UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF CONGRESSIONAL
AND INTERGOVERNMENTAL RELATIONS

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

On behalf of the U.S. Environmental Protection Agency, I am writing in response to your letter dated January 30, 2019, to Acting Administrator Andrew Wheeler, in which you sought information related to studies considered in the Draft Risk Evaluation for Pigment Violet 29.

The EPA chose C.I. Pigment Violet 29 (PV29) as one of the first ten chemicals for risk evaluation under section 6(b) of the Toxic Substances Control Act (TSCA). In conducting a literature search and review, the EPA identified certain study reports on PV29 in the European Chemicals Agency (ECHA) database of registration dossier under the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) as relevant to the PV29 risk evaluation. Under REACH, the public has access to robust summaries, but not to the full study reports, as study owners fund the research underlying these studies, giving them significant commercial value and making them proprietary.

In developing the risk evaluation for PV29, the EPA was unable to identify any U.S. entity in possession of these studies from which the EPA could obtain the full studies through the exercise of its authorities under TSCA. Therefore, the EPA requested that the European companies voluntarily provide the Agency with their studies to assist in the development of the EPA's risk evaluation. In its request, the EPA provided the companies the ability to assert claims of business confidentiality for "voluntarily submitted information" pursuant to the EPA's general confidential business information (CBI) regulations, 40 CFR part 2, subpart B, §§ 2.201-2.215, rather than with claims of business confidentiality for information reported under TSCA, to which TSCA section 14 would apply. Because TSCA section 14(b)(2) applies only to those health and safety studies that are "submitted under" the Act, the TSCA section 14 CBI provisions do not apply to voluntarily submitted studies. As such, the draft risk evaluation incorrectly described the studies as TSCA CBI. Accordingly, the discussion in the final risk evaluation will reflect the EPA's final CBI determination on this issue.

Following the procedures set forth in the EPA's CBI regulations, the Agency is currently undergoing the process to make a determination on whether the studies are entitled to confidential treatment. Upon completion of the CBI substantiation process, the Agency may be able to release additional information and studies. The Agency is committed to transparency and the public review and comment process while, at the same time, ensuring adequate protection for properly substantiated CBI.

The Agency recognizes the importance of the Committee's need to obtain information necessary to perform its legitimate oversight functions and is committed to continuing to work with your staff on how best to accommodate the Committee's interests. We look forward to working with your staff to better understand your interests and priorities with respect to the documentation you have requested.

If you have further questions, you may contact me, or your staff may contact Travis Voyles in the EPA's Office of Congressional and Intergovernmental Relations at Voyles.Travis@epa.gov or (202) 564-6399.

Sincerely,

Troy M. Lyons
Associate Administrator

cc: The Honorable Greg Walden, Ranking Member