TSCA21 New Chemical Submissions Support

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA21) was signed into law June 22nd, 2016 and has significantly impacted New Chemicals submissions.

Significant Changes to New Chemicals

- TSCA21 changes the bar to determine that a PMN substance will not result in unreasonable risk – The focus is shifted more toward the submitter to show low risk and away from the agency to prove risk. This may seem like a small change, but it has major ramifications.
- Increased scrutiny of Data Gaps. EPA now has the authority to reject or regulate a PMN based solely on lack of data. PMNs with significant data gaps may be rejected or faced with regulation, regardless of overall risk.
- Increased PMN Fees – The fee schedule has increased sharply for all New Chemical Submissions.

Initial Implementation

- Significant increase in PMNs being regulated – The percentage of PMNs that are being regulated increased from approximately 15% to >90%. In addition, LVEs and TMEAs are being denied more often.
- Consent Orders used to regulate PMNs and longer review times – Slow and difficult to negotiate, with longer review times, and are often not acceptable to downstream customers or users.
- EPA looking at all foreseeable uses, even ones not listed in the PMN or anticipated by the submitter.

Recent Updates and Changes

- Focus is shifting to only Manufacture and Uses listed in the PMN Submission
- Restrictions are being handled by SNUR Now – EPA is using two separate types of SNUR
    - Parallel SNUR – Typically applies only to the manufacture and uses as described in the PMN submission.
    - Follow-up – Applies to the manufacture and use as described in the PMN submission and others.
- An increase in the number of PMNs with the finding of "not likely to present unreasonable risk" – CERM has recently worked on an increasing number of submissions that received a "not likely" determination.

How to Secure PMN Success

- PreScreen New Chemical Submissions with existing data and predictive models to assess for hazard and risk.
- Address Hazard Data Gaps - Address significant and key data gaps through predictive methods or other means.
- Include adequate information on manufacture and use - Risk is a function of hazard and exposure, where hazard exists, use mitigation to control risk.

PMN Solutions: How CERM Can Help

- CERM can help – We have decades of experience in TSCA Submissions, with a proven track record of success.
- Chemical PreScreening – CERM has completed hundreds of assessments of all classes of chemicals.
- Data Gaps/Predictive Toxicology – CERM has the ability to help address data gaps without traditional testing.
- PMN Preparation and Review – We have worked for dozens of clients on all aspects of PMN Preparation.
- PMN Post Filing Support – We can help get a problem PMN under review by EPA back on track.

Please feel free to contact us for more information:
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