

THE NATIONAL LAW REVIEW

EPA Posts Agenda and Other Meeting Materials for December 6, 2017, New Chemicals Review Program Implementation Meeting

Thursday, November 16, 2017

On November 9, 2017, the U.S. Environmental Protection Agency (EPA) released the [agenda and meeting materials for its December 6, 2017, New Chemicals Review Program Implementation meeting](#). **NOTE WELL:** This is a critically important meeting for companies that innovate in the chemical space and are now preparing Toxic Substance Control Act (TSCA) Premanufacture Notifications (PMN) or will in the future. EPA states that this meeting will update and engage with the public on EPA's progress in implementing changes to the New Chemicals Review Program as a result of the 2016 amendments to TSCA, and will include a discussion of EPA's draft New Chemicals Decision-Making Framework. The meeting materials include:

- [Agenda for Public Meeting](#). The Agenda includes the following topics: the decision-making framework; TSCA orders and Significant New Use Rules (SNUR) in the context of new chemicals review; the Points to Consider document as well as the pilot results and other questions; the decision guidelines manual; chemical categories; sustainable futures; a discussion of questions submitted in advance; and two public comment periods. Featured speakers are Nancy Beck, Ph.D., Deputy Assistant Administrator for the Office of Chemical Safety and Pollution Prevention (OSCPP) and Jeff Morris, Ph.D., Director of the Office of Pollution Prevention and Toxics (OPPT).
- [New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA](#). EPA states that this document includes EPA's general decision framework for new chemicals and a breakdown of how EPA intends to approach each of the five types of new-chemical determinations required.
- [Points to Consider When Preparing TSCA New Chemical Notifications \(Draft\)](#). This draft document, dated November 6, 2017, provides concise information to assist submitters in preparing a PMN, Significant New Use Notice (SNUN), or exemption notice (e.g., Low Volume Exemption or LVE) that (1) meets the requirements of TSCA Section 5 and applicable regulations; and (2) facilitates EPA's review of Section 5 notices by ensuring that the information received accurately and completely reflects the intended manufacture, processing, distribution in commerce, use, and disposal of the new chemical substances subject to the Section 5 notice. EPA states this is a draft published for comment, but does not specify a deadline for submitting comments.
- [Overview of Comments Received on the Draft "Points to Consider" Document](#). This document summarizes 151 comments received on the draft Points to Consider document. It organizes them by topic. The topics addressed are aquatic haz/tox; chemistry; data; engineering; environmental release and disposal information; fate; a general category; human health haz/tox; regulatory; release to water; standard review;



Article By [Margaret R. Graham](#)
[Lynn L. Bergeson](#)
[Bergeson & Campbell, P.C.](#)
[Toxic Substances Control Act Blog](#)
[Environmental, Energy & Resources](#)
[All Federal](#)

uses; risk; exposure; and prenotice meetings. These comments have not been posted in the docket for this meeting.

- [New Chemicals Decision Guidelines Manual – Detailed Outline](#). EPA states that this manual will summarize how EPA reviews new chemical submissions and the policies and decision guidelines used in making decisions under TSCA Section 5. It will provide an overview of both risk assessment and risk management approaches. Further, it is intended to help stakeholders determine what forms of regulation and restrictions on the manufacture, distribution, use, and/or disposal of a new chemical substance may arise from an EPA determination.

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