ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0301; FRL–9321–01–OCSPP]

Simazine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of simazine in or on citrus fruits (crop group 10–10), pome fruits (crop group 11–10), stone fruits (crop group 12–12), and tree nuts (crop group 14–12) and amends the tolerance for residues in or on almond hulls. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 22, 2022. Objections and requests for hearings must be received on or before February 21, 2023, 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–2012–0301, is available at *https://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 the Public Reading Room and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Registration Division (Mail Code 7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; 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 Office of the **Federal Register**'s e-CFR site at *https://www.ecfr.gov/current/title-40.*

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–2012–0301 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 February 21, 2023. 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–2012–0301, by one of the following methods:

- *Federal eRulemaking Portal: https://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/.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 25, 2012 (77 FR 43562) (FRL–9353–6), 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 (PP2F8006) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR 180.213 be amended by establishing tolerances for residues of the herbicide simazine, in or on citrus fruits (crop group 10), pome fruits (crop group 11), stone fruits (crop group 12), and tree nuts (crop group 14, except almond hull) at 0.05, 0.03, 0.1, and 0.07 parts per million (ppm), respectively, and amending the tolerance for residues in or on almond hulls to 3 ppm. In addition, the petition requested the removal of tolerances for apple, hazelnut, peach, pecan, plum, and walnut at 0.20 ppm, and for almond, cherry, grapefruit, lemon, macadamia nut, orange, and pear at 0.25 ppm, upon establishment of the new tolerances. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA determined that the residue data for the citrus fruit crop group support a tolerance level of 0.04 ppm, not 0.05 ppm as proposed by the registrant, and a level of 0.05 ppm not 0.07 ppm is being established for crop group 14–12. The reasons for these changes are explained in Unit IV.C.

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

Simazine and Its Chlorinated Metabolites

Simazine is a chlorotriazine herbicide that is similar in structure to atrazine and propazine. These chlorotriazine herbicides, along with their common chlorinated metabolites, have been determined by the EPA to share a common neuroendocrine mechanism of toxicity and constitute the triazine common mechanism group (CMG). Because of the similar structures and metabolites among these three pesticides, they are also assumed to be of equal potency for neuroendocrine effects. Therefore, the more robust toxicological database for atrazine has been used to characterize neuroendocrine toxicity, and for endpoint selection, for all of these compounds. The neuroendocrine endpoint chosen for these chemicals is attenuation of the luteinizing hormone (LH) surge after 4 days of exposure, the most sensitive effect which protects for other downstream adverse endocrine related toxicological effects and potential effects on non-endocrine systems.

EPA has concluded that the available data do not identify a unique quantitative susceptibility in the developing organism. None of the available studies with atrazine evaluating rats exposed during gestation, lactation, or in the peri-pubertal periods have shown effects at doses lower than those eliciting the LH surge attenuation in adult female rats after 4 days of exposure. Additionally, the POD, based upon attenuation of the LH surge, is protective against adverse reproductive/developmental outcomes such as delays in onset of puberty, disruption of ovarian cyclicity and inhibition of prolactin release. For other potential adverse outcomes, the effects occurred at dose levels approximately one order of magnitude or higher than the no observed adverse effect level (NOAEL)/lowest observed adverse effect level (LOAEL) for LH surge attenuation. As simazine has been classified as ''Not likely to be carcinogenic to humans,'' cancer risk is not a concern and a quantitative cancer risk assessment was not conducted.

Hydroxysimazine and Its Hydroxylated Metabolites

In addition to the chlorotriazine metabolites, simazine also has an analogous series of metabolites, known as the hydroxy metabolites, in which the chlorine is replaced by a hydroxy moiety. While the hydroxy metabolites are all considered to be of equal toxicity to each other, these compounds exhibit different toxicological properties than the chlorinated metabolites, and risk estimates are therefore quantified separately using an endpoint and POD based on hydroxyatrazine. The available data indicate that the kidney is the primary target organ for hydroxysimazine and its metabolites.

There is no evidence for increased susceptibility in the young following *in utero* exposure or carcinogenicity in the available data for hydroxysimazine and its metabolites.

A complete discussion of the toxicological profile for simazine and specific information on the studies received and the nature of the adverse effects caused by simazine 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 *https://www.regulations.gov* in document titled Simazine. ''Human Health Risk Assessment for Registration Review and to Support the Registration of Proposed Uses on Citrus Fruit (Crop Group 10–10), Pome Fruit (Crop Group 11–10), Stone Fruit (Crop Group 12–12), Tree Nuts (Crop Group 14–12), and Tolerance Amendment for Almond Hulls'' in docket ID number EPA–HQ–OPP–2013–0251.

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 *https://www.epa.gov/science-and-assessing-pesticide-risks.*

The toxicological endpoints for simazine used for human risk assessment and an explanation for how the Agency calculated those PODs can be found in the Simazine Human Health Risk Assessment, sections 4.6–4.84, 5.4.2.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to simazine, EPA considered exposure under the petitioned-for tolerances as well as all existing simazine tolerances in 40 CFR 180.213. EPA assessed dietary exposures from simazine and its chlorinated metabolites separately from exposures to hydroxysimazine and the hydroxylated metabolites due to the different toxicities observed for the compounds. The assessments of residues of these substances in food were conducted 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 simazine and its chlorinated metabolites but not for hydroxysimazine and the hydroxylated metabolites.

In estimating acute dietary exposure to residues of simazine and its chlorinated metabolites, EPA used 2003–2008 food consumption information from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to anticipated residue levels in food, the acute assessment was refined using field trial data, default processing factors, and assumed that 100% of the proposed and registered commodities were treated.

ii. *Four-day/Chronic exposure.* Typically, chronic exposure is assessed, but for simazine and its chlorinated metabolites a four-day exposure duration is appropriate since the toxicological effect (attenuation of the LH surge) occurs after four days of exposure and is protective of exposures of longer durations. In conducting the four-day dietary exposure assessment, EPA used the food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to anticipated residue levels in food, four-day dietary assessments were partially refined using field trial studies, default processing factors, and assumed that 100% of the proposed and registered commodities were treated.

In conducting the chronic dietary exposure assessment for hydroxysimazine and its hydroxylated metabolites, EPA used the food consumption data from USDA's NHANES/WWEIA. As to anticipated residue levels in food, the chronic dietary assessment for hydroxysimazine and its hydroxylated metabolites was refined using residue levels from metabolism studies, default processing factors, and average percent crop treated data.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that neither simazine nor hydroxysimazine poses a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) 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.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The acute and four-day steady state dietary assessment for simazine assumed 100% crop treated for all registered and requested crops. The chronic (background) assessments for simazine and its chlorinated metabolites and for hydroxysimazine and its hydroxylated metabolites incorporated average percent crop treated estimates as follows: almond: 10%; apple: 10%; avocado: 5%; blueberry: 15%; caneberry: 45%; cherry: 5%; field corn: 5%; sweet corn: 2.5%; grapefruit: 20%; grape: 25%; hazelnut: 35%; lemon: 10%; nectarine: 5%; olive: 15%; orange: 25%; peach: 15%; pear: 10%; pecan: 5%; plums/prunes: 2.5%; strawberry: 5%; tangerine: 5%; and walnut: 20%. 100% CT was assumed for the remaining commodities.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figures for each existing use are derived by combining available public and private market survey data for that use, averaging across all observations, and rounding up to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which simazine may be applied in a particular area.

2. *Dietary exposure from drinking water.* Extensive and robust surface and groundwater monitoring data are available for triazines (including simazine) and were included in the drinking water assessment. The Agency also used screening-level water exposure models in the dietary exposure analysis and risk assessment for simazine in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of simazine. Estimated drinking water concentrations (EDWCs) are based on total triazine

residues, which include atrazine, propazine, and simazine, and all the related metabolites, and are not just based on simazine and its chlorinated and hydroxylated metabolites, these EDWCs may be considered high-end estimates for the simazine risk assessment. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-risk-assessment.*

Based on the Pesticide Root Zone Model Ground Water (PRZM GW), the surface water concentration calculator (SWCC), and FQPA Index Reservoir Screening Tool (FIRST) modeling, the EDWCs of simazine are estimated to be 265–610 parts per billion (ppb) for surface water and 92.6–100 ppb for groundwater for acute exposure; 265–585 ppb for surface water and 92.6–100 ppb for groundwater for the 4-day exposures; and 76–104 ppb for surface water and 5.11–7.33 ppb for groundwater for chronic exposures for non-cancer assessments.

A drinking water level of comparison (DWLOC) approach to aggregate risk was used to calculate the amount of exposure available in the total 'risk cup' for drinking water after accounting for any exposures from food and/or residential use. The DWLOCs are then compared to the EDWCs. If the DWLOCs are greater than the EDWCs, there is no aggregate risk of concern. The use of a DWLOC approach facilitates determining aggregate risks when there are multiple EDWCs or when there are potential aggregate risk estimates of concern. Water ingestion rates are included in the acute and chronic DWLOC calculations. These values vary with population subgroup, the duration time of interest, and the exposure percentile applicable for regulation. These values were determined directly from the NHANES/WWEIA water consumption data, making use of the appropriate exposure durations and percentiles. For the simazine 4-day aggregate assessments, the DWLOC approach used a reciprocal MOE calculation method since the target MOEs (level of concern based on the total uncertainty factor) are the same for all relevant sources of exposure. For the four-day assessment, water consumption is accounted for in the PBPK model when deriving the drinking water PODs and is not included in the DWLOC calculation. Infants and children were assumed to consume water 6 times a day, with a total consumption volume of 0.688557 liters per day (L/day). Youths and female adults were assumed to consume water 4 times a day, with a total consumption volume of 1.71062 L/day.

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). Simazine is currently registered for the following uses that could result in residential exposures: residential turf. There are no residential handler combined (dermal + inhalation) risk estimates of concern for simazine.

There is potential for short-term post-application exposure for individuals as a result of being in an environment that has been previously treated with simazine. There were post-application dermal risk estimates of concern for adults and children 1 to <2 years old and combined (dermal + incidental oral) risk estimates of concern for children 1 to <2 years old (LOC = 30) from high contact activities on treated turf. These scenarios are considered worst-case and are protective of all other exposure scenarios.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/operating-procedures-residential-pesticide.*

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.''

Simazine is a chlorotriazine herbicide. A cumulative risk assessment with the chlorotriazines atrazine, simazine, propazine, and their common metabolites is available at *https://www.regulations.gov,* Docket ID EPA–HQ–OPP–2013–0266.

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.* For simazine and its chlorinated metabolites, there was no increased quantitative or qualitative susceptibility in any of the guideline studies on atrazine in the rat, and there was no increased quantitative susceptibility in the rabbit study. Although there was increased qualitative susceptibility in the atrazine rabbit study, increased resorptions (deaths) at a dose level that resulted in decreased body-weight gain and clinical signs in the maternal animal the observed effects occur at higher doses than the benchmark dose lower confidence limit (BMDL) of 2.42 mg/kg/day used to assess risk. The BMDL of 2.42 mg/kg/day is protective of developmental effects in the rabbit.

For hydroxysimazine, there was no evidence of increased qualitative or quantitative susceptibility in the available toxicological data on this metabolite including a developmental rat study and female and male pubertal assays.

3. *Conclusion.* For simazine and its chlorinated metabolites, 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 based on lack of increased sensitivity for infants and children. That decision is based on the following findings:

i. The toxicity database for the chlorotriazines (including simazine) and their metabolites is considered complete.

ii. Chlorotriazines have an established neuroendocrine mode of action and LH attenuation is the most sensitive endpoint identified in the database. LH attenuation is protective of potential health outcomes associated with chlorotriazines.

iii. There was no increased quantitative or qualitative susceptibility in any of the guideline studies on atrazine in the rat, and there was no increased quantitative susceptibility in the rabbit study. Although there was increased qualitative susceptibility in the atrazine rabbit study, the observed effects occur at higher doses than the benchmark dose lower confidence limit (BMDL) of 2.42 mg/kg/day used to assess risk. The BMDL of 2.42 mg/kg/day is protective of developmental effects in the rabbit.

iv. There are no residual uncertainties identified in the exposure databases.

EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to simazine in drinking water. These assessments will not underestimate the exposure and risks posed by simazine.

For hydroxysimazine, 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 based on lack of increased sensitivity for infants and children. That decision is based on the following findings:

i. The toxicity database for hydroxysimazine is complete for a metabolite.

ii. Hydroxysimazine does not have a neuroendocrine mode of action as the parent chlorotriazines.

iii. There was no evidence of increased qualitative or quantitative susceptibility in the available toxicological data on this metabolite including a developmental rat study and female and male pubertal assays.

iv. There are no residual uncertainties identified in the exposure databases.

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. Simazine and its chlorinated metabolites.* The acute aggregate assessment considers food and water exposures. The acute DWLOC for females 13 to 49 years old is 5,500 ppb. The acute DWLOC is greater than the acute EDWCs for total chlorotriazines TCTs in surface water or ground water (EDWC range = 100–610 ppb); there is no acute aggregate risk of concern.

Hydroxysimazine and its Hydroxylated Metabolites

No toxicological effects attributable to a single dose were identified for hydroxysimazine; therefore, an acute endpoint has not been identified and no risk is expected from this exposure scenario.

2. *Four-day/Chronic risk. Simazine and its chlorinated metabolites.* The four-day aggregate risk assessments are protective for short-term, intermediate-term, and chronic aggregate risks since the POD and endpoint used for the four-day assessment are the most sensitive for any duration, and are, therefore, protective of longer durations of exposure. The calculated four-day DWLOCs are all greater than the 4-day EDWCs for TCTs in surface water or ground water; there are no four-day aggregate risks of concern.

Hydroxysimazine and its Hydroxylated Metabolites

The chronic aggregate risk assessment for the hydroxysimazine considers food and water exposures. No residential exposures to the hydroxysimazine metabolite are expected from the simazine uses. The lowest chronic DWLOC for hydroxysimazine is for all infants (<1 year old) at 1300 ppb. The chronic DWLOCs are greater than the chronic EDWCs for total hydroxytriazines (THTs) in surface water or ground water (EDWC range = 7.33–76 ppb); there is no chronic aggregate risk of concern.

3. *Aggregate cancer risk for U.S. population.* Simazine has been classified as ''Not likely to be carcinogenic to humans.'' Hydroxysimazine is also not likely to pose cancer risks based on the lack of cancer effects seen in available studies.

4. *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 simazine residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (LC–MS/MS) is available to enforce the tolerance expression.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for simazine.

C. Revisions to Petitioned-For Tolerances.

The submitted residue data support a tolerance level of 0.04 ppm for the citrus fruit crop group. The petitioner's proposed tolerance level of 0.05 ppm was based on using the maximum combined residue level of 0.038 ppm (one grapefruit sample) in the Organisation for Economic Co-operation and Development (OECD) tolerance calculation procedures. EPA's approach to tolerance calculations uses the average field trial value of 0.034 ppm, which warrants a tolerance of level of 0.04 ppm instead. Also, although the proposed tolerance level of 0.07 ppm for crop group 14–12 is supported by OECD tolerance calculations, EPA is establishing the tolerance at 0.05 ppm to harmonize with the Canadian MRL. Due to the conservatisms in the OECD calculator, the tolerance level of 0.05 ppm will be sufficient to cover residues of simazine in or on food resulting from legal applications of the pesticide.

D. International Trade Considerations

In this Final Rule, EPA is reducing the existing tolerances for the commodities of almond from 0.25 to 0.05 ppm as part of nut, tree, group 14–12; apple from 0.2 to 0.03 ppm as part of fruit, pome, group 11–10; cherry from 0.25 to 0.1 ppm as part of fruit, stone, group 12–12; grapefruit, lemon, and orange from 0.25 to 0.04 ppm as part of fruit, citrus, group 10–10; hazelnut, nut, macadamia, pecan, and walnut from 0.2 to 0.05 ppm as part of nut, tree, group 14–12; peach and plum from 0.2 to 0.1 ppm as part of fruit, stone, group 12–12; and pear from 0.25 to 0.03 as part of fruit, pome, group 11–10. The Agency is reducing these tolerances because available residue data demonstrates that the new tolerances are sufficient to cover residues on these commodities.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of this revision in order to satisfy its obligation. In addition, the SPS Agreement requires that Members provide a ''reasonable interval'' between the publication of a regulation subject to the Agreement and its entry into force to allow time for producers in exporting Member countries to adapt to the new requirement. At this time, EPA is establishing an expiration date for the existing tolerances to allow those

tolerances to remain in effect for a period of six months after the effective date of this final rule, in order to address this requirement. After the six-month period expires, residues of simazine on grapefruit, lemon, and orange cannot exceed the citrus fruits (crop group 10–10) tolerance of 0.04 ppm; apple and pear cannot exceed the pome fruits (crop group 11–10) tolerance of 0.03 ppm; cherry, peach, and plum cannot exceed the stone fruits (crop group 12–12) tolerance of 0.1 ppm; and almond, hazelnut, nut, macadamia, pecan, and walnut cannot exceed the tree nuts (crop group 14–12) tolerance of 0.05 ppm.

This reduction in tolerance levels is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. The new tolerance levels are supported by available residue data.

V. Conclusion

Therefore, tolerances are established for residues of simazine in or on Fruit, citrus, group 10–10, Fruit, pome, group 11–10, Fruit, stone, group 12–12, and Nut, tree, group 14–12 at 0.04 ppm, 0.03 ppm, 0.10 ppm, and 0.05 ppm, respectively, and the tolerance for Almond, hulls is amended to 3 ppm.

VI. Statutory and Executive Order Reviews

This action establishes and modifies 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). 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: December 16, 2022.

Daniel Rosenblatt,

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. Revise § 180.213 to read as follows:

§ 180.213 Simazine; tolerances for residues.

(a) *General.* Tolerances are established residues of the herbicide simazine, including its metabolites and degradates, in or on the commodities in table 1 to this paragraph (a). Compliance with the tolerance levels specified in table 1 to this paragraph (a) is to be determined by measuring only the sum of simazine, 6-chloro-N,N′-diethyl-1,3,5-triazine-2,4-diamine, and its metabolites 6-chloro-N-ethyl-1,3,5-triazine-2,4-diamine, and 6-chloro-1,3,5-triazine-2,4-diamine, calculated as the stoichiometric equivalent of simazine, in or on the commodity.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Almond [1]	0.25
Almond, hulls	3
Apple [1]	0.20
Avocado	0.20
Blackberry	0.20
Blueberry	0.20
Cattle, meat	0.03
Cattle, meat byproducts	0.03
Cherry [1]	0.25
Corn, field, forage	0.20
Corn, field, grain	0.20
Corn, field, stover	0.25
Corn, pop, grain	0.20
Corn, pop, stover	0.25
Corn, sweet, forage	0.20
Corn, sweet, kernel plus cob with husks removed	0.25
Corn, sweet, stover	0.25
Cranberry	0.25
Currant	0.25
Egg	0.03
Fruit, citrus, group 10–10	0.04
Fruit, pome, group 11–10	0.03
Fruit, stone, group 12–12	0.1
Goat, meat	0.03
Goat, meat byproducts	0.03
Grape	0.20
Grapefruit [1]	0.25
Hazelnut [1]	0.20
Horse, meat	0.03
Horse, meat byproducts	0.03
Lemon [1]	0.25

TABLE 1 TO PARAGRAPH (a)—Continued

Commodity	Parts per million
Loganberry	0.20
Milk	0.03
Nut, macademia [1]	0.25
Nut, tree, group 14–12	0.05
Olive	0.20
Orange [1]	0.25
Peach [1]	0.20
Pear [1]	0.25
Pecan [1]	0.20
Plum [1]	0.20
Raspberry	0.20
Sheep, meat	0.03
Sheep, meat byproducts	0.03
Strawberry	0.25
Walnut [1]	0.2

[1] This tolerance expires on June 22, 2023.

(b) through(d) [Reserved]

[FR Doc. 2022–27715 Filed 12–21–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–OLEM–2022–0191 and EPA–HQ–OLEM–2022–0680; FRL–10435–01–OLEM]

National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (''CERCLA'' or ''the Act''), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan (''NCP'') include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants or contaminants throughout the United States. The National Priorities List (''NPL'') constitutes this list. The NPL is intended primarily to guide the Environmental Protection Agency (''the EPA'' or ''the agency'') in determining which sites warrant further investigation. These further investigations will allow the EPA to assess the nature and extent of public health and environmental risks associated with the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. This rule adds two sites to the General Superfund section of the NPL.

DATES: The rule is effective on January 23, 2023.

ADDRESSES: Contact information for the EPA Headquarters:

• Docket Coordinator, Headquarters; U.S. Environmental Protection Agency; CERCLA Docket Office; 1301 Constitution Avenue NW; William Jefferson Clinton Building West, Room 3334, Washington, DC 20004, (202) 566–0276.

FOR FURTHER INFORMATION CONTACT: Terry Jeng, Site Assessment and Remedy Decisions Branch, Assessment and Remediation Division, Office of Superfund Remediation and Technology Innovation (Mail code 5204T), U.S. Environmental Protection Agency; 1301 Constitution Avenue NW, Washington, DC 20460, telephone number: (202) 566–1048, email address: *jeng.terry@epa.gov.*

The contact information for the regional dockets is as follows:

• Holly Inglis, Region 1 (CT, ME, MA, NH, RI, VT), U.S. EPA, Superfund Records and Information Center, 5 Post Office Square, Suite 100, Boston, MA 02109–3912; (617) 918–1413.

• James Desir, Region 2 (NJ, NY, PR, VI), U.S. EPA, 290 Broadway, New York, NY 10007–1866; (212) 637–4342.

• Lorie Baker, Region 3 (DE, DC, MD, PA, VA, WV), U.S. EPA, 4 Penn Center, 1600 John F. Kennedy Boulevard, Mailcode 3SD12, Philadelphia, PA 19103; (215) 814–3355.

• Sandra Bramble, Region 4 (AL, FL, GA, KY, MS, NC, SC, TN), U.S. EPA, 61 Forsyth Street, SW, Mailcode 9T25, Atlanta, GA 30303; (404) 562–8926.

• Todd Quesada, Region 5 (IL, IN, MI, MN, OH, WI), U.S. EPA Superfund Division Librarian/SFD Records Manager SRC–7J, Metcalfe Federal Building, 77 West Jackson Boulevard, Chicago, IL 60604; (312) 886–4465.

• Michelle Delgado-Brown, Region 6 (AR, LA, NM, OK, TX), U.S. EPA, 1201 Elm Street, Suite 500, Mailcode SED, Dallas, TX 75270; (214) 665–3154.

• Kumud Pyakuryal, Region 7 (IA, KS, MO, NE), U.S. EPA, 11201 Renner Blvd., Mailcode SUPRSTAR, Lenexa, KS 66219; (913) 551–7956.

• David Fronczak, Region 8 (CO, MT, ND, SD, UT, WY), U.S. EPA, 1595 Wynkoop Street, Mailcode 8SEM–EM–P, Denver, CO 80202–1129; (303) 312–6096.

• Eugenia Chow, Region 9 (AZ, CA, HI, NV, AS, GU, MP), U.S. EPA, 75 Hawthorne Street, Mailcode SFD 6–1, San Francisco, CA 94105; (415) 972–3160.

• Ken Marcy, Region 10 (AK, ID, OR, WA), U.S. EPA, 288 Martin Street, Suite 309, Blaine, WA 98230; (360) 366–8868.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

A. What are CERCLA and SARA?

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601–9675 (''CERCLA'' or ''the Act''), in response to the dangers of uncontrolled releases or threatened releases of hazardous substances, and releases or substantial threats of releases into the environment of any pollutant or contaminant that may present an imminent or substantial danger to the public health or welfare. CERCLA was