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The Director of the Office of Pollution Prevention and Toxics signed the following *Federal Register* document on July 30, 2015:

Title: **Proposed Rule; Trichloroethylene (TCE); Significant New Use Rule; TCE in Certain Consumer Products** (RIN 2070-AK50)

FRL: 9930-33

Docket No.: **EPA-HQ-OPPT-2014-0697**

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2014-0697; FRL-9930-33]

RIN 2070-AK50

Trichloroethylene (TCE); Significant New Use Rule; TCE in Certain Consumer Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under the Toxic Substance Control Act (TSCA), EPA is proposing a significant new use rule (SNUR) for trichloroethylene (TCE). The proposed significant new use is manufacture or processing for use in a consumer product, with a proposed 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 would 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 would 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: Comments must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2014-0697, 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 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.html*.

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

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Katherine Sleasman, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (202) 564-7716; email address: *sleasman.katherine@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*.

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).

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 proposed rule on or after [*insert date 30 days after the date of publication in the* **Federal Register**] 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.

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?

EPA is proposing a SNUR for trichloroethylene (TCE). The proposed significant new use is: Manufacturing and processing for any use in a consumer product of TCE except for use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray.

The proposed significant use EPA has identified in this unit is a use that EPA believes is not ongoing at the time of this proposed rule. EPA is requesting public comment on this proposal, and specifically on the Agency's understanding of ongoing uses for the chemical identified. EPA is particularly interested in whether there are any ongoing uses of this chemical in consumer products of which the Agency is currently unaware. EPA would welcome specific documentation of any such ongoing uses. 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."

This proposed SNUR would require persons that manufacture (including import) or process any of the chemicals for a significant new use, consistent with the requirements at 40 CFR 721.25, to notify EPA at least 90 days before commencing such manufacture or process of the chemical substance for a significant new use.

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 the chemical substance included in this proposed rule. This analysis, 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 proposed SNUR would require 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 $203 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 $83 per notification.

II. Chemical Substance Subject to this Proposed Rule

A. What Chemical Is Included in the Proposed SNUR?

This proposed SNUR would apply to TCE (Chemical Abstract Services Registry Number (CASRN 79-01-6) manufactured or processed 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. TCE is a volatile organic compound (VOC) that is produced and imported into the United States, with use estimated to be around 250 million pounds per year. It is a clear, colorless liquid that has a sweet odor and evaporates quickly (Ref. 1).

To ascertain if TCE is used in consumer products, EPA reviewed published literature, the National Institute of Health's (NIH) Household Product Database (HPD), Safety Data Sheets (SDSs), data submitted under EPA's Chemical Data Reporting (CDR) rule, and data submitted under EPA's Toxics Release Inventory (TRI) and communicated directly with domestic manufacturers and processors (Refs. 1 and 2). From review of these resources it was confirmed that the following consumer products containing TCE are available in retail outlets and e-commerce sites: cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray. Cleaners and solvents can be used to clean automotive parts, fabrics, and carpets. EPA does not believe that there are any other types of consumer products containing TCE (Ref. 1).

Following the release of the final risk assessment, EPA received a letter from PLZ Aeroscience Corporation on March 5, 2015, indicating their intent to reformulate their spray fixative product for consumers. Their letter states that they will no longer manufacture or process spray fixatives with TCE by September 1, 2015 (Ref. 3). EPA's review of the resources indicates this is the only TCE-containing spray fixative that is still used in a consumer product.

B. What Are the Production Volumes and Uses of TCE?

The majority (> 80 %) of TCE is used as an intermediate for manufacturing refrigerant chemicals. Much of the remainder, less than 14 percent, is used as a solvent for metals degreasing, leaving a relatively small percentage to account for all other uses, including its use in consumer products. In 2011, global consumption of TCE was 945 million pounds (lbs) and U.S. consumption was 255 million lbs. Nine companies, including domestic manufacturers and importers, reported a total production of 224.7 million lbs of TCE in 2011 to the CDR database. Based on the TRI data for 2012, 38 companies use TCE as a formulation component, 33 companies process TCE by repackaging the chemical, 28 companies use TCE as a manufacturing aid, and 1,113 companies use TCE for ancillary uses, such as degreasing. Overall, most U.S. consumption is attributable to two specific uses: as an intermediate for manufacturing the refrigerant (closed system) HFC-134a (a major alternative to CFC-12), and as a solvent for metal degreasing (Ref. 1).

C. What Are the Potential Health Effects of TCE?

A broad set of relevant studies including epidemiologic studies, animal bioassays, metabolism studies and mechanistic studies show that TCE exposure is associated with a wide array of adverse health effects. TCE has the potential to induce neurotoxicity, immunotoxicity, developmental toxicity, liver toxicity, kidney toxicity, endocrine effects, and several forms of cancer (Ref. 1).

TCE is fat soluble (lipophilic) and easily crosses biological membranes. It is readily absorbed into the body following oral, dermal, or inhalation exposure. Following oral ingestion TCE is rapidly absorbed from the gastrointestinal tract into the systemic circulation (i.e., blood), and its absorption rate is highly influenced by dose of the

chemical, dosing vehicle, and stomach content. Absorption through the skin has been shown by both vapor and liquid TCE contact. Likewise, absorption following inhalation of TCE is also rapid and the inhaled absorbed dose is proportional to the exposure concentration, duration of exposure, and lung ventilation rate. Regardless of the route of exposure, TCE is widely distributed throughout the body. TCE levels can be found in many different tissues including: brain, muscle, heart, kidney, lung, liver, and adipose tissues. Due to its lipophilicity, TCE has been found in human maternal and fetal blood and in the breast milk of lactating women (Ref. 1).

The metabolism of TCE has been extensively studied in humans and experimental rodent models. Both humans and animals metabolize TCE to numerous toxicologically active metabolites to varying degrees. These metabolites are generated from and transported across multiple tissues and play a key role in causing TCE-associated toxic effects that target the liver and kidney (Ref. 1).

TCE is characterized as carcinogenic to humans by all routes of exposure as documented in EPA's TCE Integrated Risk Information System (IRIS) assessment (Ref 4). This conclusion is based on strong cancer epidemiological data that reported an association between TCE exposure and the onset of various cancers, primarily in the kidney, liver and the immune system (i.e., non-Hodgkin lymphoma or NHL). Further support for TCE's carcinogenic characterization comes from positive results in multiple rodent cancer bioassays in rats and mice of both sexes, similar toxicokinetics between rodents and humans, mechanistic data supporting a mutagenic mode of action for kidney tumors, and the lack of mechanistic data supporting the conclusion that any of the mode(s) of action for TCE-induced rodent tumors are irrelevant to humans. Additional

support comes from the recent evaluation of TCE's carcinogenic effects by the International Agency for Research on Cancer (IARC). IARC classifies TCE as carcinogenic to humans (Ref. 5).

EPA's IRIS assessment also concluded that TCE poses a potential human health hazard for non-cancer toxicity including neurotoxicity, liver and kidney effects, immunotoxicity, reproductive, and developmental effects. Also evaluated in the IRIS assessment were TCE's and its metabolites genotoxic effects. As shown through the results of *in vitro* and *in vivo* tests, TCE has the potential to bind or induce damage to the structure of DNA or chromosomes (Ref. 4).

Neurotoxicity has been demonstrated in animal and human studies under both acute and chronic exposure conditions. Evaluation of the human studies revealed TCE-induced neurotoxic effects including alterations in trigeminal nerve and vestibular function, auditory effects, changes in vision, alterations in cognitive function, changes in psychomotor effects, and neurodevelopmental outcomes. The strongest neurological evidence of human toxicological hazard is for changes in trigeminal nerve function or morphology and impairment of vestibular function. Multiple epidemiological studies in different populations have reported TCE-induced abnormalities in trigeminal nerve function in humans, and various human studies have consistently reported vestibular system-related symptoms such as headaches, dizziness, and nausea following TCE exposure (Ref. 1).

Animals and humans exposed to TCE consistently experience liver toxicity. Specific effects include the following structural changes: Increased liver weight, increase in deoxyribonucleic acid (DNA) synthesis (transient), enlarged hepatocytes, enlarged

nuclei, and peroxisome proliferation. Several human studies reported an association between TCE exposure and significant changes in serum liver function tests used in diagnosing liver disease, or changes in plasma or serum bile acids. There was also human evidence for hepatitis accompanying immune-related generalized skin diseases, jaundice, hepatomegaly, hepatosplenomegaly, and liver failure in TCE-exposed workers. For kidney effects, studies in both humans and animals have shown changes in the proximate tubules of the kidney following exposure to TCE. TCE metabolites also appear to be the causative agents that induce renal toxicity (Ref. 1).

Immune-related effects following TCE exposures have been observed in both animal and human studies. In general, these effects were associated with inducing enhanced immune responses as opposed to immunosuppressive effects. Human studies have reported a relationship between systemic autoimmune diseases, such as scleroderma with occupational exposure to TCE. There have also been a large number of case reports in TCE-exposed workers developing a severe hypersensitivity skin disorder, often accompanied by systemic effects to the lymph nodes and other organs, such as hepatitis (Ref. 1).

The toxicological literature provides support for male and female reproductive toxicity following TCE exposure. Both the epidemiological and animal studies provide evidence of adverse outcomes to female reproductive outcomes. However, much more extensive evidence exists in support of an association between TCE exposures and male reproductive toxicity. There is evidence that the metabolism of TCE in male reproductive tract tissues is associated with adverse effects on sperm measures in both humans and animals. Furthermore, human studies support an association between TCE exposure and

alterations in sperm density and quality, as well as changes in sexual drive or function and altered serum endocrine levels (Ref. 1).

An evaluation of the overall weight and strength of the evidence of the human and animal developmental toxicity data suggests an association between pre- and/or post-natal TCE exposures and potential adverse developmental outcomes. TCE-induced heart malformations in animals have been identified as the most sensitive developmental toxicity endpoint for TCE. Human studies examined the possible association of TCE with various prenatal effects. These adverse effects of developmental TCE exposure could include death (spontaneous abortion, perinatal death, pre- or post-implantation loss, resorptions), decreased growth (low birth weight, small for gestational age), and congenital malformations, in particular cardiac defects, and postnatal effects such as growth, survival, developmental neurotoxicity, developmental immunotoxicity, and childhood cancers. There have also been some epidemiological studies that have consistently reported an increased incidence of birth defects in TCE-exposed populations from exposure to contaminated water. As for human developmental neurotoxicity, studies collectively suggest that the developing brain is susceptible to TCE toxicity. These studies have reported an association with TCE exposure and central nervous system birth defects and postnatal effects such as delayed newborn reflexes, impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit (Ref 1).

D. What Are the Potential Routes and Sources of Exposure to TCE?

The main route of exposure for TCE is inhalation due to its chemical properties and the nature of the consumer products. However, EPA recognizes that highly volatile compounds such as TCE may also be absorbed through the skin. (Ref. 1).

In EPA's final risk assessment for TCE, EPA examined acute risks for consumer exposures in residential settings. The assessment identified risks to consumers and residential bystanders from use of solvent degreasers and protective spray coatings, also referred to as spray fixatives, because of either their high TCE content or high potential for human exposure. TCE is also present in film cleaners, and mirror edge sealants, but these products were not evaluated because of either their low TCE content, less frequent use, or low exposure potential. The final risk assessment calculated indoor air concentrations using the Exposure and Fast Assessment Screening Tool Version 2 (E-FAST2) Consumer Exposure Model (CEM) for the consumer exposure. EPA used E-FAST2 CEM because of the lack of available emissions and monitoring data for the TCE containing consumer products (Ref. 1).

For the spray fixatives and solvent degreasers used by consumers who experience exposures, there is the potential for acute risks that could result from even one improper use of these products containing TCE. Most consumers would be unaware of the potential toxicity of consumer products containing TCE. Consequently, insufficient and inadequate hazard communication may lead to incorrect use and increased consumer and bystander exposures. Even if consumers are aware of such potential hazards, they may not take appropriate precautions or research the appropriate resources in which these precautions are addressed. Of particular concern is that TCE has harmful effects that occur below the

odor threshold, meaning that smelling the chemical in the home environment is not a sufficient approach to avoid hazardous effects (Ref. 1).

III. Rationale and Objectives

A. Rationale

EPA is concerned about the adverse health effects of TCE resulting from commercial and consumer uses of the chemical substance identified for a risk assessment as part of EPA's Existing Chemicals Management Program. EPA identified a work plan of 83 chemicals including TCE for further assessment under the TSCA Work Plan for Chemical Assessments in March 2012, to help focus and direct the activities of its Existing Chemicals Management Program. EPA reviewed readily available information on TCE including uses, physical and chemical properties, fate, exposure potential, and associated hazards to humans and the environment. TCE was selected based on concerns for its human health hazard (e.g., human carcinogen) and its exposure profile (i.e., widely used in consumer products and detected in drinking water, indoor environments, surface water, ambient air, groundwater, and soil) using OPPT's TSCA Work Plan screening methodology (Ref. 6). In EPA’s final risk assessment released on June 25, 2014, the Agency identified risks to workers using TCE and non-workers for 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. 1).

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, based on review of SDSs and the NIH’s HPD, EPA believes that

cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray contain TCE. EPA believes that other consumer products do not presently contain TCE, other than spray fixative product use which will be discontinued by September 1, 2015 as described in Unit II.A.

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose 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 wants to achieve the following objectives with regard to the significant new use(s) that are designated in this proposed rule:

1. EPA would receive notice of any person’s intent to manufacture or process TCE for the described significant new use before that activity begins.

2. EPA would 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 would 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 compounds subject to this proposed rule, as discussed in this unit, 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. EPA has preliminarily 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, pepper spray, and (before September 1, 2015) spray fixatives), 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., and because of these 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 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 proposed 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. 7), 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 the chemical substance(s)

that would be regulated through this proposed rule, if finalized, would have to cease any such activity before the effective date of the rule if and when finalized. 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 the use in a consumer product of TCE in spray fixatives will cease by September 1, 2015 as described in Unit II.A., EPA considers September 1, 2015 as the date from which the significant new use with respect only to such spray fixatives would be designated. To the extent that additional ongoing uses are found in the course of rulemaking, EPA would exclude those specific uses from the final SNUR. EPA has promulgated provisions to allow persons to comply with the final 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 proposed 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 proposed 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 proposed SNUR, as stated in the accompanying economic analysis of this proposed SNUR, the estimated cost of the export notification requirement on a per unit basis is $83.

X. Alternatives

Before proposing this SNUR, EPA considered the following alternative regulatory action: *Promulgate a TSCA Section 8(a) Reporting Rule.*

Under a TSCA section 8(a) rule, EPA could, among other things, generally require persons to report information to the agency when they intend to manufacture or process a listed chemical for a specific use or any use. However, for TCE, the use of TSCA section 8(a) rather than SNUR authority would have several limitations. First, if EPA were to require reporting under TSCA section 8(a) instead of TSCA section 5(a), EPA would not have the opportunity to review human and environmental hazards and

exposures associated with the proposed significant new use and, if necessary, take immediate follow-up regulatory action under TSCA section 5(e) or 5(f) to prohibit or limit the activity before it begins. In addition, EPA may not receive important information from small businesses, because such firms generally are exempt from TSCA section 8(a) reporting requirements (see TSCA sections 8(a)(1)(A) and 8(a)(1)(B)). In view of the level of health concerns about TCE if used for the proposed significant new use, EPA believes that a TSCA section 8(a) rule for this substance would not meet EPA's regulatory objectives.

XI. Request for Comment

A. Do you have comments or information about ongoing uses?

EPA welcomes comment on all aspects of this proposed rule. EPA based its understanding of the use profile of these chemicals on the published literature, the 2012 CDR submissions, market research, discussions with manufacturers, and review of SDSs. To confirm EPA's understanding, the Agency is requesting public comment on the EPA's understanding that cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray contain TCE. The Agency is also requesting public comment if any of the listed uses that contain TCE are no longer available to consumers. EPA believes that other consumer products do not contain TCE, however, EPA is interested in information indicating that there are other ongoing uses of TCE in consumer products. In providing comments on an ongoing use of TCE in a consumer product, it would be helpful if you provide sufficient information for EPA to substantiate any assertions of use.

B. What Should I Consider as I Prepare my Comments for EPA?

1. *Submitting CBI*. It is EPA's policy to include all comments received in the public docket without change or further notice to the commenter and to make the comments available on-line at www.regulations.gov, including any personal information provided, unless a comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM that you mail to EPA as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2, subpart B.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).

ii. Follow directions. The agency may ask you to respond to specific questions or organize comments by referencing a CFR part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

XII. 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. U.S. EPA. Final Risk Assessment on Trichloroethylene (TCE). June 25, 2014.

2. U.S. EPA. Economic Analysis of the Significant New Use Rule for Trichloroethylene. February 19, 2015.

3. Letter from PLZ Aeroscience Corporation. March 5, 2015.

4. U.S. EPA. (2011). Toxicological Review of Trichloroethylene (CAS No. 79-01-6). EPA/635/R-09/011F. Integrated Risk Information System, Washington, DC.

5. IARC (2014). *International Agency for Research on Cancer*. Monographs on the Evaluation of Carcinogenic Risks to Humans: Cadmium, Trichloroethylene,

Tetrachloroethylene, and Some Chlorinated Agents, Volume 106. World Health Organization, Lyon, France.

6. U.S. EPA. (2014). TSCA Work Plan for Chemical Assessments: 2014 Update. Washington. DC.

7. U.S. EPA. Significant New Uses of Certain Chemical Substances. **Federal Register** of April 24, 1990, (55 FR 173776) (FRL-3658-5).

XIII. Statutory and Executive Order Reviews

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

This proposed SNUR is not a "significant regulatory action" under the terms of the Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Order 12866 and 13563, entitled "Improving Regulation and Regulatory Review" (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.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, I hereby certify that promulgation of this SNUR would not have a significant economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows.

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 proposed 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, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

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 proposed 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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this action is not intended to address environmental health or safety risks for children.

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

This proposed 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 section.

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

This proposed 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.

List of Subjects in 40 CFR Part 721

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

Dated: July 30, 2015.

Wendy Cleland-Hamnett
Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 721--[AMENDED]

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

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

2. 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].