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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2017-0531; FRL-9984-63]**

# Prothioconazole; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of prothioconazole in or on rapeseed subgroup 20A. Bayer CropScience 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-2017-0531, 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 Goodis, 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-2017-0531 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-2017-0531, 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 27, 2018 (83 FR 8408) (FRL-9972-17), 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 7F8596) by Bayer CropScience, LP2, T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.626 be amended by establishing tolerances for residues of the fungicide prothioconazole, 2-[2-(1-chlorocylcopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, and its desthio metabolite in or on rapeseed subgroup, Crop subgroup 20A at 0.15 parts per million (ppm). That document referenced a summary of the petition prepared by Bayer CropScience, 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 requested by the petitioner as Rapeseed subgroup 20A, to be consistent with the commodity terminology commonly used by the Agency.

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

Prothioconazole degrades into different compounds in different matrices, with prothioconazole-desthio (desthio) being the metabolite and degradate of concern. The target organs of prothioconazole and the desthio metabolite include the liver, kidney, bladder, thyroid and blood. In addition, the chronic studies showed body weight and food consumption changes, and toxicity to the lymphatic and gastrointestinal systems.

Developmental studies show that prothioconazole and its metabolites produce adverse effects including malformations in the conceptus at levels equal to or below maternally toxic levels, particularly those studies conducted using prothioconazole-desthio. Reproduction studies in the rat with prothioconazole and prothioconazole-desthio suggest that these chemicals do not adversely affect reproductive parameters or the offspring except at parentally toxic dose levels. Acute and subchronic neurotoxicity studies, as well as a developmental neurotoxicity study, raise no neurotoxicity concerns. Immunotoxicity data show that prothioconazole is not an immunotoxicant.

The available carcinogenicity and/or chronic studies in the mouse and rat, using both prothioconazole and prothioconazole-desthio, show no increase in tumor incidence and EPA has concluded that prothioconazole and its metabolites are not carcinogenic.

Specific information on the studies received and the nature of the adverse effects caused by prothioconazole 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 the document titled "Prothioconazole: Human Health Risk Assessment for a Proposed Tolerance on Cottonseed Subgroup 20C, a Tolerance Amendment on Sugar Beet Roots, and New Use Requests for Cotton, Sugar Beet, Soybean, and Dried Shelled Pea and Bean" on page 32 in docket ID number EPA-HQ-OPP-2015-0722.

*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.html*.

A summary of the toxicological endpoints for prothioconazole used for human risk assessment is discussed in Unit III.B of the final rule published in the **Federal Register** of November 10, 2016 (81 FR 78917) (FRL-9953-71).

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to prothioconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing prothioconazole tolerances in 40 CFR 180.626. EPA assessed dietary exposures from prothioconazole 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.

Such effects were identified for prothioconazole for females 13-50 years old. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA; 2003-2008). As to residue levels in food, EPA assumed tolerance-level values for the proposed new uses and existing tolerances on berries, cucurbit vegetables, cottonseed, sugar beet roots, and sunflower subgroup 20B, average field trial residues for all other commodities, and DEEM default and empirical processing factors. 100 percent crop treated (PCT) was assumed for all proposed and established commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA; 2003-2008. As to residue levels in food, EPA assumed tolerance-level values for the proposed new uses and existing tolerances on

berries, cucurbit vegetables, cottonseed, sugar beet roots, and sunflower subgroup 20B, average field trial residues for all other commodities, and DEEM default and empirical processing factors. 100 PCT was assumed for all proposed and established commodities.

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

iv. *Anticipated residue information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

The Agency did not use percent crop treated estimates for the dietary assessment.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for prothioconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of prothioconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

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 prothioconazole for acute exposures are estimated to be 109 parts per billion (ppb) for surface water and 132 ppb for ground water and for chronic exposures are estimated to be 97 ppb for surface water and 128 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 132 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 128 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). Prothioconazole 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."

Prothioconazole is a member of the conazole class of pesticides containing the 1,2,4-triazole moiety. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events in mammals (EPA, 2002). In the case of conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce

developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no conclusive data to indicate that conazoles share common mechanisms of toxicity, and EPA is not following a cumulative risk approach for this the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's Web site at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

Prothioconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazolylalanine and triazolylacetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including prothioconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). The Agency retained a 3X for the LOAEL to NOAEL safety factor when the reproduction study was used. In addition, the Agency retained a 10X for the lack of studies including a developmental neurotoxicity (DNT) study. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at *http://www.regulations.gov*, Docket Identification (ID) Number EPA-HQ-OPP-2005-0497.

An updated dietary exposure and risk analysis for the common triazole metabolites 1,2,4-triazole (T), triazolylalanine (TA), triazolylacetic acid (TAA), and triazolylpyruvic acid (TP) was completed on July 18, 2017, in association with registration requests for the triazole fungicides difenoconazole and tetraconazole. That analysis concluded that risk estimates were below the Agency's level of concern for all population groups. The proposed new uses of prothioconazole are not expected to significantly increase the dietary exposure estimates for free triazole or conjugated triazoles; thus, the Agency is relying on the July 18, 2017 analysis to support its conclusion that the exposure to the triazole metabolite, including exposures from the use of prothioconazole on the commodities in subgroup 20A, does not present risks of concern. This assessment may be found on *http://www.regulations.gov* by searching for the following title and docket number: "Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address New Section 3 Registrations for Use of Difenoconazole and Tetraconazole." (located in docket ID number EPA-HQ-OPP-2016-0254).

*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*. There are adequate data in the prothioconazole/prothioconazole-desthio toxicological database to characterize the potential

for pre-natal or post-natal risks to infants and children: two-generation reproduction studies in rats; developmental studies in rats and rabbits; and a DNT study in rats. The effects seen in these studies suggest that offspring are more susceptible. Offspring adverse effects were seen at levels below the LOAELs for maternal toxicity and, in general, were of comparable or greater severity compared to the effects observed in adults. However, clear NOAELs are established for offspring and fetal effects. The most sensitive effects (malformed vertebral body and ribs, anthrogryposis, and other multiple malformations) seen in the fetuses of a rabbit developmental study are established as the toxicity endpoints with a POD of 2 mg/kg/day. This POD is protective all fetal and offspring effects seen in the developmental toxicity and developmental neurotoxicity 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 prothioconazole is complete.

ii. No neurotoxicity was seen in acute and subchronic neurotoxicity studies and other studies with prothioconazole or prothioconazole-desthio. Although offspring neurotoxicity was found, characterized by peripheral nerve lesions in the developmental neurotoxicity study on prothioconazole-desthio, the increase was seen only in the highest dose group at 105 mg/kg/day. Further, a NOAEL was established for the peripheral nerve lesions and all of the PODs used in the risk assessment were protective of this finding.

iii. Evidence of quantitative and qualitative susceptibility of offspring were observed in the developmental studies. However, basing the POD on the offspring in the most sensitive of these studies provides the needed protection of offspring.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues for the proposed new uses and existing tolerances on berries, cucurbit vegetables, cottonseed, sugar beet roots, and sunflower subgroup 20B, average field trial residue levels for the remaining uses, and DEEM default and empirical processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to prothioconazole in drinking water. These assessments will not underestimate the exposure and risks posed by prothioconazole.

*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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to prothioconazole will occupy 40% of the aPAD for females 13-49 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to prothioconazole from food and water will utilize 77% of the cPAD for all infants less than 1-year-old the population group receiving the greatest exposure. There are no residential uses for prothioconazole. 3. *Short- and Intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account

short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Both short- and intermediate-term adverse effects were identified; however, prothioconazole is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. 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 POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for prothioconazole.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, prothioconazole 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 prothioconazole residues.

**IV. Other Considerations**

*A. Analytical Enforcement Methodology*

Adequate liquid chromatography with tandem mass spectrometry (LC/MS/MS) methods are available for enforcing prothioconazole tolerances in crop and 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). 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 established MRL for prothioconazole in or on rapeseed at 0.1 ppm. The MRL is different than the tolerance established for prothioconazole in the United States. The residues of concern are not harmonized between the US and Codex, since Codex only includes prothioconazole-desthio, whereas the U.S. includes prothioconazole parent as well as prothioconazole-desthio, and harmonization may result in tolerance exceedances from use in accordance with the label.

*C. Response to Comments*

Two comments were submitted in response to the Notice of Filing for tolerance expansion. One comment (Comment A) requested that EPA deny this tolerance petition based on the radioactivity of prothioconazole and its role as a developmental toxicant. The other comment (Comment B) requested that EPA deny this petition based on the persistence of prothioconazole in the digestive system and effects on the liver, kidney, and thyroid.

*In response to Comment A*, prothioconazole is not radioactive. In some studies, the prothioconazole is radio-labeled in order to track how the chemical moves through the body of an organism after consumption, but prothioconazole itself is not radioactive. Although evidence of quantitative and qualitative susceptibility of offspring was observed in the developmental studies in rats and rabbits including the developmental neurotoxicity study; points of departure (PODs) are based on the most sensitive endpoints in the fetuses of the rabbit developmental study; therefore, the risk assessment is protective of any developmental effects of this chemical.

*In response to Comment B*, the effect of persistence and/or bioaccumulation on the toxicity of a chemical is evaluated in the repeated dose studies. For example, the severity of adverse effects and the relative dose levels at which they occur can be compared in a subchronic study versus a chronic study. In the case of prothioconazole, a comparison of the subchronic (90-day) study in the rat with the chronic (2-year) studies in the rat, using data on both the parent compound and the desthio metabolite, shows there is no basis for concern for potential persistence, because the PODs are not significantly different in the two time-periods. The same is true among the generations in the reproduction and fertility study where the subsequent generations are not shown to be more sensitive to prothioconazole toxicity than the first generation. The rat studies are referred to here because the metabolism studies which would show persistence and/or bioaccumulation were conducted in the rat. If a basis for concern were demonstrated in the toxicity database the PODs, which are based on the most sensitive endpoints, would be protective of this effect. The target organs of prothioconazole and the desthio metabolite include the liver, kidney, bladder, thyroid and blood. The risk assessment uses the most sensitive endpoints to set PODs, so the assessment is protective of all effects to the liver, kidney, and thyroid.

**V. Conclusion**

Therefore, tolerances are established for residues of prothioconazole, 2-[2-(1-chlorocylcopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, and its desthio metabolite, in or on rapeseed subgroup 20A at 0.15 ppm. In addition, EPA is removing the existing tolerance for "rapeseed, seed" as it is superseded by the new tolerance for subgroup 20A.

**VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), 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 11, 2018.

Daniel Rosenblatt,
*Acting 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 § 180.626,

a. Remove the entry for "Rapeseed, seed" from the table in paragraph (a)(1).

b. Add alphabetically "Rapeseed subgroup 20A" to the table in paragraph (a)(1).

The addition reads as follows:

**§ 180.626 Prothioconazole; tolerances for residues.**

(a) * * *

(1) * * *

| Commodity | Parts per million |
|---|---|
| * * * * * * * | |
| Rapeseed subgroup 20A | 0.15 |
| * * * * * * * | |

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[FR Doc. 2018-22857 Filed: 10/18/2018 8:45 am; Publication Date: 10/19/2018]