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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0561;FRL–8833–8]

Acetic Acid; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the existing tolerance exemption for acetic acid by establishing an exemption from the requirement of a tolerance for residues of acetic acid, also known as vinegar in or on all food crops resulting from unintentional spray and drift to non-target vegetation including non-food, food and feed crops when used as a non-selective contact herbicide spray. SummerSet Products c/o SciReg, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of acetic acid, also known as vinegar.

DATES: This regulation is effective July 14, 2010. Objections and requests for hearings must be received on or before September 13, 2010, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0561. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Cheryl Greene, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0352; e-mail address: *greene.cheryl@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. Potentially affected entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2010–0561 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 September 13, 2010. 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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2010–0561, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of November 19, 2008, (FR 69635) (FRL–8389–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 8F7319) by SummerSet Products c/o SciReg, Inc., 130 Columbia Court, Chaska, MN 55318. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of acetic acid. This notice referenced a summary of the petition prepared by the petitioner SummerSet Products, which is available in the docket, *http://www.regulations.gov*. One anonymous comment was received on the notice of filing. However, EPA was unable to address the comment because it was not specific to this action, focusing instead on the registration of pesticides generally, and therefore was not a significant comment.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require 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. . . ." Additionally, section 408(b)(2)(D) of FFDCA requires that 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's.

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information 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.

Acetic acid is a substance found or produced naturally in most plants and animals, including primates and humans. It is also naturally produced during the fermentation process in a wide range of foods. In plants and animals, it is generally produced biologically by bacteria from the genus *Acetobacter*. Acetic acid has a fundamental role in cellular metabolism, particularly in the tricarboxylic acid cycle, also known as the citric acid (Ref. 1.) or krebs cycle (Ref. 2.), which is the chemical activity in all cells that utilize oxygen as part of their respiration process. The krebs cycle is carried out in the mitochondria of the cells of plants and animals including humans. Acetic acid plays a key role in the production of carbon dioxide and is a chemical rich in adenosine triphosphate (ATP). Acetic acid occurs naturally in many commonly consumed food items such as coffee, chick peas, edible plants, brown sugar, fruits, and vegetables where it forms during post-harvest fermentation. As an organic chemical, acetic acid is readily metabolized by the tissues of the body and is used in plants and animals to synthesize proteins, carbohydrates and fatty acids. In animals, including humans, acetic acid is produced naturally as consumed sugars and alcohol containing foods or liquids such as alcoholic beverage undergo fermentation.

Acetic acid has been used as a food additive in most cultures throughout recorded history. Historical reports suggest that the first dietary consumption of acetic acid was in wine, beer and similar brewed beverages and fermented food items such as sauerkraut. Acetic acid also has a long history of use as a food additive. Acetic acid is a component of white distilled vinegar at 4%. In the form of vinegar, it is historically consumed in a wide range of commonly used condiments such as food seasonings, pickled food items, dried, preserved, canned and processed fruits and vegetables. It is also added to or found naturally in many dairy based foods including yogurt, chocolate milk and eggnog. It is included as an additive in many contemporary common foods including breakfast cereals, processed meats, prepared table top sweeteners, sports and energy drinks (CODEX GSFA, 2009) (Ref. 3.) and is used in pharmaceutical products such as antibiotics, antibacterials and antimicrobials. Acetic acid is also the main acid in vinegars, and it is the acid in vinegar that gives vinegar its characteristic odor. In commonly consumed vinegars such as white (distilled), cider, balsamic, malt, red wine, white wine, rice and sherry the percentage of acetic acid generally ranges between 3% and 8%. The Food and Drug Administration (FDA) classifies acetic acid as "Generally Recognized as Safe (GRAS)" under 21 CFR 184.1005 as a direct food substance and under 21 CFR 582.1005 as a general purpose food additive.

As a pesticide, acetic acid is registered for use as a non-selective contact herbicide for combating a wide range of weeds and some grasses. Upon contact with targeted weed and weed grasses, acetic acid destroys or damages the cell membrane of the plants which causes rapid dehydration of the plant tissues. This process is called "burnout" or "burndown" and can result in the death of the targeted plant or injury sufficient to slow the growth and reproduction of the targeted plant.

In a final rule dated August 3, 2005, (70 FR 44483) (FRL–7717–2), EPA established an exemption from the requirement of a tolerance for residues of acetic acid when used as an active ingredient as a preservative on post-harvest agricultural commodities intended for animal feed, including alfalfa, barley grain, bermuda grass; bluegrass, brome grass, clover, corn grain, cowpea hay, fescue, lespedeza, lupines, oat grain, orchard grass, peanut grass, Timothy, vetch, and wheat grain, or commodities described as grain or hay. Acetic acid is also approved for use on growing crops or raw agricultural commodities after harvest as an inert ingredient in pesticide products under 40 CFR 180.1258.

In support of the request to amend the existing exemption from the requirement of a tolerance, the Agency has reviewed all information submitted in support of this action. This petition is supported by information from open scientific literature and cited studies which are discussed in detail in this unit. When used as an indirect spray to control weeds and weed grasses according to the required label instructions, significant dietary residues of acetic acid are unlikely because direct exposure to food plants would be accidental or due to spray drift. Additionally, acetic acid rapidly biodegrades in the environment; it is non-toxic at pesticidal use concentrations; it is readily metabolized in the body; it is ubiquitous in food and the environment. Moreover, pesticidal uses of acetic acid are not expected to contribute significantly to the overall exposure of the general population, and information from the open literature indicates that acetic acid has little or no toxicity from an acute oral perspective (toxicity category III; median lethal dose (LD_{50} 3,310 milligrams/kilogram (mg/kg). (Ref. 4.)

A. Acute Toxicity

Acute toxicity information submitted to support the exemption from the requirement of a tolerance for acetic

acid confirms a low toxicity profile and reflects the Agency's findings that acetic acid poses no significant human health risk with regard to food commodities. As a biochemical pesticide, products containing acetic acid would be used to control herbaceous broadleaf weeds and weed grasses that may damage or otherwise compromise the production of food crops. Products containing acetic acid are not intended for direct use on food crops. Moreover, any food crops exposed to acetic acid when used as a biochemical pesticide would be destroyed or significantly damaged. Such exposure would most likely be accidental or from spray drift and would render the plant unsuitable or less suitable for marketing. The low toxicological profile of acetic acid when used as an herbicide provides additional justification for this exemption from the requirement of a tolerance. Further, published literature (discussed in this unit) concerning low toxicity and the extensive history of acetic acid used in foods supports this exemption from the requirement of a tolerance.

The primary routes of exposure to the general population have been determined to be through consumption of food and inhalation of air in workplaces. (Ref. 5.)

1. *Acute oral toxicity*. The acute oral median LD_{50} for acetic acid in rats was greater than 3,310 mg/kg in rats and 4,960 mg/kg in mice, which confirmed negligible toxicity through oral exposure. (Ref. 6.) The lowest observed adverse effect level (LOAEL) was determined to be 390 mg/kg and the no observed adverse effect level (NOAEL) was determined to be 195 mg/kg (Ref. 7.) Acedic acid is a toxicity category III for acute oral toxicity.

2. *Acute dermal toxicity*.The acute dermal LD_{50} for acetic acid in rats was 1,060 mg/kg, (MRID 47330503) which confirmed moderate dermal toxicity, (MRID 47330503) the requirement of sub-acute toxicity data was waived because the use pattern and personal protection equipment (PPE) requirements of products containing acetic acid mitigate any risk from dermal exposure. Specifically, acetic acid as a biopesticide is only intended for use in spray products formulated for use as contact herbicides on broadleaf weeds and grasses; the Agency requires appropriate signal word (DANGER) and corresponding precautionary language on all labels containing acetic acid as a biochemical pesticide; and the Agency requires all applicators and handlers of such products to wear PPE that includes protective eyewear, long-sleeved shirt, long pants, socks and shoes. Given these considerations, the Agency believes that repeated dermal and inhalation exposure is not expected to occur. Acetic acid is a toxicity category II for acute dermal toxicity.

3. *Acute inhalation toxicity*. The acute inhalation median LC_{50} was greater than 11.4 milligrams per liter (mg/L) in rats and showed little to no inhalation toxicity or irritation (MRID 47330503). Acetic acid is toxicity category IV for acute inhalation toxicity.

4. *Primary eye irritation*. A primary eye study showed significant potential for eye irritation. Eye corneal damage can occur from exposure to acetic acid and clarity of vision is not reversed within seven days (MRID 47330503). As such, the Agency has determined that acetic acid is Toxicity Category I for acute eye irritation. (PPE requirements of products containing acetic acid will mitigate any risk associated with the products).

5. *Acute dermal/skin sensitization*. An acute dermal irritation/skin sensitization study showed that acetic acid is corrosive at very high (60%) concentrations (MRIDs 47330503) and (47330504). However, due to the use pattern and PPE requirements of biopesticidal products containing acetic acid (see Unit III.A.2., in this unit, regarding the use pattern and PPE requirements), and a required default restricted-entry interval (REI) of 48 hours following application of products containing acetic acid, exposure risks associated with products containing acetic acid will be mitigated. Acetic acid is a Toxicity category I for acute dermal irritation/skin sensitization.

B. Subchronic Toxicity

Based on its acute toxicity profile, use pattern and biodegradation properties, residues of acetic acid are not expected to result in significant dietary exposure beyond the levels expected in background dietary exposures. Nonetheless, a subchronic oral, dermal and inhalation toxicity study satisfied the data requirements for subchronic toxicity and indicated that acetic acid has no subchronic toxicological effect.

1. *90–day oral toxicity*. A 90–day oral toxicity study (Ref. 8.) found no toxicological effects regarding mortality, clinical observations, neurotoxicity assessment, hematology, clinical chemistry, organ weights, and macroscopic or microscopic observations. Weight loss was observed in test subjects administered up to 390 mg/kg body weight (bw/day) acetic acid in drinking water for 2-4 months. The reduction in weight gain is likely attributed to reduced appetite and food consumption observed in the study. No other effects were reported. The LOAEL was determined to be 390 mg/kg bw/day, and the NOAEL was determined to be 195 mg/kg bw/day.

2. *90–day dermal toxicity*. Requirement of a 90–day dermal toxicity study has been waived. Considering the use pattern and PPE requirements of pesticide products containing acetic acid (see Unit III.A.2., in this unit, regarding the use pattern and PPE requirements), repeated dermal and inhalation exposure is not expected to occur. Additionally, the Agency does not expect significant dermal exposure since uses of acetic acid as a contact biopesticide will not involve purposeful application to the skin, nor will it result in prolonged dermal exposure to the product when label directions are followed. Moreover, acute toxicity testing of the two proposed end-use products in which acetic acid will be used as an herbicide have indicated that the products are non-irritating to slightly-irritating to the skin. Applicators are required to wear protective eye-wear, long-sleeved shirts, long pants, socks and shoes. Additionally, a REI of 48 hours has been added to these labels.

3. *90–day inhalation toxicity*. Requirements for a 90–day inhalation toxicity study have also been waived. Herbicide products containing acetic acid are liquids and it is therefore, unlikely that significant levels of repeated inhalation will occur from the use of these products. Based on the results of toxicity testing cited above, proposed herbicide products containing acetic acid are placed into Toxicity Category IV for acute inhalation toxicity and to further mitigate exposure, a REI of 48 hours has been added to these labels.

C. Developmental Toxicity

Developmental toxicity data submitted to the Agency demonstrate a clear lack of developmental toxicity for acetic acid and supports the Agency's conclusion that there is no risk of developmental toxicity associated with new food uses for acetic acid.

A prenatal developmental toxicity study (MRID 47330503) found no significant treatment-related reproductive effects. The study showed abnormalities of soft or skeletal tissue of the test group, but the abnormalities did not differ from those found in the control group. The study established a LOAEL of 1,600 mg/kg bw/day. The NOAEL is equal to 1,600 mg/kg bw/day. A second prenatal developmental toxicity study (MRID 47330503) also, found no significant treatment related to reproductive effects or fetal abnormalities. Based on this

information, the Agency believes that there is no risk of developmental toxicity associated with new food uses for acetic acid.

D. Mutagenicity

A mutagenicity study using acetic acid as the test substance was conducted. The reverse mutation assays performed (MRID 47330503) were negative for mutagenicity to bacteria exposed to concentrations of acetic acid from 0 micrograms per plate to 10,000 micrograms per plate with and without metabolic activation. In the *in-vitro* Chinese hamster tests (MRID 47330503), results were also negative for mutagenicity. Results showed that acetic acid is not mutagenic at levels less than or equal to 16 micromoles. The Agency has determined that these data are sufficient to confirm that there are no expected dietary or non-occupational risks of mutagenicity with regard to new food uses of acetic acid.

E. Endocrine Effects

There is no available evidence demonstrating that acetic acid is an endocrine disruptor in humans. As a result, the Agency is not requiring information on the endocrine effects of acetic acid at this time. However, the Endocrine Disruption Screening Program (EDSP) has established a protocol, which guides the Agency in selecting suspect ingredients for review, and the Agency reserves the right to require new information should the program require it. Presently, based on the lack of exposure and the negligible toxicity profile of acetic acid, no adverse effects to the endocrine system are known or expected. Overall, the lack of evidence of endocrine disruption is consistent with the low toxicity profile of acetic acid and supports this exemption from the requirement of a tolerance.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). The Agency has determined that there is reasonable certainty that no harm to the U.S. population will result from aggregate exposure to residues of acetic acid. This includes all exposures for which there is reliable information. The Agency arrived at this conclusion based on the low level of toxicity of the chemical, low anticipated dietary and non-dietary exposures, worker protection requirements on the label (PPE and REI requirements) and the already widespread exposure without any reported adverse effects on human health. The risks from aggregate exposure via oral, dermal and inhalation exposure are negligible.

A. Dietary Exposure

The use of acetic acid as a pesticide is not intended as a direct spray to food commodities and will not be directly applied to food commodities intended for human consumption. Therefore, the Agency anticipates negligible to no residues present at the time of consumption.

1. *Food*. The Agency expects that food commodities will only be exposed to acetic acid by accidental application or spray drift. The Agency believes that any unintentional application or drift of products containing acetic acid would kill or substantially damage food crops, making them undesirable for human consumption. However, even in the event of indirect spray to food crops, the Agency is not concerned with potential residues due to low toxicity of acetic acid and the fact that acetic acid is a weak acid that rapidly degrades into a base composed of an acetate ion and hydrogen. Finally, the Agency believes that because acetic acid biodegrades rapidly under both anaerobic and aerobic conditions in the environment, residues of toxicological concern are not expected.

2. *Drinking water exposure*. Pesticide products containing acetic acid are not applied directly to water; applications are made directly to terrestrial non food crops, and as such, drinking water exposure of humans to acetic acid from pesticidal use is unlikely. Moreover, the Agency believes that any potential exposure to surface water would be negligible because of the low application rates and rapid biodegradation of acetic acid. Therefore, drinking water exposure is not expected to pose any quantifiable risk due to a lack of residues of toxicological concern.

B. Other Non-Occupational Exposure—Non-Dietary Exposure-Dermal and Inhalation Exposure

The potential for non-dietary exposure of the general population, including infants and children, is limited based on the use patterns of acetic acid (see Unit III.A.2., in this unit, regarding the use pattern and PPE requirements) and REI requirements (48 hours) on product labels, and the lack of anticipated residues of toxicological concern. Non-dietary exposures would not be expected to pose any quantifiable risk to the general population.

1. *Dermal exposure*. Non-occupational dermal exposures to acetic acid when used as an indirect non-selective herbicide are expected to be negligible based on the use patterns of acetic acid (see Unit III.A.2., in this unit, regarding the use patterns).

2. *Inhalation exposure*. Non occupational exposures to acetic acid when used as a selective herbicide are expected to be negligible because acetic acid products are limited to targeted weeds and grasses in proximity to food crops.

V. 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 acetic acid to share a common mechanism of toxicity with any other substances, and acetic acid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that acetic acid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

VI. Determination of Safety for U.S. Population, Infants and Children

The Agency has considered acetic acid in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of acetic acid when label instructions are followed.

A. U.S. Population

A determination has been made that no unreasonable adverse effects to the U.S. population in general will result from the use of acetic acid when used as an indirect spray to control weeds and weed grasses when label instructions are followed. This conclusion is based on the unlikelihood of significant dietary residues of acetic acid because direct exposure to food

plants would be accidental or due to spray drift. Additionally, acetic acid rapidly biodegrades in the environment; it is non-toxic at pesticidal use concentrations; it is readily metabolized in the body; and, it is ubiquitous in food and the environment. Moreover, pesticidal uses of acetic acid are not expected to contribute significantly to the overall exposure of the general population, and information from the open literature indicates that acetic acid has little or no toxicity from an acute oral perspective (toxicity category III; median LD_{50} 3,310 mg/kg).

The Agency is reasonably certain that there will be no harm to residential and/or commercial workers and applicators using herbicide products containing acetic acid based on the low application rates of end-use products, the low toxicity of acetic acid, and the rapid biodegradation of acetic acid in the environment. Precautionary labeling language, personal protective equipment and a 48 hour rentry interval for contact herbicides containing acetic acid adds an additional level of assurance of no harm to residential and commercial workers using such pesticide products.

B. Infants and Children

In examining exposures to sensitive subpopulations, FFDCA section 408 directs EPA to apply an additional tenfold margin of exposure (MOE) (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database, unless EPA determines that a different MOE will be protective for infants and children. MOE are often referred to as uncertainty or safety factors. For the proposed pesticidal uses, based on all the available information, the Agency concludes that acetic acid is practically non-toxic (with the exception of severe eye irritation) to mammals, including infants and children. Acetic acid is found in many foods already consumed by infants and children, and there is no information available indicating an appreciable difference in risk between adults and infants and children from exposure to acetic acid when used as a contact herbicide. As a result, EPA has not used a MOE approach to assess the safety of acetic acid. When used as proposed, EPA expects that the contact herbicides containing acetic acid as an active ingredient would not result in residue levels that are of toxicological concern. Thus, there are no threshold effects of concern. As such, an additional margin of safety is not necessary.

VII. Other Considerations

A. Analytical Enforcement Methodology

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

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with internal 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 (Codes), as required by FFDCA section 408(b)(4). The Codex is a joint U.N. 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 acetic acid.

VIII. Conclusions

The Agency concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of acetic acid when used as an herbicide to control broadleaf weeds and grasses. Therefore, an exemption is established for residues of the biochemical acetic acid when used as a non selective, indirect contact herbicide spray for broadleaf weeds and weed grasses on all food crops.

IX. References

1. MRIDs 47350604 through 47350609).

2. MRIDs 47330501, 47330505, 47330510–47330512 and 47775901).

3. “Acetic Acid”. Codex General Standards for Food Additives Online Database. 2010. GSFA Online. January 13, 2010 *http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=170.*

4. MRIDs 47350601 through 47350603 and 47776001.

5. “Acetic Acid”. Hazardous Substances Data Base. 2010. National Library of Medicine January 13, 2010 *http://www.toxnet.nlm.nih.gov/cgibin/sis/search/f?./temp/~SWRBRt:1.*

6. MRIDs 47330503, 47330504, 47330507, 47330508 and 47330513-47330518).

7. Joint FAO/WHO Expert Committee on Food Additives. “Toxicological Evaluation of Some Microbials, Antioxidants, Emulsifiers, Stabilizers, Flour-Treatment Agents, Acids and Bases.” 1967. WHO/Food Add. January 13, 2010 *http://www.inchem.org/documents/jecfa/jecmono/40abcj37.htm.*

8. EPA Memorandum R.S. Jones to D. Benmhend. “Science Review in Support of the Registration of Eastman Acetic Acid® P Grain and Hay Preservative. . . .”. April 12, 2004.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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) (Public Law 104–4).

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: June 30, 2010.

W. Michael McDavit,

Acting Director, Biopesticides and Pollution Prevention 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 subpart D, revise §180.1258 to read as follows:

§ 180.1258 Acetic acid; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide acetic acid when used as a preservative on post-harvest agricultural commodities intended for animal feed, including Alfalfa, seed; alfalfa, hay; barley, grain; bermudagrass, hay; bluegrass, hay; bromegrass, hay; clover, hay; corn, field, grain; corn, pop, grain; cowpea, hay; fescue, hay; lespedeza, hay; lupin; oat, grain; orchardgrass, hay; peanut, hay; timothy, hay; vetch, hay; and wheat, grain, or commodities described as grain or hay.

(b) An exemption from the requirement of a tolerance is established for residues of acetic acid in or on all food crops resulting from unintentional spray and drift to non-target vegetation including non-food, food and feed crops when used as a non-selective contact herbicide spray.

[FR Doc. 2010–17163 Filed 7–13–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0325; FRL–8833–6]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises tolerances for combined residues of hexythiazox in or on stone fruit. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 14, 2010. Objections and requests for hearings must be received on or before September 13, 2010, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0325. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Olga Odiott, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9369; e-mail address: *odiott.olga@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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.gpoaccess.gov/ecfr*.

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