CPMA
COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

January 17, 2017

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

Attention: Docket Number EPA-HQ-OPPT-2016-0658

Re: Comments of the Color Pigments Manufacturers Association, Inc., on the EPA Premanufacturing Review Process for New Chemicals Submitted Under TSCA as Amended

Dear Sir or Madam:

The following comments are provided on behalf of the Color Pigments Manufacturers Association, Inc., (“CPMA”) regarding the Environmental Protection Agency ("EPA") public meeting held on December 14, 2017 on new chemical review procedures under the Toxic Substances Control Act, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Amended TSCA").

The CPMA is an industry trade association representing small, medium and large color pigments manufacturing companies in North America. In addition, the Association represents foreign color pigments manufacturers that sell products in North America and suppliers of intermediates and other chemicals products that serve North American color pigments manufacturers. The Association provides United States and international 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.

The Current Status of New Chemical Reviews

CPMA supports the comments of the American Chemistry Council and numerous other business and industry groups, which expressed significant concern with the delays in the review period for Premanufacturing Notice ("PMN") substances which have occurred since the enactment of the Amended TSCA. These delays are not justified by the changes made as a result of the Amended TSCA. In particular, when Amended TSCA was enacted, EPA extended the review period for all pending PMNs by an additional 90 days, despite the lack of statutory authority for such an action.

The Amended TSCA requirement for the EPA to make a positive declaration (“not likely to present an unreasonable risk”) regarding adding new substances to the TSCA Section 8(b) Inventory was not intended to create a new burdensome administrative review process. Furthermore, Amended TSCA did not significantly change the criteria or timing for adding new substances to the TSCA 8(b) Inventory.

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It is important that EPA maintain reasonable standards for new chemical risk evaluations under the Amended TSCA. The Amended TSCA states that the "Administrator shall make decisions under sections 2603, 2604, and 2605 based on the weight of scientific evidence." 15 U.S.C.A. §2625(i). The Amended TSCA also requires the Administrator to "use scientific information, technical procedures, measures, methods, protocols, methodologies, employed in a manner consistent with the best available science." 15 U.S.C.A. §2625(h)(1).

Since the enactment of the Amended TSCA, very few final decisions have been made on pending and new PMN submissions. On its website for PMN status updates, EPA indicates that the backlog of PMN reviews is now numbered in the hundreds, while fewer than 50 chemicals have been allowed to enter commerce. The vast majority of new chemical reviews are resulting in Section 5(e) consent orders, which are time consuming and specific to the PMN submitter and the submitter's downstream users. Where there are concerns regarding a new chemical, it is more appropriate to issue a Significant New Use Restriction, because a SNUR can be issued promptly and cover all manufacturers and downstream users. Section 5(e) consent orders result in a far more onerous and extensive regulatory burden for PMN submitters and for the new chemistries. These delays in the review of PMN submissions, along with increased regulatory burdens, are not reasonable and are hindering United States commerce, and potentially impinge upon domestic jobs.

Based on comments at the public meeting on December 14, 2016, it appears that the current process lacks reasonable opportunities for PMN submitters to respond to EPA. PMN submitters should have reasonable access to EPA new chemical analysis, particularly computer modeling estimations, and an opportunity to respond to EPA comments. EPA should utilize submitters' data and input, rather than overly conservative default assumptions, in these reviews, and not require unreasonable testing due to a precautionary viewpoint.

Unnecessary Workplace Regulation

Based on comments from industry and business, it appears that many of the delays in the review of new chemicals can be attributed to unnecessary New Chemical Exposure Limits ("NCEL") and related restrictions on workplace exposure to new chemicals, EPA is often duplicating existing Occupational Safety and Health Administration ("OSHA") workplace regulation. OSHA regulates many substances, such as inert nuisance dust exposure, based upon categorical chemical structure or properties. The Amended TSCA states that EPA should consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting prohibitions or other restrictions relating to workplace exposures. 15 U.S.C.A. §2604 (f) (5). Furthermore, the Amended TSCA provides that the EPA should consult with other agencies of the Federal government in order to "achieve the maximum enforcement of the chapter while imposing the least burdens of duplicative requirements on those subject to the Chapter." 15 U.S.C.A. §2608 (d).

Pigments are often regulated for purposes of workplace exposure based on inert nuisance dust. It is not necessary for EPA to continually establish different NCEL limits for new substances, including pigments, because of a perceived potential for inert dust exposure in the workplace.

EPA should improve the efficiency of the new chemicals program by avoiding unnecessary duplicative workplace regulation.

Inhalation Hazards of Inert Additives

In recent years EPA has classified new PMN submissions involving inert solid powders as a category of concern and a potential inhalation hazard. See for example 40 CFR §721.10231 regarding rutile, tin zinc oxide sodium doped, 76 Fed. Reg. 61580. In applying this assumption, EPA has unreasonably delayed and restricted new substances in commerce, including those substances which are sold only for encapsulation in formulated ink, paint and plastic products for industrial and commercial use. While there may be a limited concern with the specific process step in which a new chemical powder additive is incorporated into a formulated product, once encapsulated in resin or suspended in a vehicle, further concern is not warranted under foreseeable circumstances. The introduction of powder additives to formulated products is generally a controlled industrial process. Workplace exposures, including inert dusts, are managed via engineering controls and PPE (Personal Protective Equipment) to minimize release to the environment and human contact with formulation ingredients. EPA needs to take these controls and PPE into account as it reviews PMNs, rather than issue Section 5(e) consent orders or SNURs assuming no controls or PPE.

Impact on Innovation

Testimony from business and industry has indicated that, as EPA is implementing the Amended TSCA, EPA is not considering the market impact that impeding the introduction of new products will have on commerce. Unnecessary restrictions on new chemicals could have the potential to block innovation in material sciences, thereby blocking the ability of manufacturing companies to bring new and improved products to market, including “green” chemical substitutes. CPMA supports the comments of numerous business and industry groups regarding the importance of EPA considering the potential advantages in environmental impact, toxicity, safety and performance of the new products. CPMA also supports the comments which indicated that EPA should reduce unnecessary restrictions on new chemicals resulting from Section 5e orders and Significant New Use Rules. This goal could be facilitated by encouraging communication with PMN submitters regarding the comparative benefits and intended value of new substances in the environment, utilizing available data, analogs and weight of evidence in order to make timely declarations on new substances.

CPMA Members Products

Pigments represent unique crystalline solids which are known for their stability in the environment. Pigments retain crystalline structure and remain insoluble throughout the coloration process. Also, pigments are insoluble and unchanged by the material in which they are incorporated, and in general are low bioavailability and low hazard.

Once encapsulated in the matrix which makes up the final product, exposure to color pigments is effectively eliminated. The only actual exposure to color pigments occurs during the step when color pigments are added to industrial formulations, usually inks, paints or plastics. After that, the color pigments are encapsulated in the resin or vehicle which makes up the colored product or coating. Therefore, there is little, if any, exposure to color pigments in consumer items which incorporate pigments.

Because of general low hazard and low exposure, EPA should be aware that pigments do not warrant protracted assessment, delays during the PMN review process, nor regulatory restrictions in commerce.

Studies Submitted for PMN Review

Given the 90 day review period, CPMA believes that EPA should continue to allow PMN submitters to provide the EPA with robust summaries of available toxicological studies, rather than complete reports. The robust summary is just that, a fully representative presentation of the study and its quality, which also protects ownership. In cases of adverse toxicological or environmental effects, full reports can and should be submitted as part of TSCA Section 8(e) notifications to EPA.

Use of Established Nomenclature Under the Amended TSCA

In reviewing new chemical submissions, the EPA should continue to rely upon the established nomenclature and entries used to describe the existing statutory mixture, Class 1 and Class 2 entries on the TSCA Inventory. These entries should remain unchanged in order to reflect Congress's intent in the Amended TSCA. Since the original TSCA Inventory was adopted in the late 1970s, EPA and industry have utilized the established nomenclature systems to describe numerous types of substances. These include variable polymers, zeolites, complex inorganic color pigments and surfactants, among others. Congress' concern to preserve these systems is reflected in Section 8(b)(3)(A)(i) of amended TSCA, which states that EPA "shall maintain the use of Class 2 nomenclature," applicable to non-specific variable substances, on the TSCA Inventory, as it was "in use on the date of enactment" of the Amended TSCA.

In reviewing new chemicals, EPA should adhere to the current TSCA Inventory entries and related nomenclature for statutory mixtures, Class 1 and Class 2 substances. If the nomenclature used to describe new substances is different from the nomenclature used for existing entries, the contradiction in product identification and registrations could generate a new and unnecessary burden on industry, EPA and international commerce. Key aspects of this unintended negative result are:

- The burden on industry could include significant costs for prosecuting new registrations for existing substances in the United States and producing new product documentation for existing substances moving through commerce. Industry would have to do so, moreover, without the benefit of any past practice or guidance regarding the application of any new nomenclature.

- Changes in nomenclature defining classes of substances, for example, subdividing existing entries or families, would result in compromises and disconnects within the historical records and reports which companies and EPA have used to track the manufacture, import and use of chemicals in commerce.

- Virtually all industrialized nations have established chemical inventories defining the substances that can be sold in commerce. While these inventory systems vary in quantity with the scale of commerce, all of the world inventory registration schemes are based primarily on established commercial nomenclature. Changes in the entries in any one country will lead to confusion and disruption of worldwide commerce.

CPMA members encourage the EPA to communicate with industry stakeholders early in the PMN process to gain reasonable information on the hazards and potential exposures of substances. CPMA members are concerned that the EPA is using a regulatory approach to new chemicals which is may disadvantage new chemicals in the marketplace. Based on the testimony of many representatives from business and industry and the record of EPA PMN reviews provided on the EPA website, the PMN process is suffering from unnecessary delays which may have a chilling effect on innovation. EPA can and must use the best available science in order to make positive declarations on new chemicals. The Agency can do so within the 90 day review period, and without placing undue restrictions on new chemicals. There is no new statutory requirement to become unnecessarily conservative, because the Amended TSCA "not likely to present an unreasonable risk" standard is essentially the same standard that EPA has been using for several decades;

Please let me know if there are further questions or comments or if we can be of further assistance.

Sincerely,

David J. Wawer
Executive Director