PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T01–0530 to read as follows:

§ 165.T01–0530 Safety Zone; Provincetown Harbor, Provincetown, MA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Provincetown Harbor within 500 yards of the pier located at approximately 42°02′58″ N, 070°10′52″ W. These coordinates are based on NAD 83.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Southeastern New England (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative on VHF–FM channel 16 or by telephone at 866–819–9128. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Effective and enforcement period.* This section is effective from 9 p.m. on July 4, 2024, through 10 p.m. on July 5, 2024. The section will only be subject to enforcement from 9 p.m. through 10 p.m. on July 4, 2024, unless the event time is changed because of weather conditions in which case it may be subject to enforcement those same hours on July 5, 2024.

Clinton J. Prindle,

Captain, U.S. Coast Guard, Captain of the Port Sector Southeastern New England.

[FR Doc. 2024–13917 Filed 6–25–24; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2023–0639; FRL–11977–01–OCSPP]

Spiromesifen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spiromesifen in or on Oranges and Orange, oil. Bayer CropScience, LP requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 26, 2024. Objections and requests for hearings must be received on or before August 26, 2024 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–2023–0639, 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 OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/.*

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–2023–0639 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 26, 2024. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See ''Revised Order Urging Electronic Service and Filing'', dated June 22, 2023, which can be found at *https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf.*

Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf.*

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–2023–0639, 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/where-send-comments-epa-dockets.*

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 February 9, 2024 (89 FR 9103) (FRL–10579–12–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petition (PP 2E9039) by Bayer CropScience, AG, 800 N Lindbergh Blvd., St. Louis, MO 63141. The petition requested that 40 CFR 180.607 be amended by establishing tolerances for residues of the miticide spiromesifen, in or on orange at 0.15 parts per million (ppm); orange, oil at 40.0 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *https://www.regulations.gov.* Two comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

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 establishing tolerances that vary from what is requested. The reason for these changes is explained in Unit IV.D.

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 spiromesifen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with spiromesifen follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, 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 a tolerance rulemaking for spiromesifen in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to spiromesifen and established tolerances for residues of that chemical. EPA is incorporating previously published sections from this rulemaking as described further in this rulemaking, as they remain unchanged.

A. Toxicological Profile

For a discussion of the Toxicological Profile of spiromesifen, see Unit III.A. of the spiromesifen tolerance rulemaking published in the **Federal Register** of September 11, 2018 (83 FR 45844) (FRL–9982–21).

B. Toxicological Points of Departure/Levels of Concern

For a summary of the toxicity endpoint and point of departure selections for spiromesifen, please reference Unit III.B. of the September 11, 2018, rulemaking.

C. Exposure Assessment Updates

EPA's exposure assessments have been updated to include the additional dietary exposure of spiromesifen on oranges and orange, oil. EPA's aggregate exposure assessment incorporated this additional dietary exposure, as well as exposure in drinking water and from residential sources, although the latter exposures are not impacted by the new import tolerance on oranges and thus have not changed since the last assessment. The registered residential uses and exposures that are incorporated into the aggregate assessment are described in Unit III.C.3 of the September 11, 2018, final rule.

Further information about EPA's risk assessment and determination of safety can be found at *https://www.regulations.gov* in the document titled ''Spiromesifen. Section 3 Human Health Risk Assessment for Tolerances without U.S. Registration on Oranges from Brazil'' dated December 20, 2023, in docket ID EPA–HQ–OPP–2023–0639.

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children to account for potential prenatal and postnatal toxicity. In applying this provision, EPA either retains the default value of 10X, or uses a different safety factor supported by the completeness and reliability of the toxicity database and exposure considerations that is considered protective of infants and children. For spiromesifen, the risk assessment supports the reduction of the Food Quality Protection Act (FQPA) Safety Factor (SF) to 1X based on the following: (1) there was no evidence of increased susceptibility observed in the developmental toxicity studies in rats and rabbits, (2) while there was susceptibility observed in the 2-generation reproduction study in rats, the current PODs are based on these effects, with clear NOAELs/LOAELs established, and are therefore considered protective, (3) while the dog appears to be the more sensitive species in regards to thyroid toxicity in the spiromesifen database, the current PODs

based on offspring effects in rats are 2.5X lower than the lowest dose where thyroid effects occurred in dogs, (4) label changes have been made that result in MOEs at least 10X above the LOC and lower %cPAD estimates based on a less refined dietary assessment, which adds an additional built in margin of safety. Based on the overall weight of evidence, EPA concludes that the current endpoints and PODs, along with the additional built in safety margins from the recent label changes, result in risk estimates that are protective of any potential thyroid effects that may occur at sensitive lifestages in humans, including infants and children. For more details about the FQPA Safety Factor and the justification for lowering the margin from 10X to 1X, see the December 20, 2023, human health risk assessment, in docket ID EPA–HQ–OPP–2023–0639.

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). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

1. *Acute risk.* No acute dietary endpoint was selected as no appropriate toxicological effects attributable to a single dose were observed. As a result, spiromesifen is not expected to pose an acute risk.

2. *Chronic risk.* Chronic dietary risk estimates are below the Agency's level of concern of 100% of the cPAD; which were 11% of the cPAD for the general U.S. population and 21% of the cPAD for children 1 to 2 years old, the most highly exposed population subgroup. As no long-term residential exposures are expected based on the use pattern for spiromesifen, the Agency is confident that the assessment does not underestimate risk to the general U.S. population or any population subgroup.

3. *Short- and Intermediate-term risk.* EPA has concluded the highest anticipated short-/intermediate term aggregate risk estimates for children and adults did not present risks of concern, with margins of exposure of 580 for adults, and 750 for children 6 to 11 years old, which are all above the level of concern of 100. Long-term aggregate exposure is not anticipated for residential uses. Therefore, chronic aggregate risk estimates for spiromesifen include food and drinking water only, and are equivalent to the chronic dietary risk estimates, which are below the level of concern.

4. *Aggregate cancer risk for U.S.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, spiromesifen is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to spiromesifen residues. More detailed information on the subject action to establish a tolerance on oranges and orange, oil can be found in the document entitled, ''Spiromesifen. Human Health Risk Assessment for Tolerances without U.S. Registration on Oranges from Brazil'' in docket ID EPA–HQ–OPP–2023–0639.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the September 11, 2018, 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 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 spiromesifen on oranges or orange, oil.

C. Response to Comments

The Agency received two comments from anonymous sources, both expressing dislike for pesticide tolerances in general, and requesting that EPA eliminate all pesticide tolerances. While the Agency recognizes that some people do not like pesticides, it nevertheless has a statutory obligation to review pesticide applications and determine whether use of a pesticide meets the FIFRA and FFDCA/FQPA safety standards of causing no unreasonable adverse effects to people or the environment, and to ensure a reasonable certainty of no harm from potential dietary exposure (including drinking water), respectively. Here, the Agency has evaluated the aggregate risk of spiromesifen and has determined that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to spiromesifen residues. The commentors offered no relevant information that would warrant a reconsideration of the Agency's determination.

D. Revisions to Petitioned-For Tolerances

The Agency-recommended tolerance in/on orange is identical to that proposed by the petitioner. However, the Agency has determined that the proposed tolerance for orange, oil at 40 ppm should instead be set for the correct commodity definition, orange subgroup 10–10A, oil and at 10 ppm. The revised tolerance level addresses an error in the petitioner's calculations, as it appears the petitioner calculated a proposed tolerance level of 40 ppm for oil using the proposed tolerance level for orange of 0.15 ppm, multiplied by the median processing factor. However, the Agency uses the average residue for a blended commodity multiplied by the median processing factor. Using the OECD Rounding Class Practice, the recommended tolerance level for residues in/on orange subgroup 10–10A, oil is 10 ppm. For more detailed information on this revision see ''Spiromesifen. Human Health Risk Assessment for Tolerances without U.S. Registration on Oranges from Brazil'' in docket ID EPA–HQ–OPP–2023–0639.

V. Conclusion

Therefore, tolerances are established for residues of spiromesifen on orange at 0.15 parts per million and orange subgroup 10–10A, oil at 10 parts per million.

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).

Because 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 21, 2024.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA amends 40 CFR chapter 1 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 § 180.607, amend the table in paragraph (a)(1) by:
■ a. Adding the table heading ''Table 1 to paragraph (a)(1)''; and
■ b. Adding in alphabetical order the entries ''Orange[2]''; and ''Orange subgroup 10–10A, oil[2]''.

The additions read as follows:

§ 180.607 Spiromesifen; tolerances for residues.

(a) * * *
(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	
Orange[2]	0.15
Orange subgroup 10–10A, oil[2]	10
* * * * *	

[1] This use has not been registered in the United States as of August 28, 2018.

[2] There are no U.S. registrations for these commodities as of June 26, 2024.

* * * * *

[FR Doc. 2024–14001 Filed 6–25–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 410

[Docket #2024–08329]

RIN 0970–AC93

Unaccompanied Children Program Foundational Rule; Correction

AGENCY: Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Final rule; correction.

SUMMARY: The ORR is correcting a final rule that appeared in the **Federal Register** on April 30, 2024. The final rule adopted and replaced regulations relating to key aspects of the placement, care, and services provided to unaccompanied children referred to the ORR, pursuant to ORR's responsibilities for coordinating and implementing the care and placement of unaccompanied children who are in Federal custody by reason of their immigration status under the Homeland Security Act of 2002 (HSA) and the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA). The final rule established a foundation for the Unaccompanied Children Bureau Program (UC Bureau Program) that is consistent with ORR's statutory duties, for the benefit of unaccompanied children and to enhance public transparency as to the policies governing the operation of the UC Bureau.

DATES: Effective July 1, 2024.

FOR FURTHER INFORMATION CONTACT: Toby Biswas, Director of Policy, Unaccompanied Children Bureau Program, Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services, Washington, DC, (202) 205–4440 or *UCPolicy-RegulatoryAffairs@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the final rule published April 30, 2024 (89 FR 34384), there were a number of technical errors that are identified and corrected in this document. The provisions in this correction document are effective as if they had been included in the document published April 30, 2024. Accordingly, the following corrections are effective July 1, 2024.

In FR Doc. 2024–08329, appearing on page 34384 in the **Federal Register** of