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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0644; FRL-9913-35]

Zoxamide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of zoxamide in or on onion, bulb, subgroup 3-07A. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2013-0644, 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: Lois Rossi, 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-2013-0644 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2013-0644, 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 May 23, 2014 (79 FR 29731) (FRL-9910-29), 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 3F8164) by Gowan Company, P.O. Box 5569, Yuma, AZ 85366. The petition requested that 40 CFR 180.567 be amended by establishing tolerances for residues of the fungicide zoxamide, 3, 5-dichloro-*N*-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide, and its metabolites 3,5-dichloro-1,4-benzenedicarboxylic acid (RH-1455 and RH-141455) and 3,5-dichloro-4-hydroxymethylbenzoic acid (RH-1452 and RH-141452) calculated as the stoichiometric equivalent of zoxamide, in or on onion, bulb, subgroup 3-07A at 0.7 parts per million (ppm). That document referenced a summary of the petition prepared by Gowan Company, the registrant, which is available in the docket, *http://www.regulations.gov.* 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, EPA is establishing the tolerance as requested but revising the tolerance expressions for zoxamide. The reason for these changes are 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 tolerances established by this action. EPA's assessment of exposures and risks associated with zoxamide 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.

The toxicity data of zoxamide indicate that the primary target organ is the liver. Liver and thyroid weights increased along with liver histopathological change and increases in alkaline phosphatase. Systemic toxicity was not observed in the 28-day rat dermal toxicity study up to the limit dose (1,000 milligram/kilogram/day (mg/kg/day)). There are no concerns for neurotoxicity, immunotoxicity, developmental toxicity, or reproductive toxicity. There was no evidence of increased susceptibility (quantitative or qualitative) for the offspring in the reproduction studies or for fetuses following in utero exposure in the developmental studies. Zoxamide is classified as "not likely to be carcinogenic to humans" based on the lack of treatment-related tumors in acceptable/guideline carcinogenicity studies in rats and mice.

Specific information on the studies received and the nature of the adverse effects caused by zoxamide as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* in document Zoxamide. Health Risk Assessment for the Proposed New Use on Bulb Onions (Crop Subgroup 3-07A) in docket ID number EPA-HQ-OPP-2013-0644.

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 zoxamide used for human risk assessment is shown in the Table of this unit.

Table--Summary of Toxicological Doses and Endpoints for Zoxamide for Use in Human Health Risk Assessment

Exposure/Scenario	**Point of Departure and Uncertainty/Safety Factors**	**RfD, PAD, LOC for Risk Assessment**	**Study and Toxicological Effects**
Acute dietary (All Populations)	There is no indication of an adverse effect attributable to a single dose. Additionally, developmental, neurotoxicity, and reproductive effects were not observed in the database. An aRfD was not established.		
Chronic dietary (All populations)	NOAEL= 48 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.48 mg/kg/day cPAD = 0.48	Chronic Toxicity – Dog LOAEL = 255 mg/kg/day based on body weight changes, increases in liver and thyroid weights, and increases in alkaline

		mg/kg/day	phosphatase.
Dermal short-term (1 to 30 days)	There were no systemic or dermal toxicity findings in a 28-day dermal toxicity study in the rat up to the limit dose (1000 mg/kg/day) and there were no developmental, reproductive, or neurotoxicity concerns observed in the database.		
Inhalation short-term (1 to 30 days) and Inhalation Intermediate-term (1 to 6 months)	Inhalation (or oral) study NOAEL= 48 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Chronic Toxicity – Dog LOAEL = 255 mg/kg/day based on body weight changes, increases in liver and thyroid weights, and increases in alkaline phosphatase.

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to zoxamide, EPA considered exposure under the petitioned-for tolerances as well as all existing zoxamide tolerances in 40 CFR 180.567. EPA assessed dietary exposures from zoxamide in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for zoxamide; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues, 100% crop treated (CT), and default processing factors from the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 7.81 (except for grape, raisin and potato granules/flakes).

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

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for zoxamide in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of zoxamide. 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 Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of zoxamide for chronic exposures (non-cancer) are estimated to be 0.81 parts per billion (ppb) for surface water and 65.8 ppb for ground water, respectively.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 65.8 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Zoxamide is not registered for any specific use patterns that would result in residential exposure.

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

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the

FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicity studies include rat and rabbit prenatal developmental studies in addition to a reproduction and fertility effects study in rats; and the highest doses used in these studies are at or above the limit dose. In the developmental studies, maternal and fetal toxicity was not observed up to the limit dose (1,000 mg/kg/day). In the rat reproduction and fertility effects study, decreased body weights and body weight gains was observed in only the parental females at the highest dose tested. Therefore, EPA has concluded that there was no evidence of increased susceptibility (quantitative or qualitative) for the offspring in the reproduction studies or for fetuses following *in utero* exposure in the developmental studies.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for zoxamide is complete.

ii. There is no indication that zoxamide is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that zoxamide results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to zoxamide in drinking water. These assessments will not underestimate the exposure and risks posed by zoxamide.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, zoxamide is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to zoxamide from food and water will utilize 4.8% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for zoxamide.

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

Zoxamide is currently not registered for any use patterns that could result in short-term or intermediate-term residential exposure. Because short- or intermediate-term residential exposure and chronic dietary exposure have already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), further assessment of short- and intermediate-term risk is not necessary. EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for zoxamide.

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

5. *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 zoxamide residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with electron capture detection (GC/ECD) and GC with mass selective detection (GC/MSD)) 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.

Neither Codex, Canada, nor Mexico has not established a MRL for zoxamide in/on bulb onions, so there will be no need to harmonize the international standards.

C. Response to Comments

One comment was received in response to the notice of filing of Gowan Company's application. The commenter objected to the increase of chemical residues generally and expressed concerns about the carcinogenic effects of chemicals in general on humans. The Agency understands the commenter's concerns regarding toxic chemicals and their potential effects on humans. Pursuant to its authority under the FFDCA, and as discussed further in this

preamble, EPA conducted a comprehensive assessment of zoxamide, which included an assessment on the carcinogenic potential of zoxamide. Based on its assessment of the available data, the Agency has concluded that zoxamide is not likely to be a carcinogen and that there is a reasonable certainty that no harm will result from aggregate exposure to residues of zoxamide.

D. Revisions to Petitioned-For Tolerances

EPA is revising the tolerance expressions to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of Zoxamide not specifically mentioned; and

2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of zoxamide, 3, 5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide and its metabolites 3,5-dichloro-1,4-benzenedicarboxylic acid (RH-1455 and RH-141455) and 3,5-dichloro-4-hydroxymethylbenzoic acid (RH-1452 and RH-141452) calculated as the stoichiometric equivalent of zoxamide, in or on onion, bulb, subgroup 3-07A at 0.7 ppm.

In addition, EPA is revising the tolerance expressions for zoxamide contained in paragraphs (a)(1) and (a)(2), and in paragraph (b), removing the commodity ginseng, and reserving paragraph (b).

VI. Statutory and Executive Order Reviews

This final rule 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 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) (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 of 1995 (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: July 10, 2014.

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 180.567 is amended as follows:

a. Revise the introductory text of paragraph (a)(1);

b. Revise the introductory text of paragraph (a)(2);

c. Alphabetically add “Onion, bulb, subgroup 3-07A” to the table in paragraph (a)(2); and

d. Remove and reserve paragraph (b) to read as follows:

§ 180.567 Zoxamide; tolerance for residues.

(a) *General.* (1) Tolerances are established for residues of zoxamide including is metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only zoxamide (3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide).

* * * * *

(2) Tolerances are established for residues of zoxamide including is metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of zoxamide (3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide) and its metabolites 3,5-dichloro-1,4-

benzenedicarboxylic acid (RH-1455 and RH-141455) and 3,5-dichloro-4-hydroxymethylbenzoic acid (RH-1452 and RH-141452) calculated as the stoichiometric equivalent of zoxamide.

Commodity	Parts per million
Onion, bulb, subgroup 3-07A	0.7
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(b) *Section 18 emergency exemptions*. [Reserved]

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