TABLE 2—EPA-APPROVED JEFFERSON COUNTY REGULATIONS FOR KENTUCKY—Continued

Reg	Title/subject	EPA approval date	Federal Register notice	District effective date	Explanation
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[FR Doc. 2020–22128 Filed 10–21–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0281; FRL–10015–25]

Clofentezine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clofentezine in or on hop, dried cones. The Interregional Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 22, 2020. Objections and requests for hearings must be received on or before December 21, 2020 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–2019–0281, 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.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting 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–2019–0281 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 December 21, 2020. 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–2019–0281, 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 *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 *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 2, 2019 (84 FR 37818) (FRL–9996–78), 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 9E8752) by IR–4, Rutgers, the State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.446 be amended by establishing a tolerance for residues of the insecticide clofentezine, 3,6-bis(2-chlorophenyl)-1,2,4,5-tetrazine, in or on hop, dried cones at 6 parts per million (ppm). That document referenced a summary of the petition prepared by Makhteshim Agan of North America (d/b/a ADAMA), the

registrant, which is available in docket number EPA–HQ–OPP–2019–0281 at *http://www.regulations.gov.* One comment was received on the notice of filing. EPA's response to the comment is discussed in Unit IV.C.

In accordance with section 408(d)(4)(a)(i), which permits the Agency to finalize a tolerance that varies from that sought by the petition, and based upon review of the data supporting the petition, EPA has established a tolerance for residues of clofentezine on hop, dried cones at 7 ppm, rather than 6 ppm as requested. 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 clofentezine including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with clofentezine follows.

On May 29, 2019, EPA published in the **Federal Register** a final rule establishing tolerances for residues of clofentezine in or on guava based on the Agency's conclusion that aggregate exposure to clofentezine is safe for the general population, including infants and children. *See* 84 FR 24722 (FRL–9993–48) (EPA–HQ–OPP–2018–0275). EPA is incorporating the following portions of that document by reference here, as they have not changed in the Agency's current assessment: The cancer classification and conclusion that it is appropriate to assess cancer risk estimates using a linear low-dose extrapolation approach, and the conclusions about cumulative risk. Additionally, EPA is incorporating the assumptions for exposure assessment from the May 29, 2019, final rule, which have not changed except as explained in the following paragraphs.

EPA is incorporating most of the toxicological profile from the May 29, 2019, rule with the following amendments. Since that rule was issued, EPA has determined that a comparative thyroid assay (CTA) is needed. In the absence of the CTA, EPA has determined that the FQPA safety factor is retained (as a database uncertainty factor of 10X is applied for all exposure scenarios). Additionally, EPA has revised the dermal absorption factor for clofentezine from 10% to 2% based on additional data that have been submitted, reviewed and incorporated into the assessment. EPA is incorporating the points of departure from the June 14, 2016, **Federal Register** (81 FR 38604, FRL–9942–23) (EPA–HQ–OPP–2014–0749) which have not changed. However, the chronic reference dose and the chronic population adjusted dose have changed due to the inclusion of the database uncertainty factor. It should be noted that an acute dietary exposure and risk analysis was not performed since no toxicological effect was observed from acute (single) dose exposure via the dietary route that demonstrated evidence of toxicity attributable to a single dose for either the general population or for females 13–49 years of age.

EPA's dietary (food and drinking water) exposure assessments have been updated to include the additional exposure from the new use of clofentezine on hops. EPA conducted a partially refined chronic dietary (food and drinking water) exposure and risk assessment that incorporates average field trial residues, percent crop treated information that has been updated since the last assessment, and modelled drinking water estimated residues. The drinking water exposure is not impacted by the new use and thus has not changed since the last assessment from May 29, 2019.

An acute dietary endpoint (*i.e.,* single dose endpoint) for risk assessment was not identified in the toxicity database for the general U.S. population or any other subpopulation for clofentezine; therefore, an acute dietary exposure assessment was not conducted. Chronic dietary risks are below the Agency's level of concern (LOC) of 100% of the chronic population adjusted dose (cPAD); they are estimated to be 6% of the cPAD for all infants less than 1 year old, the group with the highest exposure.

There are no registered residential uses of clofentezine; therefore, the chronic aggregate risk assessment only includes dietary risk, which is not of concern. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the point of departure used to assess short- or intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary. Thus, EPA relies on the chronic dietary risk assessment for the aggregate risk assessment.

Applying the Q_1* of 3.76×10^{-2} (mg/kg/day)$^{-1}$ to the exposure value results in a cancer risk estimate of 1.7×10^{-6} for adults 20–49 years old, the most highly exposed adult population subgroup. EPA generally considers cancer risks (expressed as the probability of an increased cancer case) in the range of 1 in 1 million (or 1×10^{-6}) or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the logarithmic scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment. Although the clofentezine exposure assessment is partially refined, it retains significant conservatism in that field trial data and not market basket data is used in estimating exposure to existing uses as well as this new use. In addition, EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to clofentezine in drinking water. These assessments will not underestimate the exposure posed by clofentezine. Accordingly, EPA has concluded the aggregate cancer risk for all existing clofentezine uses and the new hops use in this action fall within the range of 1×10^{-6} and are thus negligible.

Therefore, 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 clofentezine residues. More detailed information can be found in the documents entitled, ''Clofentezine. Human Health Risk Assessment to Support a Section 3 New Use on Hops,'' in docket ID, EPA–HQ–OPP–2019–0281 and ''Clofentezine. Human-Health Risk Assessment to Support a Section 3 New Uses on Guava,'' dated May 13, 2019, in docket ID, EPA–HQ–OPP–2018–0275.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical method (high-performance liquid chromatography (HPLC)) is available to enforce the tolerances for clofentezine in plant commodities. 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 has not established MRLs for clofentezine on hop, dried cones.

C. Response to Comments

EPA received one comment requesting the EPA to establish specific pesticide tolerances for Cypermethrin, Pendimethalin and Chlorpyrifos for Crop Subgroup 4B (Leaf petioles subgroup) and Crop Subgroup 22B (Leaf petiole vegetable subgroup), as well as to name Celery and Celery Leaves (Fresh and dried) specifically as a represented commodity. This comment is unrelated to this docket and final rule and the comment does not meet the requirements for a pesticide tolerance petition that are set out in 40 CFR 180.7.

D. Revisions to Petitioned-for Tolerances

The Agency is establishing a tolerance for residues of clofentezine on hop, dried cones at 7 ppm, rather than 6 ppm as requested. The 2016 storage stability data showed a decline in storage stability, but the 2018 data did not. Therefore, only the five field trials from the 2018 data were used to establish the tolerance.

V. Conclusion

Therefore, tolerances are established for residues of clofentezine, 3,6-bis(2-chlorophenyl)-1,2,4,5-tetrazine, in or on Hop, dried cones at 7 parts per million (ppm).

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to petitions 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), nor is it considered a regulatory action under 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: October 16, 2020.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA amends 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 § 180.446, amend paragraph (a)(1) by adding to the table, in alphabetical order, the commodity ''Hop, dried cones'' to read as follows:

§ 180.446 Clofentezine; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Hop, dried cones	7
* * * * *	

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[FR Doc. 2020–23400 Filed 10–21–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0291; FRL–10012–67]

Diquat; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of diquat in or on pea and bean, dry and shelled, except soybean, subgroup 6C. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 22, 2020. Objections and requests for hearings must be received on or before December 21, 2020, 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–2017–0291, 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.

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FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, 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?

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

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- *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 September 15, 2017 (82 FR 43354) (FRL–9965–43), 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 7E8571) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide diquat in or on pea and bean, dry and shelled, except soybean, subgroup 6C at 0.08 parts per million (ppm). In the **Federal Register** of May 7, 2018 (83 FR 20008) (FRL–9976–34), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing a correction to the pesticide petition (PP 7E8571) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The corrected petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide diquat in or on pea and bean, dry and shelled, except soybean, subgroup 6C at 0.9 parts per million (ppm). Both documents referenced a summary of the petition prepared by Syngenta, 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.