

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Parts 9 and 721**

[EPA-HQ-OPPT-2014-0697; FRL-9943-83]

RIN 2070-AK05

**Trichloroethylene; Significant New Use Rule****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** Under the Toxic Substance Control Act (TSCA), EPA is finalizing a significant new use rule (SNUR) for trichloroethylene (TCE). The significant new use is the manufacture or processing for use in a consumer product, with an exception for use of TCE in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray. Persons subject to the SNUR will be required to notify EPA at least 90 days before commencing any manufacturing or processing of TCE for a significant new use. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary based on the information available at that time, an opportunity to protect against potential unreasonable risks, if any, from that activity before it occurs.

**DATES:** This final rule is effective June 7, 2016.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2014-0697, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. 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 OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** For technical information contact: Tyler Lloyd, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-4016; email address: [lloyd.tyler@epa.gov](mailto:lloyd.tyler@epa.gov).

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. Executive Summary***A. Does this action apply to me?*

You may be potentially affected by this action if you manufacture, process, or distribute in commerce chemical substances and mixtures. 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:

- Textile Product Mills (NAICS code 314).
- Wood Product Manufacturing (NAICS code 321).
- Printing and Related Support Activities (NAICS code 323).
- Chemical Manufacturing (NAICS code 325).
- Plastics and Rubber Product Manufacturing (NAICS code 326).
- Primary Metal Manufacturing (NAICS code 331).
- Fabricated Metal Product Manufacturing (NAICS code 332).
- Machinery Manufacturing (NAICS code 333).
- Computer and Electronic Product Manufacturing (NAICS code 334).
- Electrical Equipment, Appliance, and Component Manufacturing (NAICS code 335).
- Transportation Equipment Manufacturing (NAICS code 336).
- Furniture and Product Related Manufacturing (NAICS code 337).
- Miscellaneous Manufacturing (NAICS code 339).
- Clothing and Clothing Accessory Stores (NAICS code 488).
- Warehousing and Storage (NAICS code 493).
- Repair and Maintenance (NAICS code 811).
- National Security and International Affairs (NAICS code 928).

Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA

section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this final rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What is the agency's authority for taking this action?*

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

*C. What action is the agency taking?*

This final SNUR will require persons to notify EPA at least 90 days before commencing the manufacture (including import) or processing of TCE for use in a consumer product except for use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray.

The SNUR was proposed in the **Federal Register** of August 7, 2015 (80 FR 47441) (FRL-9930-33) (Ref. 1). Please consult the August 7, 2015 **Federal Register** document for further background information for this final rule. Additionally, please note that the

RIN for the proposed SNUR was inadvertently published as RIN 2070-AK50. This final SNUR bears the correct identification, RIN 2070-AK05. EPA received 4 public comments on the proposal and EPA's response to those comments appear in Unit X.

#### *D. Why is the agency taking this action?*

This SNUR is necessary to ensure that EPA receives timely advance notice of any future manufacturing and processing of TCE for new uses that may produce changes in human and environmental exposures. The rationale and objectives for this SNUR are explained in Unit III.

#### *E. What are the estimated incremental impacts of this action?*

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of TCE. This analysis (Ref. 2), which is available in the docket, is discussed in Unit IX., and is briefly summarized here.

In the event that a SNUN is submitted, costs are estimated to be less than \$8,900 per SNUN submission for large business submitters and \$6,500 for small business submitters. These estimates include the cost to prepare and submit the SNUN and the payment of a user fee. The SNUR requires first-time submitters of any TSCA section 5 notice to register their company and key users with the CDX reporting tool, deliver a CDX electronic signature to EPA, and establish and use a Pay.gov E-payment account before they may submit a SNUN, for a cost of approximately \$200 per firm. However, these activities are only required of first time submitters of section 5 notices. In addition, for persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country, which is estimated to be approximately \$80 per notification.

## **II. Chemical Substance Subject to This Rule**

This final SNUR applies to TCE (Chemical Abstract Services Registry Number (CASRN) 79-01-6) manufactured (including import) or processed for use in any consumer product, except for use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray. A consumer product is defined at 40 CFR 721.3 as "a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or

residence, in or around a school, or in recreation."

## **III. Rationale and Objectives**

### *A. Rationale*

As discussed in detail in Units II and III of the proposed rule (80 FR 47441; August 7, 2015), TCE has the potential to induce neurotoxicity, immunotoxicity, developmental toxicity, liver toxicity, kidney toxicity, endocrine effects, and several forms of cancer (Ref. 3). EPA is concerned about the adverse health effects of TCE resulting from commercial and consumer uses of the chemical substance. In EPA's final risk assessment of TCE, released on June 25, 2014, the Agency identified risks to workers using TCE and to bystanders for use as degreasers and a spot-cleaner in dry cleaning uses, and EPA also identified health risks to consumers using spray aerosol degreasers and spray fixatives (Ref. 3).

EPA believes that any additional use of this chemical substance in consumer products could significantly increase human exposure, and that such exposures should not occur without an opportunity for EPA review and control as appropriate. However, as discussed in Unit II of the proposed rule (80 FR 47441; August 7, 2015), based on review of Safety Data Sheets and the National Institutes of Health's Household Products Database, EPA believes that cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray presently contain TCE and are therefore ongoing uses of this chemical. EPA believes that other consumer products do not presently contain TCE. Spray fixative product use was discontinued by September 1, 2015, as described in Unit II.A of the proposed rule (80 FR 47441).

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to promulgate a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate

the use according to the specific parameters and circumstances surrounding that intended use.

### *B. Objectives*

Based on the considerations in Unit III.A., EPA will achieve the following objectives with regard to the significant new use(s) that are designated in this final rule:

1. EPA will receive notice of any person's intent to manufacture or process TCE for the described significant new use before that activity begins.
2. EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing TCE for the described significant new use.
3. EPA will be able to regulate prospective manufacturers or processors of TCE before the described significant new use of the chemical substance occurs, provided that regulation is warranted pursuant to TSCA section 5(e), 5(f), 6, or 7.

## **IV. Significant New Use Determination**

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

1. The projected volume of manufacturing and processing of a chemical substance.
2. The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
3. The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
4. The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use of TCE, as discussed in Unit II of the proposed rule (80 FR 47441), EPA considered relevant information about the toxicity of the substance, likely human exposures and environmental releases associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA (80 FR 47441). EPA has determined as the significant new use: Manufacture or processing for any use in a consumer product, except for use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray. Because

TCE is not used in consumer products (with the limited exceptions of use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray). EPA believes new use in consumer products could increase the magnitude and duration of human exposure to TCE. Exposure to TCE through inhalation may lead to a wide array of adverse health effects, such as neurotoxicity, immunotoxicity, developmental toxicity, liver toxicity, kidney toxicity, endocrine effects, and several forms of cancer, as further explained in Unit II.C of the proposed rule (80 FR 47441), and because of these potential adverse effects EPA would like the opportunity to evaluate such potential uses in consumer products for any associated risks or hazards that might exist before those uses would begin.

#### V. Applicability of the General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule.

Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submissions requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities on which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. In accordance with 40 CFR 707.60(b), this final SNUR does not trigger export notification for articles. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification

requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

#### VI. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376; FRL-3658-5) (Ref. 4), EPA has decided that the intent of section 5(a)(1)(B) of TSCA is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who begin commercial manufacture or processing of TCE after the proposal was published on August 7, 2015, must cease such activity before the effective date of this final rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. Uses arising after the publication of the proposed rule are distinguished from uses that exist at publication of the proposed rule. The former would be new uses, the latter ongoing uses, except that uses that are ongoing as of the publication of the proposed rule would not be considered ongoing uses if they have ceased by the date of issuance of a final rule. However, recognizing that use in a consumer product of TCE in spray fixatives was to cease and did cease by September 1, 2015 as described in Unit II.A. of the proposed rule (80 FR 47441), EPA considers September 1, 2015 as the date from which the significant new use with respect only to such spray fixatives would be designated. Public commenters on the proposed rule did not identify any additional ongoing uses. EPA has promulgated provisions to allow persons to comply with this SNUR before the effective date. If a person were to meet the conditions of advance compliance under 40 CFR 721.45(h), that person would be considered to have met the

requirements of the final SNUR for those activities.

#### VII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not usually require developing any particular test data before submission of a SNUN. There are two exceptions:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)); and

2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a section 4 test rule or a section 5(b)(4) listing covering the chemical substance, persons are required to submit only test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25, and 40 CFR 720.50). However, as a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on:

- Human exposure and environmental releases that may result from the significant new uses of the chemical substance;
- Potential benefits of the chemical substance; and
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

#### VIII. SNUN Submissions

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what data may be useful in evaluating a significant new use. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the substance. According to 40 CFR 721.1(c), persons submitting a SNUN

must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 40 CFR 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

## IX. Economic Analysis

### A. SNUNs

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substance included in this final rule (Ref. 2). In the event that a SNUN is submitted, costs are estimated at approximately \$8,900 per SNUN submission for large business submitters and \$6,500 for small business submitters. These estimates include the cost to prepare and submit the SNUN, and the payment of a user fee. Businesses that submit a SNUN would be subject to either a \$2,500 user fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business with annual sales of less than \$40 million when combined with those of the parent company (if any), a reduced user fee of \$100 (40 CFR 700.45(b)(1)). EPA's complete economic analysis is available in the public docket for this final rule (Ref. 2).

### B. Export Notification

Under section 12(b) of TSCA and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which, among other things, a rule has been proposed or promulgated under TSCA section 5. For persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical, depending on the number of required notifications (*i.e.*, the number of countries to which the chemical is exported). While EPA is unable to make any estimate of the likely number of export notifications for the chemical covered in this final SNUR, as stated in the accompanying economic analysis of this final SNUR, the estimated cost of the export notification requirement on a per unit basis is approximately \$80.

## X. Response to Public Comment

The Agency reviewed and considered all comments received related to the proposed rule. Copies of all comments are available in the docket for this action (EPA-HQ-OPPT-2014-0697). A discussion of the major comments germane to the rulemaking and the Agency's responses follow.

### A. Support for TCE SNUR

1. *Comment.* One commenter supports the proposed rule and reiterates human health effects related to TCE exposure. (Docket ID# EPA-HQ-OPPT-2014-0697-0009.)

*Response.* EPA acknowledges the comment.

2. *Comment.* One commenter supports the proposed rule and asks EPA to (a) "broaden the scope of the SNUR to: (1) Include certain commercial uses of TCE, and (2) regularly review ongoing uses of TCE and update the SNUR to include any discontinued uses" and (b) "promptly promulgate a TSCA section 6(a) rule to address identified risks of TCE from ongoing uses." (Docket ID# EPA-HQ-OPPT-2014-0697-0010.)

*Response.* The commenter points out that there are "widespread ongoing commercial uses of TCE." Currently ongoing commercial uses of TCE cannot be included in the SNUR. EPA will continue to monitor uses of TCE and consider promulgating future SNURs for discontinued or other non-ongoing uses.

TSCA section 6 provides authority for EPA to ban or restrict the manufacture (including import), processing, distribution in commerce, and use of chemicals, as well as any manner or method of disposal. EPA identified TCE for risk evaluation as part of its Work Plan for Chemical Assessment under TSCA. TCE is used in industrial and commercial processes, and also has some limited uses in consumer products. In the June 2014 TSCA Work Plan Chemical Risk Assessment, EPA identified risks associated with commercial degreasing and some consumer uses. EPA is initiating rulemaking under TSCA section 6 to address these risks. Specifically, EPA will determine whether the use of TCE in some commercial degreasing uses, as a spotting agent in dry cleaning, and in certain consumer products presents an unreasonable risk to human health and the environment such that regulation is warranted under TSCA section 6.

3. *Comment.* One commenter agrees with the EPA's understanding that TCE is not widely used, with the exception of TCE in cleaners and solvent, degreasers, film cleaners, hoof polishes,

lubricants, mirror edge sealants, and pepper spray. (Docket ID# EPA-HQ-OPPT-2014-0697-0011.)

*Response.* EPA acknowledges the comment.

4. *Comment.* One commenter asks the Agency to "rescind any exemption to issuing a notice to any party looking to begin using TCE in the production of any consumer good" because TCE "is known to be a volatile organic compound (VOC) with a close association with many adverse health and environmental effects." (Docket ID# EPA-HQ-OPPT-2014-0697-0008.)

*Response.* EPA acknowledges the comment. As described in Unit III.A., by issuing this final rule EPA defers, if and until such time as a SNUN is submitted, the opportunity to evaluate the use according to the specific parameters and circumstances surrounding that intended use before such use could occur. In the event that a SNUN is submitted, EPA will follow all regulations and guidelines, pursuant to TSCA section 5(a)(2), that guide the assessment of any environmental and health concerns resulting from the Significant New Use.

### B. Review of Work Plan Chemical Risk Assessment

1. *Comment.* One commenter contends that the final Work Plan Chemical Risk Assessment "should not serve as the basis for regulation" and notes specific concerns with it, asking EPA to respond to each. (Docket ID# EPA-HQ-OPPT-2014-0697-0011.)

*Response.* The peer-reviewed Work Plan Chemical Risk Assessment referenced by the commenter includes an assessment of the hazard of TCE. As described in the risk assessment, TCE is carcinogenic to humans and TCE exposure is associated with a range of non-cancer health effects in humans and animals, including developmental toxicity, immunotoxicity, kidney toxicity, reproductive toxicity, neurotoxicity and liver toxicity. While EPA considered relevant information about the toxicity of the substance, likely human exposures and environmental releases associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA (80 FR 47441), EPA believes that the commenter's specific concerns are not relevant to the "basis for regulation" for this SNUR.

Under section 5(a)(2), EPA is neither required to determine that a particular new use of any chemical substances presents, nor even that it may present, an unreasonable risk to human health or the environment. Rather, EPA issues a SNUR for a particular new use of a

substance if it has reason to anticipate that the use would raise significant questions related to potential exposure, so that it should have an opportunity to review the use before such use should occur. As discussed in Unit IV, EPA based this judgement on a consideration of all relevant factors, including the specific factors identified at section 5(a)(2).

## XI. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Trichloroethylene (TCE); Significant New Use Rule; TCE in Certain Consumer Products; Proposed Rule. **Federal Register** (80 FR 47441, August 7, 2015) (FRL-9930-33).
2. EPA. Economic Analysis for the Final Significant New Use Rule for Trichloroethylene (TCE). March 10, 2016.
3. EPA. TSCA Workplan Chemical Risk Assessment—Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses; Supporting and Related Material. June 25, 2014.
4. EPA. Significant New Uses of Certain Chemical Substances; Final Rule. **Federal Register** (55 FR 17376, April 24, 1990) (FRL-3658-5).

## XII. Statutory and Executive Order Reviews

### A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

### B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with existing chemical SNURs are already approved by OMB under OMB control number 2070-0038 (EPA ICR No. 1188); and the information collection activities associated with export notifications are already approved by OMB under OMB

control number 2070-0030 (EPA ICR No. 0795). If an entity were to submit a SNUN to the Agency, the annual burden is estimated to be less than 100 hours per response, and the estimated burden for export notifications is less than 1.5 hours per notification. In both cases, burden is estimated to be reduced for submitters who have already registered to use the electronic submission system.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument, or form, if applicable. EPA is amending the table in 40 CFR part 9 to list this SNUR. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of the PRA and OMB's implementing regulations at 5 CFR part 1320. Since the existing OMB approval was previously subject to public notice and comment before OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend the table is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), to amend this table without further notice and comment.

### C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, I certify that this action will not have a significant economic impact on a substantial number of small entities.

A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a "significant new use." By definition of the word "new" and based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. Since this SNUR will require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's

experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of notices per year. During the six year period from 2005-2010, only three submitters self-identified as small in their SNUN submission (Ref. 2). EPA believes the cost of submitting a SNUN is relatively small compared to the cost of developing and marketing a chemical new to a firm or marketing a new use of the chemical and that the requirement to submit a SNUN generally does not have a significant economic impact.

Therefore, EPA believes that the potential economic impact of complying with this final SNUR is not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published as a final rule on August 8, 1997 (62 FR 42690) (FRL-5735-4), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities.

### D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted by this rulemaking. As such, the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C. 1531-1538, do not apply to this action.

### E. Executive Order 13132: Federalism

This action will not have a substantial direct effect on 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

### F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This final rule does not have Tribal implications because it is not expected to have any effect (*i.e.*, there will be no increase or decrease in authority or jurisdiction) on Tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, Executive Order 13175 (65 FR 67249,

November 9, 2000) does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This final rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

Since this action does not involve any technical standards, section 12(d) of NTTAA, 15 U.S.C. 272 note, does not apply to this action.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This final rule does not invoke special consideration of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This action does not affect the level of protection provided to human health or the environment.

XIII. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 et seq., and the EPA will submit a rule report to each House of Congress and the Comptroller of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: April 4, 2016.

Wendy Cleland-Hamnett,

Director, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR chapter I is amended as follows:

PART 9—[AMENDED]

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 et seq., 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 et seq., 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 et seq., 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

■ 2. In § 9.1, add the following section in numerical order under the undesignated center heading "Significant New Uses of Chemical Substances" to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

Table with 5 columns: asterisks, 40 CFR citation, asterisks, OMB Control number, asterisks. Row 1: Significant New Uses of Chemical Substances. Row 2: 721.10851 ..... 2070-0038.

PART 721—[AMENDED]

■ 3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 4. Add § 721.10851 to subpart E to read as follows:

§ 721.10851 Trichloroethylene.

(a) Chemical substance and significant new uses subject to reporting.

(1) The chemical substance trichloroethylene (CAS 79-01-6) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) Manufacture or processing for use in a consumer product except for use in

cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray.

(b) [Reserved]

[FR Doc. 2016-08152 Filed 4-7-16; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2015-0773; FRL-9944-73-Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Attainment Plan and Base Year Inventory for the North Reading Area for the 2008 Lead National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision submitted by the Commonwealth of Pennsylvania (Pennsylvania). The revision demonstrates attainment of the 2008 lead national ambient air quality standards (NAAQS) in the North Reading 2008 lead nonattainment area (North Reading Area or Area). The attainment plan includes the base year emissions inventory, an analysis of reasonably available control technology (RACT), reasonably available control measures (RACM), and reasonable further progress (RFP), modeling demonstration of lead attainment, and contingency measures for the Area. EPA is approving Pennsylvania's lead attainment plan with the base year emissions inventory for the North Reading Area as a revision to Pennsylvania's SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on May 9, 2016.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA-R03-OAR-2015-0773. All documents in the docket are listed in the www.regulations.gov Web site. Although listed in the electronic docket, 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