

June 14, 2017

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Attn: Docket No. EPA-HQ-OPPT-2010-0572

Re: Comments on “Draft Guidance on EPA’s Section 8(a) Information Gathering Rule on Nanomaterials in Commerce”

Dear Sir or Madam:

I am writing on behalf of the Color Pigments Manufacturers Association, Inc. (“CPMA”) in response to the Notice of Availability and Request for Comment on the above-referenced draft guidance document (the “Draft Guidance”).¹ The Draft Guidance provides answers to questions EPA has received regarding reporting obligations under the final rule entitled “Certain Chemical Substances When They are Manufactured or Processed at the Nanoscale; TSCA Reporting and Recordkeeping Requirements” (the “Final Rule”).²

CPMA is an industry trade association representing small, medium and large color pigments manufacturing companies. In addition, the Association represents color pigments manufacturers that sell pigments and certain colored products and suppliers of intermediates and other chemicals products that serve color pigments manufacturers. The Association provides advocacy programs in support of the color pigments industry on matters pertaining to the environment, health, safety issues and trade. Color pigments are widely used in product compositions of all kinds, including paints, inks, plastics, glass, synthetic fibers, ceramics, color cement products, textiles, cosmetics and artists’ colors.

CPMA defines color pigments as colored particulate organic or inorganic solids, which usually are insoluble in, and essentially physically and chemically unaffected by, the vehicle or substrate in which they are incorporated. Pigments retain a crystalline or particulate structure and impart color by selective absorption or by scattering of light. The primary difference between pigments and dyes is that pigments are insoluble in the substrate during the application process, while dyes are soluble in the substrate.

At the outset, CPMA commends EPA for seeking input on a draft version of this guidance document. This practice is a key recommendation of OMB’s Final Bulletin for Agency Good Guidance Practices, which explains that “providing pre-adoption opportunity for comment on significant guidance documents can increase the quality of the guidance and provide for greater public confidence in and acceptance of the ultimate agency judgments.”³ OMB said “[p]re-adoption notice-and-comment can be most helpful for significant guidance documents that

¹ 82 Fed. Reg. 22452 (May 16, 2017).

² 82 Fed. Reg. 3641 (Jan. 12, 2017).

³ 72 Fed. Reg. 3438 (Jan. 25, 2007).

are particularly complex, novel, consequential, or controversial.”⁴ That description certainly fits issues raised by the final rule, and so CPMA appreciates that EPA has sought comments first and did not just finalize this guidance. The Final Guidance will be better as a result.

CPMA also commends the agency for extending the effective date of the Final Rule until August 14 of this year, thus giving regulated entities – and the Agency – more time to grapple with and understand the complexities involved in applying the Final Rule to the broad and varied universe of nanomaterials – complexities that are reflected in the Draft Guidance.

CPMA Appreciates the Draft Guidance’s Statements Regarding Aggregates and Agglomerates and Its Examples of Reportable Substances

Overall, with one exception discussed below, the Draft Guidance provides helpful and informative examples that will limit unnecessary reporting under the Final Rule. Not only will this save the resources of industry and EPA, it will also improve the quality and utility of the information that is reported. For example, the strong, informative statements in response to Question 4 regarding the exclusion of aggregated and agglomerated particles larger than 100 nanometers will help avoid confusion and reduce unnecessary reporting of primary particles. On a June 1 webinar hosted by SEMI,⁵ EPA’s Jim Alwood made the helpful point that, where manufactured nanoparticles naturally form aggregates or agglomerates, those aggregates and agglomerates *are* the “particles” at issue under the definition of “reportable chemical substance, and if greater than 100 nm are not covered by the definition. The Final Guidance might make this point a bit more clearly.

Several other question and answer examples in the Draft Guidance also assist users in accurately applying the definition of Reportable Substances under the Final Rule. We particularly appreciate the response to question 11:

[M]onomers, polymers, and colloids, organic and inorganic pigments and dyes, and polymer dispersions are not reportable chemical substances unless they are manufactured at the nanoscale to exhibit unique or novel properties that are not exhibited by other forms or sizes of the same chemical substance.

The Draft Guidance’s emphasis on unique and novel properties that are not exhibited by other forms or sizes of the same substance will similarly assist users of the Draft Guidance to distinguish reportable nanomaterials under the Final Rule from natural and synthetic nanomaterials, such as pigments, which have been used in numerous products for centuries. For example, Question 2 refers to the color change in gold nanoparticles as an example of a unique and novel reportable substance in the Final Rule. Because gold nanoparticles in suspension have a red or purple color that only occurs in the nanoscale, EPA identified gold nanoparticles as a reportable substance and used this example of a reportable substance in the Final Rule. The Final Guidance should additionally emphasize the two-part nature of the definition of a Reportable Substance; i.e., it exhibit a unique and novel nanoscale property *and* the manufacturer or processor intends to utilize the unique nanoscale specific property.

⁴ *Id.*

⁵ Jim’s presentation is available at <http://www.semi.org/en/sites/semi.org/files/data15/docs/EHS-2017-06-01-Nanomaterials-Webcast-Document2.pdf>.

Draft Guidance Question 3: “What is the Difference Between Enhanced Properties and Unique and Novel Properties?”

The draft answer to this question does not explain the difference between "enhanced properties" and "unique and novel properties" in the nanoscale. Indeed, the answer conflates the two concepts and thus appears to contradict other statements on the definition of "reportable substance" contained in the preamble to the Final Rule and elsewhere in the Draft Guidance – with particularly adverse potential consequences for color pigments. This is especially unfortunate because EPA *could* provide vitally important guidance by clearly distinguishing between these two concepts.

EPA's answer to Question 3 refers to the increasing "enhancement" of existing substance properties when particle size is reduced:

Enhanced properties are generally described as increased reactivity or surface area when particle size decreases. While reactivity and surface area increase, there is often little difference in the intrinsic properties of the particles in ranges above 100 nanometers. When particles are created with dimensions in the 1–100 nanometer range, the materials' properties can change significantly from those at larger scales. Not all enhanced properties are unique or novel. For example, grinding or engineering pigments for better performance which results only in incidental amounts of particles between 1-100 nm would not constitute a nanoscale material with unique or novel properties. Grinding or engineering pigments for better performance which results in almost all particles that are less than 100 nm would constitute a nanoscale material with unique or novel properties.”

The answer thus appears to adopt the view that “enhanced properties” are *any* properties that change with particle size, with “unique and novel” properties being some subset thereof. But the answer does not clearly explain that a reportable substance must exhibit a “unique and novel” attribute apart from “enhanced properties.” The latter two sentences imply that “better performance” is the dividing line, but that is problematic for multiple reasons. First, the phrase “better performance” is nowhere used in the Final Rule. Second, these two sentences actually conflict with the preamble to the Final Rule, which seems to draw a distinction between nanomaterials that perform a function “better” than other forms or sizes of the same material and those that are “different.”⁶ According to the Final Rule, “[a] property is novel when it is different from the properties associated with other forms or sizes of the same chemical substance.”

The surface area of a particle must necessarily increase as the size of that particle diminishes. Increased surface area cannot be a unique and novel property in the nanoscale, even if 100% of all particles present can be measured in the nanoscale, because then all such nanoscale particles would be reportable.

Many other properties of particles will change proportionately with particle size. Manufacturers of products such as ink, glass, paint, plastic, rubber and silicone often grind pigments and additives for consistent application prior to formulating the dispersed product. If simply increasing surface area by reducing particle size by grinding or dispersion for

⁶ 82 Fed. Reg. 3647.

consistency generated a unique and novel attribute, virtually all formulated materials in commerce would require reporting under the Final Rule. This is clearly not the Agency's intent.

One option open to the Agency is simply to stop using the phrase "enhanced properties." We note that EPA addressed this issue in the Final Rule by stating that "because not all enhanced properties are unique or novel properties, EPA replaced the word enhanced with novel in section C.5. of the reporting form."⁷

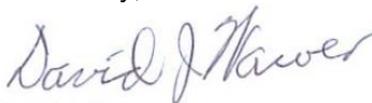
But EPA has another option: to define "enhanced properties" and "unique and novel" properties to be disjunct. During the above-referenced webinar, Jim Alwood did just that, explaining that "enhanced" properties are those that change proportionately – i.e., linearly – with particle size, and that "unique and novel" properties are those that change *disproportionately* or *nonlinearly*. *Qualitative* differences might be another adjective describing "unique and novel" properties.

An example of "enhanced" properties discussed on the webinar is the abrasive properties of chemical mechanical planarization sludges, which are a linear function based on size. Grinding or engineering pigments for better functional performance in a paint or plastic matrix also would be another example of merely "enhanced" properties, since those properties merely improve as a function of particle size. Notably, pigments generally exhibit essentially the same color at any particle size.

On the other hand, an example of a "unique and novel" property would be the change in color of gold particles from gold to red or purple in the nanoscale. Where such particles are produced at the nanoscale for the purpose of exploiting that change in optical quality, then all such nanoscale particles would be reportable.

As a general rule, color pigments do not exhibit a unique and novel property in the nanoscale. Therefore, the example provided in Question 3 is, at best, confusing to the user of the Draft Guidance and may engender inappropriate reporting under the Final Rule. Question 3 could be misinterpreted by formulators to require unnecessary reporting on each pigment used in production of formulated products, such as paint, paint dispersions, plastics and inks. In defining a reportable substance, the Final Rule excluded precisely this type of unnecessary, resource intensive reporting of established products in commerce. Given the extensive and helpful information otherwise contained in the Draft Guidance, the answer to Question 3 should be revised consistently with our recommendation above.

Sincerely,



David Wawer
Executive Director

⁷ 82 Fed. Reg. 3651.