# EPA Says It Has Eliminated Excess Backlog Under TSCA New Chemical Review Program

**US EPA, TSCA**

By ROGER PEARSON, August 29, 2017

In an **August 8 press release**[1)] U.S. EPA says that it has eliminated a backlog of pending reviews under the TSCA Section 5 program that existed at the time of the enactment of last year's revision of the Act. According to EPA the backlog has been reduced from over 600 pending cases as of June 22, 2016, the date the new law was signed, to what the agency describes as a "normal active workload" of 308 cases.

Section 5 under both the prior and current law requires chemical manufacturers and importers to file certain notices, depending on the particular action contemplated. These include preliminary manufacturing notices (PMNs) for chemicals introduced for the first time, Significant New Use Notices (SNUNs) for existing chemicals for which EPA has determined that a proposed new use could be significant, and a Microbial Commercial Technology Notice (MCAN) for certain microbial uses. Under Section 5 EPA also reviews applications for exemptions from Section 5, including a Low Volume Exemption (LVE) and a Low Exposure Exemption (LoREX).

Between the June 22 effective date of the new law and August 1 of this year, EPA states that it has completed review of 1,022 cases. These include 490 PMN/MCAN/SNUN reviews and 532 exemption requests. That has resulted in the reduction of the backlog from over 600 pending cases to the current 382 such cases. Of the latter amount EPA is waiting for further testing and long-term information from the person giving the notice. That yields the 308 pending cases touted by EPA in its press release.

EPA Administrator Scott Pruitt attributes the backlog elimination to a conscious effort on the part of both EPA staff and stakeholders working with the agency. EPA is also touting the following operating principles as part of its ongoing commitment to improve the Section 5 process:

- Where the intended uses in premanufacture notices (PMNs) or other Section 5 notices (such as low volume exemption (LVE) requests) raise risk concerns, EPA will work with submitters, and, if the submitters submit timely amended PMNs addressing those concerns, EPA will generally make determinations based on those amended submissions.

- Where EPA has concerns with reasonably foreseen uses, but not with the intended uses as described in a PMN or LVE application, as a general matter, those concerns can be addressed through significant new use rules (SNURs).

- As described in the risk evaluation rule EPA Administrator Scott Pruitt signed on June 22, 2017, identification of reasonably foreseen conditions of use will be fact-specific. It is reasonable to foresee a condition of use, for example, where facts suggest the activity is not only possible, but, over time under proper conditions, probable.

- The purpose of testing in a Section 5 order is to reduce uncertainty in regard to risk. Specifically, it is to address risk concerns that gave rise to a finding of "may present unreasonable risk" or another Section 5 finding other than "not likely to present unreasonable risk." In addition, consistent with the statute, any request for testing by EPA will be structured to reduce and replace animal testing as appropriate.

The EPA press release also commits the agency to a number of additional actions to promote continued improvement of the TSCA new chemicals program (including the assignment of more staff to the program) and to implementation of specified actions to make EPA's decision making under the program more transparent.

## Resources for this article

**1. August 8 press release**
https://www.epa.gov/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews