Updates to the TSCA Section 5 (New Chemicals) Procedural Regulations (40 CFR part 720)
Summary of the Notice of Proposed Rulemaking (NPMR) for Stakeholder Outreach
November 2020

EPA is seeking early input from stakeholders on the Notice of the Proposed Rulemaking (NPRM) to update the TSCA Section 5 procedural regulations, currently under development in the Office of Pollution Prevention and Toxics. The goals of the NPRM are to:

- Align the current regulations with the 2016 Lautenberg amendments,
- Clarify certain regulatory requirements, and
- Improve the PMN process so that its more predictable, transparent, and efficient.

Background:

- The regulations at 40 CFR part 720 specify the procedures for EPA's review of new chemical submissions under TSCA section 5.
- The regulations were not updated following the 2016 Lautenberg amendments.

Inefficiencies of the Current Section 5 Notice Review Process:

Over 99% of new chemical notices are amended with new information, often multiple times, and usually late in the review period. The frequent amendments and the reliance on suspensions creates an unpredictable, and inefficient review process. Examples include:

- Excessive 'rework' of cases: When information is omitted from notices, the EPA assessors apply conservative assumptions and use default values to determine risk. In response to the identification of potential risks, submitters often will in turn amend their notices with additional information, causing re-work and overall delay in the review.
- 'Late' information: After submitting a notice, submitters may request several months to gather new information (e.g., conduct a new study) to address the potential risks identified in the risk assessment. Once the new information is submitted, EPA must then take time to rework the risk assessment, which extends the review period well beyond what TSCA specifies.

Regulatory Changes Under Consideration:

EPA is seeking input on the potential changes to 40 CFR part 720, including but not limited to:

- Potential PMN form (CDX) improvements
  - Specific information from the June 2018 "Points to Consider" document could be reflected as new fields in CDX.
- Improvements addressing the inefficiencies described in the examples above.

Overall Question:

- What improvements do you recommend to address the inefficiencies in the new chemical notice review process described above?