

ADMINISTRATIVE WATCH

ADDRESSING ENVIRONMENTAL, ENERGY AND NATURAL RESOURCE ISSUES



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Your Company's "TO DO" List for Chemical Substances Regulation and Compliance

Now that the House of Representatives has passed Toxic Substances Control Act (TSCA) reform legislation, which is the Frank R. Lautenberg Chemical Safety for the 21st Century Act (H.R. 2576), on May 24, 2016 followed by Senate passage on June 7, 2016, the reconciled legislation is finally on its way for President Barack Obama's signature. The president is expected to quickly sign it. So what does this mean for your company? Although this is by no means complete, here is a "to do" list to frame your company's TSCA reform efforts.

- 1. PROMOTE SOUND SCIENCE:** Take advantage of public comment opportunities for your company and its scientific and legal advisors to weigh in on the USEPA's Year 1 mandate to establish a risk-based chemical screening process and criteria for designating chemicals as low or high priority substances, as well as guidance for submitting risk assessments through the new chemical review PMN process. In preparing comments, look to USEPA's 2014 TSCA Work Plan as an indicator of what USEPA's work product is likely to look like and consider weaving in real world examples of sound and proven risk assessment methodologies. The TSCA Work Plan program is the USEPA's current blueprint for conducting safety assessments, prioritizations, and risk management evaluations. So the USEPA is likely to build upon what it has already developed. Many non-rulemaking policies, procedures, and guidance must also be reviewed, revised as warranted or newly-developed by the end of Year 2 so do not miss comment opportunities as they arise.
- 2. LOOK FOR DATA GAPS:** Because all new and existing chemical substances actively being made, sold and/or distributed will ultimately be evaluated/re-evaluated by the USEPA under the risk evaluation standards that are developed, now is a good time for your company to look at the existing/available exposure data and develop new data for any information gaps.
- 3. FILE ROBUST PMNs AND SNUNs:** With the lifting of the "least burdensome" requirement, the USEPA faces fewer hurdles in restricting or banning chemicals from use. The USEPA is charged with assessing whether a chemical presents an unreasonable risk to safety (including the safety of applicable vulnerable populations) irrespective of any cost considerations. Cost considerations do come into play when making restricted use risk management decisions. So it is imperative that your company develop and submit robust risk assessments for any chemical under consideration so that the your chemical approval process has the best chance of progressing in a timely manner. Otherwise, expect the USEPA to issue an Order for information gaps. Be sure to factor additional risk assessment costs and extended review times into your new product development schedules.

4. **CONSIDER REQUESTING THE USEPA TO DESIGNATE A PARTICULAR CHEMICAL AS A HIGH PRIORITY SUBSTANCE:** Up to 50 percent of all designated high priority substances can be nominated by manufacturers (not processors) and trade associations and this may make sense for chemicals critical to your business, including but not limited to chemicals in the 2014 TSCA Work Plan. Particularly in the short term for the 2014 TSCA Work Plan chemicals important to your company, plan to participate in the USEPA's assessment of and potential restrictions on, these chemicals. For chemicals that your company nominates, be prepared to pay 100 percent of the USEPA's assessment costs (50 percent for such chemicals listed in the 2014 TSCA Work Plan).
5. **ASSESS YOUR COMPANY'S CURRENT TSCA INVENTORY STATUS:** Figure out what chemicals are currently manufactured (as well as imported), sold, distributed and/or processed by your company and identify those that have not been managed over the past 10-year period. Do this in conjunction with the USEPA's Year 1 mandate to set a process for resetting the TSCA inventory of chemical substances to align it with what is actually being used within 21st Century products. This will better equip your company to comment on the inventory reset procedures. It is expected that a significant number of the 84,000+ chemicals currently on the TSCA inventory will be moved to an Inactive Inventory List through the TSCA inventory reset process because they have not been manufactured (or imported), sold, or distributed within the prior 10-year period. Expect to submit TSCA inventory status information to the USEPA within six months of the final rulemaking. For chemicals that your company is likely to manufacture (or import), sell, or distribute in the future, request the USEPA to move your company's chemical from the TSCA Inactive Inventory List to the Active List.
6. **CHECK SUBSTANTIATION OF YOUR COMPANY'S CONFIDENTIALITY CLAIMS:** Because the TSCA inventory reset will require your company to disclose information on chemicals listed on the Confidential portion of the TSCA inventory, look at the substantiation of the confidential claims now and enhance them as warranted. Failure to adequately substantiate such claims (and re-substantiate them every 10 years hereafter) will result in disclosure of the chemicals on the TSCA public inventory.
7. **BUDGET FOR INCREASED FEES:** The USEPA will set fees to cover some of the costs of implementing the TSCA amendments through the rulemaking process. Be sure to comment on the fee collection schedule(s) as appropriate and ensure increased TSCA fees are reflected in your company's budget.
8. **CONSIDER MEMBERSHIP OPPORTUNITIES - SCIENCE ADVISORY COMMITTEE ON CHEMICALS:** Through your company's go-to trade association or within your company (or your consultant's company's) ranks, membership on the new Science Advisory Committee on Chemicals could be beneficial, particularly during USEPA's early years of implementing the amended TSCA.

Should you have questions regarding TSCA reform, please contact Colleen Grace Donofrio in Babst Calland's New Jersey office at 856-256-2495 or cdonofrio@babstcalland.com.