TABLE 1—OF SECTION 19.4 CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS—Continued

U.S. code citation	Environmental statute	Statutory penalties, as enacted	Penalties effective after January 30, 1997 through March 15, 2004	Penalties effective after March 15, 2004 through January 12, 2009	Penalties effective after January 12, 2009
42 U.S.C. 14304(g)	BATTERY ACT	10,000	10,000	11,000	16,000

[1] Note that 33 U.S.C. 1414b(d)(1)(B) contains additional penalty escalation provisions that must be applied to the penalty amounts set forth in this Table 1. The amounts set forth in this Table reflect an inflation adjustment to the calendar year 1992 penalty amount expressed in section 104B(d)(1)(A), which is used to calculate the applicable penalty amount under MPRSA section 104B(d)(1)(B) for violations that occur in any subsequent calendar year.

[2] CACSO was passed on December 21, 2000 as part of Title XIV of the Consolidated Appropriations Act of 2001, Public Law 106–554, 33 U.S.C. 1901 note.

[3] The original statutory penalty amounts of 20,000 and 50,000 under section 1432(c) of the Safe Drinking Water Act, 42 U.S.C. 300i–1(c), were subsequently increased by Congress pursuant to section 403 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law No. 107–188 (June 12, 2002), to 100,000 and 1,000,000, respectively. EPA did not adjust these new penalty amounts in its 2004 Civil Monetary Penalty Inflation Adjustment Rule (''2004 Rule''), 69 FR 7121 (February 13, 2004), because they had gone into effect less than two years prior to the 2004 Rule.

Dated: December 30, 2008.

Catherine R. McCabe,

Principal Deputy Assistant Administrator, Office of Enforcement and Compliance Assurance.

[FR Doc. E8–31452 Filed 1–6–09; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0528; FRL–8396–2]

Extract of Chenopodium ambrosioides near ambrosioides; 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 the Extract of *Chenopodium ambrosioides* near *ambrosioides* on all food commodities when applied/used as a biochemical insecticide/acaricide. AgraQuest, 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 Extract of *Chenopodium ambrosioides* near *ambrosioides* on all food commodities.

DATES: This regulation is effective January 7, 2009. Objections and requests for hearings must be received on or before March 9, 2009, 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–2008–0528. 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: Chris Pfeifer, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0031; e-mail address: *pfeifer.chris@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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also 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, 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–2008–0528 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 9, 2009.

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–2008–0528, 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 July 31, 2008 (73 FR 44720) (FRL–8374–3), 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 7F7299) by AgraQuest, Inc., 1540 Drew Avenue, Davis, CA, 95618. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of Extract of *Chenopodium ambrosioides* near *ambrosioides*. This notice included a summary of the petition prepared by the petitioner AgraQuest, Inc.. There were no substantive comments received in response to the notice of filing. However, three letters of support from prospective users expressed enthusiasm for the proposed new food uses.

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.''

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.

Extract of *Chenopodium ambrosioides* near *ambrosioides* is a blended extract derived from a flowering plant commonly known as American Wormseed. It is an amber liquid that is semi-volatile, and has a fruity, woodsy, aromatic smell. The extract is composed of many constituent ingredients, the properties of which have all been assessed previously in Agency reviews (Science Review in Support of the Registration of the active ingredient *Chenopodium ambrosioides* near *ambrosioides*, February 2008; Science Review and Tolerance Exemption Petition Review In Support of the Registration of Requiem™ 25EC containing Extract of *Chenopodium ambrosioides* near *ambrosioides* as its active ingredient, October 2008). It has had many historical medicinal uses, and was cited in the *U.S. Pharmacopoeia*. Most recently, the extract has been used as the active ingredient in a Federally registered biopesticide product intended for non-food uses as a contact insectidcide and acaracide on ornamentals. Extract of*Chenopodium ambrosioides* near *ambrosioides* has a ''non-toxic'' mode of action, which softens cuticles in target insects, resulting in a disruption of insect respiration. This rule establishes the exemption of a tolerance for Extract of *Chenopodium ambrosioides* near *ambrosioides* on all food commodities.

Extract of *Chenopodium ambrosioides* near *ambrosioides* contains three major terpene constituents—α-terpinene, p-cymene, and d-limonene—which occur naturally in fruits, vegetables, herbs, spices, and other foods and beverages, and are defined as marker compounds in the active ingredient. These three compounds are also permitted as food and fragrance additives in the U.S. and Europe. These three constituents have been fully characterized by EPA and have each been assessed for their uses in pesticides for food uses in the October 2008 risk assessment referenced above. Based on the information before the Agency, incidental exposures to these three compounds are without known toxicological incident for humans. The general public is exposed daily to low levels of these compounds via ingestion, dermal contact, inhalation through consumption of foods and beverages and dermal contact with cosmetics, in excess of any exposure expected to result from the pesticidal use of this extract. The per capita daily consumption of these terpene compounds as food additives alone amounts to 13.325 milligrams (mg) in the U.S. and 40.397 mg in Europe (WHO. Evaluation of Certain Food Additives. WHO Technical Report Series No. 928. Sixty-third Report of the Joint FAO/WHO Expert Committee on Food Additives. 2005), amounts far in excess of any potential dietary exposures resulting from exposures to residues from this pesticidal extract, as discussed below. α-Terpinene is found in the essential oils of a variety of plants including citrus, peppermint, thyme,

basil, and papaya. Per 21 CFR 172.515, it is permitted for direct addition to food for human consumption. d-Limonene is a major component of lemon oil, orange oil, and grapefruit oil, and is a minor component of other fruits, vegetables, meats, and spices. It is widely used as a flavor and fragrance and is generally recognized as safe (GRAS) by the Food and Drug Administation (FDA) as a food additive or flavoring, and as a fragrance additive (21 CFR 182.60). Limonene is a federally registered active ingredient in 15 pesticides and is exempt from the requirement of a tolerance per 40 CFR 180.539. Humans regularly consume p-Cymene through such foods as butter, carrots, nutmeg, orange juice, oregano, raspberries, lemon oil, and spices. p-Cymene is permitted by FDA for direct addition to food as a flavoring substance (21 CFR 172.515). For the reasons set forth below, EPA believes it reasonable to conclude that the terpene exposures identified above will either exceed or be comparable to exposures resulting from use of this extract as a pesticide. The balance of the constituents, while not expected to be active, are also regularly found in fruits, vegetables and plant extracts and have been assessed by EPA and determined not to be of toxicological concern when used in pesticides for food uses (Risk Assessments for Extract of *Chenopodium ambrosioides* near *ambrosioides* dated February 2008 and October 2008). Overall, a thorough analysis of the constituent compounds of Extract of *Chenopodium ambrosioides* near *ambrosioides* indicate a low toxicity profile and support this exemption from the requirement of a tolerance.

A low toxicity profile of the constituents, the fact that they have been assessed by the Agency already, and the lack of detectable residues for this contact insecticide support the Agency's determination to establish an exemption from the requirement of a tolerance. Three residue studies demonstrate that the rapid degradation of the extract leaves no opportunity for post-application exposure. A residue decline study on primrose demonstrated that when the extract is sprayed at 4X the proposed application rate, residues of the three major active ingredient components declined to non-detectable levels within 10 minutes (MRID 47209101). A second study on tomatoes involving four applications of the extract within a 24–hour period found no detectable residues on any samples collected immediately following the final application (MRID 46858903). A third residue study on mustard greens involving three applications at twice the application rate found no detectable residues within the hour after the third application (MRID 47548301). Essentially, data demonstrate that by the time Extract of *Chenopodium ambrosioides* near *ambrosioides* has dried on the plant there is no detectable residual product. Accordingly, the dietary risk assessment of Extract of *Chenopodium ambrosioides* near *ambrosioides* suggests that the lack of exposure to residues of the extract obviate any dietary hazard, and support an exemption from the requirement of a tolerance.

Summaries of the toxicological information submitted in support of this exemption from the requirement of a tolerance follow:

1. *Acute toxicity*. Acute toxicity studies submitted to support the initial registration of the manufacturing use product containing the active ingredient Extract of *Chenopodium ambrosioides* near *ambrosioides* confirm a low toxicity profile, and support the finding that this active ingredient poses no significant human health risk with regard to food uses. A summary of the acute toxicity studies follows:

i. The acute oral LD_{50}s in rats were 2,000--5,000 mg/Kg and confirm negligible toxicity through the oral route.

ii. The acute dermal LD_{50} in rats for was greater than 5,000 mg/kg. These data substantiate the active ingredient's relative dermal non-toxicity to both occupational users and the general public.

iii. The acute inhalation LC_{50} is greater than 2.03 mg/L in rats, and shows no significant inhalation toxicity.

iv. A skin irritation study on rabbits indicated that the extract was mildly irritating to the skin. Overall, the data further support the finding of negligible dermal toxicity presented in the acute dermal toxicity study.

v. The extract has been classified as a dermal sensitizer; however, no exposures (prolonged or otherwise) are expected due to the rapid degradation of the extract.

The rapid degradation of the extract is expected to preclude any route of exposure, obviating all potential acute toxic effects. Nonetheless, the acute toxicity data suggest that even in the event of any dietary exposure that the dietary risk would be considered negligible.

2. *Genotoxicity*. Three genotoxicity studies (a bacterial reverse mutation assay, an *in vitro* mammalian chromosome aberration test, and an unscheduled DNA repair assay) were performed on the active ingredient Extract of *Chenopodium ambrosioides* near *ambrosioides*. The reverse mutation assay (MRID 46456301) showed that the extract was not mutagenic to bacterial strains TA98, TA100, TA1535, TA1537, and *E. coli* strain WP2 uvrAW. The *in vitro* mammalian chromosome aberration test (MRID 46396214) demonstrated that the extract produced no statistically significant increases in chromosome/chromatid aberrations in human lymphocytes with, or without, metabolic activation. The third study, a DNA repair assay (MRID 46396215) was also negative because the extract did not cause unscheduled DNA repair in cultured rat hepatocytes. The mutagenicity studies are sufficient to confirm that there are no expected dietary, occupational, or non-occupational risks of mutagenicity with regard to new food uses.

3. *Subchronic toxicity*. As a contact insecticide, residues of the Extract of *Chenopodium ambrosioides* near *ambrosioides* in or on all food commodities are not expected to result in any repeated and/or long-term exposure by the oral, dermal or inhalation routes. As a result, no subchronic studies are required to establish the food use pattern of this extract or to exempt it from the requirement of a tolerance. Waiver requests for the subchronic toxicity studies were approved in large part on the basis of three residue studies, which confirm the extract's rapid degradation. A residue decline study on primrose (MRID 4729101) demonstrated that when the end use product (EP) containing the extract was applied at four times the application rate, the marker components were not detectable 10 minutes after application. In a second study, the EP was applied four times at twice the application rate on tomatoes (MRID 46858903). Residues of the marker components were below the limit of quantitation (LOQ) of 0.01 mg/kg when plant samples were collected and checked at 0, 3, 6, and 24 hour intervals. In another study on mustard greens (MRID 47548301), the EP was applied three times at twice the application rate to mustard greens, residues of the marker components had dissipated to below the LOQ of 0.05 ppm at 1–4 hours after the last application. With regard to subchronic dietary exposure, potential exposure to the residues is unlikely to occur because of the rapid degradation of the extract. Nonetheless, it is noted that the constituent components of the extract are already a regularized part of the

human diet, and are not known to pose a hazard at the levels approximated immediately after application (WHO, 2005). With regard to subchronic dermal or inhalation exposure, the rapid degradation of the extract, likewise, limits the potential for exposure.

4. *Developmental toxicity*. The Agency accepted information from the open scientific literature to address data requirements for developmental and reproductive toxicity (Araujo, I.B., et al. 1996. Study of the Embryofoetotoxicity of α-Terpinene in the Rat. Food and Chemical Toxicology 34:477-482.; Cornell University. Medicinal Plants Website. Medicinal Plants for Livestock, Beneficial or Toxic? .*http://www.ansci.cornell.edu/plants/medicinal/plants.html*. 2008.; HPV. The Flavor and Fragrance High Production Volume Consortia. The Terpene Consortium: Test Plan for Aromatic Terpene Hydrocarbons. 2002.). The residue data referenced in the ''subchronic toxicity'' section above demonstrate that there should be no exposures that might precipitate any developmental toxicity. All information submitted indicate that when used as proposed, Extract of *Chenopodium ambrosioides* near*ambrosioides* will not result in detectable residues. Dietary exposure would not be expected to pose any quantifiable risk, due to a lack of residues of toxicological concern. Moreover, information submitted on the constituent components of the Extract of *Chenopodium ambrosioides* near *ambrosioides* indicates that the extract is not a developmental or reproductive toxicant. The Agency has risk assessments for all the marker components in this extract on file. Those assessments demonstrate that none of the marker constituents in the extract are developmental or reproductive toxicants. Studies submitted on the constituent components of the extract also allow EPA to establish worst-case scenario toxicological endpoints - a conservative maternal NOAEL of 60 mg/kg-day and a developmental NOAEL of 30 mg/kg-day. Agency exposure assessments show all potential occupational exposures to be substantially below the worst-case endpoints presented here (BRAD on Extract of *Chenopodium ambrosioides* near *ambrosioides*). Altogether, significant exposure to female humans is not expected to occur at a level of toxicological concern based on the overall low toxicity profile of the extract, the lack of exposure due to rapid degradation of the extract, and the ubiquitous presence of the main components of the extract in the environment, food and cosmetics, all without reported hazard. Accordingly, the information submitted to the Agency to demonstrates a clear lack of both dietary exposure and developmental toxicity and supports the Agency's conclusion that there is no risk of developmental toxicity associated with the new food uses.

5. *Immunotoxicity*. A waiver request was accepted for immunotoxicity for the following reasons:

i. The potential for any immunotoxic effect is precluded by the extract's rapid degradation.

ii. The constituent components in the extract are ubiquitous in nature; and our regular exposure to these compounds is without known immunotoxicological incident.

iii. There is a long history of intentional use of the constituent compounds in food, fragrance, and flavoring, all without known immunotoxicological incident.

iv. The toxicological profile in acute toxicological studies does not suggest any immunotoxicity.

All information points to the lack of dietary risk posed by the immunotoxicity of Extract of *Chenopodium ambrosioides* near *ambrosioides* residues, and supports the exemption from the requirement of a tolerance.

6. *Effects on endocrine systems*. There is no available evidence demonstrating that Extract of *Chenopodium ambrosioides* near *ambrosioides* is an endocrine disruptor in humans. As a result, the Agency is not requiring information on the endocrine effects of Extract of *Chenopodium ambrosioides* near *ambrosioides* at this time. However, the Endocrine Disruption Screening Program (EDSP) is still in the process of establishing a protocol; 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 the extract, no adverse effects to the endocrine or immune systems are known or expected. Overall, the lack of evidence of endocrine disruption is consistent with Extract of *Chenopodium ambrosioides* near *ambrosioides*' low-toxicity profile, 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).

A. Dietary Exposure

Dietary exposure to the residues of the contact insecticide Extract of *Chenopodium ambrosioides* near *ambrosioides*, through food or water, is expected to be virtually non-existent.

1. *Food*. No dietary exposure to Extract of *Chenopodium ambrosioides* near *ambrosioides* residues is expected because the extract degrades soon after application. Residue decline studies on tomatoes, mustard greens and primrose confirm that applications of the extract do not result in detectable residues shortly after application. Accordingly, data demonstrate that dietary exposure will be precluded. But even if residues were found, they would not be cause for concern because Extract of *Chenopodium ambrosioides* near *ambrosioides* has been fully assesed and found not to be of toxicological concern. Humans regularly consume all the constituent components in the extract through consumption of fruits and vegetables. This regular dietary exposure has not resulted in any known incidents of toxic effect. Moreover, the three primary terpene constituents, comprising 70% of the active ingredient, have been approved by FDA for use in cosmetics and as food additives. Finally, information submitted on the acute toxicity, developmental toxicty, and genotoxicity of Extract of *Chenopodium ambrosioides* near *ambrosioides* confirm a very low toxicity profile. In sum, no dietary exposure is expected; but any potential dietary exposures would not be expected to pose any quantifiable risk, due to a lack of residues of toxicological concern.

2. *Drinking water exposure*. Exposure of humans to Extract of *Chenopodium ambrosioides* near *ambrosioides* in drinking water is unlikely because pesticidal applications are intended to be applied directly to terrestrial plants and because any residues would have significantly degraded in the advance of any rainfall event. Low application rates and rapid biodegradation in water (an aqueous half life of 36.11 hours) further reduce the potential for drinking water exposure. 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

No new non-occupational exposure is expected to result from the new agricultural uses of Extract of

Chenopodium ambrosioides near *ambrosioides*. The active ingredient is applied directly to food commodities and degrades extremely rapidly. However, the Agency notes that no health risks are expected from any pesticidal exposure to this active ingredient in any event. An April 2008 risk assessment of Extract of *Chenopodium ambrosioides* near *ambrosioides* makes clear that even regular occupational exposures that are associated with this active ingredient pose negligible risks.

1. *Dermal exposure*. No new non-occupational dermal exposures are expected to result from the new agricultural uses of Extract of *Chenopodium ambrosioides* near *ambrosioides*. Any new dermal exposure associated with this new agricultural use pattern is expected to be occupational in nature.

2. *Inhalation exposure*. No new non-occupational inhalation exposures are expected to result from the new agricultural uses of Extract of *Chenopodium ambrosioides* near *ambrosioides*. Any new inhalation exposure associated with this new agricultural use pattern is expected to be occupational in nature.

V. Cumulative Effects

Pursuant to FFDCA section 408(b)(2)(D)(v), EPA has considered available information concerning the cumulative effects of Extract of *Chenopodium ambrosioides* near *ambrosioides* residues and other substances that have a common mechanism of toxicity. These considerations include the cumulative effects on infants and children of Extract of *Chenopodium ambrosioides* near *ambrosioides* residues and other substances with a common mechanism of toxicity. Because no exposure to residues are expected with this application, and the components of the extract have a long history of use without incident, the Agency concludes that there are no cumulative effects arising from Extract of *Chenopodium ambrosioides* near *ambrosioides* residues in or on food commodities.

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

Health risks to humans, including infants and children, are considered negligible with regard to the pesticidal use of Extract of *Chenopodium ambrosioides* near *ambrosioides*. Acute toxicity studies indicate that Extract of *Chenopodium ambrosioides* near *ambrosioides* has negligible toxicity. Notably, the constituent ingredients of the extract are ubiquitous in nature and present in a multitude of fruits and vegetables; and to date, there is no history of toxicological incident involving their consumption. Indeed, the marker constituents of the extract are approved as direct food additives by the FDA. Most importantly however, no exposure to the residues of Extract of *Chenopodium ambrosioides* near *ambrosioides* are expected. Pesticidal applications are applied directly to commercial crops; and data confirm that detectable residues do not persist beyond the time for the active ingredient to dry on to foliar surfaces. Accordingly, no dietary exposure is expected. As such, the Agency has determined that this food use of Extract of *Chenopodium ambrosioides* near *ambrosioides* poses no foreseeable risks to human health or the environment. There is a reasonable certainty of no harm to the general U.S. population, including infants and children, from exposure to this active ingredient.

VII. Other Considerations

A. Endocrine Disruptors

There is no evidence, at this time, that suggests the Extract of *Chenopodium ambrosiodes* near *ambrosioides* will compromise the immune or endocrine systems, or that it functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

B. Analytical Method

Through this action, the Agency proposes an exemption from the requirement of a tolerance of Extract of *Chenopodium ambrosiodes* near *ambrosioides* when used on food commodities, without any numerical limitations for residues. EPA has determined that residues resulting from the pesticidal uses of Extract of *Chenopodium ambrosiodes* near ambrosioides are unlikely, and that there are no significant toxicity concerns in the event that residues of the active ingredient were somehow present. As a result, the Agency has concluded that an analytical method is not required for enforcement purposes for this proposed use of Extract of *Chenopodium ambrosiodes* near *ambrosioides*.

C. Codex Maximum Residue Level

There are no codex maximum residue levels established for residues of Extract of *Chenopodium ambrosioides* near *ambrosioides*.

VIII. Conclusions

Based on the information submitted, and other information available to the Agency, EPA is establishing an exemption from the tolerance requirements pursuant to FFDCA section 408(c) for residues of Extract of *Chenopodium ambrosioides* near *ambrosioides* in or on all agricultural commodities.

IX. 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).

X. 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: December 12, 2008.

Debra Edwards,

Director, 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 180.1287 is added to subpart D to read as follows:

§ 180.1287 Extract of Chenopodium ambrosioides near ambrosioides; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of Extract of *Chenopodium ambrosioides* near *ambrosioides* when used as an insecticide/acaricide on all food commodities.

[FR Doc. E8–31408 Filed 1–6–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0823; FRL–8392–3]

Multiple Chemicals; Extension of Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for the pesticides listed in Unit II. of the **SUPPLEMENTARY INFORMATION**. These actions are in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of these pesticides. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA.

DATES: This regulation is effective January 7, 2009. Objections and requests for hearings must be received on or before March 9, 2009, 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–2008–0823. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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 either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are 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: See the table in this unit for the name of a specific contact person. The following information applies to all contact persons: Emergency Response Team, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001.

Pesticide/CFR Citation	Contact Person
Formetanate hydrochloride 180.276	Andrew Ertman *ertman.andrew@epa.gov* 703–308–9367
Maneb 180.110	Libby Pemberton *pemberton.libby@epa.gov* 703–308–9364
Myclobutanil 180.443	Stacey Groce *groce.stacey@epa.gov* 703–30–2505
Thiophanate methyl 180.371	Andrea Conrath *conrath.andrea@epa.gov* 703–308–9356

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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions discussed above. If you have any questions regarding the applicability of this action to a particular entity, consult