

ALERT

EPA's Important Public Meeting on New Chemicals Is Next Week Tuesday, December 10; Deadline for Online Requests to Speak at the Meeting Is This Friday, December 6

December 3, 2019

Next week on December 10 from 10 a.m. – 3 p.m., the U.S. Environmental Protection Agency (EPA) will hold a public meeting at the agency's headquarters to update the public on the agency's approach to making risk decisions for new chemicals under the Toxic Substances Control Act (TSCA) Section 5 (e.g., "presents an unreasonable risk" or "not likely to present an unreasonable risk").

The meeting will focus on how EPA plans to update the "New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA" that was originally released in November 2017 for public comment.

EPA will present case studies of PMN reviews and their outcomes. For companies that are relatively new to the PMN process, including downstream customers, this part of the meeting should be particularly informative. Also at the meeting, EPA is expected to address the recent changes in its process for protecting confidential business information (CBI) during Section 5 reviews, as well as what information will be routinely made public.

For companies who file PMN reviews routinely, we do not expect the meeting to offer much in the way of new information. The meeting appears largely designed to describe the changes EPA has been trying to improve the program over the last several months, with limited success. Nevertheless, this is an important event for identifying significant programmatic concerns that should be addressed. It is an

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ideal opportunity to offer suggestions for improving the pace of reviews and clearing out the persistent backlog of filings. Other information sharing areas to consider that would shed more light on this program include:

- The length of PMN reviews. While EPA routinely publishes the number of PMNs in progress and the number of backlogged submissions, it is difficult to find public information on the protracted nature of the review process.
- Information on how these delays and heightened regulation of new chemicals since 2016 has affected commercialization opportunities and hindered innovation.
- Information on conflicts encountered with OSHA HazCom and customer acceptance of EPA-imposed workplace and use restrictions.

Only one hour has been set aside to take public comments, but written comments will be accepted through January 24.

A separate public comment period will be associated with the release of the updated "Working Approach" guidance document in the latter part of December. A copy of the prior guidance, EPA's November 2017 "New Chemicals Decision-Making Framework: Working Approach to Making Determinations under section 5 of TSCA", can be accessed at [here](#).

Online requests to speak at the December 10th meeting must be received on or before December 6, 2019.

On-site registration for both attendance and speaking will be permitted, but seating and speaking priority will be given to those who pre-register by the deadline. The meeting is accessible remotely for registered participants.

To register for the meeting, [click here](#).

For more information about the current PMN review process, a recording and presentation of the 2019 webinar by Wiley Rein partners Martha Marrapese and Erik Baptist and Jeffrey Hafer of knoell USA on how to navigate TSCA Section 5 reviews can be accessed [here](#).