

ALERT

EPA Delays TSCA Nanoscale Reporting Rule and Issues Draft Guidance

May 17, 2017

On May 8, 2017, EPA extended the effective date of the Toxic Substances Control Act (TSCA) section 8(a) reporting and recordkeeping rule for certain nanomaterials from May 12, 2017 to August 14, 2017. 82 Fed. Reg. 22088. The rule, entitled Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements, applies to all companies that manufacture (includes importers) and process nanomaterials that qualify as "reportable chemical substances" (RCSs) and their discrete forms as defined by a complex number of factors in the rule.

EPA is asking for public comments on its draft guidance document for the rule, which the agency released on May 16, 2017. 82 Fed. Reg. 22452. The draft guidance provides answers to questions the Agency has received from manufacturers and processors. Comments on the draft guidance can be submitted to docket number EPA-HQ-OPPT-2010-0572 via www.regulations.gov and are due June 15, 2017.

EPA received several requests to delay the implementation of the final rule until after the guidance was available for companies to study and use. The reason why EPA is delaying the implementation date of this rule is presumably to permit the agency to finish the guidance, which the agency stated it would issue within six months after it published the final rule in January. Because reporting was scheduled to begin in May, many companies would have had to start filing these electronic reports without the benefit of the EPA guidance. The agency's decision to delay the effective date of the rule underscores the importance of the guidance by acknowledging that "the public interest is served by complete and accurate reporting under this rule, which would be greatly facilitated by publication of

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the guidance”.

With the delay of the effective date, the rule now requires any person who manufactured or processed a reportable chemical substance within the three years prior to August 14, 2017 to file a one-time TSCA Section 8(a) report by August 14, 2018. Persons who intend to manufacture or process a reportable chemical substance for the first time on or after August 14, 2017 also will be required to file reports. Those reports are due 30 or 135 days before manufacturing or processing is initiated, depending on when a company forms the intent to commercialize for the first time.

The section 8(a) rule for reporting nanomaterials applies to nanoscale substances that are solids at 25 °C and standard atmospheric pressure; manufactured or processed in a form where any particles, including aggregates and agglomerates, are in the size range of 1–100 nanometers in at least one dimension; and manufactured or processed to exhibit one or more unique and novel properties. The rule includes criteria for distinguishing among discrete forms of an RCS based on minimum changes in size or properties, or when there is a change in shape or coating. These discrete forms will need to be separately identified in the reports submitted to EPA.

The temporary pause is welcomed news given the number of uncertainties associated with this reporting and recordkeeping rule. The expense of the rule, particularly on small businesses, and the duplicative nature of the requirement (the requested information will need to be provided by both manufacturers and their downstream processor customers) are concerning for the companies affected by the rule. EPA estimates that between 800 to 900 companies may be subject to reporting, with over half of these small business concerns. The agency estimates that a company will on average need to file up to 13 of these reports per year.

The timing of the on-going reporting obligation is complex due to the significant uncertainty about when commercialization can begin once a report is filed. More specifically, the language of the rule itself conflicts with the agency’s stated intent elsewhere that companies are free to commercialize as soon as EPA receives the report. In addition, the agency’s intent to scrutinize these reports for possible regulation may cause some companies to wait to commercialize in order to see if the agency responds. These kind of unknowns may make establishing predictable commercial launch schedules more difficult for this emerging class of products.

As the rule currently stands, manufacturers and processors should review the draft guidance, submit comments on areas in which questions persist, and plan to collect, report, and keep good records for RCSs in their portfolios beginning August 14, 2017. The required information includes the chemical identity of the reportable chemical and identification of any discrete forms. In addition, EPA is asking for production volume, descriptions for methods of manufacture, processing and use, risk management strategies, exposure and release information, and any existing environmental and health effects data that companies have on the reportable chemicals. No new testing is required in order to comply with this reporting rule.

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