At the One-Year Mark, the EPA’s Existing Chemical Review Process is Taking Shape: What Does That Mean for Your Business?

On Thursday, June 22, 2017, the Environmental Protection Agency (EPA) announced a series of actions implementing its new authority to review the safety of chemicals already in U.S. commerce under the recently amended Toxic Substance Control Act (TSCA). The actions, required under the 2016 Frank R. Launtenberg Chemical Safety Act for the 21st Century (LCSA), reflect Congress’ mandate to reinvigorate and expand the EPA’s long moribund program for reviewing so-called “existing chemicals” (chemicals previously introduced into U.S. commerce and listed on the TSCA inventory) to identify and manage unreasonable risks to human health and the environment.¹

For existing chemicals, the sheer number of substances on the TSCA inventory and in commerce, and the varying levels of data available for reviews created unique challenges, requiring the EPA to promulgate a number of procedural “framework” rules for selecting, prioritizing and conducting reviews. Many of these rules faced a one-year deadline, and the EPA’s action follows through on these obligations, establishing procedures for:

- industry reporting on which of the 84,000 chemicals listed in the current TSCA inventory of existing chemicals remain in active commerce, and which substances remain subject to claims of confidentiality (the “Inventory Rule”)
- identification and selection of high and low-priority chemicals for further risk evaluation (the “Prioritization Process Rule”)
- evaluation of risks associated with “high-priority” priority chemicals (the “Risk Evaluation Process Rule”)
- identification of which conditions of use will be within the scope of the risk evaluations for each of the first 10 chemicals already designated for risk evaluation (“Scope Documents”)
- Manufacturer’s development and submission of external party draft risk evaluations for EPA’s consideration in supporting chemical reviews (“Draft Risk Evaluation Guidance”).

Compliance with statutory deadlines is often a challenge for the EPA and other regulatory agencies tasked with implementing ambitious congressional mandates. As such, the EPA’s successful compliance with five concurrent one-year deadlines is a notable achievement, indicating that, at a time when the EPA’s new leadership is slowing, if not backtracking, on many environmental programs, the administration is still willing to dedicate the resources (staff and otherwise) needed to identify and manage risks from existing chemicals in the marketplace.
These one-year regulations are important first steps in the EPA’s implementation of its existing chemical review authority. The precedent and processes established in the framework rules and guidance will shape and guide EPA policy for years to come. If your company is covered by these rules, either directly or as a downstream chemical user relying on the availability of specific substances, you will want to read the policies in detail or obtain assistance from counsel who can walk you through the definitions, deadlines, requirements and procedures.
Contact Information
If you have any questions concerning this alert, please contact:

Charles L. Franklin  
clfranklin@akingump.com  
202.887.4378  
Washington, D.C.

Stacey H. Mitchell  
shmitchell@akingump.com  
202.887.4338  
Washington, D.C.

David H. Quigley  
dquigley@akingump.com  
202.887.4339  
Washington, D.C.

The LSCA also introduced a number of changes to definitions, standards and processes for new chemicals not yet in commerce that have already created challenges for manufacturers seeking to bring new substances to market.