

**ALERT**

# EPA Confirms It Will Regulate Most New Chemicals

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At a recent conference held in Washington, DC, the U.S. Environmental Protection Agency (EPA) announced that it had reduced by approximately 50% the number of “old” premanufacture notifications (PMNs) for new chemicals awaiting review under the amended Toxic Substances Control Act (TSCA). TSCA, as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21 Century Act (LCSA), requires that new chemicals proposed to be placed on the market must be reviewed by EPA, and that EPA must make an affirmative finding on whether the new chemical as proposed to be used constitutes an unreasonable risk.

The agency also confirmed that the sea change industry is experiencing in the outcome of EPA’s reviews is a result of EPA’s decision to now routinely impose consent orders and significant new use rules (SNURs) on PMN submitters. Under the old law, the clear majority of new chemicals passed EPA review without a consent order or SNUR. There are at least three reasons for EPA’s change in approach to new chemical reviews:

- The law now requires EPA to regulate based on the absence of sufficient information alone. This means EPA needs more and better information for a company to avoid regulation.
- The new “unreasonable risk” safety standard specifically directs EPA to consider intended conditions of use and effects on susceptible subpopulations. EPA can be expected to regulate when information to address these areas is lacking or the available information does not eliminate the perceived risk.
- Under the amended law, new chemicals cannot be placed into commerce before EPA makes a written, affirmative finding

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regarding potential risks. Under the old system, it was “no news is good news”: the results of EPA’s risk evaluation were documented internally and if EPA did not raise objections before the 90-day review period expired, a company could proceed to commercialize the new chemical. The agency PMN review findings were not widely disseminated.

The backlog in PMN reviews stems from putting these changes into practice and the agency’s decision to restart all the new chemical reviews that were in progress last June when the law was amended. At that time, EPA had 334 chemical submissions under review. EPA interpreted LCSEA to require that these previous submissions be subjected to the affirmative finding requirement and re-started these reviews. By January 2017, approximately 600 new chemical submissions were in the queue. EPA has reduced the “backlog” of submissions to about 150 and is providing weekly updates of its progress at this link: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>.

As mentioned earlier, this progress comes with a price. Since TSCA was amended, only 10% of the new chemicals reviewed have gotten through the PMN process without a consent order or SNUR (a figure that does not include withdrawn and invalid PMNs).[1] Consent orders and SNURs automatically generate more restrictions under other parts of TSCA, because companies need to submit export notifications under section 12(b) of TSCA for these chemicals and report at substantially lower quantities in Chemical Data Reporting (CDR) years. EPA is even seeking consent orders for polymers that would otherwise meet the low risk criteria of the polymer exemption, to prevent companies from making lower molecular weight versions that may have different risk profile. These orders take additional time to complete, they present certain negotiation challenges, and must be carefully reviewed and approved by company management.

The emphasis on intended conditions of use to manage chemicals in the new TSCA law was intentional by design. The precautionary approach EPA is taking to new chemicals management that has resulted was certainly less anticipated. Regulatory burdens that were once imposed judiciously now should be routinely anticipated by companies that file PMNs. Downstream processors and users should plan to make sure they understand the allowable use restrictions and increased regulatory obligations they may have, at least until PMN submitters and EPA can reach a better understanding of the information that the agency needs to avoid an overly prescriptive result.

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[1] The raw data for 2017 is available at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notice>.