READING AREA'S MOTOR VEHICLE EMISSION BUDGETS FOR THE 1997 ANNUAL $PM_{2.5}$ NAAQS IN TONS PER YEAR—Continued

Type of control strategy SIP	Year	$PM_{2.5}$	NO_X	Effective date of SIP approval
	2025	146	3,719	3/4/15

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 1. The authority citation for Part 81 continues to read as follows:

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

■ 2. Section 81.339 is amended by revising the 1997 Annual $PM_{2.5}$ NAAQS table entry for the Reading Area to read as follows:

§ 81.339 Pennsylvania.

* * * * *

PENNSYLVANIA—1997 ANNUAL $PM_{2.5}$ NAAQS

[Primary and secondary]

Designated Area	Designation [a]		Classification	
	Date [1]	Type	Date [2]	Type
* * *	*	*	*	*
Reading, PA:				
Berks County	March 4, 2015 ..	Attainment.		
* * *	*	*	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.
[2] This date is July 2, 2014, unless otherwise noted.

* * * * *

[FR Doc. 2015–04391 Filed 3–3–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0110; FRL–9921–85]

Metaldehyde; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of metaldehyde in or on multiple commodities which are 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). This regulation additionally removes the established tolerances in or on fruit, citrus group 10 and tomato as the tolerances will be superseded by tolerances established by this action.

DATES: This regulation is effective March 4, 2015. Objections and requests for hearings must be received on or before May 4, 2015, 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–2014–0110 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: Susan Lewis, 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: *Notices*@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 Publishing 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–2014–0110 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 4, 2015. 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–2014–0110, 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 February 25, 2014 (79 FR 10459) (FRL–9906–77), 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 3E8223) by IR–4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.523 be amended by establishing tolerances for residues of the molluscicide metaldehyde, 2,4,6,8-tetramethyl-1,3,5,7-tetroxocane, in or on clover, forage at 0.5 parts per million (ppm); clover, hay at 0.5 ppm; ginseng at 0.05 ppm; vegetable legume, edible podded, subgroup 6A at 0.8 ppm; pea and bean, succulent shelled, subgroup 6B at 0.2 ppm; vegetable, foliage of legume, except soybean, subgroup 7A at 1.5 ppm; tomato subgroup 8–10A at 0.24 ppm; and fruit, citrus, group 10–10 at 0.26 ppm. Clover, forage and clover, hay were proposed as tolerances with regional registrations. Additionally, the petition requested removing the established tolerances in or on fruit, citrus, group 10 at 0.26 ppm; and tomato at 0.24 ppm, upon establishment of the proposed tolerances. That document referenced a summary of the petition prepared by Lonza, Inc., the registrant, 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.

Based upon review of the data supporting the petition, EPA has modified the proposed tolerances for clover, forage and clover, hay from 0.5 ppm to 0.60 ppm. The reason for these changes are explained in Unit IV.D.

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 metaldehyde including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with metaldehyde 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 principal toxic effects for metaldehyde are clinical signs of neurotoxicity, as well as changes in the liver and testes/prostate following repeated oral dosing. The dog is the most sensitive species for neurotoxic effects. Nervous system effects observed in the subchronic and chronic oral toxicity studies include: Ataxia and tremors; twitching; salivation; emesis; rapid respiration in dogs and maternal rats; and limb paralysis, spinal cord necrosis, and hemorrhage in maternal rats. Liver effects include increased liver weight, increased incidence of liver lesions (hepatocellular necrosis, hepatocellular hypertrophy and inflammation), and an increased incidence of hepatocellular adenomas in female rats and in both sexes of mice. In dogs, atrophy of the testes and prostate was observed following subchronic and chronic exposure.

In the rat developmental toxicity study, maternal toxicity was observed as evidenced by clinical signs including ataxia, tremors, and twitching at the highest dose tested (HDT) in the absence of developmental toxicity. There was no observed developmental or maternal toxicity in the rabbit developmental toxicity study. In the 2-generation rat reproductive toxicity study, mortality and clinical signs including limb paralysis, spinal cord necrosis and hemorrhage were observed in the maternal animals. Effects on the offspring in the rat reproductive toxicity study consisted of decreased pup body weight and body weight gains; reproductive toxicity was not observed.

In the rat, clinical signs of neurotoxicity occurred at high dose levels following repeated oral exposures. In the 90-day neurotoxicity study, bilateral hindlimb paralysis was observed in one female rat at the HDT.

Chronic feeding studies in rats and mice indicated that metaldehyde produced liver effects characterized by liver hypertrophy and liver tumors. The chronic mouse toxicity study showed that metaldehyde was associated with a common tumor in both sexes (liver tumors, adenomas), and the rat chronic

toxicity study showed that metaldehyde was associated with liver adenomas in the female. EPA has determined that quantification of risk using a nonlinear Reference Dose (RfD) approach, using the chronic RfD/Population-Adjusted Dose (PAD), will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to metaldehyde. That conclusion is based on the following considerations:

1. Tumors found are commonly seen in the mouse;

2. Liver tumors (adenomas) in both species were benign;

3. Metaldehyde is not mutagenic;

4. No carcinogenic response was seen in the male rat;

5. Incidence of adenomas at the high dose in the female rat was within the historical control range of the testing lab; and

6. Both the No Observed Adverse Effect Level (NOAEL) and Lowest Observed Adverse Effect Level (LOAEL) from the chronic rat study on which the chronic RfD/PAD was based are well below the dose at which adenomas were seen.

Specific information on the studies received and the nature of the adverse effects caused by metaldehyde 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 ''Metaldehyde; Human Health Risk Assessment for Proposed New Uses on Vegetable, Legume, Edible Podded [Subgroup 6A], Pea and Bean, Succulent Shelled [Subgroup 6B], Vegetable, Foliage of Legume, Except Soybean [Subgroup 7A], Clover Forage and Hay, and Ginseng; and for Amendments to Existing Tolerances [Tomato and Crop Group 10]'' in docket ID number EPA–HQ–OPP–2014–0110.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for metaldehyde used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of November 27, 2013 (78 FR 70864) (FRL–9399–8).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to metaldehyde, EPA considered exposure under the petitioned-for tolerances as well as all existing metaldehyde tolerances in 40 CFR 180.523. EPA assessed dietary exposures from metaldehyde 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.

Such effects were identified for metaldehyde. In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model with the Food Commodity Intake Database (DEEM–FCID). This software incorporates 2003–2008 food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA used tolerance-level residues for all commodities and 100 percent crop treated (PCT) estimates. The Agency also assumed processing factors to be 1.0 for all commodities except for dried tomato, tomato juice, cranberry juice, and high fructose corn syrup; for these commodities, DEEM default processing factors were used.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA used tolerance-level residues for all commodities and assumed 100 PCT. The Agency also assumed processing factors to be 1.0 for all commodities except for dried tomato, tomato juice, cranberry juice, and high fructose corn syrup; for these commodities, DEEM default processing factors were used.

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

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for metaldehyde. 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 metaldehyde in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of metaldehyde. 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of metaldehyde for acute exposures are estimated to be 205 parts per billion (ppb) for surface water and 1,880 ppb for ground water and for chronic exposures for non-cancer assessments are estimated to be 136 ppb for surface water and 915 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration value of 1,880 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 915 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).

Metaldehyde is currently registered for the following uses that could result in residential exposures: Residential ornamentals and lawn/turf applications.

EPA assessed residential exposure using the following assumptions:

i. Adult handler short-term inhalation exposures from loading/applying metaldehyde products including liquid ready-to-use products (with manually-pressurized hand wands, hose-end sprayers, and sprinkler cans) and applying granules (via push-type rotary spreaders, belly grinders, spoons, cups, hands, and shaker cans); and

ii. Metaldehyde incidental post-application exposures assessed for children, including short-term exposure from hand-to-mouth and object-to-mouth contact with treated turf, and short- and intermediate-term exposures from treated soil ingestion. While EPA did calculate an acute incidental ingestion scenario for toddlers accidentally ingesting granules of metaldehyde, it is not appropriate to aggregate this scenario because it represents poisoning incident which is not likely to overlap with the typical post-application exposure scenario. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/science/residential-exposure-sop.html.*

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 metaldehyde to share a common mechanism of toxicity with any other substances, and metaldehyde does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that metaldehyde 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 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.* Developmental toxicity was not observed in the rat or rabbit developmental toxicity studies, and maternal toxicity was not observed in the rabbit. In the rat, maternal toxicity was observed, as evidenced by clinical signs (ataxia, tremors, and twitching) at the HDT. In the rat reproductive toxicity study, mortality and clinical signs (limb paralysis, spinal cord necrosis and hemorrhage) were observed in the maternal animals, and the effects on the offspring consisted of decreased pup body weight and body weight gains. Reproductive toxicity was not observed.

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 metaldehyde is complete.

ii. The toxicity database contains indications of neurotoxicity resulting from exposure to metaldehyde, including:

a. Clinical signs [ataxia, twitching, tremors, prostration, paresis of hind legs] in female rats in the developmental toxicity study;

b. Hindlimb paralysis, necrosis and hemorrhage in the spinal cord and vertebra luxation in F0 dams during lactation period in the 2-generation reproduction study;

c. Bilateral hindlimb paralysis observed initially on day 10 in one high-dose female sacrificed on day 22 due to poor condition in the 90-day subchronic neurotoxicity study in rats; no neuropathology was evident;

d. Clinical signs [ataxia, tremors, twitching, salivation] in the chronic dog study, which occurred within the first week of exposure and persisted through week 19; other signs observed in the chronic dog study included lateral position, reduced mobility, convulsions, and vocalization in one female, and agitation in another.

EPA has determined that the acute and developmental neurotoxicity studies are not needed, nor are additional uncertainty factors (UFs) necessary to account for neurotoxicity. There were no indications of neurotoxic effects in developing rats or rabbits in either the developmental or reproductive studies. Although there were some effects in adult rats, those effects occurred at doses much higher than in the dog study. The dog is the more sensitive species for neurotoxic effects and points of departure (30 mg/kg/day and 10 mg/kg/day) are based on the chronic dog oral toxicity study, which EPA considers to be protective of any neurotoxicity at higher dose levels.

iii. There is no evidence that metaldehyde 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.

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. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to metaldehyde 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 metaldehyde.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to metaldehyde will occupy 55% of the aPAD for all infants (less than 1 year old), the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to metaldehyde from food and water will utilize 51% of the cPAD for all infants less than 1 year old the population group receiving the greatest exposure. Chronic exposures to metaldehyde are expected for food and water only.

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). Metaldehyde 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 metaldehyde. 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 1,400 for adults and 590 for children. Because EPA's level of concern for metaldehyde 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). Metaldehyde is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to metaldehyde.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 280 for children, only. Because EPA's level of concern for metaldehyde is a MOE of 100 or below, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to metaldehyde. Cancer risk was assessed using the same cPAD and exposure estimates as discussed in Unit III.A. and Unit III.C.1.ii. for the chronic risk assessment. Based on the results discussed in Unit III.E.2., EPA concludes that aggregate exposure to metaldehyde will not pose a cancer risk.

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 metaldehyde residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with mass spectrometry (GC/MS) method (EN–CAS Method No. ENC–3/99, Revision 1) 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 metaldehyde.

C. Response to Comments

Six comments were posted in the docket for this action. However, the comments received were regarding bee concerns for a different chemical, sulfoxaflor. These comments were addressed at the time the Agency assessed sulfoxaflor. As a result, the only comments received were determined to be irrelevant to the Agency's tolerance action on metaldehyde.

D. Revisions to Petitioned-For Tolerances

The Agency has determined that tolerances of 0.60 ppm for clover hay and forage are appropriate based on available residue data and use of the OECD tolerance calculation procedures.

V. Conclusion

Therefore, tolerances are established for residues of metaldehyde in or on the following commodities: Vegetable, legume, edible podded, subgroup 6A at 0.80 ppm; pea and bean, succulent shelled, subgroup 6B at 0.20 ppm; vegetable, foliage of legume, except soybean, subgroup 7A at 1.5 ppm; tomato subgroup 8–10A at 0.24 ppm; fruit, citrus, group 10–10 at 0.26; and ginseng at 0.05 ppm; and tolerances with regional registrations for clover, forage at 0.60 ppm and clover, hay at 0.60 ppm. The regulation additionally removes the tolerances in or on fruit, citrus group 10 and tomato.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175,

entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: February 23, 2015.

Susan Lewis,

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 § 180.523:

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

■ b. Add alphabetically the entries for ''Ginseng''; ''Pea and bean, succulent shelled, subgroup 6B''; ''Tomato subgroup 8–10A''; ''Vegetable, foliage of legume, except soybean, subgroup 7A''; and ''Vegetable, legume, edible podded subgroup 6A'' to the table in paragraph (a).

■ c. Remove the entry for ''Tomato'' in the table in paragraph (a).

■ d. Add alphabetically the entries for ''Clover, forage'' and ''Clover, hay'' to the table in paragraph (c).

The amendments read as follows:

§ 180.523 Metaldehyde; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * * *	
Fruit, citrus, group 10–10	0.26
Ginseng	0.05
* * * * * * *	
Pea and bean, succulent shelled, subgroup 6B	0.20
* * * * * * *	
Tomato subgroup 8–10A	0.24
* * * * * * *	
Vegetable, foliage of legume, except soybean, subgroup 7A	1.5
Vegetable, legume, edible podded subgroup 6A	0.80
* * * * * * *	

* * * * * (c) * * *

Commodity	Parts per million
Clover, forage	0.60
Clover, hay	0.60
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0601; FRL–9922–29]

9-Octadecenoic Acid (9*Z*)-, Sulfonated, Oxidized and its Potassium and Sodium Salts; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 9-octadecenoic acid (9*Z*)-, sulfonated, oxidized; 9-octadecenoic acid (9*Z*)-, sulfonated, oxidized, potassium salts; and 9-octadecenoic acid (9*Z*)-, sulfonated, oxidized, sodium salts, when used as an inert ingredient in antimicrobial pesticide formulations used on food contact surfaces in public eating places, dairy processing equipment and food processing equipment and utensils at a maximum end-use concentration not to exceed 250 parts per million (ppm). Ecolab submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 9-octadecenoic acid (9*Z*)-, sulfonated, oxidized and its potassium and sodium salts.

DATES: This regulation is effective March 4, 2015. Objections and requests for hearings must be received on or before May 4, 2015, 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–2013–0601, 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: Susan Lewis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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–2013–0601 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 4, 2015. 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–2013–0601, by one of the following methods:

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

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

II. Petition for Exemption

In the **Federal Register** of September 12, 2013 (78 FR 56185) (FRL–9399–7), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–10549) by Ecolab, Inc. 370 N. Wabasha Street, St. Paul, MN 55102. The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of 9-octadecenoic acid (9*Z*)-, sulfonated, oxidized (CAS Reg. No. 1315321–93–7); 9-octadecenoic acid (9*Z*)-, sulfonated, oxidized, potassium salts (CAS Reg. No. 1315321–94–8); and 9-octadecenoic acid (9*Z*)-, sulfonated, oxidized, sodium salts, (CAS No. 1315321–95–9) when used as an inert ingredient in antimicrobial pesticide formulations used on food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils at a maximum end-use concentration not to exceed 250 ppm. That document referenced a summary of the petition prepared by Ecolab Inc, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no