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: January 24, 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 § 180.667, amend the table in paragraph (a) by:

■ i. Adding alphabetically the commodities ''Cherry subgroup 12–12A'', ''Hop, dried cones'', and ''Vegetable, fruiting, group 8–10'', and

■ ii. Revising the commodity ''Vegetable, cucurbit, group 9''.

The additions and revisions read as follows:

§ 180.667 Cyflufenamid; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Cherry subgroup 12–12A	0.60
* * * * *	
Hop, dried cones	5.0
Vegetable, cucurbit, group 9	0.10
Vegetable, fruiting, group 8–10	0.20

* * * * *

[FR Doc. 2018–02670 Filed 2–8–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0681; FRL–9972–69]

Zoxamide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of zoxamide in or on banana. Gowan Company, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 9, 2018. Objections and requests for hearings must be received on or before April 10, 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–2016–0681, 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, P.E., Director, 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–2016–0681 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 April 10, 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–2016–0681, 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 June 8, 2017 (82 FR 26641) (FRL–9661–14), 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 6E8524) by Gowan Company, LLC, P.O. Box 556, Yuma, AZ 85366. The petition requested that 40 CFR 180.567 be amended by establishing a tolerance for residues of the fungicide zoxamide (3, 5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxo propyl)-4-methylbenzamide), in or on banana at 0.3 parts per million (ppm). That document referenced a summary of the petition prepared by Gowan Company, LLC, the registrant, which is available in the docket, *http://www.regulations.gov*. One comment was received on the notice of filing. EPA's response is discussed in Unit IV.C. Based upon review of the data supporting the petition, EPA has determined that a tolerance of 0.20 ppm on banana is appropriate rather than the petitioned-for 0.3 ppm tolerance. The reason for this change 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 zoxamide including exposure resulting from the import tolerance established by this action.

A. Risk Assessment

In the **Federal Register** of March 8, 2016 (81 FR 12011) (FRL–9942–18), EPA established tolerances for residues of zoxamide in or on several commodities. Because much of the safety assessment of zoxamide for the current action remains the same, EPA is incorporating several aspects of that previous rule and relying in part upon the findings made in the March 8, 2016 final rule in support of this action.

A summary of the toxicological profile and endpoints used for human risk assessment is discussed in Units III.A. and III.B of the March 8, 2016 final rule. In evaluating dietary exposure for this action, EPA considered exposure under the petitioned-for tolerances as well as all existing zoxamide tolerances in 40 CFR 180.567. The residue data used for the acute and chronic dietary exposure assessments have not changed since the assessment supporting the March 8, 2016 final rule, except to incorporate the exposure associated with the tolerance on banana, for which the Agency assumed tolerance-level residues, default processing factors, and 100 percent crop treated. For a summary of how EPA assessed these dietary exposures, see Unit III.C.1 of the March 8, 2016 final rule. In addition, because there is no U.S. registration associated with the use of zoxamide on banana, the estimated drinking water exposures reported in the 2016 final rule remain the same for this rule. A summary of EPA's assessment of drinking water exposure is discussed in Unit III.C.2. of the March 8, 2016 final rule. Similarly, the Agency's assessment of cumulative risks remains the same as in the March 8, 2016 final rule.

Because there have been no changes to the potential for prenatal and postnatal toxicity or in the completeness of data with respect to toxicity and exposure, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the additional tenfold (10X) margin of safety required under section 408(b)(2)(C) (''FQPA safety factor'') were reduced to 1X. A summary of EPA's rationale for this determination is discussed in Unit III.D. of the March 8, 2016 final rule.

B. 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 exists.

No acute effects were identified in the toxicological studies for zoxamide; therefore, a quantitative acute dietary exposure assessment is unnecessary. The chronic dietary risk is 1.8% of the chronic population adjusted dose (cPAD) for the general U.S. population and 6.4% of the cPAD for children 1 to 2 years old, the population subgroup with the highest estimated chronic dietary exposure to zoxamide. The Agency level of concern are percentage numbers greater than 100% of the cPAD. Because there are no existing or proposed residential uses for zoxamide, there are no exposures expected via the residential exposure pathway. Therefore, all aggregate risk estimates are expected to be equivalent only to dietary (food and drinking water) risk estimates mentioned above.

Therefore, 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 zoxamide residues.

For a detailed discussion of the aggregate risk assessments and determination of safety for these tolerances, please refer both to the March 8, 2016 final rule and its supporting documents, available at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2014–0922, and to the risk assessment for this current action ''*Zoxamide: Human Health Risk Assessment for the Petition for a Tolerance Without U.S. Registration for Residues in/on Banana*.'' in docket ID number EPA–HQ–OPP–2016–0681.

IV. Other Considerations

A. Analytical Enforcement Methodology

A gas chromatography/mass selective detection (GC/MSD) method, modified Rohm and Haas Method #34–99–85, was previously submitted and concurrently revalidated with the submission of the current petition for the determination of residues of zoxamide in/on samples of banana. 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 zoxamide.

C. Response to Comments

One comment was received from an anonymous respondent. The comment is general to all pesticides and is against tolerances being approved for any chemical on any commodity. Although the Agency recognizes that some individuals believe that no residue of pesticides should be allowed in or on food, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes the establishment of pesticide tolerances or exemptions where the Agency determines that tolerance or exemption meets the safety standard imposed by the statute. EPA has sufficient data to support a safety determination for the tolerance for residues of zoxamide in or on banana. The commenter provided no additional information supporting a determination that the exemption is not safe.

D. Revisions to Petitioned-For Tolerances

The Agency is establishing a tolerance for residues of zoxamide in or on banana at 0.20 ppm, which is lower than the 0.30 ppm tolerance requested. This is because there is a difference between how the petitioner calculated the proposed tolerance and how the Agency calculates the tolerance. The 0.20 ppm tolerance being set on banana was calculated using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures and available field-trial residue data. The field-trial data on unbagged, whole fruit banana residues with a 0-day pre-harvest interval (PHI) were used from each field trial to calculate the tolerance.

V. Conclusion

Therefore, a tolerance is established for residues of zoxamide, (3, 5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide), in or on banana at 0.20 ppm.

VI. Statutory and Executive Order Reviews

This action establishes 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); Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997); or 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: January 23, 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 § 180.567, add alphabetically the entry ''Banana'' to the table in paragraph (a) and add footnote 1 to the table to read as follows:

§ 180.567 Zoxamide; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Banana [1]	0.20
* * * * *	

[1] There are no U.S. registrations allowing use of zoxamide on banana as of February 9, 2018.

* * * * *

[FR Doc. 2018–02668 Filed 2–8–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2016–0077; 4500030113]

RIN 1018–BB34

Endangered and Threatened Wildlife and Plants; Endangered Species Status for Texas Hornshell

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), determine endangered species status under the Endangered Species Act of 1973 (Act), as amended, for the Texas hornshell (*Popenaias popeii*), a freshwater mussel species from New Mexico, Texas, and Mexico. The effect of this regulation will be to add this species to the List of Endangered and Threatened Wildlife.

DATES: This rule becomes effective March 12, 2018.

ADDRESSES: This final rule is available on the internet at *http://www.regulations.gov* in Docket No. FWS–R2–ES–2016–0077 and in *https://www.fws.gov/southwest/es/TexasCoastal/.* Comments and materials we received, as well as supporting documentation we used in preparing this rule, are available for public inspection at *http://www.regulations.gov.* Comments, materials, and documentation that we considered in this rulemaking will be available by appointment, during normal business hours at the address shown in **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Charles Ardizzone, U.S. Fish and Wildlife Service, Texas Coastal Ecological Services Field Office, 17629 El Camino Real #211, Houston, TX 77058; or by telephone 281–286–8282. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339. Website: *https://www.fws.gov/southwest/es/TexasCoastal/.*

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Endangered Species Act, a species is added to the Federal List of Endangered and Threatened Wildlife if it is endangered or threatened throughout all or a significant portion of its range. Listing a species as an endangered or threatened species can only be completed by issuing a rule. The Lists of Endangered and Threatened Wildlife and Plants are located in title 50 of the Code of Federal Regulations (CFR) in part 17.

What this rule does. This rule finalizes the listing of the Texas hornshell (*Popenaias popeii*) as an endangered species. The species will be added to the List of Endangered and Threatened Wildlife at 50 CFR 17.11(h).

The basis for our action. Under the Endangered Species Act, we can determine that a species is an endangered or threatened species based on any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence.

The Texas hornshell is an endangered species based on impairment of water quality, loss of flowing water, and accumulation of fine sediment (Factor A), predation (Factor C), and barriers to host fish movement and the effects of climate change (Factor E).

Peer review and public comment. We prepared a species status assessment report (SSA report) for the Texas hornshell. The SSA report documents the results of the comprehensive biological status review for the Texas hornshell and provides an account of the species' overall viability through forecasting of the species' condition in the future (Service 2018, entire). We sought comments on the SSA report from independent specialists to ensure that our analysis was based on scientifically sound data, assumptions, and analyses. We received feedback from four scientists with expertise in freshwater mussel biology, ecology, and genetics. During the comment period for the proposed rule, we reached out to an additional five peer reviewers, and we received responses from three. We incorporated peer review suggestions and comments into the SSA report and the final listing rule. The SSA report and other materials relating to this proposal can be found at *http://www.regulations.gov* under Docket No. FWS–R2–ES–2016–0077.

Previous Federal Actions

On August 10, 2016, we published a proposed rule (81 FR 52796) to list the Texas hornshell as an endangered species under the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 *et seq.*). The publication of this proposed rule complied with a deadline established in a court-approved settlement agreement (Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)). That proposal had a 60-day comment period, ending October 11, 2016. We reopened the comment period for 30 days on May 30, 2017 (82 FR 24654), in order to hold two public hearings on the proposed rule. We then extended the final listing determination for 6 months due to substantial scientific disagreement about the species' status in Mexico and reopened the comment period for an additional 30 days (82 FR 37397). For a description of previous Federal actions concerning the Texas hornshell, please refer to the August 10, 2016, proposed listing rule (81 FR 52796).

Background

A thorough review of the taxonomy, life history, and ecology of Texas hornshell (*Popenaias popeii*) is presented in the SSA report (Service 2018, entire).

Species Description

The Texas hornshell is a medium-sized (3 to 4 inches long) freshwater mussel with a dark brown to green, elongate, laterally compressed shell (Howells *et al.* 1996, p. 93; Carman 2007, p. 2). The Texas hornshell was described by Lea (1857, p. 102) from the Devils River in Texas and Rio Salado in Mexico. Currently, the Texas hornshell is classified in the unionid subfamily Ambleminae (Campbell *et al.* 2005, pp. 140, 144) and is considered a valid taxon by the scientific community (Williams *et al.* 2017, p. 42).

Freshwater mussels, including the Texas hornshell, have a complex life history. Males release sperm into the water column, which are taken in by the female through the incurrent siphon (the tubular structure used to draw water into the body of the mussel). The sperm fertilize the eggs, which are held during maturation in an area of the gills called the marsupial chamber. The