that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 25, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: November 30, 2018.

Deborah Jordan,

Acting Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(509)(i)(B) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(509) * * *

(i) * * *

(B) Feather River Air Quality Management District.

(*1*) Rule 3.23, ''Natural Gas-Fired Water Heaters, Small Boilers, and Process Heaters'' adopted on October 3, 2016.

* * * * *

[FR Doc. 2018–27756 Filed 12–21–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0063; FRL–9986–85]

Chlorate; Pesticide Exemptions From Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of chlorate in or on cantaloupe and tomato under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 26, 2018. Objections and requests for hearings must be received on or before February 25, 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–2017–0063, 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: Anita Pease, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *ADFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0063 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 25, 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–2017–0063, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online

instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-For Exemptions

In the **Federal Register** of December 15, 2017 (82 FR 59604) (FRL–9970–50), 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 4F8325) by ICA Trinova, Inc., 1 Beavers Street, Suite B, Newnan, GA 30263. The petition requested that EPA (1) establish a tolerance for residues of chlorate in or on cantaloupes at 1.5 parts per million (ppm), and (2) establish an exemption from the requirement of a tolerance for residues of chlorate in or on tomatoes. Chlorate is a by-product of chlorine dioxide, which is generated from the active ingredient, sodium chlorite, when it is applied via fumigation to tomatoes and cantaloupes post- harvest, during storage and shipment. The Agency reviewed submitted residue chemistry data for chlorine dioxide and chlorate. Given that residues for chlorine dioxide were not detected and only residues of chlorate were quantified, EPA has determined that tolerance exemptions are appropriate for chlorate on both tomatoes and cantaloupes.

A summary of the petition prepared by ICA Trinova Inc., the petitioner and registrant is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing; the Agency's response to these comments is located in Unit IV.B. of this document. For reasons explained in Unit IV.C., EPA is establishing an exemption from the requirement of a tolerance for residues of chlorate in or on cantaloupe and tomato.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of 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(c)(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. In making this safety determination, EPA must take into consideration the factors laid out in section 408(b)(2)(C) and (D). Specifically, 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 chlorate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with chlorate 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.

Sodium chlorite is the active ingredient that is applied to the tomatoes and cantaloupe. Once applied, it is activated by a weak acid, creating gaseous chlorine dioxide. As chlorine dioxide is released, it also produces the byproduct, chlorate. Based on submitted residue data, the only residues of the pesticide with the potential for being present on food commodities are chlorate ions; therefore, the Agency assessed the safety of aggregate exposure to chlorate in support of this tolerance action.

Inorganic chlorates (also known as chlorate salts) encompass all chlorates including the most abundant salt, sodium chlorate. Toxicology data relevant to the human health risk assessment are summarized here and more information about the toxicology data and references can be found in the *Risk Assessment of Tomato and Cantaloupe Fumigation with Sodium Chlorite 3.2% (chlorine dioxide gas)* and *Inorganic Chlorates Human Health Assessment Scoping Document in Support of Registration Review* (Docket ID No. EPA–HQ–OPP–2016–0080–0008) both of which can be found in the docket for this action at *http://www.regulations.gov.*

The hazard database indicates that the thyroid is the primary target organ of chlorate. Effects observed in subchronic and chronic toxicity studies show increased thyroid gland weights, colloid depletion, decreases in triiodothyronine (T3) and thyroxine (T4) accompanied by increases in thyroid stimulating hormone (TSH), increased incidence of thyroid follicular cell hypertrophy, thyroid cell mineralization, follicular cell hyperplasia, and adenomas or carcinomas in rat studies. Other effects include hematological changes (hemoglobin concentration, hematocrit, decreased red blood counts (RBC), and increased reticulocyte counts in females), methemoglobin concentration changes, and pituitary vacuolization in subchronic studies starting at doses 10-fold higher than where thyroid effects are observed.

In a 2-year drinking water study, there was some evidence of thyroid gland follicular cell tumors in male rats; however, because chlorate is not mutagenic and these tumors were only seen at high doses, chlorate is not likely to be carcinogenic since the chronic reference dose is below the dose at which alteration of thyroid hormone homeostasis occurs. Moreover, although there was equivocal and marginal evidence of increased pancreatic islet carcinoma in female mice, the Agency has concluded that the selected chronic reference dose is protective of these potential cancer effects.

No increased qualitative or quantitative susceptibility in rats or rabbits was seen in reproduction and developmental studies with chlorate. Chlorate did not cause developmental effects in rats at doses up to the limit dose (1,000 mg/kg/day) or in rabbits up to half the limit dose. Although chlorate has not been evaluated for neurotoxic effects, acute and subchronic toxicity studies do not indicate any neurotoxic potential. In a 2-generation reproduction toxicity study, increased absolute and relative thyroid weight and increased incidence of slight to moderate hyperactivity of the thyroid glands were reported in parental and adult F1 males and females at doses 14x higher than the

thyroid effects identified in the adult rat subchronic and chronic studies.

The chronic oral toxicity of chlorate was examined in a study conducted by the National Toxicology Program (NTP). In this study, Fischer 344 rats (50/sex/group) were exposed to drinking water containing 0, 125, 1,000, or 2,000 mg/L chlorate for 2 years (equivalent to 5/5, 35/45, and 75/95 mg/kg/day (males/females)). T4 and T3 levels were significantly reduced at 35 and 75 mg/kg/day on day 4, and in 75 mg/kg/day males and females at week 3. TSH was significantly increased in 35 and 75 mg/kg/day males on day 4 and at week 3, in 35 and 75 mg/kg/day females on day 4, in 75 mg/kg/day females at week 3, and in 75 mg/kg/day males and females at week 13. At the high dose, increased incidences of thyroid gland follicular cell carcinoma were seen in male rats (incidence: 4/47) compared to none in controls, and of thyroid gland follicular cell adenoma or carcinoma (combined) in males (incidence: 6/47) and females (incidence: 4/46) compared to one animal in controls of both sexes. The incidences of thyroid gland follicular cell hypertrophy were significantly increased in mid- and high-dose groups of males (33/43 and 40/47 vs. 4/47 in control) and females (3/47, 7/47, 27/43, 42/46 vs. 3/47 in control).

In the Agency's 2006 risk assessment for inorganic chlorates, *Revised Inorganic Chlorates. HED Chapter of the Reregistration Eligibility Decision Document (RED)* (Docket ID No. EPA–HQ–OPP–2005–0507–0004) a lower 95% confidence limit of the benchmark dose (BMDL) of 0.9 mg/kg/day was derived, based on thyroid gland follicular cell hypertrophy at the 5 mg/kg/day dose from the rat chronic cancer study (NTP, 2005). EPA has re-considered the data and determined that the original benchmark dose derived from the study was not sufficiently supported as an effect level at 5 mg/kg/day, and that the 5 mg/kg/day dose can be supported as a NOAEL for the study. The point of departure (POD) for chronic dietary (all populations) exposures is thus the 5 mg/kg/day dose, based on changes in thyroid hormones (decreased T3, decreased T4, and increased TSH), and increased incidence of thyroid follicular cell hypertrophy in male and female rats at the next highest dose of 35/45 mg/kg/day (males and females respectively). Mineralization of the thyroid at the 5 mg/kg/day dose level was not considered to be adverse.

Specific information on the studies received and the nature of the adverse effects caused by chlorate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled ''*Risk Assessment of Tomato and Cantaloupe Fumigation with Sodium Chlorite 3.2% (chlorine dioxide gas)* in docket ID number EPA–HQ–OPP–2017–0063.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological 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 NOAEL and 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints from the documents referenced in section III, A, for chlorate used for human risk assessment is shown in Table 1.

TABLE 1—TOXICOLOGY ENDPOINTS FOR USE IN CHLORATE HUMAN HEALTH RISK ASSESSMENTS

Exposure/scenario	Point of departure	Uncertainty/FQPA safety factors	RfD, PAD, level of concern for risk assessment	Study and toxicological effects
Acute dietary (All populations, including infants and children, and females 13—49 years of age).	N/A	N/A	N/A	None of the available studies provided an endpoint of toxicity attributable to a single exposure.
Chronic dietary (All populations)	RfD = cPAD = 0.17 mg/kg/day.	UF = 30x (10x intraspecies, 3x interspecies) FQPA SF = 1x.	NOAEL = 5 mg/kg/day.	2 year NTP Study (2005)—rat. MRID 49683134. LOAEL = 35/45 mg/kg/day (male/female) based on changes in thyroid hormones after 3 weeks (decreased T4, T3, & increased TSH), increased incidence of thyroid gland follicular cell hypertrophy in males and females (after 3 weeks and 2 years).
Cancer (Oral, dermal, inhalation)	The chronic reference dose will be protective of potential carcinogenicity.			

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, N/A = not applicable

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to chlorate, EPA considered exposure under the petitioned-for tolerance and exemption as well as existing exposures to chlorate. EPA assessed dietary exposures from chlorate 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 chlorate; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA separately assessed the components of chronic dietary exposure and then aggregated them for assessing chronic risk. For existing food crop uses, EPA relied on the assessment of food crop exposures contained in the 2006 Inorganic Chlorates Reregistration Eligibility Document. For the petitioned-for use on cantaloupe, EPA based its assessment on the current version of Dietary Exposure Evaluation Model—Food Consumption Intake Database—DEEM–FCID™ (version 3.16), the food consumption data from the 2003–2008 U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA), and assumed 100 percent of the cantaloupe crop treated. For the dietary exposure resulting from use in paper mills, EPA based its exposure assessment on standard operating procedure screening-level analyses reported in the registration review human health scoping document, *Inorganic Chlorates Human Health Assessment Scoping Document in Support of Registration Review.*

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to chlorate. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1. ii.

iv. *Anticipated residue and Percent Crop Treated (PCT) information.* EPA used anticipated residue information and PCT estimates in the dietary food assessment.

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 under the following conditions:

- *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 Agency estimated the PCT for existing uses for the chronic dietary exposure assessment as follows: corn: <1%; cotton (seed treatment): 5%; dry beans/peas: <1%; flaxseed: <1%; peppers (chili peppers): <1%; potatoes; <1%; rice: 1%; safflower (seed treatment): 2%; sorghum: <1%; soybeans: 5%; soybeans (seed treatment): <1%; sunflower (seed treatment): <1%; sweet corn: <1%; wheat: 1%; and wheat seed (seed treatment): <1%. For crops not specified, 100% PCT was used.

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.

2. *Dietary exposure from drinking water.* The estimated drinking water concentration (EDWC) was obtained from monitoring data gathered between 2013–2015 and are contained in the Six-Year Review Technical Report for Chlorate. For purposes of this assessment, EPA used the median concentration of 120 micrograms/liter.

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). At this time, there are no longer any registered uses of chlorate that result in non-occupational, residential exposures.

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 inorganic chlorates to share a common mechanism of toxicity with any other substances, and chlorate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that chlorate 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

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.* No increased qualitative or quantitative susceptibility in rats or rabbits was seen in reproduction and developmental studies with chlorate. Chlorate did not cause developmental effects in rats at doses up to 1,000 mg/kg/day or in rabbits at doses up to 500 mg/kg/day. No pre- or postnatal susceptibility was observed in a reproduction study in rats.

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 chlorate is adequate to characterize the potential for prenatal or postnatal risk for infants and children.

ii. There is no indication in the available database that chlorate is a neurotoxicant.

iii. There was no pre- or postnatal sensitivity or susceptibility observed in the submitted developmental studies in rats and rabbits and the 2-generation reproduction study in rats.

iv. There are no residual uncertainties identified in the exposure databases. The dietary assessment is based on a conservative estimate of dietary exposures and drinking water monitoring data. These assessments will not underestimate the exposure and risks posed by chlorate.

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, chlorate 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 chlorate from food and water will utilize 8.4% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential pesticide uses for chlorate.

3. *Short- and Intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Short- and intermediate-term adverse effects were identified; however, chlorate is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- and intermediate-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 chlorate.

4. *Aggregate cancer risk for U.S. population.* A cancer aggregate assessment was not conducted separately, as the chronic aggregate assessment is protective of cancer for the general U.S. population. Based on the results of the assessment of chronic risk, the Agency concludes that exposure to chlorate will not result in a cancer risk of concern.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to chlorate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. Response to Comments

Two comments were received in response to the Notice of Filing, neither of which raised issues related to the safety of the tolerances in this action. Because they raise issues outside the scope of this rulemaking, the Agency is not addressing them here.

C. Revisions to Petitioned-For Tolerances

The residue data indicate that following use of the pesticide, there were detectable chlorate residues on the cantaloupe rind, although none were detected in the edible portions of the cantaloupe, and that chlorate residues on tomato were indistinguishable from background levels of chlorate on tomato. Because EPA does not anticipate use on either commodity to contribute to dietary exposure, EPA is issuing an exemption from the requirement of tolerance residues on cantaloupe and tomato. This tolerance exemption covers potential residues in or on these commodities as a result of direct application and allows for the shipment of these commodities in interstate commerce.

V. Conclusion

An exemption from the requirement of a tolerance is established for residues of chlorate in or on tomato and cantaloupe.

VI. 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) 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: November 30, 2018.

Anita Pease,

Acting Director, Antimicrobial 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. Add § 180.1364 to subpart D to read as follows:

§ 180.1364 Chlorate; exemption from the requirement of a tolerance.

Residues of chlorate in or on tomato and cantaloupe are exempt from the requirement of a tolerance when resulting from the application of gaseous chlorine dioxide as a fungicide, bactericide, and antimicrobial pesticide.

[FR Doc. 2018–27908 Filed 12–21–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA–R06–RCRA–2018–0395; FRL–9987–30–Region 6]

Louisiana: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On September 5, 2018, the Environmental Protection Agency (EPA) published a notice of proposed rulemaking to approve a revision to the State of Louisiana hazardous waste program under the Resource Conservation and Recovery Act (RCRA) and provided for a thirty-day public comment period. The public comment period closed on October 5, 2018, and EPA received fifteen comments. The EPA has reviewed and analyzed all submitted comments, and now issues this final rule. After consideration of all comments, EPA confirms that the program revisions to the State of Louisiana hazardous waste program satisfy all requirements needed to qualify for final authorization.

DATES: This final authorization is effective December 26, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R06–RCRA–2018–0395. All documents in the docket are listed in *www.regulation.gov* index. Although listed in the index, some of the information is not publicly available. *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically through *www.regulation.gov* or in hard copy. You can view and copy Louisiana's application and associated publicly available materials from 8:30 a.m. to 4:00 p.m., Monday through Friday, at the following locations: Louisiana Department of Environmental Quality, 602 N Fifth Street, Baton Rouge, Louisiana 70884–2178, phone number (225) 219–3559 and EPA, Region 6, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733, phone number (214) 665–8533.

FOR FURTHER INFORMATION CONTACT: Alima Patterson, Region 6, Regional Authorization/Codification Coordinator, Permit Section (6MM–RP), Multimedia Division, (214) 665–8533, EPA Region 6, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733, and Email address *patterson.alima@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. What revisions is EPA authorizing with this action?

On March 13, 2018, LDEQ submitted a final complete program revision application seeking authorization of its program revision in accordance with 40 CFR 271.21. EPA now makes a final decision that LDEQ's hazardous waste program revisions satisfy all the requirements necessary to qualify for final authorization. EPA will continue to implement and enforce Hazardous and Solid Waste Amendments of 1984 (HSWA) provisions for which the State is not authorized. For a list of rules that become effective with this Final Rule, please see the Proposed Rulemaking published in the September 5, 2018, **Federal Register** at 83 FR 45061.

B. What were the comments and responses to EPA's proposal?

EPA received fifteen comments. Twelve comments were supportive of EPA to grant the State of Louisiana portions of the Subtitle C Hazardous Waste Management Program and two were irrelevant to the proposed rulemaking. EPA received a written adverse comment from TD*X Associates LP, Beaumont Texas, (TD*X) requesting that EPA not authorize the State of Louisiana to implement the regulatory provisions commonly known as the ''Verified Recycler Exemption,'' or ''VRE.'' EPA received only one adverse comment, from TD*X, opposing EPA's proposal to authorize revisions to Louisiana's hazardous waste regulations. The full set of comments can be found in the docket for this action. The commenter asserts that the