Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or other laws. As noted in the above section regarding the applicability of the APA, DEA determined that there was good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1532, DEA has determined that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on December 7, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.11 by adding new paragraphs (d)(102) to (104) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

*	*	*	*	*	*	*
(102) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1*H*-indazole-3-carboxamide (other name: ADB–BUTINACA)						7027
(103) 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (other names: α-PiHP; *alpha*-PiHP)						7551
(104) 2-(methylamino)-1-(3-methylphenyl)propan-1-one (other names: 3–MMC; 3-methylmethcathinone)						1259
*	*	*	*	*	*	*

* * * * *

[FR Doc. 2023–27292 Filed 12–12–23; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0657; FRL–11567–01–OCSPP]

Dodine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of dodine in or on Fruit, pome, group 11–10; Fruit, stone, group 12–12; Nut, tree, group 14–12; and Olive, with pit. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 13, 2023. Objections and requests for hearings must be received on or before February 12, 2024, 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–2021–0657, 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 Public Reading Room and the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (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 Federal Register Office'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(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–2021–0657 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 12, 2024. 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–2021–0657, 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/dockets/where-send-comments-epa-dockets.*

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

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of April 28, 2022 (87 FR 25178) (FRL–9410–12–OCSPP), 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 1E8935) by IR–4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of dodine in or on the raw agricultural commodities: Fruit, pome, group 11–10 at 5 parts per million (ppm); Fruit, stone, group 12–12 at 5 ppm; Nut, tree, group 14–12 at 0.3 ppm; and Olive, with pit at 0.3 ppm.

The petition also requested to remove the following established dodine tolerances in or on: Apple at 5.0 ppm; Fruit, stone, crop group 12 at 5.0 ppm; Nuts, tree, crop group 14 at 0.3 ppm; and Pear at 5.0 ppm.

That document referenced a summary of the petition, which is available in the docket, *https://www.regulations.gov.* Two comments were received in response to the notice. EPA's response to these comments can be found in section IV.D.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is modifying the level at which one of the tolerances is being established. For details, see 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 therein, 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 dodine including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with dodine 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.

Because of toxicological equivalency, the Agency must also consider any applicable contribution from the antimicrobial pesticide dodecylguanidine hydrochloride (DGH). There are no direct food uses established for DGH, but there are dietary exposures from uses on paper and paperboard and in drinking water from industrial uses.

A definitive target organ was not identified for dodine or DGH in the available toxicology data, with the most common effects being decreases in body weight and/or body weight gain. When allometric scaling is used to adjust to a human equivalent dosage, the dog was found to be the most sensitive species for this endpoint.

There was no evidence of increased qualitative or quantitative susceptibility in pups or fetuses as compared to adults based on rat and rabbit developmental studies and a rat multi-generation reproduction study. In rat and rabbit prenatal developmental studies, there was no toxicity identified in the fetuses up to the highest dose tested. In the 2-generation reproduction study, decreases in body weight and food consumption were seen in pups at the same dose at which maternal toxicity (decreases in body weight, body weight gain, and food consumption) was observed. In addition, there was no evidence of neurotoxicity across the database. Dodine is classified as ''Not Likely to be Carcinogenic to Humans''.

Specific information on the studies received and the nature of the adverse effects caused by dodine and DGH as well as the no-observed-adverse-effect-levels (NOAELs) and the lowest-

observed-adverse-effect-levels (LOAELs) from the toxicity studies can be found in Appendix A of the document titled ''Dodine. Risk Assessment for the Proposed Use on Olives; Crop Group Expansions to Fruit Pome Group 11–10; and Crop Group Conversions to Stone Fruit Group 12–12 and Tree Nut Group 14–12 and Updated Registration Review Human Health Draft Risk Assessment'' (hereafter, the Dodine Human Health Risk Assessment), in docket ID number EPA–HQ–OPP–2021–0657 at *https://www.regulations.gov.*

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/pesticide-science-and-assessing-pesticide-risks.*

A summary of the Toxicological Points of Departure/Levels of Concern for dodine used for human health risk assessment can be found in Table 4.5.3.1 of the Dodine Human Health Risk Assessment, in docket ID number EPA–HQ–OPP–2021–0657 at *https://www.regulations.gov.*

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dodine, EPA considered exposure under the petitioned-for tolerances as well as all existing tolerances for dodine in 40 CFR 180.172. While there are no direct food uses established for DGH, EPA considered indirect dietary exposure from use of DGH on paper and paperboard in contact with food. EPA assessed dietary exposures from dodine in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for dodine or DGH; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* Chronic aggregate dietary exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 4.02. This software uses 2005–2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). The chronic analysis incorporated mean field trial residues for most commodities and tolerance-level residues for the remaining commodities. Percent crop treated (PCT) data were used for some crops, and 100 PCT was assumed for all other crops. The analyses incorporated default processing factors for processed commodities where no processing study was conducted. For apple juice and olive oil, empirical processing factors of 0.1X were used.

Indirect dietary exposure has the potential to occur from the use of DGH as a material preservative in paper and paperboard intended for use in contact with food, with a retention rate of up to 0.045% by weight of the paper or paperboard. This use is considered protective of other indirect food uses, including paper slimicides, materials preservative of the outermost ply of multiwalled paper bags containing dry food, adhesives and polymers, and sapstain on fruit and vegetable containers.

iii. *Cancer.* Based on the data summarized in the Dodine Human Health Risk Assessment, EPA has concluded that dodine is not likely pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and 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, and 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 annual average percent crop treated estimates used in the chronic dietary risk assessment are as follows: almonds: 2.5%; apples: 5%; cherries: 20%; nectarines: 1%; peaches: 1%; peanuts: 2.5%; pears: 2.5%; pecans: 20%; and walnuts: 1%. 100 PCT was assumed for all other crops.

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 figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5% as the average PCT value, respectively. In those cases, the Agency would use

1% or 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 2.5% as the maximum PCT.

The Agency believes that Conditions a, b, and c discussed above 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 dodine may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for dodine in drinking water. 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/models-pesticide-risk-assessment.*

A chronic surface water estimated drinking water concentration (EDWC) of 1.59 parts per billion (ppb) determined with the FQPA Index Reservoir Screening Tool (FIRST) was used for dietary assessment. Because dodine has a high partition coefficient, is relatively non-persistent in aerobic soils, and has a lack of transport in the field, leaching to groundwater is not expected to be a major route of dissipation.

Drinking water exposure to DGH has the potential to occur when drinking water intakes are downstream from cooling towers, paper mills, and/or other water systems using DGH as a slimicide. Drinking water exposure is expected to be minimal from other currently registered uses of DGH such as materials preservation of leather and textiles. The highest chronic EDWC from the modeled use patterns is 22 µg ai/L from once-through cooling towers using an application rate of 6.0 ppm DGH. This drinking water concentration is considered protective of the other uses.

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). There are no current or proposed conventional or antimicrobial residential uses of dodine or DGH.

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.''

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 dodine and any other substances and dodine does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that dodine 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.*

EPA notes that dodine and DGH are salts of the same chemical. They dissociate similarly and are considered toxicologically equivalent, as opposed to being separate chemicals that share a common mechanism of toxicity.

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 Food Quality Protection Act safety factor. 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 is no evidence of susceptibility following *in utero* and/or postnatal exposure in the developmental toxicity studies in rats or rabbits, nor in the 2-generation rat reproduction study.

3. *Conclusion.* The FQPA safety factor is reduced to 1X for all exposure scenarios except for inhalation exposure. The Agency is retaining a 10X database uncertainty factor (UF_{DB}) to assess risk to dodine inhalation scenarios to account for the lack of an acceptable inhalation toxicity study.

i. Except for an acceptable inhalation toxicity study, the toxicology database for dodine and DGH is complete and adequate to assess potential risk to infants and children. The database contains the following toxicity studies: prenatal developmental studies (rats and rabbits); and a reproduction study in rats.

ii. Neurotoxicity studies are not available for dodine or DGH. Clinical signs (excessive salivation and hunched posture/hypoactivity) were observed in chronic studies of dodine in rats and mice but were not dose-related or statistically significant. Excessive salivation in dogs after dodine (capsule) exposure showed a treatment-related dose response; however, it was not consistent with a neurological adverse effect since it was seen prior to dosing and was a persistent finding throughout the study. It is possible that the excessive salivation was a result of the irritant properties of dodine. In addition, no evidence of neuropathology was observed in the available studies. The Hazard and Science Policy Council (HASPOC) recommended waiving the requirement for the acute and subchronic neurotoxicity studies, based on (1) the low acute oral toxicity of dodine (Toxicity Category III); (2) the lack of neurotoxicity in the dodine toxicity database; and (3) no neurotoxicity concerns for structurally related compounds to dodine.

iii. Based on the available dodine and DGH toxicity studies, there was no evidence of increased susceptibility (quantitative or qualitative) in pups or fetuses as compared to adults based on rat and rabbit developmental studies

and a rat multi-generation reproduction study. In rat and rabbit prenatal developmental studies, there was no toxicity identified in the fetuses up to the highest dose tested. In the 2-generation reproduction study, decreases in body weight and food consumption were seen in pups at the same dose at which maternal toxicity (decreases in body weight, body weight gain, and food consumption) was observed.

iv. The exposure databases are sufficient to determine the nature and magnitude of the residue in food and drinking water. The dodine residue chemistry database is complete. The exposure assessment for drinking water provides a conservative approach for estimating dodine and DGH concentrations from drinking water sources, and thus is unlikely to underestimate exposure. The food and drinking water dietary exposure analyses are unlikely to underestimate exposure as they incorporated conservative assumptions for dodine and DGH.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary (food and drinking water) exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short- intermediate- and chronic-term risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists.

1. *Acute risk.* No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, dodine is not expected to pose an acute risk.

2. *Chronic risk.* The chronic dietary risk assessment includes only food and water exposure from dodine and DGH. Chronic dietary risks from dodine (food and drinking water) are below the Agency's level of concern of 100% of the cPAD; they are 6.1% of the cPAD for all infants less than 1 year old, the group with the highest exposure. Chronic dietary risks from DGH (food and water) are below the Agency's level of concern of 100% of the cPAD; they are 95% of the cPAD for children 1 to 2 years old, the group with the highest exposure.

There are no chronic non-occupational exposures, so the aggregate chronic risk assessment is equal to the chronic dietary exposure analysis of food and drinking water. The chronic aggregate assessment includes: (1) food only contributions from agricultural uses of dodine, including the proposed uses; (2) food only contributions from DGH in paper and paperboard intended for use in contact with food; and (3) drinking water only contributions from DGH in water from cooling tower uses, which is protective of drinking water exposures resulting from conventional agricultural uses of dodine. This aggregate assessment resulted in risk estimates that are below the Agency's level of concern of 100% of the cPAD; they are 98% of the cPAD for children 1 to 2 years old, the group with the highest exposure, which is considered protective for all other population subgroups.

3. *Short- and intermediate-term risk.* Short- and intermediate-term adverse effects were identified; however, dodine is not registered for any use patterns that would result in short- and/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 dodine.

4. *Aggregate cancer risk for U.S. population.* There was equivocal evidence of carcinogenicity in rat and mouse carcinogenicity studies; however, an evaluation of the carcinogenic potential of dodine was performed which concluded that the weight of evidence indicates that dodine and DGH are ''Not Likely to be Carcinogenic to Humans.'' Therefore, dodine and DGH are not expected to pose a cancer risk to humans.

5. *Determination of safety.* Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to dodine residues. More detailed information on this action can be found in the Dodine Human Health Risk Assessment in docket ID EPA–HQ–OPP–2021–0657.

IV. Other Considerations

A. Analytical Enforcement Methodology

Method 45137, which is entitled ''Dodine: Analytical Method for Dodine in Fruit,'' is available for the enforcement of tolerances of dodine in/on plant commodities. This method is a Gas Chromatograph/Mass Selective Detection (GC/MSD) procedure based on extracting dodine from fruit by homogenization with methanol. 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.

Codex has established MRLs for residues of dodine in or on apple at 5 ppm; pear at 5 ppm; cherry at 3 ppm; nectarine at 5 ppm; and peach at 5 ppm. The U.S. tolerances are harmonized with the corresponding Codex MRLs except for cherry. The cherry field trial data show that residues from the domestic labeled use of dodine may exceed the 3 ppm Codex cherry MRL. Therefore, it is not possible to harmonize with the Codex MRL based on the U.S. application pattern.

C. Revisions to Tolerances

The Agency is establishing the tolerance level for ''olive, with pit'' at 0.4 ppm instead of the requested level of 0.3 ppm. Two of the 2011 olive trials from Greece were determined to be replicates, and this determination resulted in a higher calculated maximum residue limit (MRL) than the petitioner requested.

D. Response to Comments

Two comments were received in response to the Notice of Filing by the same commenter. The commenter stated in part that ''we need to stop all chemical use on vegetables'' and that ''toxic in your body kill you.'' Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerances are safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that the dodine tolerances are safe. The commenter has provided no information indicating that a safety determination cannot be supported.

V. Conclusion

Therefore, tolerances are established for residues of dodine in or on Fruit, pome, group 11–10 at 5 ppm; Fruit, stone, group 12–12 at 5 ppm; Nut, tree, group 14–12 at 0.3 ppm; and Olive, with pit at 0.4 ppm.

Additionally, the following existing tolerances are removed as unnecessary: Apple; Fruit, stone, crop group 12; Nut, tree, crop group 14; and Pear.

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 to 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 tolerances 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 7, 2023.

Charles Smith,

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 § 180.172 to read as follows:

§ 180.172 Dodine; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide dodine, including its metabolites and degradates, in or on the commodities in table1 to this paragraph (a). Compliance with the tolerance levels specified in table1 is to be determined by measuring only dodine, *N*-dodecylguanidine acetate; in or on the following commodities.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Almond, hull	30.0
Apple, wet pomace	15.0
Banana	0.50
Fruit, pome, group 11–10	5
Fruit, stone, group 12–12	5
Nut, tree, group 14–12	0.3
Olive, with pit	0.4
Peanut	0.013
Strawberry	5.0

(b)–(d) [Reserved]

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