have a significant impact on a substantial number of small entities.

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We conclude that these information collection provisions are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or Agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an Agency against specific individuals or entities. The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records under 21 CFR 1.361.

VI. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ Accordingly, the interim rule amending 21 CFR part 1, which was published at 77 FR 10658 (February 23, 2012), is adopted as a final rule without change.

Dated: April 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07550 Filed 4–3–14; 8:45 am]

BILLING CODE 4160–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2013–0646; FRL–9908–72–Region 5]

Approval and Promulgation of Air Quality Implementation Plans; Michigan; PSD Rules for $PM_{2.5}$

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct Final Rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving revisions to Michigan's Prevention of Significant Deterioration (PSD) Program rules and definitions, including revisions to Parts 1 and 18 of Michigan's Air Pollution Control Rules into Michigan's State Implementation Plan (SIP). The revised rules address the Federal requirements for significant emission levels, and definitions for fine particulate matter ($PM_{2.5}$). The Michigan Department of Environmental Quality (MDEQ) submitted these revisions to EPA on August 9, 2013, and September 19, 2013.

DATES: This direct final rule is effective June 3, 2014, unless EPA receives adverse comments by May 5, 2014. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2013–0646, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: damico.genevieve@epa.gov.*
3. *Fax:* (312) 886–0968.
4. *Mail:* Genevieve Damico, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Genevieve Damico, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2013–0646. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Constantine Blathras, Environmental

Engineer, at (312) 886–0671 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Constantine Blathras, Environmental Engineer, Air Permits Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–0671, *Blathras.constantine@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This supplementary information section is arranged as follows:

I. Background

On August 9, 2013, MDEQ submitted revisions to Michigan rules R 336.2801, Definitions; R 336.2803, Ambient air increments; and R 336.2816, Sources impacting Federal Class I areas, additional requirements, which reflect changes to Federal rules on $PM_{2.5}$ and ozone precursors. MDEQ also submitted various revisions to Michigan rule R 336.2809 to allow for the exemption from permitting requirements of minimal air quality impacts from new sources; however, MDEQ has requested that EPA not act on subsection R 336.2809(5)(a)(iii), which creates a significant monitoring concentration (SMC) for $PM_{2.5}$. Michigan had promulgated this subsection before the U.S. Court of Appeals for the District of Columbia Circuit vacated the Federal $PM_{2.5}$ SMC on January 22, 2013. On September 19, 2013, MDEQ submitted revisions to definitions in Michigan rules R 336.1116, R 336.1119, and R 336.1122 to address additional changes to Federal rules. The revisions to rules R 336.1116 and R 336.1119 add significance levels and definitions for $PM_{2.5}$ and account for $PM_{2.5}$ and PM_{10} condensables in applicability determinations and in establishing emissions limits. The revision to R 336.1122(f) updates the definition of volatile organic compounds to exclude additional compounds with negligible reactivity in the formation of ozone that have been approved by EPA. However, MDEQ has asked EPA not to act on the revision to the definition of ''significant'' in rule R 336.1119 at this time. Michigan will resubmit revisions to that definition at a later date.

II. What action is EPA taking?

EPA is approving the submitted revisions to Michigan's Part 1 definitions, with the exception of the definition of ''significant'' in rule R 336.1119. EPA has determined that the revised rules comply with the revisions to the Federal requirements found in 40 CFR 51.100, 51.165, and 51.166, pertaining to new definitions and provisions for $PM_{2.5}$.

EPA is approving the submitted revisions to Michigan's Part 18 PSD rules into the Michigan SIP, with the exception of R 336.2809(5)(a)(iii), on which we are taking no action. EPA has determined that the revised rules comply with the revisions to the Federal definitions and provisions pertaining to $PM_{2.5}$ found at 40 CFR 51.100, 51.165, and 51.166.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant adverse written comments are filed. This rule will be effective June 3, 2014 without further notice unless we receive relevant adverse written comments by May 5, 2014. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. We then will address all public comments in a subsequent final rule based on the proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule that may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of the adverse comment. If we do not receive any adverse comments, this action will be effective June 3, 2014.

III. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by *June 3, 2014.* Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: March 17, 2014.

Susan Hedman,

Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. In § 52.1170 the table in paragraph (c) is amended by:

■ i. Revising the entries in ''Part 1. General Provisions'' for R 336.1116 and R 336.1122; and

■ ii. Revising the entries in ''Part 18. Prevention of Significant Deterioration of Air Quality'' for R 336.2801, R 336.2803, R 336.2809, and R 336.2816.

The revised text reads as follows:

§ 52.1170 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MICHIGAN REGULATIONS

Michigan citation	Title	State effective date	EPA approval date	Comments
* *	*	*	* *	*
Part 1. General Provisions				
* *	*	*	* *	*
R 336.1116	Definitions; P	11/30/2012	4/4/14, [INSERT PAGE NUMBER WHERE THE DOCUMENT BEGINS].	
* *	*	*	* *	*
R 336.1122	Definitions; V	11/30/2012	4/4/14, [INSERT PAGE NUMBER WHERE THE DOCUMENT BEGINS].	
* *	*	*	* *	*
Part 18. Prevention of Significant Deterioration of Air Quality				
R 336.2801	Definitions	11/30/2012	4/4/14, [INSERT PAGE NUMBER WHERE THE DOCUMENT BEGINS].	
* *	*	*	* *	*
R 336.2803	Ambient Air Increments	11/30/2012	4/4/14, [INSERT PAGE NUMBER WHERE THE DOCUMENT BEGINS].	
* *	*	*	* *	*
R 336.2809	Exemptions	11/30/2012	4/4/14, [INSERT PAGE NUMBER WHERE THE DOCUMENT BEGINS].	All except for section (5)(a)(iii)
* *	*	*	* *	*
R 336.2816	Sources impacting federal class I areas; additional requirements.	11/30/2012	4/4/14, [INSERT PAGE NUMBER WHERE THE DOCUMENT BEGINS].	
* *	*	*	* *	*

[FR Doc. 2014–06825 Filed 4–3–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0258; FRL–9907–67]

Metaflumizone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of metaflumizone in or on eggplant, pepper, tomato, and tomato, paste. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 4, 2014. Objections and requests for hearings must be received on or before June 3, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0258, 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: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2013–0258 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 3, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2013–0258, by one of the following methods:

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

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

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of June 5, 2013 (78 FR 33785) (FRL–9386–2), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E8146) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27790. The petition requested that 40 CFR 180.657 be amended by establishing tolerances for residues of the insecticide metaflumizone, (E and Z isomers; 2-[2-(4-cyanophenyl)-1-[3-(trifluoromethyl) phenyl]ethylidene]-*N*-[4-(trifluoromethoxy)phenyl] hydrazinecarboxamide), and its metabolite (4-{2-oxo-2-[3-(trifluoromethyl) phenyl]ethyl}-benzonitrile), in or on eggplant at 0.6 parts per million (ppm); pepper at 0.6 ppm; and tomato at 0.6 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has determined that the tolerances for eggplant and pepper should each be established at 1.5 ppm, the tolerance for tomato should be established at 0.60 ppm, and that an additional tolerance for tomato, paste should be established at 1.2 ppm. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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