

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides 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. 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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 22, 2013. 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Oxides of nitrogen, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: February 4, 2013.

**Jared Blumenfeld,**

*Regional Administrator, Region IX.*

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

#### PART 52—[AMENDED]

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

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

#### Subpart D—Arizona

■ 2. Section 52.120 is amended by adding paragraphs (c)(155), (c)(156), and (c)(157) to read as follows:

##### § 52.120 Identification of plan.

\* \* \* \* \*

(c) \* \* \*

(155) The following plan was submitted on November 6, 2009 by the Governor's designee.

(i) Incorporation by reference.

(A) Arizona Department of Environmental Quality.

(1) Affidavit by Efrem K. Sepulveda, Law Librarian, Arizona State Library, Archives and Public Records, certifying authenticity of reproduction of A.R.S. § 49–542 (2008 edition) plus title page to pocket part of Title 49 (2008 edition), signed January 11, 2013.

(2) Arizona Revised Statutes (Thomson West, 2008 Cumulative Pocket Part): Title 49 (the environment), section 49–542 ("Emissions inspection program; powers and duties of director; administration; periodic inspection; minimum standards and rules; exceptions; definition").

(ii) Additional materials.

(A) Arizona Department of Environmental Quality.

(1) Final Arizona State Implementation Plan Revision, Exemption of Motorcycles from Vehicle Emissions Inspections and Maintenance Program Requirements in Area A (October 2009), adopted by the Arizona Department of Environmental Quality on November 6, 2009, excluding appendices A and C.

(156) The following plan was submitted on January 11, 2011 by the Governor's designee.

(i) [Reserved]

(ii) Additional materials.

(A) Arizona Department of Environmental Quality.

(1) Final Addendum to the Arizona State Implementation Plan Revision, Exemption of Motorcycles from Vehicle Emissions Inspections and Maintenance Program Requirements in Area A, October 2009 (December 2010), adopted by the Arizona Department of Environmental Quality on January 11, 2011.

(157) The following plan was submitted on May 25, 2012 by the Governor's designee.

(i) Incorporation by reference.

(A) Arizona Department of Environmental Quality.

(1) Affidavit by Barbara Howe, Law Reference Librarian, Arizona State Library, Archives and Public Records, certifying authenticity of reproduction of Arizona Revised Statutes § 49–451

(*sic*) (corrected to § 49–541) (2001 pocket part), signed May 3, 2012.

(2) Arizona Revised Statutes (West Group, 2001 Cumulative Pocket Part): title 49 (the environment), section 49–541 ("Definitions"), subsection 1 [Definition of Area A].

[FR Doc. 2013–12091 Filed 5–21–13; 8:45 am]

**BILLING CODE 6560–50–P**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA–HQ–OPP–2012–0203; FRL–9386–1]

#### 1-Naphthaleneacetic acid; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of 1-naphthaleneacetic acid in or on avocado; fruit, pome, group 11–10; mango; sapote, mamey; and rambutan. This regulation additionally deletes certain tolerances, identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective May 22, 2013. Objections and requests for hearings must be received on or before July 22, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0203, 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), EPA West 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:** Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200

Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; email address: [nollen.laura@epa.gov](mailto:nollen.laura@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](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-2012-0203 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 July 22, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your

objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0203, 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.htm>.

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 May 2, 2012 (77 FR 25954) (FRL-9346-1), 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 2E7991) by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.155 be amended by establishing tolerances for residues of the plant growth regulator 1-naphthaleneacetic acid and its conjugates in or on rambutan at 3 parts per million (ppm); avocado, mango, and sapote, mamey at 0.05 ppm; and fruit, pome, group 11-10 at 0.15 ppm. The petition additionally requested to amend the tolerances in 40 CFR 180.155 by removing the tolerance for fruit, pome, group 11 at 0.15 ppm, as it will be superseded by the tolerance on fruit, pome, group 11-10 at 0.15 ppm. That document referenced a summary of the petition prepared on behalf of IR-4 by Amvac Chemical Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance on rambutan from 3.0 ppm to 2.0 ppm. The Agency has also revised the tolerance expression for all established commodities to be consistent with current Agency policy. The reason for these changes is explained in Unit IV.C.

##### III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in that section, 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 1-naphthaleneacetic acid, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with 1-naphthaleneacetic acid 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.

Based on structural activity relationship and metabolism data, all forms of 1-naphthaleneacetic acid, its salts, ester, and acetamide which are collectively referred to as naphthalene acetates (NAA), are expected to exhibit similar toxicological effects. In selecting endpoints of toxicity for risk assessment to exposures to the various NAA forms, the most conservative endpoint was selected from the studies that showed the lowest NOAELs for assessing a particular exposure. In addition, all forms degrade to the acid fairly quickly in the field and in biological systems.

Therefore, EPA has concluded that required toxicity testing on any form should serve for all members of this group of chemicals.

Repeated oral exposures to NAA in rats and dogs resulted in decreased body weights, and body weight gains accompanied by decreased food consumption. The major target organs from subchronic and chronic oral exposures were the liver, stomach, and lung. Repeated oral exposures also resulted in decreased hematocrit and hemoglobin, along with reduced red blood cell count in rats and dogs and hypocellularity of the bone marrow in dogs.

There was no developmental toxicity at the highest dose of NAA (the acid) tested in the rat or in the rabbit (orally gavaged), but developmental toxicity (decreased fetal weight and minor skeletal changes) were seen in rats orally gavaged with the sodium salt. Reproductive effects of NAA sodium salts were limited to reduced litter survival and pup weight throughout lactation in both generations of offspring in a 2-generation reproduction study.

NAA and its acetamide and the ethyl ester were tested for mutagenic effects in a gene mutation bacterial assay, mouse lymphoma assay, and mouse erythrocyte micronucleus assay, mouse

lymphoma assay, and mouse erythrocyte micronucleus assay and were not found to be mutagenic. Additionally, NAA was tested for mitotic gene conversion and dominant lethality in rats and found to be negative. In a published carcinogenicity study of NAA acetamide in mice and a guideline chronic/oncogenicity study of NAA sodium salt in rats and mice, NAA compounds were not carcinogenic in mice or rats.

Specific information on the studies received and the nature of the adverse effects caused by NAA 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: "Naphthalene Acetates Human Health Risk Assessment for a Proposed Use on Avocado, Mango, Mamey Sapote, Rambutan, and Updating Crop Group Fruit, Pome, Group 11–10." at pages 42–50 in docket ID number EPA–HQ–OPP–2012–0203.

#### *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 (LOC) 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 (U/SF) 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 NAA used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR NAA 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 (General population including infants and children and females 13–49 years of age)	An acute RfD for the general population or any population subgroups was not selected because no effect attributable to a single exposure was observed in animal studies.		
Chronic dietary (All populations) ....	NOAEL = 15 mg/kg/day ..... UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.15 mg/kg/day ..... cPAD = 0.15 mg/kg/day	Chronic Toxicity—Dog LOAEL = 75 mg/kg/day based on stomach lesions in 75% of the males and by slight sinusoidal histiocytosis in the liver of 50% of the males.
Dermal short-term (1 to 30 days) ..	Dermal study ..... NOAEL = 300 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100 .....	21-Day dermal: NAA Na salt LOAEL = 1,000 mg/kg/day based on reduced body weight gain and food efficiency.
Inhalation short-term (1 to 30 days).	Oral study ..... NOAEL = 50 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 10x	LOC for MOE = 1,000 .....	Developmental Rat: NAA LOAEL = 150 mg/kg/day based on decreased body weight gain during gestation period.
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 = milligrams/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<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = 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 NAA, EPA considered exposure under the petitioned-for tolerances as well as all existing NAA tolerances in 40 CFR 180.155. EPA assessed dietary exposures from NAA 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 NAA; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16, which uses food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA), conducted from 2003–2008. As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues for all commodities. In addition, DEEM version 7.81 default processing factors were used, when appropriate.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that NAA 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 PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for NAA. Tolerance level residues and/or 100 PCT 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 NAA in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of NAA. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) and Concentration in Ground Water (SCI-GROW) models, the estimated drinking

water concentrations (EDWCs) of NAA for chronic exposures for non-cancer assessments are estimated to be 2.99 parts per billion (ppb) for surface water and 0.0226 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 3.0 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). NAA is currently registered for root dip and sprout inhibition applications to ornamentals, which could result in residential exposures. There is a potential for short-term dermal and inhalation exposures to residential handlers, resulting from loading and applying NAA. There are no residential uses for NAA that result in exposure to children via incidental oral activities. The rooting compounds are applied by holding the plant and dipping the roots into solution. Very little exposure is expected from this use. Sprout inhibitors are applied by spray or paint brush/roller after pruning trees, or by spraying near the base of the tree after pruning root suckers. There is very little potential for postapplication exposure to NAA for adults or children based on the residential use pattern; therefore, residential postapplication exposure is not expected, nor is intermediate- or long-term exposure scenarios based on the intermittent nature of applications by homeowners.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

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 NAA to share a common mechanism of toxicity with any other substances, and NAA does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that NAA 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 Web site 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 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 low concern and no residual uncertainty for pre- and/or postnatal toxicity resulting from exposure to the NAA group of chemicals. The available data provided no indication of increased quantitative or qualitative susceptibility of rats or rabbits to *in utero* exposure to NAA or to prenatal and postnatal exposure in rat reproduction studies. In the developmental toxicity study conducted with NAA sodium salt in rats, fetal toxicity (mainly decreased fetal weights and minor skeletal changes) was observed at a dose lower than the maternally toxic dose.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF was reduced to 1X for the oral and dermal routes of exposure and retained at 10X for the inhalation route of exposure. That decision is based on the following findings:

i. The toxicity database for NAA is not complete. EPA concluded that a 28-day inhalation toxicity study is required for NAA, based on a weight-of-evidence approach. A 10X SF was retained for the inhalation route of exposure due to the lack of the required 28-day inhalation study and given that the endpoint for subchronic inhalation is based on a developmental study (NOAEL = 50 mg/kg/day) that noted decreased body weight gains during gestation.

Additionally, recent changes to 40 CFR part 158 imposed new data requirements for immunotoxicity testing

(OCSPP Guideline 870.7800) for pesticide registration. While an immunotoxicity study is not available for NAA, the toxicology database does not show any evidence of treatment-related effects on the immune system and the overall weight-of-evidence suggests that this chemical does not directly target the immune system. Consequently, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower POD than that currently used for overall risk assessment, and therefore, an additional safety factor is not needed to account for lack of this study.

Acute and subchronic neurotoxicity studies are also required as a part of new data requirements in 40 CFR part 158; however, EPA has waived the requirement for these studies at the present time. This decision is based on: (1) The lack of neurotoxicity and neuropathology in the available toxicology studies for NAA; and (2) liver, stomach, and lung were identified as the target organs, with dogs being the most sensitive species. Therefore, neurotoxicity studies conducted in rats would not provide a more sensitive endpoint for risk assessment, and studies would be unlikely to yield PODs lower than the current PODs used for overall risk assessment.

ii. There is no indication that NAA 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 NAA 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. In the developmental toxicity study conducted with NAA sodium salt in rats, fetal toxicity was observed at a dose lower than the maternally toxic dose. However, there were clear NOAELs in this developmental study and the PODs used in the chronic dietary assessment (15 mg/kg/day) are protective of the fetal effects observed in the study.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment was performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to NAA in drinking water. Based on the discussion in Unit III.C.3., regarding limited residential use patterns, exposure to residential handlers is very low and EPA does not anticipate postapplication exposure to children or incidental exposures to

toddlers resulting from use of NAA in residential settings. These assessments will not underestimate the exposure and risks posed by NAA.

#### *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, NAA 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 NAA from food and water will utilize 2.0% 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 NAA 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). Though there is potential for short-term dermal and inhalation exposures to adult handlers resulting from residential applications of NAA to ornamentals, aggregate risk was not estimated for NAA because the toxicity endpoints selected for the chronic dietary route of exposure and those selected for inhalation and dermal routes of exposure are not based on common effects i.e., the chronic dietary endpoint is based on systemic effects and the dermal and inhalation endpoints are based on decreased body weight gain. Exposure pathways and routes are only aggregated when they share a common toxic effect.

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).

Because no intermediate-term adverse effect was identified, NAA is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, NAA 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 NAA residues.

## **IV. Other Considerations**

### *A. Analytical Enforcement Methodology*

An adequate enforcement method, a high performance liquid chromatography (HPLC) method using fluorescence detection (Method NAA-AM-001) and a similar method (Method NAA-AM-002), is available to enforce the tolerance expression for NAA in plant commodities.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

### *B. International Residue Limits*

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

The Codex has not established a MRL for NAA.

### *C. Revisions to Petitioned-For Tolerances*

Based on the data supporting the petition, EPA revised the proposed tolerance on rambutan from 3.0 ppm to

2.0 ppm. The Agency revised this tolerance level based on analysis of the residue field trial data using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures.

Finally, the Agency has revised the tolerance expression to clarify: (1) That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of NAA not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

## V. Conclusion

Therefore, tolerances are established for residues of NAA, 1-naphthaleneacetic acid, in or on avocado at 0.05 ppm; fruit, pome, group 11–10 at 0.15 ppm; sapote, mamey at 0.05 ppm; mango at 0.05 ppm; and rambutan at 2.0 ppm. This regulation additionally removes the tolerance in or on fruit, pome, group 11 at 0.15 ppm and the time-limited tolerance in or on avocado at 0.05 ppm.

## VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: May 14, 2013.

**Daniel J. Rosenblatt,**

*Acting 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. Section 180.155 is revised to read as follows:

#### § 180.155 1-Naphthaleneacetic acid; tolerances for residues.

(a) *General.* Tolerances are established for the residues of 1-naphthaleneacetic acid, including its metabolites and degradates in or on the commodities in the following table. Compliance with the tolerance levels specified is to be determined by measuring only 1-naphthaleneacetic acid and its conjugates, calculated as the Stoichiometric equivalent of 1-naphthaleneacetic acid, in or on the commodity.

Commodity	Parts per million
Avocado .....	0.05
Cherry, sweet .....	0.1
Fruit, pome, group 11–10 .....	0.15
Mango .....	0.05
Olive .....	0.7
Orange .....	0.1
Pineapple <sup>1</sup> .....	0.05
Potato .....	0.01
Rambutan .....	2.0
Sapote, mamey .....	0.05
Tangerine .....	0.1

<sup>1</sup> There are no U.S. registrations since 1988.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2013–12207 Filed 5–21–13; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 45 CFR Part 152

[CMS–9995–IFC3]

RIN 0938–AQ70

### Pre-Existing Condition Insurance Plan Program

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

**ACTION:** Interim final rule with comment period.

**SUMMARY:** This interim final rule with comment period sets the payment rates for covered services furnished to individuals enrolled in the Pre-Existing Condition Insurance Plan (PCIP) program administered directly by HHS beginning with covered services furnished on June 15, 2013. This interim