

September 25, 2017

To: General Issues Committee

**RE: 2017 EPA Nanomaterials Reporting - Guidance for Color Pigments Industry
Downstream Customers**

The final EPA rule entitled *Chemical Substances When Manufactured or Processed at the Nanoscale Final Rule*, 82 Fed. Reg. 3641 (the Final Rule) went into effect August 14, 2017. The Final Rule was a very big regulatory win for CPMA, as well as other traditional industries making products which contain some portion of nanoscale materials. Color pigments are generally not reportable under the Final Rule. Persons who manufacture or process a reportable nanomaterial during the three years prior to the final effective date of the Final Rule must report to EPA by August 14, 2018. See the Final Rule and EPA's Final Guidance [here](#).

Impact on Pigments:

The Final Guidance strongly substantiates and supports CPMA's position that the Final Rule does not apply to substances such as pigments, because pigments do not present unique and novel properties in the nanoscale. The Final Guidance addresses all the concerns raised by CPMA in its comments on the Draft Guidance.

Grinding or generation of nanoparticles: In the Final Guidance, EPA agreed with the CPMA public policy recommendation that the mere grinding or generation of nanoscale particles which, apart from particle size and surface area do not present any properties different from those of the same product at larger particle sizes, does not constitute a unique and novel property in the nanoscale.

Unique and novel properties - Questions 1 & 2: In the Final Guidance, EPA completely revised the questions and answers regarding what properties constitute unique and novel attributes in the nanoscale. In the Final Guidance, questions 1 & 2 are a much more substantiated version of the Draft Guidance question and answer 2, with repeated emphasis on (and examples of) how reportability is tied to whether you manufactured a substance in the nanoscale to take advantage of a unique and novel feature that it offers only in that scale. Question 2 now contains three examples of substances which may exhibit unique and novel properties in the nanoscale. The example of nanoscale gold is discussed at greater length, as are carbon black and titanium dioxide. The emphasis in all three examples is on unique and novel attributes which only occur in the nanoscale.

Enhanced properties - Question 3: The Final Guidance asks whether enhanced properties or continuously scaling properties (such as thermal conductivity or surface area) should be considered unique and novel properties. EPA's answer states that these enhanced properties are not considered unique and novel properties. EPA adopted the CPMA recommendation that EPA distinguish between properties that emerge only in the nanoscale (unique and novel; therefore reportable) and properties that scale proportionately with size (enhanced, not unique and novel; not reportable). EPA removed completely the previous vague language about better performance of enhanced properties. In its response, EPA uses an example of a blue pigment to clarify the distinction:

A pigment which adds, at all sizes, blue tones to a resin, but the blue tones are more apparent when the pigment is on the nanoscale (1-100 nm), is an enhanced property. If the pigment only added blue tones when used on nanoscale (1-100 nm), and not at other particle sizes, that would be a unique and novel property.

Surface area - Question 5: Consistently, Questions 2 and 5 make the point that size and surface area do not constitute unique and novel properties (since they scale proportionately with size), without some other attribute unique to the nanoscale. Question 5 now asks if a product which contains particles with differing surface areas, in different grades of the same product, qualifies as a unique and novel attribute. EPA responded that surface area is not considered a unique and novel property. It will vary proportionately with a smaller particle size.

EPA again reiterates the issue in question 15 regarding whether large polymerized molecules within the nanoscale are reportable under the Final Rule. EPA responds that:

While these categories of large molecules are not automatically exempt, monomers, polymers, and colloids, organic and inorganic pigments and dyes, and polymer dispersions are not reportable chemical substances unless they are solid particles manufactured or processed at the nanoscale to exhibit unique and novel properties that are not exhibited by other forms or sizes of the same chemical substance.

Importer reporting: In question 15 involving who must report, an importer asked if imported inks and toners containing pigments or additives within the nanoscale require reporting. EPA responded by stating that importers of ink and toner would be required to report if reportable substances are present in the ink and toner products. The EPA response does not address the attributes of the pigment or additive or whether a pigment is reportable due to the unique and novel requirement. The EPA response was not intended to address the unique and novel requirement, but only the issue of reporting by importers.

Responding to Downstream Customers/Processors:

- Color pigments are generally not reportable under the EPA Nanomaterials Reporting Rule
- The mere grinding or generation of nanoparticles does not constitute a unique and novel property
- Enhanced properties are not considered unique and novel
- Size and surface area do not constitute unique and novel properties
- If a processor is doing something to the raw material (such as a color pigment) that produces a unique and novel property in the nanoscale, then that processor may have to report their final product to EPA as a nanomaterial. This may be an extremely rare occurrence, however.