.15 ppm, fescue, hay at 7.0 ppm, fescue, straw at 6.0 ppm, orchardgrass, forage at 0.15 ppm, orchardgrass, hay at 7.0 ppm, orchardgrass, straw at 6.0 ppm, and ryegrass, forage at 0.15 ppm, ryegrass, hay at 7.0 ppm, and ryegrass, straw at 6.0 ppm.

DATES: This regulation is effective June 22, 2018. Objections and requests for hearings must be received on or before August 21, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0167, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m.,