EPA-APPROVED MICHIGAN NONREGULATORY AND QUASI-REGULATORY PROVISIONS—Continued

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Comments
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[FR Doc. 2023–12304 Filed 6–8–23; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0314; FRL–10994–01–OCSPP]

Sedaxane; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of sedaxane in or on Onion, bulb, subgroup 3–07A and Vegetable, cucurbit, group 9. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 9, 2023. Objections and requests for hearings must be received on or before August 8, 2023, 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–2022–0314, is available at *https://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 and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; 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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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–2022–0314 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 8, 2023. 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–2022–0314, by one of the following methods:

- *Federal eRulemaking Portal: https://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 *https://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 20, 2022 (87 FR 43231) (FRL 9410–03–OCSPP), 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 2F8986) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.665 be amended by establishing tolerances for residues of the fungicide sedaxane, N-[2-[1,1′-bicyclopropyl]-2-ylphenyl]-3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide, in or on Vegetable, dry bulb, crop subgroup 3–07A and Vegetable, cucurbit, group 9 at 0.01 parts per million (ppm). The July 20, 2022, notice of filing referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *https://www.regulations.gov.*

There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is revising the commodity definition for ''Vegetable, dry bulb, crop subgroup 3–07A'' to ''Onion, bulb, subgroup 3–07A''. The reason for this change is 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 FFDCA section 408(b)(2)(D), and the factors specified therein, 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 sedaxane, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with sedaxane follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published in tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for sedaxane, most recently in the **Federal Registers** of December 8, 2017 (82 FR 57867) (FRL–9970–04) and August 27, 2019 (84 FR 44703) (FRL–9998–22), in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to sedaxane and established tolerances for residues of that pesticide chemical. EPA is incorporating previously published sections from the 2017 and 2019 rulemakings as described further in this rulemaking, as they remain unchanged.

A. Toxicological Profile

For a discussion of the Toxicological Profile of sedaxane, see Unit III.A. of the 2019 rulemaking.

B. Toxicological Points of Departure/Levels of Concern

For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Unit III.B. of the 2017 rulemaking.

C. Exposure Assessment

Much of the exposure assessment remains the same since the 2019 rulemaking, although the new exposure assessment incorporates additional dietary exposures from the petitioned-for tolerances. The updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, see Unit III.C. of the 2019 rulemaking.

Dietary exposure from food and feed uses. In evaluating dietary exposure to sedaxane, EPA considered exposure under the petitioned-for tolerances as well as all existing sedaxane tolerances in 40 CFR 180.665. For the acute and chronic dietary exposure assessments, EPA used tolerance-level residues for all registered and proposed commodities. The acute and chronic analyses used 100 percent crop treated (PCT) for all commodities.

Drinking water exposure. Drinking water exposures are not impacted by the proposed seed treatment uses on Onion, bulb, subgroup 3–07A and Vegetable, cucurbit, group 9. Since the 2019 rulemaking, EPA has conducted a new drinking water assessment for the registration review of sedaxane and subsequently updated that assessment with respect to seed treatment uses. Estimated drinking water concentrations (EDWCs) for annual potato seed treatments resulted in the highest concentrations for total sedaxane residues. The proposed seed treatment uses are not expected to result in total sedaxane residues at concentrations higher than the annual potato seed treatments; therefore, the EDWCs for annual potato seed treatments are protective. The groundwater EDWCs are 22.0 parts per billion (ppb) for acute exposures and 19.3 ppb for chronic exposures. These EDWCs were calculated with the Pesticide Root Zone Model for Groundwater (PRZM–GW).

Non-occupational 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). Sedaxane is not registered for any specific use patterns that would result in residential exposure, and residential exposures are not impacted by the proposed seed treatment uses.

Cumulative exposure. 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.'' Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to sedaxane and any other substances. For the purposes of this action, therefore, EPA has not assumed that sedaxane has a common mechanism of toxicity with other substances.

D. Safety Factor for Infants and Children

EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor to 1X. See Unit III.D. of the 2019 rulemaking for a discussion of the Agency's rationale for that determination.

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 population-adjusted dose (aPAD) and chronic population-adjusted dose (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 points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 1.4% of the aPAD for

all infants (<1 year old), the population group receiving the greatest exposure. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 1.4% of the cPAD for all infants (<1 year old), the population group receiving the greatest exposure.

Short- and intermediate-term aggregate exposure risks take into account short- and intermediate-term residential exposures, respectively, plus chronic exposure to food and water (considered to be a background exposure level). Because there are no proposed or registered residential uses of sedaxane, short- and intermediate-term risk assessments were not performed. The chronic risk assessment is protective for any short- and intermediate-term exposures from food and drinking water.

Because the chronic risk is below the Agency's level of concern, EPA concludes the chronic dietary risk assessment adequately accounts for any potential carcinogenicity that could result from exposure to sedaxane.

Therefore, 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 sedaxane residues. More detailed information can be found at *https://www.regulations.gov* in the document titled ''Sedaxane. Human Health Risk Assessment for a Proposed Seed Treatment Use on Bulb Onion Crop Subgroup 3–07A and Cucurbit Vegetables Crop Group 9'' in docket ID number EPA–HQ–OPP–2022–0314.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the 2019 rulemaking.

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 has not established an MRL for sedaxane in or on Onion, bulb, subgroup 3–07A and Vegetable, cucurbit, group 9.

C. Revisions to Petitioned-For Tolerances

The petition requested a tolerance for ''Vegetable, dry bulb, crop subgroup 3–07A''. Since the time of submission, EPA has updated the preferred vocabulary for establishing pesticide tolerances, and the correct commodity definition is ''Onion, bulb, subgroup 3–07A''. The Agency is therefore revising the commodity definition for ''Vegetable, dry bulb, crop subgroup 3–07A'' to ''Onion, bulb, subgroup 3–07A''.

V. Conclusion

Therefore, tolerances are established for residues of sedaxane, N-[2-[1,1′-bicyclopropyl]-2-ylphenyl]-3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide, in or on Onion, bulb, subgroup 3–07A at 0.01 ppm and Vegetable, cucurbit, group 9 at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action 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 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). 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 tolerances 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: May 26, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. In § 180.665, the table in paragraph (a) is amended by:

■ a. Adding a table heading; and

■ b. Adding in alphabetical order the entries ''Onion, bulb, subgroup 3–07A'' and ''Vegetable, cucurbit, group 9''.

The additions read as follows:

§ 180.665 Sedaxane; tolerances for residues.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	
Onion, bulb, subgroup 3–07A	0.01
* * * * *	
Vegetable, cucurbit, group 9	0.01
* * * * *	

* * * * *

[FR Doc. 2023–12321 Filed 6–8–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1739–F]

RIN 0938–AU24

Medicare Program; Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final action.

SUMMARY: This final action establishes a policy concerning the treatment of patient days associated with persons enrolled in a Medicare Part C (also known as ''Medicare Advantage'') plan for purposes of calculating a hospital's disproportionate patient percentage for cost reporting periods starting before fiscal year (FY) 2014 in response to the Supreme Court's ruling in *Azar* v. *Allina Health Services,* 139 S. Ct. 1804 (June 3, 2019).

DATES: The policy set out in this final action is effective August 8, 2023.

FOR FURTHER INFORMATION CONTACT: Donald Thompson, *DAC@cms.hhs.gov,* (410) 786–4487.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This final action creates a policy governing the treatment of days associated with beneficiaries enrolled in Medicare Part C for discharges occurring prior to October 1, 2013, for the purpose of determining the additional Medicare payments to subsection (d) hospitals under section 1886(d)(5)(F) of the Social Security Act (the Act).

2. Summary of Major Provisions

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) payment adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is more common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the SSI fraction or SSI ratio) is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the hospital inpatient prospective payment system (IPPS) for acute care hospitals, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 implement the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment.

3. Summary of Costs and Benefits

Including days associated with patients enrolled in Medicare Part C in the calculation of the Medicare fraction and excluding them from the calculation of the numerator of the Medicaid fraction, does not have any additional costs or benefits relative to the Medicare DSH payments that have already been made because those payments were made under the policy reflected in the fiscal year (FY) 2005 IPPS final rule (69 FR 49099) (prior to it having been vacated). The effect of this final action is to provide certainty as to how Part C days will be treated for DSH calculations for cost years not governed by the FY 2014 IPPS/Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) final rule (78 FR 50614; hereinafter referred to as ''the FY 2014 IPPS final rule''), resolving any uncertainty that may otherwise continue into the future.

B. Background

In August 2020, we issued a proposed rule, which appeared in the **Federal Register** on August 6, 2020 (85 FR 47723) (hereinafter referred to as the ''August 2020 proposed rule''). The proposed rule would establish a policy concerning the treatment of patient days associated with persons enrolled in a Medicare Part C (also known as ''Medicare Advantage'' or ''MA'') plan for purposes of calculating a hospital's disproportionate patient percentage for cost reporting periods starting before October 1, 2013, in response to the Supreme Court's ruling in *Azar* v. *Allina Health Services.*

We received approximately 110 timely pieces of correspondence containing multiple comments on the August 2020 proposed rule. Summaries of the public comments received and our responses to those public comments are set forth in section II. of this final action.