PRE-PUBLICATION NOTICE

On November 4, 2019, Andrew R. Wheeler, the EPA Administrator, signed the following document:

Action:	Notice.
Title:	N-Methylpyrrolidone (NMP); Draft Toxic Substances Control Act (TSCA) Risk Evaluation and TSCA Science Advisory Committee on Chemicals (SACC) Meeting; Notice of Availability, Public Meeting, and Request for Comment
FRL #:	10001-87
Docket ID #:	EPA-HQ-OPPT-2019-0236

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For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0236; FRL-10001-87]

N-Methylpyrrolidone (NMP); Draft Toxic Substances Control Act (TSCA) Risk Evaluation and TSCA Science Advisory Committee on Chemicals (SACC) Meeting; Notice of Availability, Public Meeting, and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is announcing the availability of and soliciting public comment on the draft Toxic Substances Control Act (TSCA) risk evaluation of N-Methylpyrrolidone (NMP). The purpose of the risk evaluation process under TSCA is to determine, upon issuance of a final risk evaluation, whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. EPA is also submitting the same document to the TSCA Science Advisory Committee on Chemicals (SACC) for peer review and is announcing that there will be an in-person public meeting of the TSCA SACC to consider and review the draft risk evaluation. Preceding the in-person meeting, there will be a preparatory virtual public meeting for the panel to consider the scope and clarity of the draft charge questions for the peer review.

DATES: Virtual Meeting: The preparatory virtual meeting will be held on November 12, 2019, from 1:00 p.m. to approximately 4:00 p.m. (EST). You must register online on or before November 12, 2019, to receive the webcast meeting link and audio teleconference information. Submit your written comments for the preparatory virtual meeting, or request time to present oral comments, on or before 10:00 a.m. on November 12, 2019.

In-Person Meeting: The in-person meeting will be held on December 5-6, 2019, from 8:00 a.m. to approximately 6:00 p.m. (EST) on the first day, and 8:00 a.m. to 12:30 p.m. on the second day. Any comments submitted on the draft risk evaluation on or before November 26, 2019, will be provided to the SACC for their consideration before the meeting. Comments received after November 26, 2019, and prior to the oral public comment period during the meeting will be available to the SACC for their consideration during the meeting. Please submit requests to present oral comments during the in-person meeting on or before December 3, 2019, to be included on the meeting agenda. All comments received by the end of the comment period will be considered by EPA.

Comments: All comments on the draft risk evaluation must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **Federal Register**].

For additional instructions, see Unit III. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: *Virtual Meeting:* Please visit *http://www.epa.gov/tsca-peer-review* to register.

In-Person Meeting: The in-person meeting will be held at the Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA. Additional meeting information can be found on the TSCA SACC website at *http://www.epa.gov/tsca-peer-review*.

Comments: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0236 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*: OPPT Docket, Environmental Protection Agency Docket Center (EPA/DC),

(28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

Requests to present oral comments and requests for special accommodations. Submit requests for special accommodations, or requests to present oral comments during the virtual meeting and/or the in-person peer review meeting, to the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT** by the deadline identified in the **DATES** section.

FOR FURTHER INFORMATION CONTACT: *TSCA SACC meeting:* Dr. Todd Peterson, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-6428; email address: *peterson.todd@epa.gov*.

Draft Risk Evaluation: Dr. Stan Barone, Office of Pollution Prevention and Toxics (7403M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-1169; email address: *barone.stan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may be of interest to persons who are or may be required to conduct testing and those interested in risk evaluations of chemical substances under TSCA, 15 U.S.C. 2601 *et seq*. Since other entities may also be

interested in these draft risk evaluations, the EPA has not attempted to describe all the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that provide instruction on chemical substances that must undergo evaluation, the minimum components of a TSCA risk evaluation, and the timelines for public comment and completion of the risk evaluation. TSCA also requires that EPA operate in a manner that is consistent with the best available science, make decisions based on the weight of the scientific evidence and consider reasonably available information. 15 U.S.C. 2625(h), (i), and (k).

The statute identifies the minimum components for all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information on specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2)

describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposures. 15 U.S.C. 2605(b)(4)(F)(i)-(ii) and (iv)-(v). Each risk evaluation must not consider costs or other nonrisk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

The statute requires that the risk evaluation process last no longer than three years, with a possible additional six-month extension. 15 U.S.C. 2605(b)(4)(G). The statute also requires that the EPA allow for no less than a 30-day public comment period on the draft risk evaluation, prior to publishing a final risk evaluation. 15 U.S.C. 2605(b)(4)(H).

C. What action is EPA taking?

EPA is announcing the availability of and seeking public comment on the draft risk evaluation of the chemical substances identified in Unit II. EPA is seeking public comment on all aspects of the draft risk evaluation, including any preliminary conclusions, findings, and determinations, and the submission of any additional information that might be relevant to the draft risk evaluation, including the science underlying the draft risk evaluation and the outcome of the systematic review associated with the chemical substances. This 60-day comment period on the draft risk evaluation satisfies TSCA section 6(b)(4)(H), which requires EPA to "provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation," and 40 CFR 702.49(a), which states that "EPA will publish a draft risk evaluation in the **Federal Register**, open a docket to facilitate receipt of public comment, and provide no less than a 60-day comment period, during which time the public may submit comment on EPA's draft risk evaluation." In addition to any new comments

on the draft risk evaluation, the public should resubmit or clearly identify any previously filed comments, modified as appropriate, that are relevant to the draft risk evaluation and that the submitter feels have not been addressed. EPA does not intend to respond to comments submitted prior to the release of the draft risk evaluation unless they are clearly identified in comments on the draft risk evaluation.

EPA is also submitting the draft risk evaluation and associated supporting documents to the TSCA SACC for peer review and announcing the meeting for the peer review panel. All comments submitted to the dockets on the draft risk evaluation by the deadline identified in the **DATES** section will be provided for consideration to the TSCA SACC peer review panel, which will have the opportunity to consider the comments during its discussions.

D. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or email. 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 as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed 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.

2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

II. Draft TSCA Risk Evaluation

A. What is EPA's risk evaluation process for existing chemicals under TSCA?

The risk evaluation process is the second step in EPA's existing chemical process under TSCA, following prioritization and before risk management. As these chemicals are part of the first ten chemical substances undergoing risk evaluation, these chemical substances were not required to go through prioritization (81 FR 91927, December 19, 2016) (FRL-9956-47). The purpose of risk evaluation is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. As part of this process, EPA must evaluate both hazard and exposure, not consider costs or other nonrisk factors, use reasonably available information and approaches in a manner that is consistent with the requirements in TSCA for the use of the best available science, and ensure decisions are based on the weight-of-scientific-evidence.

The specific risk evaluation process that EPA has established by rule to implement the statutory process is set out in 40 CFR part 702 and summarized on EPA's website at *http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca.* As explained in the preamble to EPA's final rule on procedures for risk evaluation (82 FR 33726, July 20, 2017) (FRL-9964-38), the specific regulatory process set out in 40 CFR part 702, subpart B will be followed for the first ten chemical substances undergoing risk evaluation to the maximum extent practicable.

B. What is NMP?

N-methylpyrrolidone (NMP), also called N-methyl-2-pyrrolidone, or 1-methyl-2-pyrrolidone, is a chemical that is widely used during the manufacture and production of polymers, pharmaceuticals, agrichemicals and petroleum products. Information from the 2016 Chemical Data Reporting (CDR) for NMP indicates the reported production volume is more than

160 million lbs/year (manufacture and import).

Information about the problem formulation and scope phases of the TSCA risk evaluation for this chemical is available at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-n-methylpyrrolidone-nmp-0.*

III. TSCA SACC

A. What is the purpose of the TSCA SACC?

The TSCA SACC was established by EPA in 2016 and operates in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix 2 *et seq*. The TSCA SACC provides expert independent scientific advice and consultation to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated under TSCA.

The TSCA SACC is comprised of experts in: toxicology; human health and environmental risk assessment; exposure assessment; and related sciences (e.g., synthetic biology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, physiologically based pharmacokinetic modelling (PBPK) modeling, computational toxicology, epidemiology, environmental fate, and environmental engineering and sustainability). When needed, the committee will be assisted in their reviews by ad hoc participants with specific expertise in the topics under consideration.

B. How can I access the TSCA SACC documents?

EPA's background documents, related supporting materials, and draft charge questions to the TSCA SACC are available on the TSCA SACC website and in the docket established for the specific chemical substances. In addition, EPA will provide additional background documents (e.g., TSCA SACC members participating in this meeting and the meeting agenda) as the

materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available, in the docket at *http://www.regulations.gov* and the TSCA SACC website at *http://www.epa.gov/tsca-peer-review*.

After the public meeting, the TSCA SACC will prepare meeting minutes summarizing its recommendations to EPA. The meeting minutes will be posted on the TSCA SACC website and in the relevant docket.

C. What do I need to know about the TSCA SACC public meetings?

The focus of the public meeting is to peer review EPA's draft risk evaluation. After the peer review process, EPA will consider peer reviewer comments and recommendations, and public comments, in finalizing the risk evaluation. The draft risk evaluation contains: discussion of chemistry and physical-chemical properties; characterization of conditions of use; environmental fate and transport assessment; human health exposures; environmental hazard assessment; risk characterization; risk determination; and a detailed description of the systematic review process developed by the Office of Pollution Prevention and Toxics to search, screen, and evaluate scientific literature for use in the risk evaluation process.

D. How do I participate in the public meetings?

You may participate in the public meetings by following the instructions in this unit. To ensure proper receipt by EPA, it is imperative that you identify the corresponding docket ID number in the subject line on the first page of your request.

1. Preparatory virtual meeting. The preparatory virtual meeting will be conducted via webcast and telephone. You may participate in the preparatory virtual meeting by registering to join the webcast. You may also submit written comments or request time for oral comments.

i. *Registration.* You must register to participate in the preparatory virtual meeting. To

participate by listening or making a comment during this meeting, please go to the EPA website to register: *http://www.epa.gov/tsca-peer-review*. Registration online will be confirmed by an email that will include the webcast meeting link and audio teleconference information.

ii. *Written comments*. Written comments for consideration during the preparatory virtual meeting should be submitted, using the instructions in **ADDRESSES** and this unit, on or before the date set in the **DATES** section.

iii. *Oral comments*. Requests to make brief oral comments to the TSCA SACC during the preparatory virtual meeting should be submitted when registering online or with the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before noon on the date set in the **DATES** section. Oral comments before the TSCA SACC during the preparatory virtual meeting are limited to approximately 5 minutes due to the time constraints of this virtual meeting.

2. *In-person meeting.* You may participate in the in-person public meeting by attending and by providing written or oral comments. The in-person meeting may also be webcast. Please refer to the TSCA SACC website at *http://www.epa.gov/tsca-peer-review* for information on how to access the webcast. Please note that for the in-person meeting, the webcast is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the in-person meeting will continue as planned.

i. *Seating at the meeting*. Seating at the meeting will be open and on a first-come basis.

ii. *Written comments*. To provide the TSCA SACC the time necessary to consider and review your comments, written comments must be submitted by the date set in the **DATES** section and using the instructions in the **ADDRESSES** section and this unit. Comments received after the date set in the **DATES** section and prior to the end of the oral public comment period during the meeting will still be provided to the TSCA SACC for their consideration.

iii. *Oral comments*. To be included on the meeting agenda, submit your request to make brief oral comments at the in-person meeting to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before the date set in the **DATES** section. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment. Oral comments before TSCA SACC during the in-person meeting are limited to approximately 5 minutes unless prior arrangements have been made. In addition, each speaker should bring 30 copies of the comments and presentation for distribution by the DFO to the TSCA SACC at the meeting.

Authority: 15 U.S.C. 2601 *et seq*.

Dated: November 4, 2019.

Andrew R. Wheeler,

Administrator.