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Administrator Pruitt Strengthens TSCA New Chemical Review Program to Ensure Safety, Transparency and Continuous Improvements

WASHINGTON (August 7, 2017) – Following through with Administrator Pruitt's commitment to eliminating the backlog of new chemical cases that were stuck in EPA's review processes upon his confirmation, Administrator Pruitt is reporting that the backlog is eliminated.

"EPA has a tremendous responsibility to review new chemicals intended to enter the U.S. market for safety," said EPA Administrator Scott Pruitt. "EPA can either be a roadblock to new products, or it can be supporter of innovation and ever-improving chemical safety. I am happy to report that the backlog of new chemical reviews is eliminated. With the ongoing commitment of the staff working on TSCA reviews, and input from stakeholders, our goal is to ensure a new chemicals program that is both protective of human health and the environment, while also being supportive of bringing new chemicals to market."

The Toxic Substances Control Act (TSCA), amended by the 2016 Lautenberg Chemical Safety Act, ensures that EPA must make an affirmative safety determination before a new chemical can come to market. EPA can request more information from chemical companies if it needs more information to make a safety determination.

When Administrator Pruitt was confirmed, over 600 new chemicals were 'stuck' in the EPA review process. The current caseload is back at the baseline and now in line with the typical active workload. Administrator Pruitt committed to being a partner in the regulatory process, and ensuring safety for health and the environment, while also seeking ways to allow new chemicals to enter the market quickly, once EPA is assured that the chemical is not likely to present unreasonable risk for the intended and reasonably foreseen uses.

In addition to announcing the elimination of the backlog, EPA Administrator Pruitt is committing the Agency to a more predictable and transparent process for making safety determinations through a commitment to following operating principles; continuously improving; and, increasing the transparency in the decision-making for new chemical safety determinations.

"Not only do I support reducing the backlogs that have built up at this Agency, I also encourage continuous improvement and increased transparency," said EPA Administrator Scott Pruitt.

Additional Details of New Measures to Strengthen EPA's New Chemicals Review

EPA is committing to the following operating principles in its review of new chemicals:

- 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.
- 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.

EPA supports continued improvement of EPA’s TSCA new chemicals program, including:

- Redeploying staff to increase the number of Full-Time Equivalent (FTE) staff working on new chemicals.
- Initiating a LEAN exercise to streamline work processes around new chemicals review.
- Institutionalizing a voluntary pre-submission consultation process so that submitters have a clear understanding of what information will be most useful for EPA’s review of their new chemical submission, and of what they can expect from EPA during the review process. While such engagement prior to submission is an additional up-front time and resource commitment by submitters and EPA, it should more than pay for itself with faster, better-informed EPA reviews.

EPA needs to be more transparent in how it makes decisions on new chemicals under TSCA:

- In Fall 2017, EPA’s Office of Pollution Prevention and Toxics (OPPT) intends to release, for public comment and stakeholder engagement, draft documents that will provide the public with more certainty and clarity regarding how EPA makes new chemical determinations and what external information will help facilitate these determinations.
- EPA will facilitate a public dialogue on the Agency’s goal of continued improvement in the new chemicals review program.
- EPA will continue posting weekly web updates of program statistics, so that manufacturers and the public can determine the disposition of cases as quickly as possible.

For more information on the TSCA program, please visit:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>

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