shall be the 30 boiler-operating-day rolling average in terms of lb/hr emissions of NO_X. Records of the 30 boiler-operating-day rolling average for NO_X must be maintained by the owner or operator for each boiler-operating-day and made available upon request to EPA and ADEQ representatives. Under these circumstances, the compliance determination requirements and the reporting and recordkeeping requirements under paragraph (c)(5)(iii) of this section would not apply.

* * * * *

(7) *SO_2 and NO_X Compliance dates for Domtar Ashdown Mill Power Boiler No. 2.* The owner or operator of the boiler must comply with the SO_2 and NO_X emission limits listed in paragraph (c)(6) of this section by October 27, 2021.

(8) *SO_2 and NO_X Compliance determination and reporting and recordkeeping requirements for Domtar Ashdown Mill Power Boiler No. 2.* (i) NO_X and SO_2 emissions for each day shall be determined by summing the hourly emissions measured in pounds of NO_X or pounds of SO_2. Each boiler-operating-day of the 30-day rolling average for the boiler shall be determined by adding together the pounds of NO_X or SO_2 from that day and the preceding 29 boiler-operating-days and dividing the total pounds of NO_X or SO_2 by the sum of the total number of hours during the same 30 boiler-operating-day period. The result shall be the 30 boiler-operating-day rolling average in terms of lb/hr emissions of NO_X or SO_2. If a valid NO_X pounds per hour or SO_2 pounds per hour is not available for any hour for the boiler, that NO_X pounds per hour shall not be used in the calculation of the 30 boiler-operating-day rolling average for NO_X. For each day, records of the total SO_2 and NO_X emitted for that day by the boiler must be maintained by the owner or operator and made available upon request to EPA and ADEQ representatives. Records of the 30 boiler-operating-day rolling average for SO_2 and NO_X for the boiler as described in this paragraph (c)(8)(i) must be maintained by the owner or operator for each boiler-operating-day and made available upon request to EPA and ADEQ representatives.

(ii) The owner or operator shall continue to maintain and operate a CEMS for SO_2 and NO_X on the boiler listed in paragraph (c)(6) of this section in accordance with 40 CFR 60.8 and 60.13(e), (f), and (h), and appendix B of 40 CFR part 60. The owner or operator shall comply with the quality assurance procedures for CEMS found in 40 CFR part 60. Compliance with the emission limits for SO_2 and NO_X shall be determined by using data from a CEMS.

(iii) Continuous emissions monitoring shall apply during all periods of operation of the boiler listed in paragraph (c)(6) of this section, including periods of startup, shutdown, and malfunction, except for CEMS breakdowns, repairs, calibration checks, and zero and span adjustments. Continuous monitoring systems for measuring SO_2 and NO_X and diluent gas shall complete a minimum of one cycle of operation (sampling, analyzing, and data recording) for each successive 15-minute period. Hourly averages shall be computed using at least one data point in each fifteen-minute quadrant of an hour. Notwithstanding this requirement, an hourly average may be computed from at least two data points separated by a minimum of 15 minutes (where the unit operates for more than one quadrant in an hour) if data are unavailable as a result of performance of calibration, quality assurance, preventive maintenance activities, or backups of data from data acquisition and handling system, and recertification events. When valid SO_2 or NO_X pounds per hour emission data are not obtained because of continuous monitoring system breakdowns, repairs, calibration checks, or zero and span adjustments, emission data must be obtained by using other monitoring systems approved by the EPA to provide emission data for a minimum of 18 hours in each 24-hour period and at least 22 out of 30 successive boiler operating days.

(iv) If the air permit is revised such that Power Boiler No. 2 is permitted to burn only pipeline quality natural gas, this is sufficient to demonstrate that the boiler is complying with the SO_2 emission limit under paragraph (c)(6) of this section. Under these circumstances, the compliance determination requirements under paragraphs (c)(8)(i) through (iii) of this section would not apply to the SO_2 emission limit listed in paragraph (c)(6) of this section.

(v) If the air permit is revised such that Power Boiler No. 2 is permitted to burn only pipeline quality natural gas and the operation of the CEMS is not required under other applicable requirements, the owner or operator may demonstrate compliance with the NO_X emission limit under paragraph (c)(6) of this section by calculating NO_X emissions using fuel usage records and the applicable NO_X emission factor under AP–42, Compilation of Air Pollutant Emission Factors, section 1.4, Table 1.4–1. Records of the quantity of natural gas input to the boiler for each day must be compiled no later than 15 days after the end of the month and must be maintained by the owner or operator and made available upon request to EPA and ADEQ representatives. Records of the calculation of NO_X emissions for each day must be compiled no later than 15 days after the end of the month and must be maintained and made available upon request to EPA and ADEQ representatives. Each boiler-operating-day of the 30-day rolling average for the boiler must be determined by adding together the pounds of NO_X from that day and the preceding 29 boiler-operating-days and dividing the total pounds of NO_X by the sum of the total number of hours during the same 30 boiler-operating-day period. The result shall be the 30 boiler-operating-day rolling average in terms of lb/hr emissions of NO_X. Records of the 30 boiler-operating-day rolling average for NO_X must be maintained by the owner or operator for each boiler-operating-day and made available upon request to EPA and ADEQ representatives. Under these circumstances, the compliance determination requirements under paragraphs (c)(8)(i) through (iii) of this section would not apply to the NO_X emission limit.

* * * * *

(10) *PM compliance dates for Domtar Ashdown Mill Power Boiler No. 2.* The owner or operator of the boiler must comply with the PM BART requirement listed in paragraph (c)(9) of this section by November 28, 2016.

(11) Alternative *PM Compliance Determination for Domtar Ashdown Paper Mill Power Boiler No. 2.* If the air permit is revised such that Power Boiler No. 2 is permitted to burn only pipeline quality natural gas, this is sufficient to demonstrate that the boiler is complying with the PM BART requirement under paragraph (c)(9) of this section.

* * * * *

[FR Doc. 2019–19877 Filed 9–26–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0651; FRL–9996–66]

2-Phenoxyethanol; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 2-

phenoxyethanol when used as an inert ingredient (solvent or cosolvent) limited to 0.2% by weight in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. The Dow Chemical Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 2-phenoxyethanol when used in accordance with the terms of the exemption.

DATES: This regulation is effective September 27, 2019. Objections and requests for hearings must be received on or before November 26, 2019, 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–2017–0651, 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, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 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–2017–0651 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 November 26, 2019. 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–2017–0651, 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. Petition for Exemption

In the **Federal Register** of June 14, 2018 (83 FR 27743) (FRL–9978–41), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11069) by The Dow Chemical Company, 1803 Building, Washington Street, Midland, MI 48764. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of 2-phenoxyethanol (CAS Reg. No. 122–99–6) when used as an inert ingredient (solvent or co-solvent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. That document referenced a summary of the petition prepared by The Dow Chemical Company, the petitioner, which is available in the docket, *http://www.regulations.gov*. One comment was received on the notice of filing. EPA's response is discussed in Unit V.C.

Based upon review of the data supporting the petition, EPA has limited the maximum end-use concentration of 2-phenoxyethanol as not to exceed 0.2% by weight in pesticide formulations, when ready for use. The reason for this change is explained in Unit V.B.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption

from the requirement for 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 . . . .'' EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), 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 2-phenoxyethanol including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 2-phenoxyethanol follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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.

Single and repeat-dose studies in rats indicated that 2-phenoxyethanol is rapidly and nearly completely absorbed after oral administration and more than 90% of the administered dose is excreted in urine within 24 hours of exposure. Following oral and dermal exposure the terminal hydroxyl group of 2-phenoxyethanol is metabolized, mainly in the liver, by alcohol dehydrogenase (ADH) to 2-phenoxyacetaldehyde and then by aldehyde dehydrogenase (ALDH) to 2-phenoxyacetic acid (PhAA).

2-Phenoxyethanol exhibits low levels of acute toxicity. Acute studies in rats showed oral LD_{50} ranging from 1,260 to more than 2,500 mg/kg. The dermal LD_{50} in two rabbit studies were more than 2,200 and more than 3,653 mg/kg and 14391 mg/kg in a rat study. The inhalation LC_{50} in the rat was more than 1,000 mg/m^3. 2-Phenoxyethanol is considered to be an eye irritant and a mild skin irritant. However, it was not found to be a dermal sensitizer.

Studies on 2-phenoxyethanol show that the target organ in rats and mice is the kidney, most likely due to an extensive first-pass metabolism and formation of high amounts/concentrations of 2-phenoxyacetic acid in systemic circulation. Following oral and dermal exposure the terminal hydroxyl group of 2-phenoxyethanol is metabolized, mainly in the liver, to 2-phenoxyacetic acid (PhAA). Data suggest that mice are somewhat more resistant to the toxic effects of 2-phenoxyethanol and its main metabolite 2-phenoxyacetic acid than rats.

In addition to the effects on the kidney, hematotoxicity was also observed. This appears to be the result of exposure to the parent compound. Although hemotoxic effects of 2-phenoxyethanol were observed in repeat dose studies, the available repeat dose dataset indicates that the rabbit is the most sensitive species. The hemolysis was less pronounced in rats and mice. Based on differences in metabolism, humans are expected to be the least susceptible to RBC hemolysis.

In developmental toxicity studies in rats and rabbits, no evidence of developmental toxicity was observed. In a two-generation reproductive toxicity study in mice, an effect on fertility was observed but only at a dose level above limit dose values. Offspring toxicity was observed, but only in the presence of maternal toxicity (*i.e.,* decreased body weight and increased liver weight).

There is no evidence that exposure to 2-phenoxyethanol suppresses or otherwise harms immune function in humans. No signs of neurotoxicity were reported in acute or repeat-dose oral studies. There were also no signs of carcinogenicity in the database including the 2-year feeding studies. Similarly, all tests were negative for genotoxicity and mutagenicity. The available data suggests that 2-phenoxyethanol is not carcinogenic.

Specific information on the studies received and the nature of the adverse effects caused by 2-phenoxyethanol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) identified from the toxicity studies can be found at *http://www.regulations.gov* in the document ''IN–11069; 2-Phenoxyethanol: Human Health Risk and Ecological Effects—Assessment of a Food Use Pesticide Inert Ingredient'' at pages 9–32 in docket ID number EPA–HQ–OPP–2017–0651.

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.htm.*

A summary of the toxicological endpoints for 2-phenoxyethanol used

for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR 2-PHENOXYETHANOL FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Chronic dietary (All populations)	NOAEL = 369 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 3.69 mg/kg/day. cPAD = 3.69 mg/kg/day	90-Day Drinking Water Toxicity (rat). LOAEL = 10,000 mg/L (687 mg/kg/day in males and 1,000 mg/kg/day in females) based on hematotoxicity and histopathological changes in the kidney and bladder.
Incidental oral short-term (1 to 30 days).	NOAEL = 369 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-Day Drinking Water Toxicity (rat). LOAEL = 10,000 mg/L (687 mg/kg/day in males and 1,000 mg/kg/day in females) based on hematotoxicity and histopathological changes in the kidney and bladder.
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months).	Dermal study NOAEL = 500 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-Day Dermal Toxicity Study (rabbit). LOAEL = 600 mg/kg/day from hemolysis and death seen in the Developmental Toxicity-Dermal (rabbit).
Inhalation short-term (1 to 30 days).	Inhalation study NOAEL = ~12.7 mg/kg/day (inhalation absorption rate = 100%). UF_A = 100x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	14-Day Inhalation Toxicity Study (rat). LOAEL = ~65 mg/kg/day based on respiratory effects (*i.e.,* degeneration/squamous metaplasia of respiratory epithelium in the nasal cavity, hyperplasia of the respiratory epithelium in the nasal cavity of all males and females, inflammatory cell infiltrates in the nasal cavity, and statistically significant increased absolute lung weights in males).
Inhalation (1 to 6 months)	Inhalation study NOAEL = 12.7 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x UF_S = 10x FQPA SF = 1x	LOC for MOE = 1,000.	14-Day Inhalation Toxicity Study (rat). LOAEL = ~65 mg/kg/day based on respiratory effects (*i.e.,* degeneration/squamous metaplasia of respiratory epithelium in the nasal cavity, hyperplasia of the respiratory epithelium in the nasal cavity of all males and females, inflammatory cell infiltrates in the nasal cavity, and statistically significant increased absolute lung weights in males).
Cancer (Oral, dermal, inhalation).	No evidence of carcinogenicity in the available database.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day (= milligram/kilogram/day). MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_S = use of a short-term study for long-term risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 2-phenoxyethanol, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 2-phenoxyethanol in food as follows:

Because no acute endpoint of concern was identified, a quantitative acute dietary exposure assessment is unnecessary. In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM– FCID™, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What we eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. The Inert Dietary Exposure Evaluation Model (I–DEEM) is a highly conservative model with the assumption that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has tolerance-level residues. In the case of 2-phenoxyethanol, a 0.2% by weight limitation in formulation was incorporated into the model.

A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk

Assessments for the Inerts.'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for 2-phenoxyethanol, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). 2-Phenoxyethanol is currently approved as a nonfood use inert ingredient. A review of residential products containing this inert ingredient revealed that it is currently used in antimicrobial cleaning products and in pet spot-on treatment products. There is also a potential for outdoor uses in pesticides applied to residential lawns and turf. In a conservative effort to assess exposure, the EPA has conducted a screening level assessment using high-end exposure scenarios for pesticidal use on lawns/turf, in antimicrobial spray cleaning products, and in pet spot-on application.

In addition to the proposed and current pesticidal uses of 2-phenoxyethanol, 2-phenoxyethanol is also used in various non-pesticidal products such as paints and coatings, personal care/cosmetic products, and cleaning products. The Agency incorporated known non-pesticidal background exposure to 2-phenoxyethanol used in latex paint, cosmetic products, and cleaning products into this risk assessment.

For each residential scenario, short-term exposure for both the handler (adult) and post-application exposure (adult and child) is expected. Based on the proposed use pattern, intermediate-term and long-term pesticidal exposures from residential uses are not expected. Non-pesticidal use in cosmetics can result in short-term, intermediate-term, and long-term 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.''

EPA has not found 2-phenoxyethanol to share a common mechanism of toxicity with any other substances, and 2-phenoxyethanol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 2-phenoxyethanol does not have 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 *http://www.epa.gov/pesticides/cumulative.*

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.* A reproductive toxicity study showed effects on reproductive parameters of fertility at doses of 4,000 mg/kg/day. These effects were not seen in animals dosed with 2,000 mg/kg/day which is above the limit dose of 1,000 mg/kg/day. Although evidence of adverse effects were observed in the offspring (*i.e.,* decreased pup weight), this effect was only seen in the presence of maternal toxicity. In addition, two developmental studies showed no effect on offspring at the limit dose of 1,000 mg/kg/day.

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 2-phenoxyethanol is complete.

ii. There is no indication that 2-phenoxyethanol is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that 2-phenoxyethanol results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. All evidence of toxicity was seen in the presence of maternal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and incorporated a limitation of 0.2% by weight in pesticide formulation. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to 2-phenoxyethanol in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by 2-phenoxyethanol.

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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, 2-phenoxyethanol is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to 2-phenoxyethanol from food and water will utilize 0.00007% of the cPAD for children 1 to 2 years of age, the population group receiving the greatest exposure. Based on the explanation in this unit, regarding residential use patterns, chronic residential exposure to residues of 2-phenoxyethanol is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus

chronic exposure to food and water (considered to be a background exposure level). 2-Phenoxyethanol is currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to 2-phenoxyethanol. However, the mode of action of the toxicological effect must be the same across routes of exposure in order to aggregate the exposure. In this case, the toxic effects are different by one route and duration from those produced by a different route and duration. To produce an aggregate risk estimate in situations in which it is not appropriate to aggregate exposures due to differing toxicological effects, risk measures are calculated separately for each route and duration for a given toxic effect for each hypothetical ''individual.'' In these situations, multiple aggregate assessments are performed for a single chemical of interest if the relevant toxicological endpoints for all routes/pathways are not the same. When that is the case, a separate aggregate assessment is then performed for each toxic effect of concern.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs above the Agency's level of concern. Aggregate dermal exposures resulted in a MOE of 114 for adults and a MOE of 165 in children. Because EPA's level of concern for 2-phenoxyethanol is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term and long-term risk.* Intermediate- and long-term aggregate exposure takes into account intermediate- or long-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term and long-term adverse effect was identified; however, 2-phenoxyethanol is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in intermediate- or long-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Long-term risk is assessed based on long-term residential exposure plus chronic dietary exposure. Although intermediate- and long- term residential pesticidal uses of 2-phenoxyethanol are not expected, because 2-phenoxyethanol is used in cosmetics, intermediate- and long-term residential exposure is possible. However, in this case, the relevant toxicological endpoints resulting from intermediate- and long-term exposure from cosmetic use and chronic dietary exposures from pesticidal uses are not the same; therefore, an intermediate- and long-term aggregate risk assessment was not conducted.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, 2-phenoxyethanol is not expected to pose a cancer risk to humans.

6. *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 2-phenoxyethanol residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of 2-phenoxyethanol in or on any food commodities. EPA is establishing limitations on the amount of 2-phenoxyethanol that may be used in pesticide formulations applied pre- and post-harvest. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for food use that exceeds 0.2% by weight of 2-phenoxyethanol in the final pesticide formulation.

B. Revisions to Petitioned for Tolerances

Although the petition did not specify a limitation on concentration of this inert ingredient in end-use pesticide formulations, the Agency is establishing this exemption with the limitation of 0.2% by weight in pesticide formulations. Based upon an evaluation of the data included in the petition, as well as publicly available literature, it was determined that 2-phenoxyethanol has biocidal properties; therefore, EPA is establishing a limitation in formulation, when ready for use, (*i.e.,* the end-use concentration is not to exceed 0.2% by weight). This limitation is being placed to ensure that the chemical is functioning as an inert ingredient and not a biocide. This limitation is explained in the Agency's risk assessment which can be found at *http://www.regulations.gov* in document *IN–11069; 2-Phenoxyethanol: Human Health Risk and Ecological Effects Assessment of a Food Use Pesticide Inert Ingredient* in docket ID number EPA–HQ–OPP–2017–0651.

C. Response to Comments

One comment was submitted generally opposing the establishment of tolerance exemptions. 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 Federal Food, Drug and Cosmetic Act (FFDCA) authorizes EPA to establish tolerances when it determines that the tolerance is 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 this exemption from the requirement of a tolerance is safe. The commenter provided no information to support a conclusion that the exemption was not safe.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for 2-phenoxyethanol (CAS Reg. No. 122–99–6) when used as an inert ingredient (solvent or co-solvent) limited to 0.2% by weight in pesticide formulations applied to growing crops and raw agricultural commodities after harvest.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance 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).

VIII. 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: September 16, 2019.

Michael Goodis,

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 § 180.910, add a heading to the table and alphanumerically add inert ingredient ''2-phenoxyethanol (CAS Reg. No. 122–99–6)'' to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO 180.910

Inert ingredients	Limits	Uses
* * *	* * *	*
2-Phenoxyethanol (CAS Reg. No. 122–99–6)	0.2% by weight in pesticide formulation	Solvent or co-solvent.
* * *	* * *	*

[FR Doc. 2019–20529 Filed 9–26–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 19–57, RM–11827; DA 19–492]

Radio Broadcasting Services; Caliente, Nevada

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: At the request of SSR Communications Inc., the Audio Division amends the FM Table of Allotments, by allotting Channel 264A at Caliente, Nevada, as the first local service. A staff engineering analysis indicates that Channel 264A can be allotted to Caliente consistent with the minimum distance separation requirements of the Commission's rules without a site restriction. The reference coordinates are 37–36–02 NL and 114–30–32 WL.

DATES: Effective September 27, 2019.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MB Docket No. 19–57, adopted May 30, 2019, and released May 31, 2019. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street SW, Washington, DC 20554. The full text is also available online at *http://apps.fcc.gov/ecfs/.* This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. The Commission will send a copy of the *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336 and 339.