

The corrections do not involve changes to the technical standards related to test methods or monitoring methods; thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) do not apply.

The corrections also do not involve special consideration of environmental justice-related issues as required by EO 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. 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 80

Environmental protection, Administrative practice and procedure, Agriculture, Air pollution control, Confidential business information, Diesel fuel, Energy, Forest and forest products, Fuel additives, Gasoline, Imports, Labeling, Motor vehicle pollution, Penalties, Petroleum, Reporting and recordkeeping requirements.

Dated: April 8, 2013.

Gina McCarthy,

Assistant Administrator, Office of Air and Radiation.

40 CFR part 80 is amended as follows:

PART 80—[AMENDED]

■ 1. The authority citation for part 80 continues to read as follows:

Authority: 42 U.S.C. 7414, 7521(1) and 7601(a).

■ 2. Section 80.1454 (k)(1) introductory text and (k)(2) introductory text are revised to read as follows:

§ 80.1454 What are the recordkeeping requirements under the RFS program?

* * * * *

(k)(1) Biogas and electricity in pathways involving feedstocks other than grain sorghum. A renewable fuel producer that generates RINs for biogas or electricity produced from renewable biomass (renewable electricity) for fuels that are used for transportation pursuant to § 80.1426(f)(10) and (11), or that uses process heat from biogas to generate RINs for renewable fuel pursuant to § 80.1426(f)(12) shall keep all of the following additional records:

* * * * *

(2) Biogas and electricity in pathways involving grain sorghum as feedstock. A renewable fuel producer that produces fuel pursuant to a pathway that uses grain sorghum as a feedstock shall keep all of the following additional records, as appropriate:

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[FR Doc. 2013-09068 Filed 4-16-13; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0134; FRL-9382-6]

Methyl Jasmonate; 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 biochemical methyl jasmonate in or on all food commodities when applied pre-harvest. Becker Underwood, 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 methyl jasmonate when applied pre-harvest.

DATES: This regulation is effective April 17, 2013. Objections and requests for hearings must be received on or before June 17, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0134, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West

Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Chris Pfeifer, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 308-0031; email 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. 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 Printing 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-2012-0134 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 June 17, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0134, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

In the **Federal Register** of May 2, 2012 (77 FR 25957) (FRL-9346-1), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1F7941) by Becker Underwood, Inc.; 801 Dayton Avenue, Ames, IA 50010. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of methyl jasmonate. That document referenced a summary of the petition prepared by the petitioner Becker Underwood, Inc., which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

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 FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), 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, FFDCA section 408(b)(2)(D) 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 FFDCA section 408(b)(2)(D), 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.

Methyl jasmonate is a biochemical pesticide active ingredient intended for use as a systemic acquired resistance (SAR) inducer on a variety of agricultural crops. It is applied pre-harvest as a seed treatment and an in-furrow soil treatment. Methyl jasmonate is a naturally occurring biochemical hormone found in most plants. It acts by eliciting plant defense responses in vulnerable seedlings. Methyl jasmonate

is the principal compound of a class of plant hormones known as jasmonates, which are common to most plants but particularly concentrated in jasmine and honeysuckle. As a group, jasmonates are known to trigger plant responses to a variety of stresses. Methyl jasmonate, in particular, is known to bolster plant defenses against extreme temperature changes and attacks by insects, fungi and bacteria. It has a non-toxic mode of action and is present in most fruits, with especially high concentrations in apples and strawberries. As such, it is already a normal part of the human diet.

With regard to dietary risks related to pesticidal use, EPA has determined that the information submitted by the applicant satisfies the required human health assessment data requirements and demonstrates that any potential residues of methyl jasmonate in or on foods do not pose a toxicological risk. First, methyl jasmonate is a ubiquitous and naturally occurring plant hormone that is already regarded as a safe and natural part of the human diet through such commonly consumed fruits as apples and strawberries (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). Data demonstrate that humans, including infants, regularly ingest methyl jasmonate in fruits and plants at much higher levels than what can be expected to be ingested from the pesticidal use of this active ingredient (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). Second, the toxicity data demonstrate that methyl jasmonate is virtually non-toxic to humans and other non-target organisms, through all routes of exposure, including oral (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). Third, methyl jasmonate has been assessed and approved by Food and Agriculture Organization/World Health Organization (FAO/WHO) as a food additive (JECFA, 2005). Their robust assessment concluded that methyl jasmonate was non-toxic as a food additive, establishing a threshold of 540 microgram/day (ug/day), far above the maximum anticipated pesticidal residues of 373 ug ai/kg of seed (JECFA, 2005). Fourth, no toxicological endpoints have been identified for methyl jasmonate through any route of exposure (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). Fifth, methyl jasmonate’s non-toxic mode of action has been well established (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). Further, methyl jasmonate biodegrades readily within four weeks (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). Because applications necessarily occur early in

the growing season due to its mode of action as a SAR inducer on seeds and seedlings, no significant pesticidal residues are anticipated for any harvested foods. Data show that any potential exposures are expected to be well within the range of exposures that would occur naturally, and are therefore not of concern (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). For all of the foregoing reasons, EPA finds that methyl jasmonate is virtually non-toxic and poses no dietary risks to humans.

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

A. Acute Toxicity

Acute toxicity studies, submitted to support the registration of the products containing methyl jasmonate, confirm a virtually non-toxic profile and support the finding that this active ingredient poses no significant human health risk with regard to new food uses. The acute toxicity data show virtual non-toxicity for all routes of exposure and suggest that any dietary risks associated with this naturally occurring plant hormone would be inconsequential.

1. The acute oral median lethal doses (LD₅₀s) in rats were greater than 3,129 milligrams per kilogram (mg/kg) and confirmed virtual non-toxicity through the oral route of exposure. There were no observed toxicological effects on the test subjects in the acute oral study submitted (Master Record Identification Number (MRID No.) 48653901). Methyl jasmonate is Toxicity Category III for acute oral toxicity.

2. The acute dermal median lethal dose (LD₅₀) in rats was greater than 5,050 mg/kg. There were no clinical signs of toxicity or dermal irritation throughout the study. The data substantiate methyl jasmonate's virtual non-toxicity through the dermal route of exposure. (MRID No. 48653902). Methyl jasmonate is Toxicity Category IV for acute dermal toxicity.

3. The acute inhalation median lethal concentration (LC₅₀) was greater than 2.23 milligrams per liter (mg/L) in rats and showed no consequential inhalation toxicity (MRID No. 48653903). Methyl jasmonate is Toxicity Category III for acute inhalation toxicity.

4. A skin irritation study on rabbits indicated that methyl jasmonate was not irritating to the skin (MRID No. 48653905). Methyl jasmonate is Toxicity Category IV for dermal irritation.

5. Data indicated methyl jasmonate is not a dermal sensitizer (MRID No. 48653906).

Data indicate that methyl jasmonate is not acutely toxic. No toxic endpoints were established in any of the acute toxicity studies, and no significant toxicological effects were observed in any of the acute toxicity studies.

B. Subchronic Toxicity

Based on its biodegradation properties, residues of methyl jasmonate are not expected to result in significant dietary exposure beyond the levels expected in background dietary exposures. Sufficient information (MRID No. 48653908) on methyl jasmonate was submitted to satisfy requirements for subchronic toxicity testing [i.e., 90-day Oral (OCSPP 870.3100), 90-day Inhalation (OCSPP 870.3465), and 90-day Dermal (OCSPP 870.3250)]. The information submitted was found acceptable based on the toxicological and exposure profile of methyl jasmonate, summarized below.

Methyl jasmonate is a naturally occurring compound found in fruits and other plants and is already consumed in the human diet. This compound has a history of safe dietary exposure (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). The proposed use pattern of this active ingredient results in exposure levels that are lower than the current estimated dietary exposure (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). Oral exposure of children and adults to methyl jasmonate calculated from food consumption information from the U.S. EPA Exposure Factors Handbook (U.S. EPA, 2009) were found to be less than the residues resulting from a maximum application. Methyl jasmonate was reviewed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2005) and was identified as a non-toxic flavoring agent. Methyl jasmonate is not known or expected to be metabolized differently following exposure by the dermal route than the oral route, and a literature search yielded no reports of subchronic dermal toxicity effects in rodents or humans from methyl jasmonate exposure (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). Prolonged dermal exposure is not expected because the product is not purposely applied to the skin and because handlers and applicators are required to wear appropriate personal protective equipment (PPE). There is a long history of safe inhalation exposure to methyl jasmonate because it is a naturally occurring volatile component of common plants. The potential inhalation exposure concentration from use of products containing methyl jasmonate will be less than or equal to naturally occurring concentrations from

crops and other plants (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). Significant exposure to humans is not anticipated based on low application rates and, more importantly, rapid degradation in the environment (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012).

C. Developmental Toxicity and Mutagenicity

The applicant provided adequate information (MRID No. 48653908) to fulfill the developmental toxicity and mutagenicity data requirements [i.e., Prenatal Development (OCSPP 870.3700), Bacterial Reverse Mutation Test (OCSPP 870.5100), *In vitro* Mammalian Chromosome Aberration (OCSPP 870.5375), and *In vitro* Mammalian Cell Assay (OCSPP 870.5300)]. The submitted information is sufficient to confirm that there are no expected dietary or non-occupational risks of mutagenicity with regard to new food uses. The information submitted was found acceptable based on the toxicological and exposure profile of methyl jasmonate, summarized below.

There is a long history of safe dietary exposure to methyl jasmonate because it naturally occurs in apples, strawberries and mangos (Lalel *et al.*, 2003), fruits that are part of the normal diet. The potential oral exposure to methyl jasmonate from the proposed uses of methyl jasmonate is well below the average exposure for women of child-bearing age from the consumption of fruits that naturally contain methyl jasmonate, and also well below the Joint FAO/WHO Expert Committee on Food Additives (JECFA) human exposure threshold (Munro, 1999). Methyl jasmonate has been evaluated for safety by the FAO and determined to be metabolized to innocuous end products that are eliminated in the urine (Lalel *et al.*, 2003). A literature search yields no reports of genotoxicity in laboratory studies on methyl jasmonate (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). Significant exposure to child-bearing women is not anticipated based on low application rates, appropriate PPE requirements on the label, and rapid degradation in the environment.

D. Effects on Endocrine Systems

There is no available evidence demonstrating that methyl jasmonate is an endocrine disruptor in humans. As a result, the Agency is not requiring information on the endocrine effects of methyl jasmonate 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 virtually non-toxic profile of methyl jasmonate, no adverse effects to the endocrine are known or expected. Overall, the lack of evidence of endocrine disruption is consistent with methyl jasmonate's negligible toxicity profile and supports this exemption from the requirement of a tolerance.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in or on 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

Because of methyl jasmonate's ability to biodegrade quickly relative to the time it is to be applied on seeds or to soil near planting, the Agency does not anticipate significant residues being present in or on food at the time of consumption. Moreover, any residues that are present in or on food at the time of consumption as a result of pesticide use are likely to be indistinguishable from naturally occurring methyl jasmonate due to its ubiquitous presence in plants. Finally, the Agency believes that it is unlikely that any exposure to the residues of methyl jasmonate will result in dietary risks because of the non-toxic mode of action as a SAR inducer and the pesticide's virtually non-toxic profile.

1. *Food.* Exposure to residues of methyl jasmonate on foods is expected to be negligible. The application of methyl jasmonate is made directly to seeds through a contained seed-treatment or through in-furrow or soil drench applications. This application scenario prevents drift and minimizes exposure to humans. Although applications will result in minimal exposure, the Agency has calculated that exposures associated with maximum application rates are still lower than the current estimated dietary exposure for regular fruit consumption (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). Further, the data indicate that methyl jasmonate is readily biodegradable within four weeks (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). Because applications necessarily occur early in

the growing season due to its mode of action as a SAR inducer on seeds and seedlings, no significant pesticidal residues are anticipated for any harvested foods. However, in the event of exposure to residues of methyl jasmonate, no dietary risks are anticipated. As described in Unit III, acute, subchronic, mutagenic and developmental studies and information support its nontoxic profile. Furthermore, it is already present in the human fruit and vegetable diet without any known detrimental effects. There is no information in the public literature suggesting any health issues to either animals or plants relative to this compound. It is estimated that humans consume at least .348 ug/day on average, based on EPA models for apple and strawberry consumption (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). Finally, the dietary use of methyl jasmonate as a food additive was approved by the Joint FAO/WHO Expert Committee on Food Additives, which found methyl jasmonate to be non-toxic at a conservative threshold of 540 ug/day. (JECFA, 2005). By comparison, maximum residues have been calculated to be 373 ug ai/kg of seed (Memorandum from Miachel Rexrode, Ph.D., July 19, 2012). In sum, minimal dietary exposure is expected; however, any potential dietary exposures would not be expected to pose any consequential risk, mainly due to methyl jasmonate's virtually non-toxic profile.

2. *Drinking water exposure.* Residues of methyl jasmonate are not expected to be present in drinking water because applications of methyl jasmonate are made directly to seeds, seedlings and soil. Methyl jasmonate residues are not expected to percolate through the soil because residues are not expected to persist beyond the time it would typically take for any residues to percolate into the groundwater. Nonetheless, given methyl jasmonate's virtually non-toxic profile as described in Unit III, risks from aquatic exposure would be negligible.

B. Other Non-Occupational Exposure

Non-occupational exposure is not expected because methyl jasmonate is intended for commercial use. The active ingredient is applied directly to seeds or agricultural furrows, and it degrades rapidly. Further, health risks are not expected from any pesticidal exposure to this active ingredient, no matter the circumstances. A February, 2013 Agency risk assessment of methyl jasmonate establishes that even a worst case exposure scenario involving

prolonged and regular occupational exposures, which are not associated with this active ingredient, would pose negligible risks (Methyl Jasmonate BRAD, February 28, 2013). Methyl jasmonate is characterized by its biodegradability; low toxicity profile; nontoxic, SAR-inducing mode of action; and demonstrable lack of dietary effects.

1. *Dermal exposure.* Non-occupational dermal exposures to methyl jasmonate are expected to be negligible because of its directed agricultural use. Even in the event of dermal exposure to residues, the nontoxic profile of methyl jasmonate (as described in Unit III) is not expected to result in any risks through this route of exposure.

2. *Inhalation exposure.* Non-occupational inhalation exposures are not expected to result from the agricultural uses of methyl jasmonate. Any inhalation exposure associated with this new agricultural and commercial use pattern is expected to be occupational in nature.

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 methyl jasmonate to share a common mechanism of toxicity with any other substances, and methyl jasmonate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that methyl jasmonate 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>.

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 methyl jasmonate. As illustrated in Unit III, acute toxicity studies indicate that methyl jasmonate is virtually non-toxic. It is ubiquitous in nature and present in fruits and vegetables. There is no history of any toxicological incident involving its

consumption, and its use in food supplements is already allowed by the United States Food and Drug Administration. For all of these reasons, the Agency has determined that this food use of methyl jasmonate poses no foreseeable risks to human health or the environment. Thus, there is a reasonable certainty of no harm to the general U.S. population, including infants and children, from exposure to this active ingredient.

A. U.S. Population

The Agency has determined that there is a reasonable certainty that no harm will result from aggregate exposure to residues of methyl jasmonate to the U.S. population. This includes all anticipated dietary exposures and other non-occupational exposures for which there is reliable information. The Agency arrived at this conclusion based on the low levels of mammalian dietary toxicity associated with methyl jasmonate, the natural ubiquity of methyl jasmonate in food, and information suggesting that the pesticidal use of methyl jasmonate will not result in significant exposure. For these reasons, the Agency has determined that methyl jasmonate residues in and on all food commodities will be safe, and that there is a reasonable certainty that no harm will result from aggregate exposure to residues of methyl jasmonate.

B. Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless the EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessments either directly or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

Based on all the information evaluated for methyl jasmonate, the Agency concludes that there are no

threshold effects of concern and, as a result, 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 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 methyl jasmonate.

VIII. Conclusions

Therefore, an exemption is established for residues of methyl jasmonate in or on all food commodities when applied preharvest.

IX. References

Complete citations to the references used in this document are set forth in Appendix C to the document captioned "Methyl Jasmonate BRAD (Biopesticides Registration Action Document) Methyl Jasmonate PC Code: 028100" (document ID number EPA-HQ-OPP-2012-0134-0006), found in the OPP docket listed under docket ID number EPA-HQ-OPP-2012-0134, and may be seen by accessing the www.regulations.gov Web site.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735,

October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 22, 2013.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1320 is added to subpart D to read as follows:

§ 180.1320 Methyl jasmonate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of methyl jasmonate in or on all food commodities when methyl jasmonate is applied pre-harvest.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

World Trade Center Health Program; Certification of Breast Cancer in WTC Responders and Survivors Exposed to PCBs

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Change in certification requirements.

SUMMARY: On September 12, 2012, HHS published a final rule in the **Federal Register** adding certain types of cancer to the List of World Trade Center (WTC)-Related Health Conditions (List) established in the WTC Health Program regulation. Breast cancer was included on the List, although only individuals

experiencing nighttime sleep disruption as a result of response and cleanup activities involving shiftwork are currently considered to have experienced exposure relevant for certification. A recent publication in *The Lancet Oncology* by the International Agency for Research on Cancer (IARC) concludes that there is limited evidence that polychlorinated biphenyls (PCBs) cause breast cancer in humans. As described below, the WTC Program Administrator (Administrator) has found that PCBs were present in WTC dust in the New York City disaster area and, accordingly, the Program will now certify breast cancer in eligible WTC responders and survivors who were exposed to either shiftwork/nighttime sleep disruption or PCBs as a result of the 9/11 attacks.

DATES: This change in certification requirements is effective April 17, 2013.

FOR FURTHER INFORMATION CONTACT: Paul Middendorf, Senior Health Scientist, 1600 Clifton Rd. NE., MS: E-20, Atlanta, GA 30329; telephone (404)498-2500 (this is not a toll-free number); email pmiddendorf@cdc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

On September 7, 2011, the Administrator received a written petition to add cancers to the List of WTC-Related Health Conditions in 42 CFR 88.1 (Petition 001). On October 5, 2011, the Administrator formally exercised his option to request a recommendation from the WTC Health Program Scientific/Technical Advisory Committee (STAC) regarding the petition.¹ The Administrator requested that the STAC “review the available information on cancer outcomes associated with the exposures resulting from the September 11, 2001, terrorist attacks, and provide advice on whether to add cancer, or a certain type of cancer, to the List specified in the Zadroga Act.” Following three public meetings where the Committee deliberated on the issues, the STAC submitted its recommendation on Petition 001 to the Administrator on April 2, 2012. After considering the STAC’s recommendation, the Administrator issued a notice of proposed rulemaking on June 13, 2012 [77 FR 35574]. On September 12, 2012, HHS published a final rule in the **Federal Register** adding certain types of cancer to the List of WTC-Related Health Conditions in 42 CFR 88.1 [77 FR 56138]. On October 12, 2012, HHS published a **Federal Register** notice to

correct errors in Table 1 of the final rule (the list of cancers covered by the Program) [77 FR 62167].

B. Administrator’s Determination on the Inclusion of Female Breast Cancer

In the final rule, the Administrator established a four-pronged Methodology for evaluating whether to add certain types of cancer to the List: Epidemiologic Studies of September 11, 2001 Exposed Populations (Method 1); Established Causal Associations (Method 2); Review of Evaluations of Carcinogenicity in Humans, requiring both Published Exposure Assessment Information, and Evaluation of Carcinogenicity in Humans from Scientific Studies (Method 3, including criteria 3A and 3B); and Review of Information Provided by the WTC Health Program Scientific/Technical Advisory Committee (Method 4). A full narrative description and graphic of the Methodology were published in the final rule [77 FR 56138, 56142–56143 (September 12, 2012)].

At the time of the Administrator’s deliberation, breast cancer was determined to meet Method 4 (the STAC had provided a reasonable basis for its inclusion on the List). In its April 2, 2012 recommendation, the STAC had reported that:

There is evidence of PCB [polychlorinated biphenyl] exposures to WTC responders and survivors based on air samples, window film samples and one biomonitoring study. Studies have linked total and congener-specific PCB levels in serum and adipose tissue with breast cancer, although evidence has been conflicting. PCBs and some other substances at the WTC site are endocrine disruptors. Breast cancer risks are highly related to hormonal factors, including endogenous and exogenous estrogens, and could plausibly be affected by endocrine disruptors. A recent study found that PCBs enhanced the metastatic properties of breast cancer cells by activating rho-associated kinase. Shiftwork involving circadian rhythm disruption has been classified by IARC as probably carcinogenic to humans, based in part on epidemiologic studies associating shiftwork with increased risks of breast cancer. Both shiftwork and long shifts were common for workers involved in rescue, recovery, clean up, restoration and other activities at the WTC site.² [references omitted]

Although the STAC specified that PCBs might be causally associated with breast cancer, the Committee provided stronger evidence (IARC classification as a carcinogen) that shiftwork

² STAC [World Trade Center Health Program Scientific/Technical Advisory Committee] [2012]. Letter from Elizabeth Ward, Chair to John Howard, MD, Administrator. This letter is included in NIOSH Docket 257, <http://www.cdc.gov/niosh/docket/archive/docket257.html>.

¹ See 42 CFR 88.17(a)(2)(i).