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Should 90 Day New Chemical Reviews Take Their Place with the Dinosaurs under TSCA?

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On January 2 EPA released an update to its guidance under the Toxic Substances Control Act (TSCA) for New Chemical Determinations: A Working Approach for Making Determinations under TSCA Section 5 (Working Approach). Earlier, U.S. Environmental Protection Agency (EPA) held a public meeting on December 6 to brief the public on the information this document contains. During that meeting, EPA's presentation including several case studies on polymers and other chemistries, and summarized developments in 2019 in the area of confidential business information protection.

On a positive note, EPA's update offers insights and certainty on how it reaches decisions and what outcomes to expect during new chemical reviews. This document is a welcome supplement to other new chemical guidance, such as EPA's Points to Consider When Preparing TSCA New Chemical Notifications.

Notably, EPA provides helpful new explanations for considerations such as the difference between an intended, known, or reasonably foreseeable condition of use that signal a more focused approach. Intended uses are those that the submitter of a section 5 new chemical submission identifies, and reasonably foreseeable uses are those that EPA might expect the chemical to be used. EPA is now taking a narrow view of a "known" use, which appears to be limited to uses that EPA identifies for a new chemical that is being manufactured pursuant to a TSCA exemption from section 5 premanufacture review or used abroad.

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Elsewhere in the document on page 7, EPA indicates that it could choose to issue a SNUR following a "Not Likely" determination for a use that may present risk concerns should it occur in the future – even if the use is not reasonably foreseen. In such cases, however, section 5(a)(2) of TSCA calls on EPA to consider "reasonably anticipated" manner and methods of manufacturing, processing, distribution in commerce and disposal. These sound like equivalent determinations, and according to the dictionary meaning of anticipated and foreseen, they are. As a result, a follow on SNUR for a use that is not contemplated now or in the future would probably need to be justified on the additional grounds available for agency consideration in section 5(a)(2), such as changes in the magnitude, type, and duration of exposure.

At a very high level, the Working Approach document addresses when EPA will consider the information that it has on a new chemical to be sufficient and when an identified risk will be considered unreasonable. Importantly, this guidance document firmly establishes that risk determinations will factor in the workplace practices and exposure controls that companies use.

EPA also explains when it will issue orders and/or Significant New Use Rules (SNURs) in the case of insufficient information, or where there is a finding of hazard or significant exposure. EPA describes when it will SNURs either before or after a "not likely" determination and when a SNUR will be issued following a consent order determination.

When EPA issued this document for the first time in 2017, it was subject to a legal challenge concerning its legal force and effect. That challenge was ultimately withdrawn, but EPA is careful to note that the updated version is not intended to create new authority or bind the public.

This document is not intended to address or resolve the lengthy delays of well over 90 days that innovators continue to regularly experience since TSCA was updated in 2016. The Working Approach document illustrates just how much work EPA is doing on every new chemical file. The agency has taken on a new level of detail in its work that it finds is necessitated by needing to understand conditions of use and publicly documenting its calls. EPA does not offer here or elsewhere any assurance that the agency can accomplish all of the described tasks with the process it has and meet the 90-day review deadline more frequently. Even though the agency clearly wants these reviews to be more efficient, EPA would have to routinely complete risk determinations by day 45, streamline consent orders, and dramatically speed up the pace of SNURs to meet the 90- day completion time for new chemicals that it decides to regulate.

The changes to the new chemicals program were immediately effective when the Lautenberg Act was signed into law in 2016. This left EPA little choice at the time to do anything other than work within the old program framework. In 2020, we hope EPA will begin anew to re-imagine the process. Comments are invited on the Working Approach through February 3, 2020.