

PMN Solutions: PMN Preparation and Support



CERM offers a full range of TSCA New Chemical Submission Services. We can work with you on all aspects of PMN, LVE, TMEA, SNUN, and Bone Fide submission preparation. We also can help with Polymer Exemption Determinations. That may include preparation of the full submission, as described below, or support and review of a prepared submission, to aid in follow-up with a submission already under review. In addition, we offer supportive Chemical Hazard, Exposure and Risk screening level modeling services to further aid New Chemicals Submission.

Since the implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA 21), New Chemical Submissions have come under increasing scrutiny by the US EPA; with an increased number of submissions subject to restrictions or regulation.

Recently, however, EPA has been shifting their focus primarily to information provided for Manufacture and Uses identified in the PMN submission. In addition, EPA is focusing more on Significant New Use Rules (SNURs) to address concerns, rather than Consent Orders, to address concerns.

The result of these changes is an increase in well-crafted PMNs receiving a finding of “not likely to present and unreasonable risk to human health or the environment” and allowed to proceed to manufacture. This coupled with the increase in PMN filing fees, result in the need for strong, professional PMN and other new chemical submissions.

In recent months, CERM has had more than 4 PMNs we drafted be dropped with a “not likely” finding and be able to proceed to manufacture. In addition, we have had multiple other submissions come to negotiated solutions that are acceptable to the EPA and the submitter.

Our history of working successfully with EPA on PMN and other new chemical submissions is long. We collectively have decades of experience developing strong submissions. We know the EPA review process, the common areas that lead to concerns, and effective ways to gather and present information to address potential concerns.

New Chemical Submission Work Scope – The general scope described here covers preparation of a PMN or LVE submission for a single or consolidated PMN, LVE, or other TSCA21 New Chemicals submission by CERM. This scope of work is generally applicable up to the initial submission, as well as basic tracking of the submission as required. However, we can fit an individual scope to fit your exact needs.

This scope is intended to give a representative list of tasks to be used as a starting point. CERM can prepare an individualized scope and cost estimate for any specific project. Please feel free to contact us for more information:

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