



CPMA

COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

March 20, 2017

Ms. Wendy Cleland-Hamnett
Acting Assistant Administrator
Office of Chemical Safety & Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Attention Docket No. EPA-HQ-OPPT-2016-0636

**Re: Comments of the Color Pigments Manufacturers Association, Inc. on
Procedures for Prioritization of Chemicals for Risk Evaluation under the
Toxic Substances Control Act**

Dear Ms. Cleland-Hamnett:

The Color Pigments Manufacturers Association, Inc. ("CPMA") is pleased to provide the following comments on the Environmental Protection Agency ("EPA")'s proposed Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act ("TSCA"), as amended by Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Amended TSCA").¹

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 environment, health, and 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.

**I. The Prioritization Process Must Be Transparent and Open to Public Participation,
Particularly if EPA Finalizes Its Pre-Prioritization Concept**

The TSCA Work Plan process is the closest precedent for the prioritization task that Congress has assigned EPA, and the Agency "has drawn from the TSCA Work Plan methodology and EPA's experience in implementing that process in developing this proposed rule."² The key lesson that EPA should take from that experience is that stakeholders must have adequate opportunity to comment on, provide information on, and correct EPA decisions with respect to the information selected for application to assessment of chemical hazards and exposures and the resulting ranking of risks posed by those chemicals. The ranking of chemicals in the 2012 EPA Work Plan did not provide for industry comment on the information EPA chose to apply in its scoring program. In the case of the four pigments selected for

¹ 82 Fed. Reg. 8245.

² *Id.* at 4828.

the Work Plan, the information selected was incorrect.³ It is absolutely crucial that EPA provide stakeholders with sufficient opportunities to provide input into the prioritization process. This is particularly critical if EPA proceeds with its proposed pre-prioritization phase, when EPA would gather data and apply ranking algorithms to that data. For pre-prioritization and then for prioritization, EPA must publish the sources and the values that the Agency uses in its algorithm equation(s), along with any assumptions and default values. This is necessary in order to achieve the transparency required by Amended TSCA, to allow stakeholders to offer input and corrections on hazard, exposure, and conditions of use, and to avoid repeating the mistakes of the Work Plan process.

Missing information and mistakes at the pre-prioritization phase will necessarily lead to misidentified chemicals and incorrect proposed priority assignments. These in turn will compromise products in the marketplace and encourage ill-advised chemical substitution. They will also lead to extensive and costly administrative rulemaking that would be a waste of EPA's and industry's resources.

II. Congress Mandated that Prioritization Be a Risk-Based Screening Process

Congress expressly defined prioritization as a "risk-based screening process."⁴ As a result, prioritization – including pre-prioritization – must be based on the potential for *risk*, not the potential for hazard or exposure alone. The nine criteria that EPA lists for pre-prioritization⁵ are purely hazard-based, and hence are insufficient, without consideration of exposure, to prioritize chemicals. The criteria are also overly broad – indeed, the ninth is open ended.

For the same reason, prioritization be a *screening* process. There is no minimum data set for prioritization, but EPA needs to be as quantitative as practical in the screening process. EPA should be cautious regarding its use of hazard lists in the screening process, and should use the highest quality scientific data and make decisions based on the weight of evidence, as required by Amended TSCA. Potential review of substitutes belongs in risk mitigation, not in pre-prioritization, prioritization or risk evaluation.

As part of its prioritization process, EPA should identify and confirm the actual uses and volumes of chemicals in commerce in the United States. These should then be factored into the prioritization screening process. By contrast, that process should not be based on every potential use, misuse and accidental release, since prioritization is still limited to "reasonably foreseen" conditions of use.

III. CPMA Endorses the Comments of the Society of Chemical Manufacturers & Affiliates ("SOCMA") on the Proposed Rule

CPMA particularly endorses the following specific points advocated in SOCMA's comments:

- EPA needs to conduct a supplemental rulemaking on the pre-prioritization process to establish the specific mechanism EPA will use to ensure transparency, enable public participation, and make pre-prioritization decisions.

³ CPMA submitted comments dated August 24, 2016 in connection with the Agency's August 10 public meeting on the prioritization process. ("Comments of the Color Pigments Manufacturers Association, Inc. in Connection with the Public Meeting on Chemical Prioritization Under Amended TSCA," Docket Number EPA-HQ-OPPT-2016-0400.) The August 24, 2016 comments review the TSCA Work Plan scoring for C.I. Pigment Violet 29 and the three other Work Plan pigments. Using those specific examples, the August 24, 2016 comments request that EPA provide for stakeholder input into EPA's process of selecting information for prioritizing chemicals, the algorithm used for ranking and the application of the algorithm to the selected information. CPMA repeats the points made in those comments, attached for your convenience.

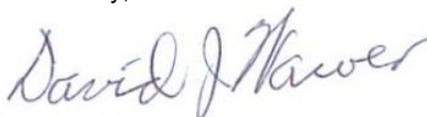
⁴ Section 6(b)(1)(A), 15 U.S.C. § 2605(b)(1)(A).

⁵ 82 Fed. Reg. 4830.

- It is entirely consistent with the statutory mandate to make decisions based on the “best available science”⁶ for EPA to accept “robust study summaries,” such as those developed for REACH, OECD SIDS Initial Assessment Reports, the Canadian Categorization of the DSL and the High Production Volume program. EPA does not need to review full study results in all cases because, as defined by the REACH regulation, these summaries provide “a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimizing the need to consult the full study report.”⁷ Manufacturers should not unnecessarily be compelled to try to track down and obtain rights to robustly-summarized studies that they do not own outright – a process that can be protracted and costly, as it can involve determining who the current legal owners are and negotiating data sharing arrangements.
- As a general rule, any amount of experimental data, including that which is derived from legally-required robust summary under REACH, should trump a default, policy or modeled assumption. After all, such assumptions have been expressly adopted to fill in for missing information, not to supplant it.
- Most existing chemicals have been in commerce since before TSCA was enacted; many for a century or more. In many cases, chemicals’ uses in the United States have been quite well-established for long periods of time, potentially many decades. EPA’s default assumption should be that the only reasonably foreseeable uses of a chemical are those to which it has historically been put.
- EPA also should not rely on Amazon or Google search results to establish that a condition of use is occurring or even feasible. It is not uncommon for companies, particularly importers based outside of the United States, to advertise the ability to manufacture a chemical that they do not currently make.

Please let me know if you have any questions regarding this submission or if we can be of any further assistance.

Sincerely,



David J. Wawer
Executive Director

⁶ 15 U.S.C. § 2625(h).

⁷ Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Dec. 18, 2006), Article 3(28); English version available at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1907&from=EN>.



CPMA

COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

August 24, 2016

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

Attention: Docket Number EPA-HQ-OPPT-2016-0400

Re: Comments of the Color Pigments Manufacturers Association, Inc. in Connection with the Public Meeting on Chemical Prioritization Under Amended TSCA

Dear Sir or Madam:

The Color Pigments Manufacturers Association, Inc. (CPMA) appreciates this opportunity to provide input to the Environmental Protection Agency (EPA) in connection with the August 10 public meeting on chemical prioritization under the Toxic Substances Control Act (TSCA) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.¹

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. 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 believes that amended TSCA requires EPA's chemical prioritization rule to:

- Seek and rely upon experimental data, rather than model results, whenever such data exist;
- Where experimental data are not available, use:
 - The best available and most current data as inputs into models; and
 - The most current versions of models that are appropriate to the chemical being prioritized; and
- Establish a fully transparent process that:
 - Gives the public at least 90 days to provide input at the outset of the prioritization process for a chemical; and
 - Clearly lays out, and allows for 90 days of public review and comment on (i) the selection of information to use in scoring, (ii) the algorithm used, and (iii) the application of the algorithm to the selected information.

Such a process would ensure that EPA does not unnecessarily devote costly and limited time and resources to conducting risk evaluations of substances that actually do not require that step.

¹ See 81 Fed. Reg. 48789 (July 26, 2016).

The Work Plan process that EPA has used thus far to prioritize chemicals for evaluation has not consistently met this standard – a fact illustrated prominently by the process's treatment of color pigments. Below, we explain generally how the Work Plan process has come to mischaracterize the bioaccumulation potential of the four color pigments that it addresses. We then provide detailed discussions of inaccuracies associated with each pigment. EPA should ensure that its forthcoming proposed rule on the prioritization process does not allow these problems to recur.

The Shortcomings with EPA's Scoring Thus Far of Color Pigments

At the public meeting, Dr. Maria Doa introduced the current EPA program for prioritizing chemicals for potential assessment by providing an overview entitled "Work Plan Methodology for Chemical Assessments." Dr. Doa reviewed the methods used by EPA to choose and rank chemicals based on predicted hazard, exposures and potential for persistence and bioaccumulation. This presentation included a review of information sources used by EPA to screen existing chemicals in commerce in the development of the EPA Work Plan.

CPMA has worked with EPA on issues related to prioritization of color pigments under the Work Plan since the first Work Plan chemicals and scoring results were published in 2012. Ms. Leslie Cronkhite provided CPMA with information on references cited by EPA for its Work Plan scoring of four color pigments in an email dated May 24, 2012.

CPMA has not objected to the basic algorithm used by EPA to score and rank chemicals for persistence, bioaccumulation and toxicity for purposes of the Work Plan. Rather, CPMA has been concerned with the information used by EPA as inputs to that algorithm. In the case of the four color pigments, EPA has unfortunately selected inaccurate information. As a result, the Work Plan categorizes these pigments as high priorities for review when, in fact, they are not.

Although EPA's estimated values would signal concern, extensive actual testing has shown that, due to their extremely low solubility, both in lipids and in water, color pigments are not bioavailable, do not bioaccumulate in individuals, and do not bioconcentrate in the food chain.

Furthermore, color pigments do not yield a toxic exposure in use. The only significant potential for exposure to color pigments occurs during the step when color pigments are added to formulations (usually inks, paints or plastics). After that, the color pigments are encapsulated in the resin which makes up the colored product or coating and exposure to them is effectively eliminated.

The four color pigments which EPA identified through the process of developing the 2012 Work Plan are C.I. Pigment Red 52, a monoazo red pigment; C.I. Pigment Violet 29, a perylene pigment; C.I. Pigment Yellow 65, a monarylide yellow monoazo pigment; and C.I. Pigment Yellow 83, a diarylide pigment.

The EPA Work Plan Chemicals Methods Document, dated February, 2012, indicates that EPA derived its persistence and bioaccumulation scores for the four color pigments using the EPISUITE computer models in the absence of measured data. However, color pigments have been recognized as being model-difficult substances and, therefore, have not been included in the "design sets" of models – i.e., the list of chemicals that were taken into account when the models were developed and validated. In effect, color pigments are outside the calibration range of the models. Accordingly, models like EPISUITE historically have tended to predict a much higher solubility and, therefore, a much higher toxicity outcome, than experimental results actually determine.

In order to facilitate the correction of solubility and toxicity estimates in the EPISUITE and PBT Profiler computer models, CPMA met with EPA representatives on December 5, 2002 and subsequently submitted data on April 17, 2003 regarding pigments containing metals which should not be reported in EPISUITE and the PBT Profiler. Subsequently, CPMA submitted data on melting points and solubility for color pigments on November 29, 2004.

The most recent edition of the PBT Profiler was updated as Version 2.0 with extensive upgrades of the EPISUITE modeling programs on September 4, 2012 – after issuance of the 2012 Work Plan and its associated Methods Document. The current PBT Profiler and EPISUITE estimates appear to be more reflective of the unique nature of color pigments.

We analyzed the four Work Plan color pigments using the current edition of the PBT Profiler. It now categorizes the four pigments as persistent, but not bioaccumulative. For example, the report generated by the current PBT Profiler states that C.I. Pigment Yellow 83 "is not expected to bioaccumulate in the food chain because it does not exceed bioconcentration factor values." The predicted melting point for C.I. Pigment Yellow 83 is 350 degrees Centigrade, and the resulting water solubility estimate is 1.684×10^{-8} mg/L. C.I. Pigment Red 52 is not reported in the PBT Profiler because compounds containing metals are not reported. www.pbtprofiler.net.

Additionally, the European Chemical Agency, Environment and Climate Change Canada, and Health Canada have all accepted the principle that chemical substances do not bioaccumulate when the measured n-octanol solubility in $\mu\text{g/L}$ is less than two times the Molecular Weight (Sol. oct. $< 2 * \text{M.W.}$) – as is the case with color pigments.

EPA should ensure that its forthcoming prioritization rule relies on use of existing experimental data and requires use of the most current versions of models that are appropriate to the chemical being prioritized. The most current version of EPISUITE would meet this standard, but the version that EPA used in 2012 would not. The rule should also ensure that EPA discloses exactly how it derived its results, so that others can readily evaluate and comment on them. EPA cannot afford to waste its limited resources and bandwidth on the basis of prioritization decisions that are less than optimal.

Specific Inaccuracies Regarding the Color Pigments Prioritized in the Work Plan

C.I. Pigment Violet 29 – CAS 81-33-4

The source for information cited by EPA for the toxicity of this color pigment is described as the:

"OECD.org, Canadian Categorization Results" from "the Ecological Categorization Results From the Canadian Domestic Substances List" which "provided underlying data regarding inherent toxicity to aquatic organisms". Email, Ms. Leslie Cronkhite, May 24, 2012.

In fact, Environment and Climate Change Canada and Health Canada did not find this color pigment to be a risk to human health and the environment:

http://www.ec.gc.ca/lcpe-cepa/eng/subs_list/DSL/DSLsearch.cfm

The Chemical Data Report cited by EPA as a source of information may have provided a misleading picture of the volume C.I. Pigment Violet 29 in commerce, since the majority of its production is consumed as a site limited chemical substance, at one facility known to be manufacturing this color pigment.

This color pigment has been registered under REACH and a complete robust summary of relevant toxicological data is available:

<http://echa.europa.eu/ja/registration-dossier/-/registered-dossier/10330>

Since the EPA PBT Profiler and EPISUITE computer models indicate that C.I. Pigment Violet 29 is persistent, but not bioaccumulative, CPMA has not been able to identify any information which justifies the inclusion of this color pigment in the EPA Work Plan. www.pbtprofiler.net. Based on the foregoing information, we would expect that a future prioritization rule would classify C.I. Violet 29 as a low priority for risk evaluation.

C.I. Pigment Red 52 – CAS 17852-99-2

The May 4, 2012 letter from EPA cited the source of ecological toxicity information for this color pigment as:

"The LC50 for acute toxicity to aquatic invertebrates is 4.481 mg/L which falls within the range of concentrations identified as "high" in the methods document." Email, Ms. Leslie Cronkhite, May 24, 2012.

Environment and Climate Change Canada and Health Canada did not categorize this color pigment as hazardous to health and the environment:

<http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=9C4DA306-1>
http://www.ec.gc.ca/lcpe-cepa/eng/subs_list/DSL/DSLsearch.cfm

A full copy of an aquatic toxicity study representing this color pigment was provided to EPA by a CPMA member company and is being evaluated.

Because C.I. Pigment Red 52 contains a metal in its structure, it is not suitable for analysis using the PBT Profiler. CPMA has not been able to identify any information which justifies the inclusion of this color pigment in the EPA Work Plan. Based on the foregoing information, we would expect that a future prioritization rule would classify C.I. Pigment Red 52 as a low priority for risk evaluation.

C.I. Pigment Yellow 65 – CAS 6528-34-3

The source for information cited by EPA for the toxicity of this color pigment is described as the:

"OECD.org, Canadian Categorization Results" from "the Ecological Categorization Results From the Canadian Domestic Substances List" which "provided underlying data regarding inherent toxicity to aquatic organisms". Email, Ms. Leslie Cronkhite, May 24, 2012

In fact, this color pigment was not classified by Environment and Climate Change Canada and Health Canada as being hazardous to human health and the environment during the categorization process:

http://www.ec.gc.ca/lcpe-cepa/eng/subs_list/DSL/DSLsearch.cfm?critSearch=CAS&critCAS=6528-34-3

The LC50 of 4.781 mg/l appears to be derived from models. We would refer EPA to the available summaries in the REACH dossier, which contains experimental information. For example, actual experimental water and octanol solubility values are much lower than those estimated from models. Aquatic toxicity studies show that there is no harm to the environment:

<http://echa.europa.eu/ja/registration-dossier/-/registered-dossier/5965>

Since the EPA PBT Profiler and EPISUITE computer models indicate that C.I. Pigment Yellow 65 is persistent, but not bioaccumulative, CPMA has not been able to identify any information which justifies the inclusion of this color pigment in the EPA Work Plan. www.pbtprofiler.net. Based on the foregoing information, we would expect that a future prioritization rule would classify C.I. Pigment Yellow 65 as a low priority for risk evaluation.

C.I. Pigment Yellow 83 – CAS 5567-15-7

The EPA states in its Benzidine Dyes Action Plan (2010), p.2, that:

In reviewing the benzidine congener-based pigments, EPA believes that the presence of pigments in such consumer products as printing inks, paints, plastics, and textiles was unlikely to present an exposure concern, because the pigments are not bioavailable and are not absorbed into the body (Environment Canada, 2009, Golka, et al, 2004, OECD, 2003.)

http://www.epa.gov/sites/production/files/2015-09/documents/dcb_action_plan_06232010.noheader.pdf

Consistently, Environment and Climate Change Canada and Health Canada reviewed C.I. Pigment Yellow 83 in their report entitled "Benzidine-based Substance Grouping for Certain Diarylide Yellow Pigments." The two agencies came to the joint conclusion that this and similar color pigments did not constitute a risk to human health and the environment:

http://www.ec.gc.ca/ese-ees/AE21E557-06F2-47BF-B6D1-F1CD20D82CD0/FSAR_Grouping-Azo-Pkg1-Diarylide_EN.pdf

The source cited by EPA for the toxicity of C.I. Pigment Yellow 83 was described as an:

"EPA Hazard Characterization Document; Supporting Chemical C.I. Pigment Yellow 83 includes a summary of health effects data submitted for SIDS Endpoints. The LC50 for acute mammalian toxicity is 1,750 mg/kg falls within the range of concentrations identified as moderate in the EPA Work Plan methods document." Email, Ms. Leslie Cronkhite, May 24, 2012.

The LC50 1,750 mg/kg from the CPMA Diarylide Pigment HPV Test Plan came from the 2003 OECD SIDS Dossier which concluded that there was no need for further study because these color pigments do not present a recognized risk to human health and the environment. The study cited was an acute oral ingestion study of a formulated product consisting of a one-third concentration of C.I. Pigment Yellow 83. The LD 50 for the formulated product was >5000 mg/kg. The 1,750 mg/kg value is the result of discounting based on concentration:

<http://webnet.oecd.org/hpv/ui/handler.axd?id=7450284D-EACC-4DD9-B1CB-24FAE5914EED>

The REACH dossier supports these conclusions as well and provides an extensive list of experimental testing results, including a water solubility 8.1µg/L.

Since the EPA PBT Profiler and EPISUITE computer models indicate that C.I. Pigment Yellow 83 is persistent, but not bioaccumulative, CPMA has not been able to identify any information which justifies the inclusion of this color pigment in the EPA Work Plan. www.pbtprofiler.net. Based on the foregoing information, we would expect that a future prioritization rule would classify C.I. Pigment Yellow 83 as a low priority for risk evaluation.

Conclusion

As the above discussion of these four color pigments indicates, the choice of information used by EPA and the application of that information during the EPA Work Plan scoring process produced significant errors in the scoring of these color pigments and their subsequent erroneous inclusion in the Work Plan. The final prioritization rule should ensure that EPA uses experimental data where it exists, the best inputs into the most current and appropriate models, and a process, consistent with TSCA Section 6(b)(1)(C), that allow stakeholders and the public adequate time to provide input at the beginning of the prioritization

process and to review and correct mistakes, such that low priority non-toxic substances, including color pigments, are not misidentified as high priority substances warranting expensive and time consuming risk assessment.

We hope this information is helpful to the EPA in allocating resources and appropriately classifying substances under its forthcoming prioritization protocol.

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

Sincerely,

A handwritten signature in blue ink that reads "David J. Wawer". The signature is written in a cursive style with a large, stylized 'D' and 'W'.

David J. Wawer
Executive Director