UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
GENERAL COUNSEL

March 14, 2019

BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED AND EMAIL

Dr. Ulrich Veith
Head of Product Stewardship and Masterdata
BASF Colors & Effects Switzerland AG
Klybeckstrasse 141
4057 Basel, Switzerland

Re: Freedom of Information Act Request EPA-HQ-2019-001853; Final Confidentiality Determination

Dear Dr. Veith:

BASF Colors & Effects GmbH (or "BASF C&E GmbH") has asserted a claim of confidentiality for certain information contained within nine full study reports (referred to as "full study reports" or "studies") related to Pigment Violet 29 (also called "PV29").[1] These nine full study reports are among 24 full study reports described in EPA's draft risk evaluation of PV29 that are responsive to a Freedom of Information Act ("FOIA") request designated, EPA-HQ-2019-001853. By letter dated December 20, 2018, EPA requested that BASF C&E GmbH substantiate the company's claims of confidentiality to any of the 24 full study reports identified in the FOIA request ("request for substantiation") within 15 working days. EPA also sent a separate request for substantiation for the same full study reports to Sun Chemical Group Coöperatief U.A, the company that submitted the full study reports at issue to EPA under a data sharing agreement with BASF C&E GmbH. On January 11, 2019, you requested a 30-day extension to run from the end of the initial 15 working day deadline. Due to the lapse in appropriations of the U.S. federal government, EPA granted the request from BASF C&E GmbH on February 1, 2019. On February 5, 2019, the Agency received the Company's timely substantiation.

[1] The substantiation submission from BASF C&E GmbH, at page 1 and Attachment A, cites eight studies for which confidentiality claims are asserted. However, EPA's draft risk evaluation for PV29 treats one of these ("BASF 2013 study report. Physical-chemical properties of Paliogen Violet 5011. Study No. 11L00105," listed as entry 7 in the first list on Substantiation Attachment A) as two separate full study reports that share a cover page. Accordingly, for purposes of this CBI determination, EPA will continue to treat that submission as two separate full study reports.

BASF C&E GmbH substantiated confidentiality claims for portions of nine full study reports and the Company withdrew any confidentiality claims for the remaining full study reports in which BASF C&E GmbH has an interest.[2] Substantiation at 1. BASF C&E GmbH also simultaneously submitted to EPA sanitized versions of the nine full study reports with the confidential portions redacted. On February 8, 2019, Sun Chemical Group Coöperatief U.A. responded to the Agency's request for substantiation and indicated that Sun Chemical Group Coöperatief U.A. supported the claims made by BASF C&E GmbH and had no additional confidentiality claims. Email from Martjin Schoonenberg, Sun Chemical Group Coöperatief U.A. at 1.

EPA has carefully considered the substantiation provided by BASF C&E GmbH and the Program Recommendation from the EPA Office of Chemical Safety and Pollution Prevention ("OCSPP").[3] For the reasons stated below, the Agency finds that the information claimed as confidential qualifies for confidential treatment and is exempt from release pursuant to Exemption 4 of the Freedom of Information Act.[4] However, BASF C&E GmbH voluntarily waived any confidentiality claim for the unredacted information in the sanitized version of the nine full study reports and 15 full study reports.[5] Therefore, the sanitized versions of the nine full study reports may be released.

BACKGROUND

In December 2016, EPA announced it was conducting a risk evaluation of PV29. 81 Fed. Reg. 91927. TSCA Section 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Agency expects to consider as part of the risk evaluation. A thorough explanation of the risk evaluation process for PV29 and its current status is available on EPA's website at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-pigment-violet-29-anthra219-def6510.

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[2] BASF C&E GmbH's substantiation waived its confidentiality claims for 12 specific studies. However, one study the company identified, ("BASF. (1975c). Eye irritation / corrosion," listed as entry 3 in the second list on Substantiation, Attachment A), does not correspond to an individual study considered in the risk evaluation. Accordingly, this CBI determination reflects that there are 11, not 12, full study reports covered by the FOIA request for which no CBI claims are made.

[3] EPA also received two letters from third parties interested in the treatment of the CBI claims to the studies at issue. The first was a letter dated December 6, 2018 signed by representatives from six interested Non-Governmental Organizations expressing concern over the initial withholding of the 24 studies cited in the Draft Risk Evaluation. The second was a letter dated February 5, 2019 from the American Chemistry Council supporting the confidential treatment of the studies. Letter from Michael P. Walls, American Chemistry Council to Scott M. Sherlock dated February 5, 2019 ("ACC Letter").

[4] Appendix A to this determination provides a list of the 24 full study reports at issue in the FOIA request and the confidentiality status of each study.

[5] Of the remaining 15 full study reports covered by the FOIA request, four had been submitted to EPA by a third company, and one was originally obtained from the U.S. Food and Drug Administration (FDA). EPA sent a request for substantiation on December 20, 2018 to the company that had submitted four of the full study reports. That company responded on February 8, 2019 that it waived any confidentiality claims to those four full study reports. The full study report originally obtained from the FDA was later also received by EPA directly from the company that owned it. All confidentiality claims to that study have been waived as well.

As part of the risk evaluation process, EPA searched for reasonably available information to consider in its PV29 Risk Evaluation. In its search, EPA identified PV29 studies in the European Chemicals Agency ("ECHA") database. EPA determined that due to the process established by the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") regulation in the European Union, ECHA only had access to what are called "robust summaries" of the studies and did not possess the full study reports. From June to November 2017, EPA discussed acquisition of the full study reports from their European owners, ultimately obtaining 19 of the full study reports from a Dutch company, Sun Chemical Group Coöperatief U.A., by way of a limited license agreement between it and BASF Colors & Effects GmbH, the German company that owned the studies. EPA did not exercise any statutory authority under TSCA to secure any of these full study reports. Rather, EPA requested that Sun Chemical Group Coöperatief U.A. voluntarily submit the studies the Company obtained from BASF C&E GmbH under the licensing agreement. Sun Chemical Group Coöperatief U.A. submitted the full study reports to EPA with the understanding that they were voluntarily submitted and claimed all 19 of the full study reports as confidential on behalf of itself and the owner of the studies, BASF C&E GmbH.

DISCUSSION

In its substantiation, for each of the nine full study reports, BASF C&E GmbH provided a basis for confidentiality claims made for the names of individuals at the laboratory that conducted the study (but not their titles), and for contact information for the study author(s) and study sponsor. Substantiation at 8. Additionally, the Company claimed as confidential "certain data or data tables and certain BASF-related information" in one full study report. *Id.* at 8. This decision addresses whether the information claimed as confidential falls within Exemption 4.[6]

Exemption 4 of the FOIA exempts from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). In order for information to meet the requirements of Exemption 4, the Agency must find that the information is either (1) a trade secret; or (2) commercial or financial information obtained from a person and privileged or confidential.

I. TRADE SECRET

The definition of "trade secret" under the FOIA is limited to "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1288 (D.C. Cir. 1983). This definition requires that there be a "direct relationship" between the information and the production process. *Id.* BASF C&E GmbH has neither asserted a claim that

[6] BASF C&E GmbH's substantiation also argued that the names and contact information are exempt from disclosure pursuant to FOIA Exemption 6 as personal information. Because this information is withheld under Exemption 4, this decision does not address whether Exemption 6 also applies.

any of the information at issue is a trade secret, nor has the Company explained how the Agency's release of any of this information would identify a plan, formula, process, or device. Thus, the Company has not demonstrated how disclosure of the information at issue would identify or reveal a trade secret. Consequently, EPA finds that the information does not constitute a trade secret.

II. CONFIDENTIAL BUSINESS INFORMATION (CBI)

If the information does not reveal a trade secret, it may still be exempt from release under Exemption 4 of the FOIA if it is confidential business information, i.e., "commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). The terms "commercial" or "financial," for purposes of Exemption 4 of the FOIA, "should be given their ordinary meanings." *Pub. Citizen*, 704 F.2d at 1290 (citing *Washington Post Co. v. HHS*, 690 F.2d 252, 266 (D.C. Cir. 1982)). The information at issue relates to a business, thereby meeting the ordinary definition of "commercial." BASF C&E GmbH also meets the definition of the term "person," as defined by EPA's regulations at 40 C.F.R. § 2.201(a).

To be exempt from release under Exemption 4 of the FOIA as confidential business information, the information must also be "privileged or confidential." BASF C&E GmbH has claimed this information to be confidential, but the Company has not claimed this information to be privileged. The Agency has no indication that the information is subject to a common-law privilege and will therefore limit its discussion to the issue of confidentiality. For purposes of FOIA Exemption 4, the standard to determine whether information is confidential depends on whether the affected business *voluntarily* submitted the information or provided it as a *required* submission. EPA regulations at 40 C.F.R. § 2.208(a)-(e) implement these standards. This determination first discusses each element of § 2.208(a)-(c), then determines the voluntariness of the submissions under 2.208(e) and the applicable legal standards. Since discussion on the applicability of other statutes under 40 C.F.R. § 2.208(d) is predicated on the determination that the submission was or was not voluntarily submitted, that section is discussed last.

1. Threshold Requirements - 40 C.F.R. § 2.208(a)-(c)

EPA's regulations at 40 C.F.R. § 2.208(a)-(c) implementing the Agency's analysis under FOIA Exemption 4 set forth the threshold requirements that for business information to be entitled to confidential treatment, the Agency must have determined that, *inter alia*:

> (a) The business has asserted a claim of confidentiality and that claim has not expired by its terms, nor been waived, nor withdrawn;
> (b) The business has satisfactorily shown that it has taken reasonable measures to protect the confidentiality of the information, and that it intends to continue to take such measures;
> (c) The information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means (other than

> discovery based on a showing of special need in a judicial or quasi-judicial proceeding).

40 C.F.R. § 2.208(a)-(c).

In its substantiation, BASF C&E GmbH stated that the Company sought confidential treatment for the information permanently or for a minimum of ten years if EPA requires a time frame; that no interceding events have negated your previous claim; and that the information has not become stale. Substantiation at 9. The Company has shown that it has taken, and continues to take, reasonable measures to protect the confidentiality of the information and that the information has not been obtained by a third party without the Company's consent. *Id.* at 10-12. In addition, Sun Chemical Group Coöperatief U.A. entered into a data sharing agreement with BASF C&E GmbH stating that it would not release the information to anyone other than EPA. *Id.*, Attach. 2. In that agreement, Sun Chemical Group Coöperatief U.A. also agreed to treat the information as confidential and to take measures to protect the confidentiality of the information. *Id.*, Attach. 2, at 2. In EPA's analysis of this matter, the Agency has not found any reason to doubt these assertions by BASF C&E GmbH. Since the information claimed as confidential meets the threshold requirements of 40 C.F.R. § 2.208(a)-(c), we will move on to the remainder of the FOIA analysis to determine whether the information otherwise meets the definition of confidential business information under 40 C.F.R. § 2.208(d)-(e).

2. *Voluntary Submission – 40 C.F.R. § 2.208(e)*

Two distinct standards have been established to determine whether information submitted to a federal agency is "confidential" under Exemption 4 of the FOIA. This distinction is based on whether the affected business voluntarily submitted the information or provided it as a required submission. In the Company's substantiation, BASF C&E GmbH claims that the full study reports at issue were submitted voluntarily to EPA. Substantiation at 9-16. This sub-section addresses the threshold issue of whether the studies' submission was voluntary or required and then whether the redacted information is entitled to confidential treatment.

EPA's regulation at 40 C.F.R. § 2.201(i) defines "voluntarily submitted information" to mean business information in EPA's possession:

> (1) The submission of which EPA had no statutory or contractual authority to require; and (2) the submission of which was not prescribed by statute or regulation as a condition of obtaining some benefit (or avoiding some disadvantage) under a regulatory program of general applicability…

As noted in BASF C&E GmbH's substantiation, EPA specifically asked Sun Chemical Group Coöperatief U.A. to voluntarily provide the full study reports. Substantiation at 13. Sun Chemical Group Coöperatief U.A. voluntarily submitted BASF C&E GmbH's full study reports to EPA with BASF C&E GmbH's consent. *Id.* at 2, 5-6. BASF C&E GmbH explained that the studies cannot be considered required submissions because they were not submitted by either

company under EPA's TSCA authority. *Id.*, 4-6. Further, BASF C&E GmbH claims that since these studies were not submitted to EPA under TSCA, only EPA's general FOIA CBI regulations should apply, rather than any TSCA-specific CBI standards under TSCA section 14 or 40 C.F.R. § 2.306. *Id.* at 6.

The Agency finds that the information was submitted voluntarily. In the absence of clear congressional intent, statutes are presumed to apply only within the territorial jurisdiction of the United States. *EEOC v. Arabian Am. Oil. Co.*, 499 U.S. 244, 248 (1991). EPA has identified no clear congressional intent involving TSCA jurisdiction that would overcome this presumption against extraterritoriality for purposes of examining whether the studies at issue in this case were voluntarily submitted. The owner of the full study reports (BASF C&E GmbH, located in Germany) and the data submitter/licensee (Sun Chemical Group Coöperatief U.A., located in The Netherlands) are European companies that do not manufacture, process, or distribute chemical substances in the United States, and are therefore considered to be outside the territorial jurisdiction of the United States for purposes of this determination. Substantiation at 6. Based on the information in EPA's possession, EPA lacked statutory authority under TSCA (including under TSCA sections 8(a), 8(d) and 11(c)) to compel BASF C&E GmbH and Sun Chemical Group Coöperatief U.A. to submit the studies.

While both BASF C&E GmbH and Sun Chemical Group Coöperatief U.A. have U.S. affiliates or subsidiaries that would be subject to TSCA, those affiliates/subsidiaries (BASF Colors & Effects USA and Sun Chemical Corporation, respectively) did not own or possess the studies, and did not submit the studies to EPA. Those U.S. affiliates/subsidiaries are separate and distinct legal entities from the entities that owned and submitted the studies at issue. Moreover, based on the information in EPA's possession, EPA could not establish under the facts and circumstances of this case that the European companies' U.S. affiliates/subsidiaries had control over the nine studies in the European companies' possession, such that EPA could have obtained the nine studies from the European companies by issuing and enforcing a subpoena against the U.S. affiliates/subsidiaries under TSCA section 11(c). *See generally U.S. Int'l Trade Comm'n v. ASAT, Inc.*, 411 F.3d 245, 253-54 (D.C. Cir. 2005).

Finally, to be considered voluntarily submitted, 40 C.F.R. § 2.201(i) also requires that the information was not submitted to the Agency as a condition of obtaining some benefit or avoiding some disadvantage. Based on the information in EPA's possession, neither BASF C&E GmbH nor Sun Chemical Group Coöperatief U.A. submitted any of the full study reports to EPA as a condition of obtaining some benefit (or avoiding some disadvantage) under TSCA or its implementing regulations.

For the above reasons, the Agency concludes that the information was voluntarily submitted to EPA. The determination will now discuss whether the redacted information qualifies for Exemption 4 confidential treatment under legal standards for voluntary submissions. First, the standard found in EPA's regulations at 40 C.F.R. § 2.208(e)(2) is examined, then the Court's analysis in *Critical Mass Energy Project v. Nuclear Regulatory Commission*, 975 F.2d 871, 879 (D.C. Cir. 1992) (en banc), *cert. denied*, 507 U.S. 984 (1993) is applied.

a. *Disclosure would be likely to impair EPA's ability to obtain necessary information in the future. (40 C.F.R. § 2.208(e)(2)).*

Under EPA's regulations, information submitted voluntarily is entitled to confidential treatment if "its disclosure would be likely to impair the Government's ability to obtain necessary information in the future." 40 C.F.R. § 2.208(e)(2).[7] The inquiry focuses on whether the submitting entities would not provide such information in the future if it were subject to public disclosure. *See, e.g., Inner City Press/Cmty. on the Move v. Bd. of Governors of Fed. Reserve Sys.*, 463 F.3d 239, 242 (2d Cir. 2006) (citing *Nadler v. FDIC*, 92 F.3d 93 (2d Cir. 1996)). Conversely, protection under the impairment prong may be denied when disclosure will not, in fact, diminish the flow of information to the agency -- for example, when the benefits associated with submission of particular information make it unlikely that the agency's ability to obtain future such submissions would be impaired. *See, e.g., McDonnell Douglas Corp. v. U.S. Dep't of the Air Force*, 215 F. Supp. 2d 200, 205 & n.3 (D.D.C. 2002), *aff'd in part & rev'd in part on other grounds*, 375 F.3d 1182 (D.C. Cir. 2004), *reh'g en banc denied*, No. 02-5342 (D.C. Cir. Dec. 16, 2004).

In the Company's substantiation, BASF C&E GmbH explained that:

> European data owners are very unlikely to provide EPA with confidential studies, however, if they know that EPA will make those studies publicly available. Data owners have invested large sums in paying for those studies to be conducted. The studies have commercial value that public release would destroy, at least in part. Accordingly, they would have a substantial disincentive to provide confidential studies to EPA if EPA will not keep them confidential. Certainly, BASF C&E and its European affiliates would be very unlikely to authorize additional submission of confidential studies to EPA if EPA makes full copies of the Studies public.

Substantiation at 7. Consistent with the Company's substantiation, the American Chemistry Council stated that:

> If EPA rejects the confidentiality claims here and releases the complete, unredacted copies of the studies of interest, it will send a clear message to foreign owners of relevant data who may consider voluntarily submitting to EPA studies they have generated. The message would be that foreign companies (particularly European companies who have considerable information as a result of the REACH regulation) who are not subject to TSCA cannot—or should not—rely on EPA to maintain the confidentiality of their voluntarily-submitted and commercially valuable studies. It should

[7] This use of the "impairment prong" for voluntary submissions set forth in EPA regulations – which predate the D.C. Circuit's *Critical Mass* decision - follows the standard for voluntary submissions still in use by courts outside of the D.C. Circuit. *See, e.g., Nadler v. FDIC*, 92 F.3d 93, 96 n.1 (2d Cir. 1996); *O'Harvey v. Comp. Programs Workers*, 188 F.3d 514 (9th Cir. 1999); *Frazee v. U.S. Forest Serv.*, 97 F.3d 367, 372 (9th Cir. 1996).

> be clear that this result would have a detrimental impact on EPA's ability to obtain confidential studies cited in REACH or other dossiers generated in foreign jurisdictions.

Letter from Michael P. Walls, American Chemistry Council to Scott M. Sherlock dated February 5, 2019 ("ACC letter"). EPA sought the full study reports at issue to conduct the risk evaluation for PV29. These full study reports enhanced EPA's risk evaluation process for PV29 and allowed the Agency to efficiently proceed with the evaluation process on a reasonable timeline consistent with EPA's statutory deadlines. In its program recommendation on this matter, EPA OCSPP agreed with the reasoning in the Company's substantiation that release of the full study reports would be likely to impair EPA's ability to receive similar full study reports generated and stored in foreign states in the future. As noted in the letter from the American Chemistry Council, European companies have considerable information that could be useful for EPA's future risk evaluations. ACC Letter at 1. The inability to receive similar studies from foreign entities in the future would likely impair the Agency's ability to efficiently obtain and consider information necessary for conducting risk evaluations, a process that is central to EPA's duties and obligations under TSCA. The Agency concludes that if EPA were to release the information at issue, then foreign entities such as BASF C&E GmbH would not be likely to provide similar studies containing the type of information necessary for EPA to conduct risk evaluations in the future. *See Critical Mass.*, 975 F.2d at 879 ("It is a matter of common sense that the disclosure of information the Government has secured from voluntary sources on a confidential basis will both jeopardize its continuing ability to secure such data on a cooperative basis and injure the provider's interest in preventing its unauthorized release").

For these reasons, the Agency finds that disclosure of any of this information would be likely to impair the Government's ability to obtain necessary information in the future.

b. *The Withheld Information Meets the Critical Mass standard*

The Agency also recognizes that the United States Court of Appeals for the D.C. Circuit has held that information submitted to the Government on a voluntary basis should be exempt from disclosure "if it is of a kind that would customarily not be released to the public by the person from whom it was obtained." *Critical Mass*, 975 F.2d at 879 (D.C. Cir. 1992). The Agency's review must be objective and "must meet the burden of proving the provider's custom." *Id.* Courts have not articulated a clear standard for whether information has been customarily disclosed to the public, but they do offer guidance. Information that has been previously disclosed may nonetheless receive Exemption 4 protection as long as the submitter has not made the kind of information being claimed as CBI available to the general public. *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 244 F.3d 144, 151-53 (D.C. Cir. 2001).

In its substantiation, BASF C&E GmbH explained that the information at issue is not customarily released to the public. Substantiation at 13. In fact, the European Chemical

Agency, the entity that regulates chemicals in the European Union, only requires the submission of a "robust study summary," which does not include the information at issue.[8] As a result, these full study reports are not publicly available nor received by the European Chemical Agency. Further, BASF C&E GmbH has explained that the full study reports have value, and accordingly, it does not disclose this information. *Id.* at 11-13, 16-17. For example, BASF C&E GmbH explained that disclosure of the redacted names could allow competitors to try to recruit or otherwise obtain confidential information from the identified individuals. *Id.* at 8. Likewise, competitors could take advantage of using the data without paying for its use. In its analysis of this matter, the EPA has not found any reason to doubt BASF C&E GmbH's assertion that the withheld information is not customarily disclosed.

Therefore, the Agency finds that the redacted information in the full study reports is not customarily disclosed, and accordingly the information is entitled to confidential treatment under the *Critical Mass* standard.

3. No Statute Requires Disclosure - 40 C.F.R. § 2.208(d)

EPA's regulations also consider whether any statute requires disclosure of the information at issue. 40 C.F.R. § 2.208(d). Because the studies are being used by EPA in the context of a TSCA risk evaluation, the Agency considers whether TSCA section 14 requires disclosure.

TSCA section 14 states that its provisions only apply to information "reported to, or otherwise obtained by, the Administrator under" TSCA. TSCA § 14(a)(1). This language describing TSCA section 14's applicability has remained substantively unchanged since TSCA's original enactment in 1976. *See* TSCA § 14(a) (1976) ("any information reported to, or otherwise obtained by, the Administrator (or any representative of the Administrator) under this Act").[9]

EPA's use of a third party's information for EPA's TSCA work does not automatically mean that EPA obtained that information under TSCA. EPA regulations implementing TSCA section 14 provide in relevant part that "[i]nformation 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." 40 C.F.R. § 2.306(b). These regulations distinguish between information that meets this description (i.e., information that is or could have been acquired under statutory authority of TSCA), and "voluntarily submitted information" to which the TSCA

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[8] *See* "How to report robust study summaries, Practical Guide 3, European Chemicals Agency" Version 2.0, (November 2012), at p. 7 *available at*:
https://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf

[9] TSCA section 14(b)(2) also states that any health and safety study submitted under TSCA with respect to a chemical substance or mixture offered for commercial distribution is not exempt under the FOIA as confidential business information. Assuming *arguendo* that the full study reports at issue could be considered health and safety studies, the threshold question to consider in whether TSCA requires disclosure is whether the EPA obtained the full study reports *under* TSCA.

CBI provisions do not apply. *Id.* § 2.306(g); *see* 43 Fed. Reg. 39997, 40008 (Sept. 8, 1978); 43 Fed. Reg. 2637, 2639 (Jan. 18, 1978). EPA explained when proposing these regulations that, "No information to which § 2.306 would apply would be voluntarily submitted information because it is (or could be) required to be submitted under TSCA." 43 Fed. Reg. at 2639. But as EPA clarified when finalizing these rules, "[t]his does not mean that EPA would not receive information that relates to [TSCA] that is voluntarily submitted." 43 Fed. Reg. at 40008. That is, EPA may receive voluntarily submitted information that relates to TSCA but is not obtained under TSCA, and thus is not subject to TSCA section 14 or 40 C.F.R. § 2.306.[10]

Applying this standard, EPA did not obtain the Company's full study reports under TSCA. As explained above, the Agency has concluded that the information was voluntarily submitted to EPA and that it was not, and could not have been, acquired under statutory authority of TSCA. Therefore, TSCA section 14 and 40 C.F.R. § 2.306 do not govern the studies, and TSCA section 14(b)(2) does not require their disclosure. As neither TSCA nor any other statute requires disclosure of the redacted information, the Agency finds that the criterion under 40 C.F.R. § 2.208(d) has been met.

Lastly, the Agency recognizes that its November 15, 2018 draft risk evaluation stated that the full study reports "contain information protected under statute as Confidential Business Information ("CBI") by the Toxic Substances Control Act (TSCA)." PV29 Draft Risk Evaluation at 6, 20. This statement was an error. A CBI determination had not been completed when the statement was made. As discussed in this determination, the Agency finds that the full study reports at issue here were submitted voluntarily, not pursuant to TSCA.

CONCLUSION

The Agency hereby finds that the information redacted by BASF C&E GmbH in the nine studies at issue is entitled to confidential treatment. Therefore, this information is withheld under Exemption 4 of the FOIA. Pursuant to EPA's regulations at 40 C.F.R. § 2.205(f), this constitutes the final EPA determination concerning BASF C&E GmbH's business confidentiality claims.

For your reference, in response to the above-referenced FOIA Request EPA-HQ-2019-001853, EPA will release the studies for which no claims were made and the sanitized versions of the studies containing confidential business information in the PV29 risk evaluation docket: Docket ID No. EPA-HQ-OPPT-2018-0604 at http://www.regulations.gov.

[10] Recent amendments to TSCA by the Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016 did not change this understanding. As amended, TSCA section 14(a) generally applies the FOIA Exemption 4 standard for treating information as confidential, but section 14(c) only speaks to the confidentiality standard for required submissions. The two provisions would be in conflict if section 14 were understood to apply to voluntary submissions as well.

Should you have any questions concerning this matter, please call Casey Pickell at (202) 564-2962.

Sincerely,

Kevin M. Miller
Assistant General Counsel
General Law Office
Office of General Counsel
U.S. Environmental Protection Agency

cc: Scott M. Sherlock, Office of Chemical Safety & Pollution Prevention
Mark Duvall, Beveridge & Diamond, P.C.