

*clinical trials for COVID-19.* For the duration of the President's national emergency regarding the COVID-19 outbreak, TRICARE will cover cost-sharing for those TRICARE-eligible patients selected to participate in NIAID-sponsored Phase I, II, III, and IV studies examining the treatment or prevention of COVID-19 and its associated sequelae (*e.g.*, cardiac and pulmonary issues). TRICARE will continue to cover cost-sharing for any eligible beneficiary enrolled in such a study until the conclusion of that study, even if the national emergency ends before the conclusion of the study.

(1) TRICARE will cost-share all medical care (including associated health complications) and testing required to determine eligibility for an NIAID-sponsored trial, including the evaluation for eligibility at the institution conducting the NIAID-sponsored study. TRICARE will cost-share all medical care required as a result of participation in NIAID-sponsored studies. This includes purchasing and administering all approved pharmaceutical agents (except for NIAID-funded investigational drugs), all inpatient and outpatient care, including diagnostic, laboratory, rehabilitation, and home health services not otherwise reimbursed under an NIAID grant program if the following conditions are met:

(i) Such treatments are NIAID-sponsored Phase I, Phase II, Phase III, or Phase IV protocols;

(ii) The patient continues to meet entry criteria for said protocol;

(iii) The institutional and individual providers are TRICARE-authorized providers; and

(iv) The requirements for Phase I protocols in paragraph (e)(26)(iii)(B)(2) of this section are met.

(2) Requirements for Phase I protocols are:

(i) Standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative;

(ii) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative;

(iii) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise; and

(iv) The referring physician has concluded that the enrollee's participation in such a trial would be appropriate based upon the satisfaction of paragraphs (e)(26)(iii)(B)(2)(i) through (iii) of this section.

(3) TRICARE will not provide reimbursement for care rendered in the NIH Clinical Center or costs associated with non-treatment research activities associated with the clinical trials.

(4) Cost-shares and deductibles applicable to TRICARE will also apply under the NIAID-sponsored clinical trials.

(5) The Director, Defense Health Agency (or designee), shall issue procedures and guidelines establishing NIAID-sponsorship of clinical trials and the administrative process by which individual patients apply for and receive cost-sharing under NIAID-sponsored COVID-19 clinical trials.

\* \* \* \* \*

Dated: October 27, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R05-OAR-2019-0302, EPA-R05-OAR-2019-0676; FRL-10015-49-Region 5]

### Air Plan Approval; Ohio; Volatile Organic Compounds

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is approving under the Clean Air Act, a State Implementation Plan (SIP) submittal from the Ohio Environmental Protection Agency (OEPA). This SIP revision request, submitted on April 5, 2019, and supplemented on November 21, 2019, consists of amendments and additions to the volatile organic compound (VOC) rules in the Ohio Administrative Code (OAC). These changes provide clarity to facilities that are subject to multiple VOC requirements in the SIP, or whose applicable requirements have been moved to other sections within the OAC as a result of a previous revision. The changes also correct errors and provide general administrative cleanup. An alternative monitoring, recordkeeping, and reporting program was added to the requirements for the BP-Husky Refining LLC, Toledo Refinery. In addition, the SIP submittal adds a mechanism for Ohio to approve alternate limitations for site-specific miscellaneous industrial adhesive and sealant facilities and includes alternate site-specific

limitations for certain process lines at the Accel Group, Incorporated (Accel) facility in Wadsworth, Ohio. EPA proposed to approve this action on July 22, 2020, and received no adverse comments.

**DATES:** This final rule is effective on November 30, 2020.

**ADDRESSES:** EPA has established dockets for this action under Docket ID Nos. EPA-R05-OAR-2019-0302 (pertaining to amendments to OAC Chapter 3745-21) and EPA-R05-OAR-2019-0676 (pertaining to site-specific alternate VOC SIP limits for the Accel facility). All documents in the dockets are listed on the [www.regulations.gov](http://www.regulations.gov) website. Although listed in the index, some information is not publicly available, *i.e.*, 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 through [www.regulations.gov](http://www.regulations.gov) or 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 and facility closures due to COVID-19. We recommend that you telephone Anthony Maietta, Environmental Protection Specialist, at (312) 353-8777 before visiting the Region 5 office.

**FOR FURTHER INFORMATION CONTACT:** Anthony Maietta, Environmental Protection Specialist, Control Strategies Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353-8777, [maietta.anthony@epa.gov](mailto:maietta.anthony@epa.gov).

### SUPPLEMENTARY INFORMATION:

Throughout this document whenever "we," "us," or "our" is used, we mean EPA.

### I. Background Information

On July 22, 2020, EPA proposed to approve amendments and additions to the VOC rules located at OAC Chapter 3745-21, including an alternative monitoring, recordkeeping, and reporting program for the BP-Husky Refining LLC, Toledo Refinery at OAC 3745-21-09(T)(4), and alternate site-specific limitations for the Accel facility contained in its September 19, 2019, operating permit (85 FR 44255). An explanation of the applicable Clean Air Act requirements, a detailed analysis of the revisions, and EPA's reasons for

proposing approval were provided in the notice of proposed rulemaking (NPRM) and will not be restated here. The public comment period for this proposed rule ended on August 21, 2020. EPA received one supportive comment (from BP-Husky) on the proposal. Therefore, we are finalizing our action as proposed.

## II. Final Action

EPA is approving the revisions to OAC Chapter 3745–21, specifically to the following rules: 3745–21–09, 3745–21–10, 3745–21–25, 3745–21–26, 3745–21–28, and 3745–21–29, as contained in Ohio's April 5, 2019 submittal. EPA is also approving into the SIP the addition of paragraphs B.4, B.6, B.8, B.9.c), C.1.b)(1)d, C.1.b)(2)a, C.1.d)(2), C.1.d)(3), C.1.e)(3), C.1.f)(1)c, C.2.b)(1)d, C.2.b)(2)a, C.2.d)(2), C.2.d)(3), C.2.e)(3), and C.2.f)(1)e as listed in the September 19, 2019 operating permit for the Accel facility.

## III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Ohio Regulations described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these documents generally available through [www.regulations.gov](http://www.regulations.gov), and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the Clean Air Act as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.<sup>1</sup>

## IV. 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 Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because it is not a significant regulatory action under Executive Order 12866;
- 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 (Pub. L. 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, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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 December 29, 2020. 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. 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, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: October 8, 2020.

**Kurt Thiede**,  
Regional Administrator, Region 5.

For the reasons stated in the preamble, EPA amends title 40 CFR part 52 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 § 52.1870 amend:
  - a. The table in paragraph (c) under “Chapter 3745–21 Carbon Monoxide, Ozone, Hydrocarbon Air Quality Standards, and Related Emissions Requirements” by revising the entries for 3745–21–09, 3745–21–10, 3745–21–25, 3745–21–26, 3745–21–28, and 3745–21–29; and
  - b. The table in paragraph (d) by adding a new entry for “Accel Group, Inc.” before the entry for “AK Steel Corporation”.

<sup>1</sup> 62 FR 27968 (May 22, 1997).

The revisions and addition read as follows:

**§ 52.1870 Identification of plan.**

(c) \* \* \*

**EPA-APPROVED OHIO REGULATIONS**

Ohio citation	Title/subject	Ohio effective date	EPA approval date	Notes
*	*	*	*	*
<b>Chapter 3745–21 Carbon Monoxide, Ozone, Hydrocarbon Air Quality Standards, and Related Emission Requirements</b>				
3745–21–09 ....	Control of emissions of volatile organic compounds from stationary sources and perchloroethylene from dry cleaning facilities.	2/16/2019	10/30/2020, [INSERT <b>Federal Register</b> CITATION].	*
3745–21–10 ....	Compliance test methods and procedures .....	2/16/2019	10/30/2020, [INSERT <b>Federal Register</b> CITATION].	*
3745–21–25 ....	Control of VOC emissions from reinforced plastic composites production operations.	2/16/2019	10/30/2020, [INSERT <b>Federal Register</b> CITATION].	*
3745–21–26 ....	Surface coating of miscellaneous metal and plastic parts ....	2/16/2019	10/30/2020, [INSERT <b>Federal Register</b> CITATION].	*
3745–21–28 ....	Miscellaneous industrial adhesives and sealants .....	2/16/2019	10/30/2020, [INSERT <b>Federal Register</b> CITATION].	*
3745–21–29 ....	Control of volatile organic compound emissions from automobile and light-duty truck assembly coating operations, and cleaning operations associated with these coating operations.	2/16/2019	10/30/2020, [INSERT <b>Federal Register</b> CITATION].	*

\* \* \* \* \* (d) \* \* \*

**EPA-APPROVED OHIO SOURCE-SPECIFIC PROVISIONS**

Name of source	Number	Ohio effective date	EPA approval date	Comments
Accel Group, Inc .....	P0120345	9/16/2019	10/30/2020, [INSERT <b>Federal Register</b> CITATION].	Only paragraphs B.4, B.6, B.8, B.9.c), C.1.b)(1)d, C.1.b)(2)a, C.1.d)(2), C.1.d)(3), C.1.e)(3), C.1.f)(1)c, C.2.b)(1)d, C.2.b)(2)a, C.2.d)(2), C.2.d)(3), C.2.e)(3), and C.2.f)(1)e.
*	*	*	*	*

\* \* \* \* \*  
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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 170**

[EPA–HQ–OPP–2017–0543; FRL–10016–03]

**RIN 2070–AK49**

**Pesticides; Agricultural Worker Protection Standard; Revision of the Application Exclusion Zone Requirements**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is finalizing revisions to the Agricultural Worker Protection

Standard (WPS) to clarify and simplify the application exclusion zone (AEZ) requirements. This rulemaking is responsive to feedback received from stakeholders and the Agency's efforts to reduce regulatory burden, while providing the necessary protections for agricultural workers and the public. EPA remains committed to ensuring the protection of workers and persons in areas where pesticide applications are taking place. The AEZ and no contact provisions aim to ensure such protections. EPA also has a strong interest in promulgating regulations that are enforceable, clear, and effective.

**DATES:** This final rule is effective December 29, 2020.