Withdrawal of Proposed Rules; Discontinuing Three Rulemaking Efforts Listed in the Semiannual Regulatory Agenda

RIN 2070-AK03; 2070-AK11 and 2070-AK07

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of proposed rules.

SUMMARY: The Environmental Protection Agency (EPA) is withdrawing the proposed regulatory requirements described in the three proposed rules that are identified in this document. This document summarizes the proposed rules and provides a brief explanation for the Agency’s decision not to finalize the proposed actions.

DATES: As of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], the proposed rule published on December 16, 2016 (81 FR 91592; FRL-9949-86); the proposed rule published on January 19, 2017 (82 FR 7432; FRL-9950-08); and the portion of the proposed rule published on January 19, 2017 (82 FR 7464; FRL-9958-57) that pertains to n-Methylpyrrolidone (NMP) and methylene chloride in commercial paint and coating removal, are withdrawn.

ADDRESSES: The dockets are available at http://www.regulations.gov or at the EPA Docket Center (EPA/DC), 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, for the OPP Docket it is (703) 305-5805, and the telephone number for the OPPT Docket is (202) 566-0280.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to
provide remote customer service via email, phone, and webform. For the information on EPA/DC services, submitting comments and docket access, please visit

https://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman (7101M), Mission Support Division, Office of Program Support, Office of Chemical Safety and Pollution Prevention, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-0409; email address: sleasman.katherine@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

This action is directed to the public in general and may be of particular interest to those persons who follow proposed rules issued under section 6(a) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605. Since others may also be interested, the Agency has not attempted to describe all the specific entities potentially interested.

II. Why is EPA Issuing this Withdrawal of Proposed Rules?

This document serves the following purposes:

1. It announces to the public that EPA is withdrawing certain proposed rules for which the Agency no longer intends to issue a final rule; and

2. It officially terminates the ongoing rulemaking activities, which allows the Agency to close out the individual rulemaking entries for these actions that appear in EPA’s Semiannual Regulatory Agenda.

All agencies publish Semiannual Regulatory Agendas describing regulatory actions they are developing or have recently completed. These agendas are published in the Federal Register, usually during the spring and fall of each year, as part of the Unified Agenda of Federal Regulatory and Deregulatory Actions (Semiannual Regulatory Agenda). The Agency publishes the EPA Semiannual Regulatory Agenda to update the public about: Regulations and major policies currently under development, reviews of existing regulations and major policies,
and rules and major policies completed or canceled since the last Semiannual Regulatory Agenda.

The Semiannual Regulatory Agenda is often used as a tool to solicit interest and participation from stakeholders. As such, EPA believes that the public is best served by a Semiannual Regulatory Agenda that reflects active rulemaking efforts. The withdrawal of these inactive rulemaking efforts will streamline EPA’s Semiannual Regulatory Agenda and allow the public to better identify and focus on those rulemaking activities that are active.

For the individual reasons described in this document, the Agency has decided not to complete these actions at this time. By withdrawing the proposed rules, the Agency is eliminating the pending nature of those prior regulatory actions and clarifying its intent for future risk management action concerning these chemicals. Specifically, EPA is initiating separate risk management actions to address unreasonable risks identified for these chemicals following the recent issuance of final risk evaluations under TSCA section 6(b) for trichloroethylene (TCE), methylene chloride (MC) (for portions related to commercial paint and coating removal), and NMP.

III. Which Proposed Rules are Being Withdrawn?

This unit identifies the proposed regulatory actions that are being withdrawn and provides a summary of what was proposed. The “RIN” refers to the regulatory identification number assigned to the rulemaking effort in the Semiannual Regulatory Agenda.

EPA issued three proposed rules under sections 6(a) and 26(l)(4) of the TSCA, 15 U.S.C. 2605(a) and 2625(l)(4) (82 FR 7464; FRL-9958-57); (81 FR 91592; FRL-9949-86); (82 FR 7432; FRL-9950-08). Two of the actions proposed to address unreasonable risks that EPA had preliminarily identified with certain uses of TCE, which is a volatile organic compound widely used in industrial and commercial processes with some uses in consumer and commercial products; and one of the actions proposed to address unreasonable risks that EPA had preliminarily identified with certain uses of NMP and MC, which are solvents used in a variety
of applications, including paint and coating removal (although the Agency is only withdrawing
the portions related to NMP and MC commercial paint and coating removal).

A. Trichloroethylene (TCE); Regulation of Certain Uses Under TSCA § 6(a); Proposed Rule;
RIN 2070-AK03.

On December 16, 2016 (81 FR 91592; FRL-9949-86), EPA issued a proposed rule under
TSCA section 6(a), 15 U.S.C. 2605(a), to address unreasonable risks that EPA had preliminarily
determined exist with certain uses of TCE: aerosol degreasing and spot cleaning in dry cleaning.
EPA proposed to prohibit the manufacture, processing, and distribution in commerce of TCE for
use in aerosol degreasing and for use in spot cleaning in dry cleaning facilities; to prohibit
commercial use of TCE for aerosol degreasing and for spot cleaning in dry cleaning facilities; to
require manufacturers, processors, and distributors, except for retailers of TCE for any use, to
provide downstream notification of these prohibitions throughout the supply chain; and to
require limited recordkeeping.

The rulemaking docket for this action is available under docket ID number EPA-HQ-
OPPT-2016-0163.

B. Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a);
Proposed Rule; RIN 2070-AK11.

On January 19, 2017 (82 FR 7432; FRL-9950-08), EPA issued a proposed rule under
TSCA section 6(a), 15 U.S.C. 2605(a), to address unreasonable risks that EPA had preliminarily
determined exist with use of TCE in vapor degreasing. EPA proposed to prohibit the
manufacture (including import), processing, and distribution in commerce of TCE for use in
vapor degreasing; to prohibit commercial use of TCE in vapor degreasing; to require
manufacturers, processors, and distributors, except for retailers of TCE for any use, to provide
downstream notification of these prohibitions throughout the supply chain; and to require limited
recordkeeping.

The rulemaking docket for this action is available under docket ID number EPA-HQ-
On January 19, 2017 (82 FR 7464; FRL-9958-57), EPA issued a proposed rule under TSCA section 6(a), 15 U.S.C. 2605(a), to address risks that EPA had preliminarily identified with certain uses of NMP, which is a solvent used in a variety of applications, including paint and coating removal. EPA preliminarily identified significant health risks associated with NMP use in commercial and consumer paint and coating removal and EPA proposed a determination that these are unreasonable risks. EPA co-proposed two different options: one co-proposal was to prohibit the manufacture (including import), processing, and distribution in commerce of NMP for all consumer and commercial paint and coating removal; to prohibit the use of NMP for all commercial paint and coating removal; to require downstream notification of these prohibitions throughout the supply chain; to require recordkeeping; and to provide a time-limited exemption from these proposed regulations on NMP for coating removal uses critical for national security. As an alternate proposal, EPA proposed that (1) commercial users of NMP for paint and coating removal establish a worker protection program for dermal and respiratory protection and not use paint and coating removal products that contain greater than 35 percent NMP by weight (except for product formulations destined to be used by Department of Defense (DoD) or its contractors performing work only for DoD projects); and (2) processors of products containing NMP for paint and coating removal reformulate products such that these products do not exceed a maximum of 35 percent NMP by weight, identify gloves that provide effective protection for the formulation, and provide warning and instruction labels on the products. The rulemaking docket for this action is available under docket ID number EPA-HQ-OPPT-2016-0231. This withdrawal applies to provisions related to NMP of the proposed rule that published on January 19, 2017.
The proposed rule on January 19, 2017 (82 FR 7464; FRL-9958-57), which was identified under RIN 2070-AK07, also proposed requirements for MC. Requirements addressing the use of MC for consumer paint and coating removal were subsequently finalized under RIN 2070-AK07 (see 84 FR 11420, March 27, 2019) (FRL-9989-29). The Agency also announced an advance notice of proposed rulemaking on March 27, 2019, (84 FR 11466; FRL-9989-30) to solicit public input on training, certification, and limited access requirements that could address any unreasonable risks that EPA could potentially find to be presented by MC when used for commercial paint and coating removal. This withdrawal only applies to provisions of the January 19, 2017 proposed rule related to commercial paint and coating removal of MC. The rulemaking docket for this action is available under docket ID number EPA-HQ-OPPT-2016-0231.

IV. Why are these Proposed Rules Being Withdrawn?

The 2016 and 2017 proposed rules addressed a limited number of conditions of use (COUs) for TCE, MC and NMP pursuant to TSCA sections 6(a) and 26(l)(4). The COUs not otherwise addressed by final regulatory action that were the subject of the earlier EPA risk assessments and proposed rules, as well as additional COUs for these chemical substances, were evaluated as part of the first ten risk evaluations conducted under TSCA section 6(b). Final risk evaluations for all three substances have been issued recently under TSCA section 6(b) and, consistent with the statute, EPA is proceeding to initiate regulatory action to address the unreasonable risks identified in the final risk evaluations for TCE (85 FR 37942, June 24, 2020; FRL-10011-16); MC (85 FR 75010, November 24, 2020; FRL-10016-91; FRL-9989-29); and NMP (the announcement is scheduled to publish in the Federal Register on December 30, 2020 and can be identified under FRL-10017-18). As a result, the retention of the inactive prior proposals on the Agency’s regulatory agenda is not necessary; indeed, retaining these inactive proposals could be duplicative or could create unnecessary public confusion about the extent and nature of the regulatory actions the Agency intends to take to address unreasonable risks identified for these chemical substances. Furthermore, EPA is withdrawing the proposed rules to
promote regulatory efficiency because it is impossible for EPA to finalize the rules as proposed and at the same time meet its statutory obligation under TSCA section 6 for risk management rulemaking following finalization of risk evaluations in which EPA makes findings of unreasonable risk. If EPA were to finalize the 2016 and 2017 rules as proposed, the Agency would be leaving out efforts to address additional COUs for these chemical substances that were determined to present unreasonable risk as part of the TSCA section 6(b) risk evaluations. EPA would not be able to say that its obligations under TSCA section 6 were met with regard to these chemical substances without issuing supplemental proposed and final rules for the additional COUs determined to present unreasonable risks in the TSCA section 6(b) risk evaluations. While the Agency has discretion to undertake multiple risk management actions with regard to unreasonable risks associated with different COUs for a single chemical substance (and, in fact, did so to address the acute unreasonable risks associated with MC in consumer paint and coating removal), it is more efficient to take risk management action on multiple COUs at once where unreasonable risks are identified, particularly where regulatory approaches to different COUs can be combined. In addition, where EPA has completed risk evaluations for chemical substances, EPA believes the Agency will be able to more efficiently address obligations under TSCA section 6(c) (requirements applicable to promulgation of TSCA section 6(a) rules), section 26 (including requirements related to best available science and weight of scientific evidence), and other requirements applicable to TSCA section 6(a) rulemakings through a single rulemaking process, rather than supplementing prior proposals. Therefore, EPA will initiate regulatory actions to address all of the COUs determined to present unreasonable risks for a given chemical substance and will withdraw the earlier proposed actions.

EPA proposed these rules under TSCA section 6(a), which provides authority for EPA to ban or restrict the manufacture (including import), processing, distribution in commerce, use, and disposal of chemical substances, with certain limitations. TSCA section 26(l)(4) authorizes EPA to issue rules under TSCA section 6(a) for chemicals listed in the 2014 Update to the TSCA
Work Plan for Chemical Assessments for which EPA published completed risk assessments prior to June 22, 2016, consistent with the scope of the completed risk assessment and other applicable requirements of TSCA section 6.

In the June 2014 TSCA Work Plan Chemical Risk Assessment for TCE, EPA characterized risks from the use of TCE in commercial degreasing and in some consumer uses. On December 16, 2016, based on the 2014 Risk Assessment for TCE, EPA preliminarily determined that these risks are unreasonable risks and proposed regulatory action; specifically, EPA proposed to prohibit the manufacture, processing, distribution in commerce, or commercial use of TCE in spot cleaning in dry cleaning facilities and aerosol degreasing (81 FR 91592; FRL-9949-86). On January 19, 2017, EPA proposed to address the unreasonable risks from TCE when used in vapor degreasing (82 FR 7432; FRL-9950-08). These uses of TCE were subsequently identified as conditions of use within the scope of the risk evaluation for TCE under TSCA section 6(b). EPA issued the final risk evaluation for TCE in November 2020 (85 FR 75010, November 24, 2020; FRL-10016-91) which determined that 52 out of 54 conditions of use of TCE present unreasonable risks of injury to health. EPA is withdrawing the 2016 and 2017 proposed rules on TCE for the reasons discussed earlier in this section. For more information about TCE and details about the risk evaluation for TCE, see the TSCA website at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-trichloroethylene-tce-0#riskevaluation.

In the March 2015 TSCA Work Plan Chemical Risk Assessment for NMP, EPA characterized risks from use of this chemical in paint and coating removal. On January 19, 2017, based on the 2015 Risk Assessment for NMP, EPA preliminarily determined that the use of NMP in commercial and consumer paint and coating removal poses an unreasonable risk of injury to health, and proposed options for addressing that risk. The uses of NMP in commercial and consumer paint and coating removal were identified as conditions of use within the scope of the risk evaluation for NMP under TSCA section 6(b). EPA issued the final risk evaluation for
NMP in December 2020 (the announcement is scheduled to publish in the **Federal Register** on December 30, 2020 and can be identified under FRL-10017-18). EPA evaluated commercial and consumer use of NMP in paint and coating removal as COUs in the scope of the risk evaluation, along with other COUs for NMP. In response to public and peer review comments on the draft risk evaluation, EPA modified its approach for calculating dose-response, which resulted in a change in the point of departure and modified risk estimates for many COUs, including modified risk estimates for the use of NMP in consumer paint and coating removal. These changes are discussed in the Executive Summary and in Section 3.2, for the points of departure, of the final NMP risk evaluation and differ from the preliminary determination of unreasonable risk in the draft NMP risk evaluation and the 2017 proposed NMP rule. EPA is withdrawing the 2017 proposed rule on NMP, *i.e.*, those portions of the proposal not related to the final rule on MC in consumer paint and coating removal, for the reasons discussed earlier in this section. The withdrawal of this rulemaking effort may have an immediate effect on other TSCA requirements for NMP. Withdrawal of the proposal would terminate export notification requirements for NMP. However, the Agency believes withdrawing the proposal will clarify which action the Agency is currently pursuing, and reduce the need for additional, piecemeal or supplemental risk management actions as a result of the final determinations in the risk evaluation conducted under TSCA section 6(b). As noted in Unit V., the Agency is initiating risk management action on this chemical. For more information about NMP and details about the risk evaluation for NMP, see the TSCA website at [https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-n-methylpyrrolidone-nmp-0](https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-n-methylpyrrolidone-nmp-0).

On March 27, 2019, in the final rule for MC in consumer paint and coating removal (RIN 2070-AK07), EPA explained that the Agency was not finalizing the proposed risk determination or proposed regulation for MC commercial paint and coating removal as part of that action. Similar to NMP, EPA evaluated commercial use of MC in paint and coating removal as a COU in the scope of the TSCA section 6(b) risk evaluation for MC, along with other COUs. EPA
issued the final risk evaluation for MC on June 24, 2020 (85 FR 37942; FRL-10011-16). For more information about MC and details about the risk evaluation for MC, see the TSCA website at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-methylene-chloride.

V. How does EPA intend to proceed?

Given the subsequent issuance of final risk evaluations under TSCA for TCE, MC and NMP that incorporated the COUs which the three proposed rules would have addressed, and the initiation of new rulemakings for TCE, MC and NMP following issuance of the final risk evaluations in which EPA made findings of unreasonable risk, EPA has determined that the previous proposed rules should be withdrawn. The next step in the process required by TSCA section 6 is addressing the unreasonable risks determined in the risk evaluations through rulemaking. EPA has initiated new rulemaking efforts to address the unreasonable risks determined in the final risk evaluations and has one year to propose and take public comments on any risk management actions. Although these new rulemaking efforts did not commence in time to be included in the Fall 2020 edition of the EPA’s Unified Regulatory Plan and Agenda, these rulemaking efforts will appear in the Spring 2021 edition of EPA’s semiannual Regulatory Agenda. As part of this effort, EPA will consider comments received on the previously-referenced ANPRM issued in 2019 soliciting input on training, certification and limited access
requirements that could address the unreasonable risks associated with methylene chloride in commercial paint and coating removal.

For these reasons, EPA is withdrawing the proposed rule that published on December 16, 2016 (81 FR 91592; FRL-9949-86); the proposed rule that published on January 19, 2017 (82 FR 7432; FRL-9950-08); and the provisions related to NMP and to MC in commercial paint and coating removal in the proposed rule that published on January 19, 2017 (82 FR 7464; FRL-9958-57).


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Administrator.

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