

ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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March 21, 2019

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Administrator Wheeler:

This letter follows our request from January 30 that you provide us with the health and safety studies considered in your draft risk evaluation of Pigment Violet 29 (PV29) under the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), which updated the Toxic Substances Control Act (TSCA).

As we noted at that time, TSCA does not allow health and safety studies submitted or used by the Environmental Protection Agency (EPA) under the Lautenberg Act to be protected as Confidential Business Information (CBI). EPA's decision to label those health and safety studies as CBI was contrary to the statute and has impaired transparency and public participation in the comment period for the PV29 risk evaluation. Although we received a response from you on February 15 acknowledging that the studies were not eligible for protection under TSCA, EPA did not provide the requested studies. We are, therefore, forced to renew that request.

In your response, you argued that you are protecting the health and safety studies that you relied on to make your decision under your general CBI regulations, rather than the specific CBI provisions established by the recent TSCA revisions. We appreciate your concession that the specific CBI provisions in TSCA do not support the protection of any health and safety studies as CBI. However, we take issue with your argument that you have separate, additional authority to mask health and safety information used under TSCA because that argument is contradicted by the plain language of the statute and your own regulations.

Section 14 of TSCA explicitly bars labeling as CBI any information obtained from health and safety studies. The Section applies, by its plain wording, to "any health and safety study

submitted under this Act”¹ and to “any information reported to, or otherwise obtained by, the Administrator from a health and safety study”² on a chemical offered for distribution in commerce. No one has contested that PV29 has been offered for distribution in commerce in the United States or that the Administrator has obtained information from those studies. The studies are thus excluded from protection under TSCA §14(b)(2)(B) because of your use of them, regardless of how they were obtained.

Further, your regulations make clear that the studies should also be excluded from protection under TSCA §14(b)(2)(A). In your response, you focused on the phrase “submitted under this Act” and argued that the studies were not submitted under the Act but were rather submitted to the Agency voluntarily. However, your regulations implementing section 14 of TSCA establish that:

“Information will be considered to have been provided under the Act if the information could have been obtained under authority of the Act, whether the Act was cited as authority or not, and whether the information was provided directly to EPA or through some third person.”³

Although you were unable to identify any U.S. entity in possession of the particular studies submitted to the European Chemical Agency on PV29 that you labeled as CBI, you easily could have obtained the information from U.S. entities manufacturing and distributing PV29. Section 4 and section 8 of TSCA provide ample authority to require those companies to generate or obtain the information for submission.

Turning to your suggestion that voluntarily-submitted health and safety studies can be protected under “general” CBI regulations, outside the requirements of TSCA, we refer you again to your own regulations. 40 CFR §2.202 states clearly that “the basic rules of §§2.201 through 2.215 govern except to the extent that they are modified or supplanted by the special rules of §§2.301 through 2.311.” As stated above, §2.306 provides special rules for information obtained under TSCA. Section 2.202 also establishes a preference for disclosure by stating that in cases of a conflict between two special rules, “the rule which provides greater or wider availability to the public of the information shall govern.”

We are alarmed by your efforts to skirt the balanced system of CBI protection established by the Lautenberg Act and reiterate our request for the health and safety studies considered in your draft risk evaluation on PV29. Please provide those studies to the Committee and make them available to the public no later than Monday, March 25.

¹ 15 U.S.C. 2613(b)(2)(A)

² 15 U.S.C. 2613(b)(2)(B)

³ 40 CFR §2.306

The Honorable Wheeler
March 21, 2019
Page 3

Thank you in advance for your expeditious consideration of these matters. If you have any questions, please contact Jacqueline Cohen with the Committee staff at (202) 225-4407.

Sincerely,

Handwritten signature of Frank Pallone, Jr. in blue ink.

Frank Pallone, Jr.
Chairman

Handwritten signature of Paul D. Tonko in blue ink.

Paul D. Tonko
Chairman
Subcommittee on Environment and
Climate Change

cc: The Honorable Greg Walden, Ranking Member

The Honorable John Shimkus, Ranking Member, Subcommittee on Environment and
Climate Change