Products, Food and Drug Administration, 301–796–5616, *melissa.burns@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an immediately in effect guidance for industry entitled ''Compliance Policy for Combination Product Postmarketing Safety Reporting.'' This guidance describes FDA's compliance policy for combination product applicants and constituent part applicants and activities under 21 CFR part 4, subpart B, which was published in the **Federal Register** of December 20, 2016 (81 FR 92603) and addresses postmarketing safety reporting for combination products. We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment, because we have determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i)) and § 10.115(g)(2)). We made this determination because FDA needs to communicate its compliance policy in a timely manner given the upcoming compliance deadlines for certain provisions in 21 CFR part 4, subpart B, and the amount of time needed for firms to prepare for them. Although this guidance is immediately effective, it remains subject to comment in accordance with FDA's GGP regulation.

Published elsewhere in this issue of the **Federal Register,** FDA is announcing the availability of the draft guidance entitled ''Postmarketing Safety Reporting for Combination Products.''

This guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314.80(c) and (e), as well as for 21 CFR 314.81(b) are approved under OMB control numbers 0910–0001, 0910–0230, and 0910–0291. The information collection provisions for 21 CFR 600.80 and 600.81 are approved under OMB control number 0910–0308. Those for 21 CFR 606.170 are approved under OMB control number 0910–0116. Those for 21 CFR 606.171 are approved under OMB control number 0910–0458. The information collection provisions for 21 CFR 803.50, 803.53, and 803.56 are approved under OMB control numbers 0910–0291 and 0910–0437. The information collection provisions for 21 CFR 806.10 and 806.20 are approved under OMB control number 0910–0359. The information collection provisions for §§ 4.102, 4.103, and 4.105 are approved under OMB control number 0910–0834.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: March 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05688 Filed 3–20–18; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

Requirements for Preparation, Adoption, and Submittal of Implementation Plans

CFR Correction

■ In Title 40 of the Code of Federal Regulations, Parts 50 to 51, revised as of July 1, 2017, on page 478, in Part 51, Appendix M, following *Reynolds Number.,* Equation 10 is reinstated to read as follows:

$$N_{re} = 8.64 \times 10^{5} \left[\frac{P_s M_w}{T_s} \right] \left[\frac{Q_s}{\mu} \right] \qquad \text{(Eq. 10)}$$

[FR Doc. 2018–05798 Filed 3–20–18; 8:45 am]

BILLING CODE 1301–00–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0639; FRL–9974–63]

Aluminum tris (O-ethylphosphonate); Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends a tolerance for residues of aluminum tris (O-ethylphosphonate) in or on Fruit, citrus, group 10. Fosetyl-al is the common name for aluminum tris (O-ethylphosphonate). Tessenderlo Kerley, Inc requested the amended tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 21, 2018. Objections and requests for hearings must be received on or before May 21, 2018, 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–2016–0639, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2016–0639 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 May 21, 2018. 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–2016–0639, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 26, 2017 (82 FR 34664) (FRL–9963–50), 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 6F8517) by Tessenderlo Kerley, Inc, 2255 N. 44th St., Suite 300, Phoenix, AZ 85008. The petition requested that 40 CFR 180.415 be modified by amending tolerances for residues of the fungicide aluminum tris (O-ethylphosphonate), in or on fruit, citrus, group 10 from 5.0 parts per million (ppm) to 9.0 ppm. That document referenced a summary of the petition prepared by Tessenderlo Kerley, Inc, the registrant, which is available in the docket, *http://www.regulations.gov*. No comments were received on this notice of filing.

Because EPA does not issue group tolerances for groups that have been updated or superseded, the petitioner submitted a revised petition, clarifying that its request was to establish tolerances for residues of the fungicide aluminum tris (O-ethylphosphonate) in or on the updated crop group fruit, citrus, group 10–10 at 9.0 ppm. EPA published notice of this revised petition in the **Federal Register** on December 19, 2017 (82 FR 60167) (FRL–9971–11). That document referenced a summary of this updated petition, which is available in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for aluminum tris (O-ethylphosphonate) including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with aluminum tris (O-ethylphosphonate) 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.

The major target organs following repeated oral exposure to fosetyl-Al are the reproductive system in the dog (testicular degeneration: Spermatocytic and/or spermatidic giant cells in the lumen of the seminiferous tubules) and the urinary system in the rat (histopathological changes in the kidney, impairment of calcium/phosphorus metabolism, calculi and hyperplasia in the urinary tract, bladder tumors).

The prenatal developmental studies in rabbits and rats and the 3-generation reproduction study in rats showed no indication of increased susceptibility following *in utero* and/or postnatal exposure to fosetyl-Al. Developmental toxicity was not observed in the rat at the limit dose or in the rabbit at the highest dose tested (500 mg/kg/day). Reproductive toxicity was not observed

at the limit dose, and offspring toxicity (decreased pup body weight at 600 mg/kg/day) was observed at the same dose as maternal toxicity (decreased body weight gain and urinary tract changes). The toxicology database for fosetyl-Al does not show any evidence of neurotoxicity.

Fosetyl-Al is classified as not likely to be carcinogenic to humans since it was negative for carcinogenicity except at extremely high doses (>limit dose) in rats and mice, and it did not show any genotoxic potential. Fosetyl-Al is not acutely toxic *via* the oral, dermal, and inhalation routes, is not a skin irritant or dermal sensitizer, but is a severe eye irritant.

Specific information on the studies received and the nature of the adverse effects caused by aluminum tris (O-ethylphosphonate) 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 document Fosetyl-Aluminum (Fosetyl-Al): Human Health Risk Assessment in Support of the Amended Registration for the Proposed 0-day Pre-Harvest Interval (PHI) for Citrus Fruit Group 10–10 at pages 9–14 in docket ID number EPA–HQ–OPP–2016–0639.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides*.

A summary of the toxicological endpoints for aluminum tris (O-ethylphosphonate) used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ALUMINUM TRIS (O-ETHYLPHOSPHONATE) FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations) ..	No appropriate endpoint was identified. There were no adverse effects observed in oral toxicity studies that could be attributed to a single-dose exposure.		
Chronic dietary (All populations)	NOAEL = 250mg/kg/day. UFA = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 2.5 mg/kg/day. cPAD = 2.5 mg/kg/day	Chronic oral toxicity (dog). LOAEL = 500 mg/kg/day based on an increased incidence of testicular degeneration (spermatocytic and/or spermatidic giant cells in the lumen of the seminiferous tubules).
Incidental oral (Short- and intermediate-term).	NOAEL = 300 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE <100.	3-generation reproduction (rat). LOAEL = 600 mg/kg/day based on decreased body weight gains in the F2b generation and urinary tract changes in adults and decreased pup body weights.
Dermal (All durations)	No potential hazard *via* the dermal route, based on the lack of systemic effects following repeat dermal exposure of rabbits at dose levels up to 1,500 mg/kg/day, which is greater than the limit dose.		
Inhalation (Short- and intermediate -term).	NOAEL = 300 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential and Occupational LOC for MOE <100.	3-generation reproduction (rat). LOAEL = 600 mg/kg/day based on decreased body weight gains in the F2b generation and urinary tract changes in adults.
Cancer (Oral, dermal, inhalation).	Not likely to be carcinogenic to humans.		

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).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to aluminum tris (O-ethylphosphonate), EPA considered exposure under the petitioned-for tolerances as well as all existing aluminum tris (O-ethylphosphonate) tolerances in 40 CFR 180.415. EPA assessed dietary exposures from aluminum tris (O-ethylphosphonate) 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 aluminum tris (O-ethylphosphonate); therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA Nationwide Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, the chronic dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM–FCID; version 3.16). The unrefined chronic analysis is based on tolerance-level residues and 100% crop treated assumptions. Default processing factors were used for all crops, except for citrus where processing studies showed no residue concentration; thus, the processing factor was set to one for processed citrus commodities.

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

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for aluminum tris (O-ethylphosphonate). Tolerance-level residues and/or 100% CT were assumed for all food commodities.

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

Environmental fate properties suggest that aluminum tris (O-ethylphosphonate) is not likely to reach ground or surface water under most conditions, and if it does reach surface water, it is expected to degrade rapidly. However, if aluminum tris (O-ethylphosphonate) reached groundwater, it could persist. Based on the Screening Concentration in Ground Water (SCI–GROW) model, the estimated drinking water concentration (EDWC) of aluminum tris (O-ethylphosphonate) for chronic exposures for non-cancer assessments is estimated to be 0.006 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 0.006 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Aluminum tris (O-ethylphosphonate) is currently registered for the following uses that could result in residential exposures: Turf and ornamental plants. EPA assessed residential exposure using the following assumptions: Inhalation exposure from the hose end sprayer for turf applications, and incidental oral exposure from post-application exposure to treated turf. Because no dermal endpoint was identified, non-occupational dermal exposures were not assessed. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide*.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found aluminum tris (O-ethylphosphonate) to share a common mechanism of toxicity with any other substances, and aluminum tris (O-ethylphosphonate) does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that aluminum tris (O-ethylphosphonate) 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.* There is no concern for increased quantitative or qualitative susceptibility of the young following *in utero* (rats and rabbits) and post-natal exposure (rats) to fosetyl-Al. Also, there is no evidence of developmental toxicity, reproductive toxicity, neurotoxicity, or immunotoxicity at dose levels that do not exceed the limit dose.

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 aluminum tris (O-ethylphosphonate) is complete.

ii. There is no indication that aluminum tris (O-ethylphosphonate) 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 aluminum tris (O-ethylphosphonate) results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 3-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues and are not likely to underestimate risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to aluminum tris (O-ethylphosphonate) 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 aluminum tris (O-ethylphosphonate).

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, aluminum tris (O-ethylphosphonate) 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 aluminum tris (O-ethylphosphonate) from food and water will utilize 14% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of aluminum tris (O-ethylphosphonate) 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).

Aluminum tris (O-ethylphosphonate) is currently 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 aluminum tris (O-ethylphosphonate).

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 of 3200 for male adults, 3300 for female adults and 480 for children 1–2 years old. Because EPA's level of concern for aluminum tris (O-ethylphosphonate) is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, aluminum tris (O-ethylphosphonate) is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no 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 intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for aluminum tris (O-ethylphosphonate).

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, aluminum tris (O-ethylphosphonate) 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 aluminum tris (O-ethylphosphonate) residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Pesticide Analytical Manual (PAM) II method, which uses diazomethane as the methylating agent and quantitation of aluminum tris (O-ethylphosphonate) by Gas Chromatography with Flame Photometric Detector (GC/FPD)) is available to enforce the tolerance expression.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for aluminum tris (O-ethylphosphonate) on citrus fruit.

C. Response to Comments

EPA received five comments on the second notice of filing. Two comments pertained to the general concern over addition of more chemicals to the daily diet and onset of autoimmune diseases but did not contain any specific information relevant to the potential risks from aluminum tris (O-ethylphosphonate). In response, the Agency explains that it has complied with the requirements of the FFDCA, which allow the Agency to establish or modify tolerances if the Agency determines they are safe. When new or amended tolerances are requested for the presence of the residues of a pesticide and its toxicologically significant metabolite(s) in food or feed, the EPA, as is required by section 408 of the FFDCA, estimates the risk of the potential exposure to these residues by performing an aggregate risk assessment. Such a risk assessment integrates the individual assessments that are conducted for food, drinking water, and residential exposures. Additionally, the Agency, as is further required by section 408 of the FFDCA, considers available information concerning what are termed the cumulative toxicological effects of the residues of that pesticide and of other substances having a common mechanism of toxicity with it. The Agency has concluded after this assessment that there is a reasonable certainty that no harm will result from exposure to the residues of interest. Therefore, the Agency may establish the tolerances requested in this petition.

Another citizen was concerned about the risk to pollinators. The commenter stated this use should be denied due to toxicity to pollinators and that keeping them healthy should be our top priority. The comment primarily appears directed to the registration of the pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and are not relevant to the underlying safety finding made under the FFDCA; therefore, the EPA will consider impacts to the environment and non-target species under the authority of FIFRA. The remaining two comments were not

germane to this action; therefore, no further response from the Agency is required.

V. Conclusion

Therefore, tolerances are amended for residues of aluminum tris (O-ethylphosphonate), in or on fruit, citrus, group 10–10 at 9.0 ppm.

VI. Statutory and Executive Order Reviews

This action amends and expands an existing crop group 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). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 7, 2018.

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 § 180.415,

■ a. Remove the entry for ''Fruit, citrus, group 10'' from the table in paragraph (a).

■ b. Add alphabetically an entry to the table in paragraph (a) for ''Fruit, citrus, group 10–10''.

The addition reads as follows:

§ 180.415 Aluminum tris (*O*-ethylphosphonate); tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Fruit, citrus, group 10–10	9.0
* * * * *	

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0817; FRL–9974–32]

Flutianil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flutianil in or on multiple commodities that are identified and discussed later in this document and an exemption for indirect or inadvertent residues of flutianil on other crops rotated into fields previously treated with flutianil. OAT AGRIO Company, Ltd. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 21, 2018. Objections and requests for hearings must be received on or before May 21, 2018, 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–2015–0817, 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 L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200