(2) The restricted area is in effect twenty four hours per day and seven days a week.

(3) Should warranted access into the restricted navigation area be needed, all entities are to contact the Supervisor of Shipbuilding, Conversion and Repair, USN, Gulf Coast, Pascagoula, Mississippi, or his/her authorized representative on Marine Communication Channel 16.

(c) *Enforcement.* The regulation in this section shall be enforced by the Supervisor of Shipbuilding, Conversion and Repair, USN, Gulf Coast, Pascagoula, Mississippi, and/or such agencies or persons as he/she may designate.

Dated: July 16, 2012.

Richard C. Lockwood,

Chief, Operations and Regulatory, Directorate of Civil Works.

[FR Doc. 2012–17780 Filed 7–19–12; 8:45 am]

BILLING CODE 3720–58–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0458; FRL–9354–8]

Trifloxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of trifloxystrobin in or on artichoke, globe. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 20, 2012. Objections and requests for hearings must be received on or before September 18, 2012, 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–2011–0458, is available either electronically through *http://www.regulations.gov* or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, 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: Dominic Schuler, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–0260; email address: *schuler.dominic@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 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://ecfr.gpoaccess.gov/cgi/t/text/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–2011–0458 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 September 18, 2012. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0458, 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 4, 2012 (77 FR 20334) (FRL–9340–4), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7845) by Bayer CropScience, 2 TW Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.555 be amended by establishing tolerances for residues of the fungicide trifloxystrobin, [benzeneacetic acid, (E,E)-α-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)phenyl]ethylidene] amino]oxy]methyl]-methyl ester], in or on artichoke, globe at 1.0 parts per million (ppm). That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov.*

There were no comments received in response to 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 trifloxystrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with trifloxystrobin 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.

Trifloxystrobin exhibits very low toxicity following single oral, dermal and inhalation exposures. It is a strong dermal sensitizer. In repeated dose tests in rats, the liver is the target organ for trifloxystrobin; toxicity is induced following oral and dermal exposure for 28 days. There is no evidence of increased susceptibility following prenatal exposure to rats and rabbits and postnatal exposures to rats. Trifloxystrobin was determined not to be carcinogenic in mice or rats following long-term dietary administration. Trifloxystrobin is positive for mutagenicity in Chinese Hamster V79 cells, albeit at cytotoxic dose levels. However, trifloxystrobin is negative in the remaining mutagenicity studies. Specific information on the studies received and the nature of the adverse effects caused by trifloxystrobin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of June 11, 2010 (75 FR 33190) (FRL–8829–2), and at *http://www.regulations.gov* in the document ''Trifloxystrobin. Human Health Risk Assessment for a Section 3 Petition Proposing Increased Tolerances for Residues in/on Field, Sweet and Pop Corn,'' pp. 17–21 in docket ID number EPA–HQ–OPP–2009–0278.

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 trifloxystrobin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of June 11, 2010.

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to trifloxystrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing trifloxystrobin tolerances in 40 CFR 180.555. EPA assessed dietary exposures from trifloxystrobin in food as follows:

i. Acute exposure. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for trifloxystrobin. In estimating acute dietary exposure for females 13–49 years old, EPA conducted an analysis using the Dietary Exposure Evaluation Model (DEEM\TM\ 7.81), which used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance level residues. EPA assumed all commodities with established or proposed tolerances were treated with trifloxystrobin.

ii. Chronic exposure. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance level residues for all commodities with the exception of apples, oranges and grapes. For these commodities EPA used anticipated residues from field residue trials. EPA assumed all commodities with established or proposed tolerances were treated with trifloxystrobin.

iii. Cancer. Based on the data summarized in Unit III.A., EPA has concluded that trifloxystrobin does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. Anticipated residue and percent crop treated (PCT) information. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. Dietary exposure from drinking water. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for trifloxystrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of trifloxystrobin. 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of trifloxystrobin plus its major degradation product, CGA–321113 for the proposed artichoke, globe use are estimated to be 47.98 parts per billion (ppb) and 47.31 ppb for surface water for acute and chronic exposures, respectively. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

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).

Trifloxystrobin is currently registered for the following uses that could result in residential exposures: Ornamentals and turfgrass. EPA assessed residential exposure under the following exposure scenarios: Adult post-application dermal exposure; and children's post-application dermal and/or hand to mouth exposure. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.*

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 trifloxystrobin to share a common mechanism of toxicity with any other substances, and trifloxystrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that trifloxystrobin 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 Web site 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 rabbits to trifloxystrobin. In the prenatal developmental study in rats, there was no developmental toxicity at the limit dose. In the prenatal developmental study in rabbits, developmental toxicity was seen at a dose that was higher than the dose that caused maternal toxicity. In the 2-generation reproduction study, there was no offspring toxicity at the highest dose tested.

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 database is complete except for an immunotoxicity study and an inhalation study. Although an immunotoxicity study is needed, the entire trifloxystrobin toxicity database was examined and there was no indication that this chemical directly targets the immune system. EPA does not believe that conducting an immunotoxicity study will result in a dose less than the points of departure already used in this risk assessment and an additional database uncertainty factor (UF) for potential immunotoxicity does not need to be applied. Regarding the requirement for an inhalation toxicity study, the Agency has increased its focus on the uncertainties associated with route-to-route extrapolation (i.e., the use of oral toxicity studies for inhalation risk assessment) and is presently requiring inhalation toxicity studies more frequently. Although an inhalation toxicity study is now required for trifloxystrobin based on OPP's current weight of the evidence (WOE) approach, residential inhalation exposure is not anticipated; therefore, there are no uncertainties with respect to residential inhalation exposures to trifloxystrobin and no need to retain an additional database uncertainty factor for this safety finding.

ii. There is no indication that trifloxystrobin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. A waiver for a subchronic neurotoxicity study has been granted. There is no evidence of neurotoxicity in subchronic and chronic toxicity studies (rats, dogs, mice), in developmental toxicity studies (rats, rabbits), or in a reproductive toxicity study (rats). There is no concern for neurotoxicity for trifloxystrobin based on the available database, limited findings in an acute neurotoxicity study, and lack of neurotoxicity in other fungicides of the strobilurin class.

iii. There is no evidence that trifloxystrobin 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 acute dietary exposure assessment was unrefined, and the chronic dietary exposure assessment was partially refined, assuming 100 PCT and tolerance-level residues for all commodities except for apples, grapes, and oranges where the average field trial residues were used. By using these screening-level assessments with minor refinement, actual exposures/risks from residues in food will not be underestimated. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to trifloxystrobin 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 trifloxystrobin.

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. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to trifloxystrobin will occupy 1.9% of the aPAD for females 13–49 years old, the population group receiving the greatest exposure.

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to trifloxystrobin from food and water will utilize 64% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of trifloxystrobin is not expected.

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

Trifloxystrobin 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 trifloxystrobin. 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 1,100 for adults (dermal residential + dietary food and drinking water exposures); 650 for children 1–2 years (dermal residential + dietary food and drinking water exposures); and 130 for children 1–2 years (incidental oral residential + dietary food and drinking water exposures). Because EPA's level of concern for trifloxystrobin is a MOE of 100 or less, 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). Trifloxystrobin is not expected to pose an intermediate-term risk based on a short soil half-life (approximately 2 days).

5. Aggregate cancer risk for U.S. population. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, chemical name is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with nitrogen phosphorus detection (GC/NPD), Method AG–659A and liquid chromatography with tandem mass spectrometry detection (LC/MS/MS), Method No. 200177) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

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

The Codex has not established a MRL for trifloxystrobin on artichoke, globe. Therefore, international harmonization is not an issue.

V. Conclusion

Therefore, a tolerance is established for residues of trifloxystrobin, [benzeneacetic acid, (E,E)-α-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)phenyl]ethylidene] amino]oxy]methyl]-methyl ester], in or on artichoke, globe at 1.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

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

Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 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: July 11, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.555 is amended by alphabetically adding ''Artichoke, globe'' to the table in paragraph (a) to read as follows:

§ 180.555 Trifloxystrobin; tolerance for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Artichoke, globe	1.0
* * * * *	

* * * * *

[FR Doc. 2012–17630 Filed 7–19–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 156

[CMS–9965–F]

RIN 0938–AR36

Patient Protection and Affordable Care Act; Data Collection To Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule establishes data collection standards necessary to implement aspects of section 1302 of the Patient Protection and Affordable Care Act (Affordable Care Act), which directs the Secretary of Health and Human Services to define essential health benefits. This final rule outlines the data on applicable plans to be collected from certain issuers to support the definition of essential health benefits. This final rule also establishes a process for the recognition of accrediting entities for purposes of certification of qualified health plans.

DATES: *Effective Date:* These regulations are effective on August 20, 2012.

FOR FURTHER INFORMATION CONTACT:

Adam Block at (410) 786–1698, for matters related to essential health benefits data collection.

Deborah Greene at (301) 492–4293, for matters related to accreditation of qualified health plans.

SUPPLEMENTARY INFORMATION:

Executive Summary

Beginning in 2014, all non-grandfathered health plans in the individual and small group market, and other plans will cover the essential health benefits (EHB), as defined by the Secretary of Health and Human Services (the Secretary). The Affordable Care Act directs that the EHB reflect the scope of benefits covered by a typical employer plan and cover at least the following 10 general categories of items and services: Ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. EHB will promote predictability for consumers who purchase coverage in these markets, facilitate comparison across health plans, and ensure that individual and small group subscribers have the same access to the same scope of benefits provided under a typical employer plan.

This final rule includes data reporting standards for health plans that represent potential State-specific benchmark plans. Specifically, the final rule establishes that issuers of the largest three small group market products in each state report information on covered benefits.

In addition, this rule establishes the first phase of a two-phased approach for recognizing accrediting entities to implement the standards established under the Affordable Care Act for qualified health plans (QHPs) to be accredited on the basis of local performance by an accrediting entity recognized by the Secretary on a timeline established by the Exchange and addresses some data sharing and performance requirements of the recognized accrediting entities. In phase one, the National Committee for Quality Assurance (NCQA) and URAC are recognized as accrediting entities on an interim basis. In phase two, a criteria-based review process will be adopted through future rulemaking.

I. Background

Section 2707 of the Public Health Service Act, as added by section 1201 of the Affordable Care Act, directs that, for plan years beginning on or after January 1, 2014, health insurance issuers offering non-grandfathered plans in the individual or small group market ensure such coverage includes EHB as described in section 1302(a) of the Affordable Care Act. Section 1302 of the Affordable Care Act provides for the establishment of EHB, to be defined by the Secretary. The law also directs that EHB reflect the scope of benefits covered by a typical employer plan and cover at least the 10 general categories of items and services previously listed. Section 1302(b)(4) of the Affordable Care Act further establishes that the Secretary define EHB such that it:

- Sets an appropriate balance among the 10 general categories;
- Does not discriminate based on age, disability, or expected length of life;
- Takes into account the health care needs of diverse segments of the population; and
- Does not allow denials of essential benefits based on age, life expectancy, disability, or degree of medical dependency and quality of life.

Section 1302(b)(4) of the Affordable Care Act further directs the Secretary to