



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2019-0626; EPA-HQ-OPP-2020-0082; and EPA-HQ-OPP-2020-0345; FRL-10022-28]

### Difenoconazole; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of difenoconazole in or on olive; olive, with pit; pepper, black; and persimmon, Japanese. Syngenta Crop Protection, LLC. and the American Spice Trade Association, Inc. 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 dockets for these actions, identified by docket identification (ID) numbers EPA-HQ-OPP-2019-0626, EPA-HQ-OPP-2020-0082, and EPA-HQ-OPP-2020-0345, are 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, 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](mailto: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 Publishing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](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(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-2019-0626, EPA-HQ-OPP-2020-0082, and/or EPA-HQ-OPP-2020-0345 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-2019-0626, EPA-HQ-OPP-2020-0082, and/or EPA-HQ-OPP-2020-0345, 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 February 10, 2020 (85 FR 7499) (FRL-10004-54) and May 29, 2020 (85 FR 32338) (FRL-10009-84), EPA issued documents pursuant to FFDC section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 9E8793 and PP 9E8814) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419-8300. In the *Federal*

*Register* of September 10, 2020 (85 FR 55810) (FRL-10013-78), EPA issued documents pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E8834) by the American Spice Trade Association, Inc., 1101 17th St. NW, Suite 700, Washington, DC 20036. The petitions requested that 40 CFR 180.475 be amended by establishing tolerances for residues of the fungicide difenoconazole, in or on persimmon, Japanese at 0.7 parts per million (ppm) (9E8793); olive (including oil) at 2 ppm (9E8814); and pepper, black at 0.1 ppm (0E8834). Those documents referenced summaries of the petitions prepared by Syngenta Crop Protection, LLC, and the American Spice Trade Association, Inc., the petitioners, which are available in the dockets for these actions, EPA-HQ-OPP-2019-0626, EPA-HQ-OPP-2020-0082, and EPA-HQ-OPP-2020-0345 at <http://www.regulations.gov>. Two comments were received related to the import tolerance on black pepper. EPA's responses to these comments are discussed in Unit IV.B.

FFDCA section 408(d)(4)(A)(i) permits the Agency to finalize a tolerance that varies from that sought by the petition. Based upon review of the data supporting the petition, EPA has corrected the commodity definition of “olive (including oil)” to “olive” and “olive, with pit”, and the tolerance level set with “olive” varies from that sought by the petition. The reasons for these changes are explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

#### *A. Statutory Background*

Section 408(b)(2)(A)(i) of the 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 it 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), 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 difenoconazole and to make a determination on aggregate exposure for difenoconazole, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with difenoconazole follows.

#### *B. Difenoconazole Aggregate Risk Assessment*

Information on aggregate risk from difenoconazole is found in the “Difenoconazole. Human Health Risk Assessment for the Establishment of Tolerances with No U.S. Registrations in/on Japanese Persimmon, Olive, and Black Pepper” in docket ID numbers EPA-HQ-OPP-2019-0626, EPA-HQ-OPP-2020-0082, and EPA-HQ-OPP-2020-0345.

#### *C. 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 liver is the target organ in mice and rats; however, effects occur in mice at lower doses and with higher severity than in rats. Furthermore, difenoconazole is classified as “Suggestive Evidence of Carcinogenic Potential” based on liver tumors (adenomas) in male and female mice. Apart from the liver effects in rodents, chronic exposure in dogs leads to lenticular cataracts.

In dermal studies, no systemic toxicity was detected in rats or male rabbits, while in female rabbits, liver effects occurred at the limit dose. Skin hyperkeratosis was detected in rats at the exposure site after repeated exposure to the limit dose. Slight skin irritation was detected after an acute single dose (Toxicity Category IV). Difenoconazole is not a skin sensitizer.

No quantitative susceptibility in fetus or offspring was seen in the database.

Neurotoxicity was detected in an acute neurotoxicity battery study (decreased fore-limb strength in males only), but not in a subchronic neurotoxicity battery study with difenoconazole.

In an immunotoxicity study in mice, decreased mean immunoglobulin M levels were detected at dose levels  $\geq 177$  mg/kg/day. There is no other indication of immunotoxicity in the difenoconazole database.

Specific information on the studies received and the nature of the adverse effects caused by difenoconazole 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 "Difenoconazole. Human Health Risk Assessment for the Establishment of Tolerances with No U.S. Registrations in/on Japanese Persimmon, Olive, and Black Pepper." at page 20 in docket ID numbers EPA-HQ-OPP-2019-0626, EPA-HQ-OPP-2020-0082, and EPA-HQ-OPP-2020-0345.

#### *D. 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 difenoconazole used for the human health risk assessment is shown in the risk assessment posted to the dockets.

#### *E. Exposure Assessment*

EPA's chronic dietary (food and drinking water) exposure assessments have been updated to include the additional exposure from the import tolerances of difenoconazole on olive; olive, with pit; pepper, black; and persimmon, Japanese. The exposure assessment used tolerance-level residues and default processing factors for all processed commodities. The percent crop treated numbers used for the chronic dietary assessment vary from what was used in the previous assessment and are available in the human health risk assessment posted to the dockets.

Drinking water exposures are not impacted by the import tolerances on olive; olive, with pit; pepper, black; and persimmon, Japanese. The estimated drinking water concentrations (EDWCs) of total toxic residues (TTR) of difenoconazole can be found in the human health risk assessment.

Acute dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the acute population adjusted dose (aPAD): they are 53% of the aPAD for all infants less than 1-year old, the population subgroup with the highest exposure estimate. Chronic dietary risks are below the Agency's level of concern of 100% of the chronic population adjusted dose (cPAD): they are 38% of the cPAD for all infants less than 1-year old, the population subgroup with the highest exposure estimate.

For the aggregate risk assessment, exposures to difenoconazole in food and drinking water are combined with residential exposures for the relevant exposure duration period. Because acute, intermediate-term, or long-term residential exposures are not expected, aggregate acute and chronic risk is equivalent to the dietary risks, which are below EPA's level of concern. Moreover, a separate cancer dietary risk assessment was not required since the approach used for chronic dietary exposure assessment was found to be adequately protective

of all chronic toxicity, including carcinogenicity, that could result from exposure to difenoconazole. Short-term aggregate risk, which combines chronic dietary exposure with the expected residential handler inhalation exposures from applications to gardens/ornamentals via hose-end sprayer, yields a margin of exposure (MOE) of 5,000, which is not of concern because it exceeds EPA's level of concern (MOEs less than or equal to 100). Previously the residential exposure assessments for difenoconazole included a dermal endpoint; however, that endpoint is no longer relevant because the database does not show systemic effects after exposure via the dermal route at doses that would be relevant to risk assessment.

*F. 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to difenoconazole and any other substances, although EPA has previously concluded that there are no conclusive data that difenoconazole shares a common mechanism of toxicity with other conazole pesticides. Although the conazole fungicides (triazoles) produce 1,2,4 triazole and its acid-conjugated metabolites (triazolylalanine and triazolylacetic acid), 1,2,4 triazole and its acid-conjugated metabolites do not contribute to the toxicity of the parent conazole fungicides (triazoles). A separate aggregate risk assessment was conducted for 1,2,4 triazole and the conjugated triazole metabolites "Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address the Establishment of a Difenoconazole Tolerances with No U.S. Registration for Imported Olive and Black Pepper and to include updated Estimated Drinking Water Concentrations; DP458929", dated September, 14, 2020 and it can be found at <https://www.regulations.gov> at docket ID numbers EPA-HQ-OPP-2019-0626, EPA-HQ-OPP-2020-0082, and EPA-HQ-OPP-2020-0345. These new tolerances of difenoconazole considered



with existing uses of triazole compounds do not result in a risk of concern for 1,2,4-triazole and the conjugated metabolites. Difenoconazole does not appear to produce any other toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that difenoconazole has 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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

#### *G. Safety Factor for Infants and Children*

There were no changes since the last risk assessment regarding prenatal and postnatal sensitivity. The FQPA Safety Factor (SF) is still reduced to 1X; however, the safety factor reduction rationale section has been modified to:

i. The toxicity database for difenoconazole is sufficient for a full hazard evaluation and is considered adequate to evaluate risks to infants and children.

ii. The only study that showed neurotoxicity is used as the point of departure for risk assessment and the effect is well characterized with a clear NOAEL and LOAEL. There are signs of neurotoxicity in the acute neurotoxicity battery study (decreased fore-limb strength in males), but not in the subchronic neurotoxicity battery study, nor in any other studies in the database. This risk assessment is protective of the observed neurotoxicity effects because they are used to establish the point of departure (POD) for the acute oral assessment.

iii. There is no evidence that difenoconazole results in increased quantitative susceptibility in in utero rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. No fetal effects were detected in rats. Fetal effects in rabbits and pup effects in rats occurred at the same doses as maternal effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on tolerance-level residues and 100% CT for the acute assessment while the chronic assessment assumed tolerance-level residues, the

available empirical or HED's 2018 Default Processing Factors, and average percent crop treated (PCT) information for some commodities. These assumptions will not underestimate dietary exposure to difenoconazole. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to difenoconazole in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children. These assessments will not underestimate the exposure and risks posed by difenoconazole.

#### *H. Determination of Safety*

Therefore, based on the risk assessments and information described above, 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 difenoconazole residues. More detailed information about the Agency's analysis can be found in "Difenoconazole. Human Health Risk Assessment for the Establishment of Tolerances with No U.S. Registrations in/on Japanese Persimmon, Olive, and Black Pepper." dated March 23, 2021 in docket ID numbers EPA-HQ-OPP-2019-0626, EPA-HQ-OPP-2020-0082, and EPA-HQ-OPP-2020-0345.

### **IV. Other Considerations**

#### *A. Analytical Enforcement Methodology*

An adequate tolerance enforcement method, gas chromatography with nitrogen-phosphorus detection (GC/NPD) method AG-575B, is available for the determination of residues of difenoconazole in/on plant commodities. An adequate enforcement method, gas chromatography with mass spectrometry detection (GC/MSD) method AG-676A, is also available for the determination of residues of difenoconazole per se in/on canola and barley commodities. A confirmatory method, GC/MSD method AG-676, is also available.

An adequate tolerance enforcement method, Method REM 147.07b, is available for livestock commodities. The method determines residues of difenoconazole and CGA-205375 in livestock commodities by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). Adequate confirmatory methods, Method AG-544A and Method REM 147.06, are

available for the determination of residues of difenoconazole and CGA-205375, respectively, in livestock 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).

Codex has established MRLs for residues of difenoconazole in/on olive commodities using the same data submitted in support of the U.S. tolerances with no U.S. registrations. Codex stipulates that residues should be expressed on a whole-fruit basis. The U.S. recommended tolerance level for olive, with pit (2 ppm) is harmonized with the Codex MRL for residues of difenoconazole in/on table olives (2 ppm). In addition, a tolerance is being set at 3 ppm on olive, defined in OCSPP Guideline 860.1000 as fruits after removal of the stems and pits, which is the commodity analyzed for enforcement.

Codex has not established MRLs for residues of difenoconazole in/on pepper, black. MRLs for of difenoconazole in/on peppercorn (black, green and white) at 0.3 ppm have been established in the European Union (EU). Discussion on why EPA did not harmonize with that tolerance is covered in the Responses to Comments section in Unit IV.B.

A Codex MRL for difenoconazole has been established at 4 ppm in/on pome fruit for post-harvest use. Codex includes Japanese persimmon in the pome fruit group. The tolerance being set at this time is based on late-season foliar use rather than post-harvest use; therefore, the tolerances are not the same and harmonization is not possible.

#### *C. Responses to Comments*

EPA received one comment on the docket for difenoconazole in/on black pepper (EPA-HQ-OPP-2020-0345) opposing pesticide residues in food, although no substantive information was provided for EPA to take into consideration in its safety assessment. The commenter generally expressed concern about the potential for exposure to difenoconazole to be carcinogenic. EPA has evaluated the available data on carcinogenicity and exposure and determined that aggregate exposure to difenoconazole will not cause a cancer risk. In addition, the commenter expressed concern about fluoride in chemicals; however, difenoconazole molecules do not contain any fluoride. The FFDCFA authorizes EPA to establish tolerances that permit certain levels of pesticide residues in or on food when the Agency can determine that such residues are safe. EPA has made that determination for the tolerances subject to this action, and the commenter provided no information relevant to that conclusion.

A comment from the government of the People's Republic of China (P.R. China) was received through the World Trade Organization comment process. This comment has been posted to the docket for difenoconazole in/on black pepper (EPA-HQ-OPP-2020-0345). It requests that EPA set the tolerance on pepper, black at 0.3 ppm to match the current EU tolerance. EPA consulted with the registrant regarding the possibility to harmonize the tolerance with the EU limit standards. The registrant, through its consultant, recommended against harmonizing the tolerance with the current EU MRL for residues of difenoconazole in/on black pepper (0.3 ppm) based on the following rationale. According to the registrant, the current EU MRL is not based on supporting data and is of unknown origin. It is expected that any EU MRL not supported by data, such as in this case, would be evaluated during the Article 12 EU MRL Review Process. If no supporting data are submitted during the review process, the EU MRL would be reduced to 0.01 ppm by 2026. The Agency notes that it is also possible that the same data that support the tolerance with no U.S. registration established in this action (0.1 ppm) could be submitted as supporting data to the EU and/or Codex, in which case future harmonization is possible. In addition, the P.R. China comment requests that EPA share the data

and reports supporting the tolerance. More detailed information about the Agency's analysis can be found in the risk assessments posted to docket ID number EPA-HQ-OPP-2020-0345.

#### *D. Revisions to Petitioned-For Tolerances*

Although the summary of the petition cited in Unit II of this preamble indicated a request for a tolerance on "olive," the actual petition sought a tolerance for "olive (including oil)." The originally requested tolerance of 2 ppm in/on "olive (including oil)" has been revised to 2 ppm in/on "olive, with pit" and 3 ppm in/on "olive." The commodity definition commonly used in the 40 CFR is "olive," meaning fruits after removal of the pits, and the terminology "olive, with pit" is descriptive of the Codex residue expression. Use of both terms allows harmonization with Codex while also maintaining the way that the commodity is analyzed for enforcement in the United States.

#### **V. Conclusion**

Therefore, tolerances are established for residues of difenoconazole, in or on olive at 3 ppm; olive, with pit at 2 ppm; pepper, black at 0.1 ppm; and persimmon, Japanese at 0.7 ppm.

#### **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCFA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCa section 408(d), such as the 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: May 20, 2021.

**Marietta Echeverria,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

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

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

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

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

2. In § 180.475, amend paragraph (a)(1) by adding alphabetically to the table entries for “Olive<sup>1</sup>”; “Olive, with pit<sup>1</sup>”; “Pepper, black<sup>1</sup>” and “Persimmon, Japanese<sup>1</sup>” to read as follows:

**§ 180.475 Difenoconazole; tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

Commodity	Parts per million
* * *	* * *
Olive <sup>1</sup>	3
Olive, with pit <sup>1</sup>	2
* * *	* * *
Pepper, black <sup>1</sup>	0.1
Persimmon, Japanese <sup>1</sup>	0.7
* * *	* * *

<sup>1</sup>There are no U.S. registrations for these commodities.

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