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Re: In The Matter of Elementis Chromium, Inc.
Docket No. TSCA-HQ-2010-5022

Dear Sir or Madam:

Enclosed for filing, please find the Appeal Brief of Appellant, Elementis Chromium Inc., in the above-referenced matter.

Thank you for your assistance and cooperation.

Respectfully submitted,

John J. McAleese III

JJM:drw

Enclosure

cc: Honorable Susan L. Biro (via Overnight Courier)
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BEFORE THE ENVIRONMENTAL APPEALS BOARD
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

In the Matter of:	)	
Elementis Chromium Inc., f/k/a Elementis Chromium, L.P.,	)	Docket No. TSCA-HQ-2010-5022
Appellant.	)	

APPEAL BRIEF OF APPELLANT ELEMENTIS CHROMIUM INC.

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I. INTRODUCTION

On November 25, 2013, Appellant Elementis Chromium Inc. ("Elementis") filed a Notice of Appeal to challenge the Initial Decision of Chief Administrative Law Judge Susan L. Biro in the action styled *In the Matter of Elementis Chromium Inc.*, Docket No. TSCA-HQ-2010-5022. In conjunction with the Notice of Appeal, Elementis and the United States Environmental Protection Agency (the "Agency" or "EPA") filed a Joint Motion for Enlargement of Time to file Elementis' Appeal Brief and EPA's Response Brief to January 15, 2014 and February 24, 2014, respectively. The Board granted the motion on December 5, 2013.

The underlying matter involves the Agency's enforcement action brought against Elementis alleging that Elementis violated Sections 8(e) and 15(3)(B) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. §§ 2607(e) and 2614(3)(B), by failing to submit to EPA an epidemiological study (the "Four Plant Study" or "Final Four Plant Report") Elementis received in October 2002. Section 8(e) of TSCA, entitled "**Notice to Administrator of substantial risks**" provides that:

> Any person who manufactures, processes, or distributes in commerce a chemical substance or mixtures and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

15 U.S.C. § 2607(e).

The bases for Elementis' appeal are: 1) the Agency brought this enforcement action in September 2010, beyond the five-year statute of limitations period that applies to such actions and Chief Judge Biro therefore erred in refusing to grant judgment to Elementis on that basis; and 2) Chief Judge Biro incorrectly concluded on the merits that the epidemiological report at issue was required to be submitted pursuant to TSCA Section 8(e). The appeal arises on a record

that includes, most notably: (a) an Elementis motion for judgment on the pleadings (and the Agency's opposition) based on Elementis' statute of limitations defense, (b) Chief Judge Biro's written opinion denying the motion, (c) a multi-day merits hearing held in December 2011, involving substantial evidentiary submissions from both sides, including party stipulations, witness testimony, and documentary submissions, and (d) Chief Judge Biro's final written Initial Decision issued in November 2013.

II. STATEMENT OF ISSUES PRESENTED FOR REVIEW

The following issues are presented for review:

A. Whether Chief Judge Biro erred in concluding that the five-year statute of limitations on the Agency's claim against Elementis had not expired by the time the Agency brought its Complaint in September 2010?

B. Whether Chief Judge Biro erred in concluding that the report at issue was required to be submitted pursuant to TSCA Section 8(e)?

III. STATEMENT OF NATURE OF CASE AND FACTS RELEVANT TO ISSUES PRESENTED FOR REVIEW

A. FACTUAL HISTORY RELATED TO THE FINAL FOUR PLANT STUDY AND OTHER STUDIES

Much in this case – at least factually – is not in dispute, as is revealed through the direct trial testimony and Chief Judge Biro's own conclusions regarding what was common ground. First, it has been well known for at least 60 years that hexavalent chromium is a human carcinogen. Tr. at 1034 (Gibb).[1] Following World War II, several studies of United States chromate production workers reported an increased risk of lung cancer over the risk faced by the general population. CX 62 at 2. Nor has EPA itself been shy in either asserting this fact or in directly establishing it through its own studies. For example, in 1984, EPA itself determined that there was a linear relationship between airborne exposure to hexavalent chromium and the risk of

[1] References to the record in this case will be abbreviated in this Appeal Brief as follows: Hearing Transcript, Tr.; Joint Exhibits, JX; Complainant's Exhibits, CX; and Respondent's Exhibits, RX.

lung cancer. RX 25 at 27. Similarly, in 2000, Dr. Herman Gibb, EPA's then-Assistant Center Director for the National Center for Environmental Assessment, published an EPA-funded study in the American Journal of Industrial Medicine (the "Gibb Study"). That study, based on a cohort of 2,357 workers employed at a chromate production plant in Baltimore, Maryland, CX 62 at 1, concluded that certain cumulative hexavalent chromium exposure levels were associated with an increased lung cancer risk and that the risk rises as cumulative exposure increases. CX 62 at 1; Tr. at 1037 (Gibb); Opinion at 38. Much of this case turns on what, if anything, the Four Plant study added to this widely known, and well-established, understanding.

In 1998, the Chromium Chemicals Health and Environmental Committee (the "Chromium Committee") of the Industrial Health Foundation ("IHF") retained Applied Epidemiology to conduct an epidemiology study based on records of workers at five chromium manufacturing facilities. CX 45. Elementis, along with Occidental Chemical Corporation ("Occidental") and Bayer AG ("Bayer") were the industry members of the Chromium Committee at the time Applied Epidemiology was retained. Tr. at 649 (Mundt); Tr. at 964 (Barnhart). The five plants proposed for the study were owned and operated by the three member companies, with one being owned by Occidental (Castle Hayne, North Carolina), two being owned by Bayer (Leverkusen and Uerdingen) and two being owned by Elementis (Corpus Christi, Texas and Eaglescliffe, England).[2] Tr. at 653-654 (Mundt); CX 45 at 11-22. In commissioning the Final Four Plant Study, the Committee anticipated that the results could be published in scientific journals and, indeed, insured that the final decision on the Final Four Plant Study's content would rest with the Study's author and that whether to publish the results also would rest not with them, as industry members, but with the Dr. Mundt. CX 45 at 4.

[2] In 1999, it became apparent that the data from Elementis' Eaglescliffe, England plant would not be compiled in time to be included in the study. This plant was thus eliminated from the study, resulting in just four plants in the study. Tr. at 967-968 (Barnhart).

From 1998 to 2002, Dr. Kenneth Mundt of Applied Epidemiology conducted the Chromium Committee requested study and in October 2002 produced the Final Four Plant Report providing his findings. RX 12, CX 1. It is undisputed that Applied Epidemiology's study found that only those workers who fell into the highest group of cumulative exposure showed an increased risk of lung cancer when compared to the general population. Tr. at 698, 737-742 (Mundt); CX 1 at 98, Opinion at 38. More specifically, as detailed in the Final Four Plant Report and as Dr. Mundt explained at the hearing, the study evaluated the relationship between cumulative total exposure (sometimes also referred to as "dose") and reported lung cancer. CX 1 at 89-90; Tr. at 737-742. That evaluation revealed that only those workers whose total cumulative exposures were in the fourth (highest) quartile had a statistically significant increase in cancer risk. Tr. at 737 (Mundt); CX 1 at 89 ("we identified an increase in lung cancer mortality among those with the highest cumulative exposures"). For this fourth quartile, *i.e.* those with exposure greater than 200 micrograms per liter years (a measure of cumulative exposure related to chromium levels found in urine), "there's roughly a doubling of the risk that is statistically significant." *Id.* Conversely, and in sharp contrast, for workers in the three other, lower exposure quartiles, the study did not find any statistically significant increase in the risk of lung cancer when compared to the general population. Tr. at 737-742 (Mundt); CX 1 at 90 ("For cumulative concentrations less than 200 ug/L-years, however, there was no excess mortality from lung cancer"); Opinion at 38 ("[t]here is no dispute that the only excess cases of lung cancer reported by the Final Report . . . were within the highest exposure category"). Moreover, the study did not identify *any* increased risk of lung cancer in the workers at the Elementis plant

located in Corpus Christi, Texas.[3] Tr. at 1042-1043 (Gibb). Put another way, the excess risk resulted from a higher than normal cancer risk among the most highly exposed German plant workers, rather than those in the United States. Tr. at 923 (Mundt). This appeared to have occurred because production processes at use in the German plants, and changes to those processes to reduce exposure made over five or more years, Tr. At 656 (Mundt), had still allowed higher cumulative exposures to some workers in the German cohort. Tr. at 997-998 (Barnhart).

Thus, the Final Four Plant Report confirmed what the industrial health community and, most importantly, EPA, already knew: higher cumulative exposure to chromium is associated with an increased risk to lung cancer. CX 1 at 89-90; Tr. at 1034, 1037 (Gibb); Opinion at 38 ("no party disputes that the two studies [Gibb and Final Four Plant] show the same general trend, i.e. that as exposure increases so does cancer risk"). Moreover, it is undisputed that the Final Four Plant Report offered nothing new concerning risks at the lower levels of exposure. This was for two reasons. First, as Dr. Mundt explained, for the lowest three exposure quartiles, the Final Four Plant Report showed no increased risk through cumulative exposure when compared to a general population. Tr. at 737 (Mundt). As to those groups, the study necessarily could not have revealed new "risk" information – instead, the study showed the absence of risk. Second, it is undisputed that the cumulative exposure level at which risk *was shown* in the Final Four Plant Report was a cumulative exposure level *much higher* than the cumulative exposure level at which Dr. Gibb's study had already shown risk to be present. Tr. at 1076 (Gibb); Tr. at 1097-1098 (Speizer); Tr. at 436-440 (Clapp); Tr. at 241 (Cooper); Opinion at 38 ("[t]here is also no

[3] The study also did not identify any increased risk of lung cancer at the other United States plant, the Occidental plant in Castle Hayne, North Carolina, which was purchased by Elementis in December 2002. Tr. at 1042-1043 (Gibb).

dispute that the Gibb Study showed statistically significant risk at lower cumulative exposures than the Final Report").

Applied Epidemiology's finding of elevated risk among the highest exposed workers in the two German plants, plants where there had been delays in process changes, was entirely consistent with findings of many prior epidemiologic studies, including the EPA-funded Gibb Study. Tr. at 1057 (Gibb). That is, given that the Final Four Plant Report showed a statistically significant increased risk of cancer to those in the highest exposure group and no such increased risk in the lower three exposure groups, the Final Four Plant Report simply corroborated what Gibb and other studies had shown – *i.e.*, that cumulative hexavalent chromium exposures at certain higher levels was associated with an increased lung cancer risk. Tr. at 1037 (Gibb). Indeed, the Final Four Plant Report itself nicely summed up its result and its place as to what was already known, stating: "Consistent with other recent studies attempting to quantitatively assess occupational chromium exposure and lung cancer, this study demonstrates a modest overall increase in risk among exposed cohort members, largely limited to those in the highest exposure categories." CX 1 at 18. As further confirmation that the substantial risk finding of the Final Four Plant Report simply confirmed the findings of the Gibb Study, despite both EPA and OSHA having had access to the study results for many years, neither agency has concluded that any changes in regulatory information or standards are called for due to the Final Four Plant Study's results. Tr. at 259-260 (Cooper); Tr. at 1139 – 1151 (Eden).

Dr. Joel Barnhart of Elementis testified that when he received the Final Four Plant Report in 2002, he was aware of the Mancuso study, which EPA used in its 1984 Health Assessment document to generate its cancer potency calculation. Tr. at 995 (Barnhart). Also, Dr. Barnhart knew from EPA's 1984 Health Assessment that EPA believed there was a linear relationship

between risk of cancer and exposure to hexavalent chromium. Tr. at 995 (Barnhart). In addition, by the time Dr. Barnhart received the Final Four Plant Report in 2002, he believed that "everyone working in the plants as well as the people working in the field of understanding the risks would say that the relationship is the greater the exposure, the higher the risk." Tr. at 996 (Barnhart).

More specifically, Dr. Barnhart was also well aware of the Gibb Study, which was published in 2000. Tr. at 984 (Barnhart). Dr. Barnhart further testified that he had attended a presentation of the Gibb Study by Dr. Gibb or one of his co-authors while it was being developed. Tr. at 984 (Barnhart). Thus, Dr. Barnhart testified that after receiving the Final Four Plant Report, he compared it to the Gibb Study and concluded that the information did not show greater risk and was not something that needed to be reported because it was not different than the information EPA already had obtained through the Gibb Study. Tr. at 981-984; 990-991 (Barnhart). Moreover, as to the Gibb Study, he knew that EPA had funded it and, therefore, that "EPA would be knowledgeable and know that it was going on." Tr. at 984 (Barnhart). Dr. Barnhart testified that given Dr. Gibb's employment with EPA at the time, he "believed that EPA had knowledge of the Dr. Gibb Study." Tr. at 985-986 (Barnhart). In sum, because of this, *i.e.* because the Final Four Plant Report did not show risk at cumulative exposure levels any lower than Gibb had already established, Dr. Barnhart believed that the Final Four Plant Report did not need to be provided to EPA pursuant to Section 8(e) of TSCA. Tr. at 985-986 (Barnhart).[4]

Although the companies (Bayer, Elementis and Occidental) were not required to provide the Final Four Plant Report to EPA pursuant to TSCA, Applied Epidemiology widely shared the

[4] EPA has not disputed that it had actual knowledge of the Gibb Study, nor plausibly could it, given that it paid for the study, Dr. Gibb was an EPA employee at the time he conducted the study, and EPA gave Dr. Gibb a major award, based on the study's importance. Tr. at 1027-1028 (Gibb).

Report's findings with independent reviewers, as well as with the epidemiology expert community.[5] Tr. 705 -714 (Mundt). In fact, prior to providing the Final Four Plant Report to the Chromium Committee in October 2002, Applied Epidemiology presented the study's finding to an international conference of epidemiologists in Barcelona in September 2002. Tr. at 704-705 (Mundt). At this conference, Dr. Mundt received substantial negative comments from his peers on methodologies employed in the Four Plant Study. Tr. 712 -714 (Mundt), comments that led him to conclude he would need to substantially rework the study, and actually convert it into two separate scientific papers to satisfy peer review standards for publication. Tr. at 887-889 (Mundt).

B. PROCEDURAL HISTORY OF THE PROCEEDING

On September 2, 2010, nearly eight years after the Final Four Plant Study was received by Elementis, EPA filed the Complaint in this action, alleging that Elementis was required to provide the Final Four Plant Report to EPA pursuant to Section 8(e) of TSCA "immediately" upon Elementis' receipt of the Report in October 2008. *See* Complaint. EPA alleged that Elementis' failure to do so violated TSCA Section 8(e) of TSCA, and EPA sought penalties for each day that Elementis failed to provide the Report. Complaint, Section III. On December 15, 2010, Elementis filed a Motion for Judgment on the Pleadings on the grounds that the Complaint was filed by EPA after the five-year statute of limitations had run. On March 25, 2011, Chief Judge Biro denied the motion, holding that the violation alleged in the Complaint, *i.e.* a violation of TSCA Section 8(e)'s reporting requirement, was a "continuing" violation, and that, therefore, the Agency benefited from a special accrual rule that effectively works to "toll" the statute of limitations. Order on Motion for Judgment on the Pleadings, at 6.

[5] Neither Bayer nor Occidental (companies that are far larger with more resources than Elementis) submitted the Final Four Plant Report to EPA. Tr. at 618 (Ellis). Nonetheless, EPA has not pursued either of those companies under Section 8(e) of TSCA. Tr. at 619 (Ellis).

Chief Judge Biro held a hearing on December 12-14, 2011, and issued the Initial Decision on November 12, 2013.

IV. SUMMARY OF ARGUMENT

This enforcement action alleging that Elementis violated of Section 8(e) of TSCA is subject to the five-year statute of limitations set forth in 28 U.S.C. § 2462. Section 8(e) of TSCA requires immediate reporting of information reasonably supporting the conclusion that a substance presents a substantial risk of injury to human health, and EPA has defined "immediate" for the purposes of Section 8(e) to be within 30 days of receipt of the reportable information. Thus, because this is a government enforcement action, and Congress did not include any language in the statute that a failure to report under Section 8(e) is a "continuing" violation, the statute of limitations began running on the 31st day after Elementis' receipt of the Final Four Plant Report, or November 8, 2002. EPA's Complaint in this action, which EPA filed on September 2, 2010, therefore was filed well beyond five years after the alleged violation would have occurred and must be dismissed.

Even if this action is not dismissed because it was filed beyond the statute of limitations, the evidence presented at hearing unequivocally established that Elementis was not required to submit the Report to EPA under Section 8(e) of TSCA. The finding of substantial risk in the study, as detailed in the Final Four Plant Report, corroborated the well-known and well-established adverse health effects associated with hexavalent chromium. Under the express provisions of TSCA § 8(e) and EPA's own guidance, Elementis had no obligation to report the information under TSCA § 8(e).

In the Initial Decision, Chief Judge Biro acknowledged that "[t]here is no dispute that the only excess cases of lung cancer reported by the Final Report in the SMR analyses were within the highest exposure category," and that "[t]here is no dispute that the Gibb Study showed

statistically significant risk at lower cumulative exposures than the Final Report." Opinion at 38. Nonetheless, Chief Judge Biro found that the Elementis failed to prove that the Agency was adequately informed of the information in the Final Four Plant Report which reasonably supports the conclusion that hexavalent chromium presents a substantial risk of injury to human health, and thus Elementis should have immediately provided the Final Four Plant Report to EPA when it received it in October 2002. In getting to this result, Chief Judge Biro improperly interpreted the statute at issue, broadening its scope far beyond what the plain language permit. Having done so, Chief Judge Biro identified features in the development or construction of the Final Four Plant Report that was different or distinguishable from prior studies, and using those distinguishing features as the basis for her conclusion that Elementis violated Section 8(e) of TSCA because the Final Four Plant Report contained new "substantial risk information." This effort, though, which is essentially based on the argument that mere differences in scientific study methods or subjects between studies is sufficient to generate a reporting obligation – even if none of those differences are part of what contributes to "reasonably concluding" a risk is present and even if the later study ultimately serves to substantially support only what was previously known – is not consistent with the statute's plain language, which only requires reporting by a chemical manufacturer, distributor or processor of "information reasonably supporting the conclusion that a substance ... presents a substantial risk of injury to human health..." unless it knows that the Agency is already aware of the substantial risk.

In this case, Elementis proved that the Agency was already aware of the only information in the Final Four Plant Report which reasonably supports the conclusion that hexavalent chromium presents a substantial risk of injury to human health, namely that high cumulative exposures to hexavalent chromium lead to an increased risk of lung cancer.

V. ARGUMENT

A. STANDARD OF REVIEW

The Board's scope of review of the Initial Decision is *de novo*. *In re: Euclid of Virginia, Inc.*, 13 E.A.D. 616, 625 (2008). As provided in the Consolidated Rules, the Board shall "adopt, modify, or set aside" the ALJ's findings of fact and conclusions of law or exercise of discretion. *See* 40 C.F.R. § 22.30; *see also* Administrative Procedures Act § 8(b), 5 U.S.C. § 557(b) ("on appeal from or review of the initial decision, the agency has all the powers it would have in making the initial decision except as it may limit the issues on notice or by rule").

B. THE COMPLAINT BROUGHT BY EPA IN THIS MATTER WAS BROUGHT AFTER THE APPLICABLE STATUTE OF LIMITATIONS HAD RUN AND THEREFORE SHOULD BE DISMISSED

In her March 25, 2011 Order On Respondent's Motion For Judgment On The Pleadings ("Order"), Chief Judge Biro incorrectly found that Complainant's claims are not barred by the five-year statute of limitations applicable to TSCA enforcement actions. She wrongfully concluded that, despite the obvious temporal characteristic of TSCA § 8(e)'s obligation, *i.e.*, the duty to "immediately inform," it falls within a limited exception to the statute of limitation known as the "continuing violation" exception. To reach her conclusion, Chief Judge Biro misread TSCA § 8(e), misunderstood the effect of the word "immediately" contained therein, and essentially added words to the statute that simply are not there. As explained below, the natural reading of the statute and the case law applying similar requirements clearly indicate that she reached an erroneous conclusion.

1. TSCA Enforcement Actions Are Subject To A Five-Year Statute Of Limitations, Which Begins Running When The Claim "First Accrues".

TSCA enforcement actions, such as this one, are subject to the general five-year statute of limitations period of 28 U.S.C. § 2462. *See 3M Co. v. Browner*, 17 F.3d 1453 (D.C. Cir. 1994).

> Except as otherwise provided by Act of Congress, an action, suit or proceeding for the enforcement of any civil fine, penalty, or forfeiture, pecuniary or otherwise, shall not be entertained unless commenced within five years from the date when the claim first accrued if, within the same period, the offender or the property is found within the United States in order that proper service may be made thereon.

28 U.S.C. § 2462 (emphasis added). "A claim first accrues on the date that a violation first occurs." *National Parks and Conservation Ass'n, Inc. v. Tennessee Valley Authority*, 502 F.3d 1316, 1322 (11th Cir. 2007) (emphasis added); *see also, Gabelli v. S.E.C.*, 133 S. Ct. 1216, 1220 (2013) ("A claim accrues when the plaintiff has a complete and present cause of action") (internal quotations omitted); *3M Co.* at 1460 ("A claim normally accrues when the factual and legal prerequisites for filing suit are in place").

Here, there is no question that EPA's claim first accrued in late 2002 and is therefore barred by the express language of 28 U.S.C. § 2462. Respondent obtained the Final Report on October 8, 2002. TSCA § 8(e) requires the immediate reporting of certain information to the EPA as follows:

> (e) Notice to Administrator of substantial risks
>
> Any person who manufactures, processes, or distributes in commerce as chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

15 U.S.C. § 2607(e). EPA guidance on TSCA § 8(e) interprets "immediate" to mean "within 30 days." *See* EPA Toxic Substances Control Act (TSCA) Section 8(e) Notices, http://www.epa.gov/oppt/tsca8e/ ("8(e) notices should be submitted within 30 calendar days after obtaining information that a substance or mixture presents a substantial risk").

Thus, in accordance with its current guidance (and assuming Elementis was obligated to inform EPA of the Final Report), EPA's cause of action first accrued on November 8, 2002 -- 31 days after Elementis received the Final Report. *See National Parks and Conservation*, 502 F.3d at 1322; *Gabelli*, 133 S. Ct. at 1220; *3M Co.* at 1462 (stating that "an action, suit or proceeding to assess or impose a civil penalty must be commenced within five years of the date of the violation giving rise to the penalty").

In sum, for the Agency's claims to have been timely, it would have had to bring an action against Elementis by November 7, 2007 – five years after its claim "first accrued." 28 U.S.C. § 2462.[6] It did not do so, and its claims are therefore barred by 28 U.S.C.§ 2462.

2. The Continuing Violation Exception Does Not Apply To TSCA § 8(e).

Although Chief Judge Biro recognized the applicability of the five-year statute of limitations here, she misinterpreted TSCA § 8(e) and wrongfully applied an exception that is reserved for "continuing violations." Generally speaking, under the continuing violations exception, the statute of limitations is tolled for a claim that otherwise would be time-barred where the violation giving rise to the claim is on-going and continues to occur within the limitations period. *National Parks and Conservation Ass'n,*, 502 F.3d at 1322; *United States v. Illinois Power Co.*, 245 F. Supp. 2d 951, 955 (S.D. Ill. 2003).

As discussed below, the United States Supreme Court recently held, in a situation similar to this one, that an exception to the five-year statute of limitations does not apply. In addition, many other courts that have analyzed statutory and regulatory requirements that demand compliance within a particular timeframe, such as TSCA § 8(e), have found that the continuing

[6] The parties entered into a Tolling Agreement on June 30, 2009, which tolled claims from that date onward. However, by that time the five-year statute of limitations period of 28 U.S.C. §2462 had already expired.

violation exception does not apply for a multitude of reasons, all of which (as discussed below) are applicable here.

a) As Stated By The United States Supreme Court, Courts Are To Apply Exceptions To The Five-Year Statute Of Limitations Period "With Great Caution."

The United States Supreme Court recently cautioned against applying exceptions to 28 U.S.C. § 2462:

> As we held long ago, the cases in which a statute of limitation may be suspended by causes not mentioned in the statute itself ... are very limited in character, and are to be admitted with great caution; otherwise the court would make the law instead of administering it.

Gabelli, 133 S. Ct. at 1224 (declining to apply a "discovery rule" that would have extended the limitations period of 28 U.S.C. § 2462) (internal citations and quotation marks omitted).

In *Gabelli*, the Securities and Exchange Commission ("SEC") brought a civil enforcement action for an alleged fraud. The SEC argued that, in actions sounding in fraud, the "discovery rule" should apply and the limitations clock should start to tick, not when the alleged violator commits the fraud, but when the SEC discovers it. *Gabelli*, 133 S. Ct. at 1221. Otherwise, the SEC argued, the limitations clock would run even when the SEC had no knowledge of the fraud. *Gabelli*, 133 S. Ct. at 1222.

The Supreme Court disagreed, declined to apply the discovery rule exception, and held that the five-year limitations period begins when the violator allegedly committed the fraud -- even if the SEC did not know about it until years later. *Gabelli*, 133 S. Ct. at 1224. The Supreme Court stated that "the most natural reading" of 28 U.S.C. § 2462 is that "a right accrues when it comes into existence." *Gabelli*, 133 S. Ct. at 1220 (quoting *United States v. Lindsay*, 346 U.S. 568, 569 (1954)). "This reading sets a fixed date when exposure to the specified Government enforcement efforts ends ... ." *Gabelli*, 133 S. Ct. at 1221. It noted that statutes of

limitations are "vital to the welfare of society" and "promote justice" by advancing the policies behind them (*e.g.*, repose, elimination of stale claims, and certainty about a plaintiff's opportunity for recovery and a defendant's potential liabilities). *Id.* (quoting *Wood v. Carpenter*, 101 U.S. 135, 139 (1879)).

The Supreme Court was particularly critical of applying exceptions to 28 U.S.C. § 2462 in a civil penalty action brought by the Government (as opposed to an action for damages by an injured party):

> In a civil penalty action, the Government is not only a different kind of plaintiff, it seeks a different kind of relief. The discovery rule helps to ensure that the injured receive recompense. But this case involves penalties, which go beyond compensation, are intended to punish, and label defendants wrongdoers.
>
> ...
>
> Chief Justice Marshall used particularly forceful language in emphasizing the importance of time limits on penalty actions, stating that it "would be utterly repugnant to the genius of our laws" if actions for penalties could "be brought at any distance of time." *Adams v. Woods*, 2 Cranch 336, 342, 2 L.Ed. 297 (1805). Yet grafting the discovery rule onto § 2462 would raise similar concerns. It would leave defendants exposed to Government enforcement action not only for five years after their misdeeds, but for an additional uncertain period into the future. Repose would hinge on speculation about what the Government knew, when it knew it, and when it should have known it. *See Rotella*, 528 U.S., at 554, 120 S. Ct. 1075 (disapproving a rule that would have "extended the limitations period to many decades" because such a rule was "beyond any limit that Congress could have contemplated" and "would have thwarted the basic objective of repose underlying the very notion of a limitations period").

Gabelli, 133 S. Ct. at 1223.

The issues in *Gabelli*, and the interests at stake, are remarkably similar to the issues here. *Gabelli* dealt with the same statute of limitations (28 U.S.C. § 2462), which expressly and unambiguously states that an enforcement action must be brought within five years from the date

when the claim first accrued. *See* 28 U.S.C. § 2462. Like *Gabelli*, this is a government enforcement action seeking penalties, and it would be "repugnant" if "actions for penalties could be brought at any distance of time." *Gabelli*, 133 S. Ct. at 1223. And like *Gabelli*, the government here has argued for an exception to 28 U.S.C. § 2462 because the government did not know about the alleged violation until more than 5 years later. But this policy concern is outweighed by the policies behind statutes of limitations, "which are vital to the welfare of society." *Gabelli*, 133 S. Ct. at 1221.

One notable difference between the instant matter and *Gabelli* is that *Gabelli* involved an enforcement action sounding in fraud – the instant matter does not. Yet, even in an action sounding in fraud where the government did not know of the alleged fraud, the Supreme Court declined to permit an exception to 28 U.S.C. § 2462's requirement that the action be commenced within five years from the date when the claim first accrued -- *i.e.*, when the alleged fraud was first committed.

Moreover, the "continuing violation" exception at issue here effectively operates like the "discovery rule" that was found in *Gabelli* to be inapplicable to government enforcement actions. Here, Chief Judge Biro found that the limitations period for TSCA § 8(e) should be tolled until an alleged violator eventually provides certain information to the EPA. *See* Order, p. 9 (finding that the violation continues "as long as the information remains withheld from the Administrator"). In other words, Chief Judge Biro held that the limitations period is tolled until the EPA is aware of, or discovers, the violation. But, as explained above, such an exception does not apply to government enforcement actions. *See Gabelli*, 133 S. Ct. at 1224.

Therefore, given these remarkable similarities between the instant matter and the "discovery rule" at issue in *Gabelli*, Chief Judge Biro erred in applying the continuing violation

exception to toll the limitations period "as long as the information remains withheld from the Administrator." *See Gabelli*, 133 S. Ct. at 1224.

b) The Language Of TSCA § 8(e) Does Not Support Application Of The Continuing Violation Exception.

Even if Gabelli is not viewed as controlling or highly persuasive, nothing in the language of TSCA § 8(e) supports application of the continuing violations exception. Whether a violation can be characterized as one that falls within the continuing violation exception depends on the plain language of the statute. *See AKM LLC dba Volks Constructors v. Secretary of Labor*, 675 F.3d 752, 755 (D.C. Cir. 2012); *U.S. v. EME Homer City Generation, L.P.*, 727 F.3d 274, 284 (3rd Cir. 2013). The five-year statute of limitations period applies "[u]nless Congress has told us otherwise in the legislation at issue." *See AKM LLC dba Volks Constructors*, 675 F.3d at 756-757 (quoting *Bay Area Laundry & Dry Cleaning Pension Trust Fund v. Ferbar Corp.*, 522 U.S. 192, 201 (1997)). The statute must provide a "sufficiently clear indication" that the continuing violation exception applies. *In re: Lazarus, Inc.*, 7 E.A.D. 318, 378-379 (1997).

A continuing violation is one in which the language of the statute or regulation indicates that each day of non-compliance is a "fresh violation." *See EME Homer City Generation,* 727 F.3d at 284-285; *United States v. Midwest Generation, LLC*, 720 F.3d 644, 647 (7th Cir. 2013). If compliance depends on acting within a particular timeframe, as evidenced by the language of the statute or regulation at issue, then the continuing violation exception does not apply. *See AKM LLC dba Volks Constructors*, 675 F.3d at 755; *Illinois Power Co.*, 245 F. Supp. 2d at 957 (stating that if compliance must be performed within a particular time, rather than "at some later point in time," then the continuing violation exception does not apply).

The TSCA § 8(e) reporting requirement obligates a person subject to its requirement to "immediately inform" the EPA of certain information. *See* 15 U.S.C. § 2607(e) (emphasis

added). With the use of the word "immediately," the statutory language plainly, expressly and unambiguously establishes a temporal component to compliance. The "immediate" nature of the requirement cannot be ignored. Indeed, EPA has interpreted TSCA § 8(e) to mean that the required reporting must be performed within 30 days. Thus, in its view, it can bring suit as soon as Day 31 after reportable information is received but not reported to the Agency.

As another court has put it for a continuing violation to exist, there must be a "fresh violation" on each day of non-compliance. *See EME Homer City Generation,* 727 F.3d at 284-285; *see also Midwest Generation,* 720 F.3d at 647. However, it is not a "fresh violation" of a duty to "immediately inform" if the alleged violator fails to do so on Day 300, for example. By Day 300, the failure to "immediately inform" is long complete and far from "fresh." In other words, a failure to inform on Day 300 is just that -- a failure to inform -- not a failure to "immediately" inform. The failure to "immediately" inform already happened long ago, back on Day 31.

Notably, in order for Chief Judge Biro to apply the continuing violation exception here, she demonstrably edited the language of the statute to change the meaning of the temporal component it imposes and to add a duty it does not impose. In her Order she stated:

> [T]he illegal act due to failing to inform as required by TSCA § 8(e) can be seen to occur "immediately" and continue thereafter, as long as the information remains withheld from the Administrator.

Order at 9. In the statute, the word "immediately" precedes and qualifies the word "inform." 15 U.S.C. § 2607(e). In her interpretation, she removed "immediately" from that location. Even more critically, she blithely described the duty as one that "continues thereafter," words that do not exist in the statute. In other words, by shifting and adding words, Chief Judge Biro changed the meaning of the statute from one establishing a duty to "immediately inform" into one that establishes never-ending duty to inform that begins immediately. Thus, it is not an interpretation

based in the statute's plain language. *See AKM LLC dba Volks Constructors*, 675 F.3d at 755; *EME Homer City Generation*, 772 F.3d at 284.[7]

Such a reworked interpretation is simply beyond what the statute says. The case law is clear that the temporal elements in a statute that require compliance by a particular time cannot be interpreted to establish a starting point for continuing violations. *See EME Homer City Generation*, 727 F.3d at 284, 287 (finding that the requirement to obtain a pre-construction permit is not subject to the continuing violation exception because the statute "does not say that 'a violation starts'" when the construction begins without the permit); *Midwest Generation,* 720 F.3d at 647. But that is exactly what Chief Judge Biro did here. TSCA § 8(e) does not say that a "violation starts" immediately after obtaining information. *Id.* Rather, the violation occurs and is complete once the "immediate" time period ends. *Id.*

3. Chief Judge Biro Improperly Considered The Perceived Consequences Of A TSCA § 8(e) As A Basis To Extend The Statute Of Limitations.

In determining whether to characterize a violation as "continuing," it is important to distinguish between the "present consequences of a one-time violation," which do not extend the limitations period, and "a continuation of a violation into the present," which does. *See National Parks and Conservation Ass'n,* 502 F.3d at 1322. Lingering effects or consequences of a discrete violation do not extend the statute of limitations. *See Midwest Generation,* 720 F.3d at

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[7] Chief Judge Biro also rejects the idea that the term "immediate" connotes a "temporal limitation" because she notes that the term is not a date certain but one that can vary according to facts and circumstances. Order, at 7-8. But that is a *non sequitur* (in addition to being in tension with the Agency's own position that "immediate" here can be given clear content – it means within 30 days). The fact that there may be room to argue about when an "immediate" period has passed does not mean it imposes no "temporal limitation;" it means simply that there may be room to argue, in any particular case, when that limitation has been reached. Put another way, Congress in choosing a temporal limitations has many options – it can choose a calendar date certain (e.g. July 1); it can choose a date that is relatively concrete but non-calendar (e.g. "within ten days of an event happening", or it can choose something as it did here that permits a bit of flexibility from case to case ("immediately" upon an event happening). But that the fact that each of those approaches introduces some additional element of factual inquiry (e.g. when did the event happen or what should be considered immediate in the circumstances) does not mean that the temporal limitation does not exist. It means simply that additional analysis, other than simply looking at a calendar, is required to determine when the temporal limitation was triggered.

647 (stating that "enduring consequences of acts that precede the statute of limitations are not independently wrongful"); *Adebowale v. Griffith*, 2013 WL 5366849 at *2 (7th Cir. Sep. 26, 2013).

Here, Chief Judge Biro improperly focused on the consequences of an alleged failure to "immediately inform," rather than on the temporal discreteness of the "immediate" requirement. In the Order, she reasoned that the policy behind TSCA § 8(e) is to ensure that EPA receives timely access to information and to avoid the situation where human health and the environment are only protected after serious injury has occurred. *See* Order at 11. She further reasoned that this goal would be frustrated if a manufacturer could "violate the reporting requirement without fear of punishment if it could successfully hide the evidence ... for five years." Order at 11 (quoting *U.S. v. Advance Machine Co.*, 547 F. Supp. 1085, 1090 (D. Minn. 1982)).

Although, as Chief Judge Biro observed, an alleged failure to "immediately inform" may have consequences that may extend over time after the alleged violation occurs, these consequences do not operate to extend the statute of limitations. *See National Parks and Conservation, Inc.*, 502 F.3d at 1322; *Midwest Generation,* 720 F.3d at 647; *Adebowale*, 2013 WL 5366849 at *1. In turning to such a justification, Chief Judge Biro erred in relying on what she perceived to be the broad policy behind TSCA, rather than on the statute's plain language. But "it frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute's primary objective"—such as expanding the Agency's access to scientific studies—"must be the law." *See EME Homer City Generation,* 727 F.3d at 295 (quoting *Rodriguez v. United States*, 480 U.S. 522, 525-526 (1987)).

Indeed, Chief Judge Biro's reasoning was precisely the type of reasoning that the United States Supreme Court admonished in *Gabelli.* Such reasoning fails to recognize that it is for

Congress, and only Congress, to assess how to draw the balance and, thus, if Congress wishes to create an exception to the normal statute of limitations it must "[tell] us otherwise in the legislation at issue." *AKM LLC dba Volks Constructors*, 675 F.3d at 756-57. It also ignores the Supreme Court's reminder that the reasons for extending a statute of limitations to injured parties who are unaware that they have been harmed do not apply to the government in enforcement actions. *See Gabelli*, 133 S. Ct. at 1222-1223. Thus, Chief Judge Biro's reasoning that the five-year statute of limitations would "frustrate" TSCA's goals provides no support for her decision.

4. Other Case Law Interpreting Requirements Similar To TSCA § 8(e) Support The Conclusion That The Continuing Violation Exception Does Not Apply Here.

There are multiple cases, including those discussed below, that analyze requirements similar to those imposed by TSCA § 8(e) and find that the continuing violation exception does not apply.

a) *In re: Lazarus, Inc.*, 7 E.A.D. 318 (1997)

In *In re: Lazarus, Inc.*, 7 E.A.D. 318 (1997), the Environmental Appeals Board ("Board") made a significant distinction between those regulations that establish a continuing violation and those that do not.

At issue in *Lazarus* was the application of the continuing violation exception to two different types of TSCA regulations. One regulation required PCB transformers to be registered with the local fire department. The other regulation required the preparation of annual PCB reports by a date certain. In examining the applicability of the continuing violation exception to each of these regulations, the Board stated:

> Words and phrases connoting continuity and descriptions of activities that are typically ongoing are indications of a continuing nature. In contrast, a continuing nature may be negated by requirements that must be fulfilled within a particular time frame.

In re: Lazarus, Inc., 7 E.A.D. at 378-379 (emphasis added).

The Board found that the obligation to prepare the annual PCB report was not subject to the continuing violation exception. It explained that this obligation occurs "at a specific point in time" and that the language of the statute and regulation provided no "sufficiently clear indication" that the report preparation was an obligation of a "continuing nature." *In re: Lazarus, Inc.*, 7 E.A.D. at 379.

Comparatively, the Board found that the obligation to register PCB transformers was subject to the continuing violation exception. The Board reasoned that registration of the PCB transformers is a condition of the continued use of PCBs. *In re: Lazarus, Inc.*, 7 E.A.D. at 378-379 ("[C]onditions of use ... must be continuing obligations"). This reasoning is not applicable here, as use of a chemical substance or mixture is not conditioned upon TSCA § 8(e) compliance. *See* Order at 8 ("[N]othing in TSCA makes it unlawful for a chemical manufacturer to continue to use a chemical or operate its facility in whole or in part if it has not complied with the information disclosure requirement of TSCA § 8(e)"). When the continued operations are not expressly linked to compliance with a statutory requirement, then a violation of that requirement cannot be read to be a "continuing violation." *See In re: Lazarus, Inc.*, 7 E.A.D. at 379; *National Parks and Conservation Ass'n*, 502 F.3d at 1324; *Midwest Generation,* 720 F.3d at 647-648; *EME Homer City Generation,* 727 F.3d at 284-285.

Here, the TSCA § 8(e) obligation to "immediately inform" is similar to the regulation requiring annual PCB reports and not subject to the continuing violation exception. Both require compliance "within a particular time frame." And both laws provide no "sufficiently clear indication" of continuing obligation. To the contrary, the TSCA § 8(e) obligation is quite clear that compliance must be "immediate" and is not of a continuing nature.

b) *AKM LLC dba Volks Constructors v. Secretary of Labor*, 675 F.3d 752, 758 (D.C. Cir. 2012)

AKM LLC dba Volks Constructors v. Secretary of Labor, 675 F.3d 752, 758 (D.C. Cir. 2012) is highly instructive here. There, the District of Columbia Circuit held that a regulatory OSHA violation for failure to record information about work-related injuries within seven calendar days of receiving the information was not subject to the continuing violations exception. *See AKM LLC dba Volks Constructors*, 675 F.3d at 758.

The *AKM* Court found that violations that would be subject to the exception bear certain characteristics that do not apply when the requirement requires compliance within a particular timeframe. For one, continuing violations are those whose character as a violation do not become clear until they are repeated during the limitations period, typically because it is only the cumulative impact that reveals their illegality. *See AKM LLC dba Volks Constructors*, 675 F.3d at 757.

In addition, failure to right a wrong does not toll the limitations period. "[W]e have stated in no uncertain terms that the lingering effect of an unlawful act is not itself an unlawful act, and that the mere failure to right a wrong cannot be a continuing wrong which tolls the statute of limitations, for if it were, the exception would obliterate the rule." *See AKM LLC dba Volks Constructors*, 675 F.3d at 757 (internal citations and quotations omitted). The Court explained that there is a marked difference between continued actions and inaction. "While we held that continued actions may extend the statute of limitations, nothing in that case suggests that inaction has the same effect, and this case is about inactions ... ." *AKM LLC dba Volks Constructors*, 675 F.3d at 758. "In short, the ... continuing violations theory would transform the failure to right a past wrong into a reason not to start the limitations clock—a result our precedents plainly proscribe." *AKM LLC dba Volks Constructors*, 675 F.3d at 758.

All of the *AKM* Court's reasons for not applying the continuing violation exception apply here. TSCA § 8(e) requires compliance within a particular timeframe. The failure to "immediately inform" is not repeated during the limitations period, and the failure to do so is not revealed by some "cumulative impact." Moreover, application of the continuing violation exception here would toll the limitations period, not through a period of continuing actions, but through a period of inaction. Thus, Chief Judge Biro impermissibly transformed a failure to right an alleged past wrong (*i.e.*, an alleged failure to "immediately inform") into a reason to toll the limitations period, and the law "plainly proscribe[s]" this result. *AKM LLC dba Volks Constructors*, 675 F.3d at 758.

c) *U.S. v. Illinois Power Co.*, 245 F. Supp. 2d 951 (2003)

The decision in *Illinois Power Co.* is also highly instructive. There, the Court examined, and distinguished between, Clean Air Act requirements to obtain a "preconstruction permit" on one hand and an "operating permit" on the other.

As the names of these permits suggest, a preconstruction permit is required *before* constructing a "major emitting facility" (which emits significant air pollution), whereas an operating permit is required for the ongoing operation of a major facility. *Illinois Power Co.*, 245 F. Supp. 2d at 957 ("Preconstruction permits have a finite existence while operational permits can be ongoing violations.").

The preconstruction permit is one of the requirements of the "prevention of significant deterioration" ("PSD") program. The PSD program also requires the use of "best available control technology" ("BACT") and includes certain reporting requirements: (i) an owner or operator must notify the EPA of certain changes to an existing facility within 60 days, or as soon as practicable, before the change is commenced; and (ii) an owner or operator must conduct

performance tests and submit a written report no later than 180 days after the initial startup of the facility. *See Illinois Power Co.*, 245 F. Supp. 2d at 958.

The *Illinois Power* Court found that failure to obtain a preconstruction permit is not subject to the continuing violation exception. *See Illinois Power Co.*, 245 F. Supp. 2d at 957-958. The Court reasoned that, unlike operating permits, preconstruction permits must be obtained at a discrete point in time – before construction begins. *See Illinois Power Co.*, 245 F. Supp. 2d at 957 ("[A]ny preconstruction violation occurs when the actual construction is commenced, and not at some later point in time"). Operating permits, on the other hand, are a condition of a facility's ongoing operations. *See Illinois Power Co.*, 245 F. Supp. 2d at 957. Courts of Appeal are in agreement with *Illinois Power* that, because the requirement to obtain a preconstruction permit occurs at a discrete point in time, it is not subject to the continuing violation exception. *See e.g, EME Homer City Generation,* 727 F.3d at 284 ("We agree with the unanimous view of the other courts of appeals that have addressed this question."); *National Parks and Conservation Ass'n,* 502 F.3d at 1322-1326; *Midwest Generation,* 720 F.3d at 647.

Importantly, the *Illinois Power* Court found that the Clean Air Act's notification and reporting obligations were also not subject to the continuing violation exception. The Court explained that these obligations were "discrete violations that were complete at the time of construction." *See Illinois Power Co.*, 245 F. Supp. 2d at 958.

The reasoning of the *Illinois Power* Court (as well as the reasoning of other courts that have examined the permitting issue under the PSD program) applies here. The alleged failure to "immediately inform" the EPA was "complete" (as per EPA's guidance) 31 days after Respondent obtained the information and did not occur "at some later point in time." *See Illinois Power Co.*, 245 F. Supp. 2d at 957. And, unlike the requirement to obtain an operating permit

under the Clean Air Act, compliance with TSCA § 8(e) is not a condition to the ongoing use of a chemical substance. *See* Order at 8. For these reasons, like the PSD preconstruction permits and the related reporting obligations, TSCA § 8(e) is not subject to the continuing violations exception.

As against this large and compelling body of precedent, Chief Judge Biro appears to rely primarily on four cases – *United States v. Reaves*, 923 F. Supp. 153 (M.D. Fla. 1996); *Union Carbide Corp.*, EPA Docket No. TSCA85-H-02, 1985 EPA ALJ LEXIS 13 (ALJ, October 3, 1985), Order at 9; *United States v. Advance Machinery Co.*, 547, F. Supp. 1085 (D. Minn. 1982), Order at 11; and *United States v. Canal Barge Co.*, 631 F.3d 347 (6th Cir. 2011), *Id.* None is compelling, or controlling, here, for multiple reasons. First, only *Union Carbide* even involves TSCA Section 8(e) and its reasoning both lacks the benefit of the more recent decisions we present, while falling victim to many of the same analytical errors as does Chief Judge Biro (e.g. justifying a conclusion in terms of later felt effects). The same is true of the decision on which *Union Carbide* relied, the *Advance Machinery* decision from a single district court rendered more than 25 years ago, which in turn involved not the TSCA statute but a Consumer Products Safety Commission statute. *Reaves* does not even involve a statute containing the word "immediately" but, rather, involved a Clean Water Act violation through illegal discharge of fill material. Finally, *Canal Barge* was limited by its own terms to considering the import of the word "immediately" for purposes of federal court venue determinations and in a circumstance where the word "immediately" appeared in the regulation, not the statute. Thus, it failed to present the same kinds of direct challenge to the balanced statutory scheme and language Congress had put directly in place in Section 8(e) of TSCA. Moreover, the portion of *Canal Barge* which Chief Judge Biro quoted extensively also focused heavily on the later consequences

that could result if the word "immediately" were not read to allow a continuing violation, an approach other courts have repeatedly warned against.

C. CHIEF JUDGE BIRO ERRED BY NOT APPLYING THE PLAIN MEANING OF SECTION 8(e) OF TSCA.

Section 8(e) of TSCA, entitled "**Notice to Administrator of substantial risks**" provides that:

> Any person who manufactures, processes, or distributes in commerce a chemical substance or mixtures and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

15 U.S.C. § 2607(e).[8] Fundamental to properly applying this statute, and thus to determining when it does and does not apply, is to recognize the many required elements contained within it. The fundamental duty it imposes is that a chemical manufacturer "inform the Administrator of such information." Thus, the statute clearly emphasizes, through use of the modifier "such," that it is not all information, or any information, but information of a very particular type that is subject to the requirement. The further statutory language specifying the characteristics of information that triggers reporting -- and by implication which identifies information that is not sufficient to trigger -- represent limits Congress established to avoid creating an unbridled or unmanageable reporting burden.

First among these additional requirements is that for "information" to be reportable, it must "reasonably support the conclusion that a substance or mixture presents a substantial risk of injury to health or the environment." Thus, information which may hint at or lightly suggest, but

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[8] Both of these documents, although not promulgated regulations, were intended to set forth "the Administrator's interpretation of and policy towards section 8(e)..."and "assist the potential respondents who manufacture, import, process or distribute chemical substances in complying with Section 8(e)..."(CX 17 at 2, CX 21 at 2).

does not "reasonably support," a conclusion is not covered. Moreover, the conclusion to be supported must be of a very particular type – it must be the conclusion that "the substance or mixture presents a substantial risk of injury." Thus, the focus is multi-fold – it must be information that can be related to a "substantial risk," it must be the information that shows the risk derives from a mixture or substance, and the information must be sufficiently developed or robust that it "reasonably supports concluding" that the substantial risk is presented. Finally, of course, as yet a further protection to the regulated community, Congress provided that such information need not be reported where the chemical manufacturer knows that EPA is aware of "such information," *i.e.* that information that meets the multi-part test.

Thus, based on the plain reading of the statute, there are four distinct, serial inquiries in determining whether a reporting obligation exists under Section 8(e):

1. Is there a conclusion that the substance or mixture presents a substantial risk of injury to human health or the environment?

2. If yes, does the information at issue reasonably support that conclusion (including, importantly, precisely what "conclusion" is it that is reasonably supported)?

3. If the answer to questions 1 and 2 are yes, then it must be determined whether EPA was aware of that information, but only that information, which "reasonably supports that conclusion"; and

4. If EPA was aware of the information, did the manufacturer, processor or distributor know that EPA was so aware.

For purposes of her opinion, Chief Judge Biro describes information meeting the first two aspects of this test as "Substantial Risk Information ("SRI")," *i.e.*, Chief Judge Biro is explicit that, in her opinion, the term "SRI" refers to information that meets all of the basic statutory requirements to require reporting. Opinion at 38. We therefore turn now to that decision and the defects in its reasoning.

1. The Final Four Plant Report Concluded that Hexavalent Chromium Presented a Substantial Risk of Injury to Human Health But It Was Also Acknowledged That This Information Alone Did Not Make the Study Reportable Under Section 8(e) Given the Commonality With the Gibb Study.

At the outset, it is worth noting what is not at issue here, as that sets the stage for the findings Chief Judge Biro made. First, the parties stipulated that the Final Four Plant Report concluded that there was a substantial risk of injury to human health presented by hexavalent chromium for workers who had the highest cumulative exposure within the studied cohort. Specifically, the parties stipulated that:

> The Final Four Plant Report found elevated risk of lung cancer from exposure to hexavalent chromium for the high exposure group (≥200 μg/L-years) using standard mortality ratio analysis.

JX 1 at 2. Nor did Elementis dispute that this conclusion was reasonably supported. As Dr. Mundt testified, the study determined that the highest cumulative exposure group experienced a "statistically significant" increased incidence of lung cancer compared to the general population, while none of the other three exposure groups experienced such an increase. Tr. at 737 (Mundt). Therefore, the study both presented a conclusion, and reasonably supported the conclusion, that the highest cumulative exposure group experienced an increased risk of lung cancer.

It was also undisputed that the Gibb Study had already shown statistically significant increased risk of lung cancer at lower cumulative exposure levels than shown in the Final Four Plant Report. Opinion at 38. Thus, as Chief Judge Biro acknowledged, given "these commonalities" it was necessary to determine what "new SRI" might have been presented in the Final Four Plant Report. Id. And as she further acknowledged, "[r]esolution of this matter requires initially determining what in the Final Report constitutes . . . SRI." Opinion at 38.

2. Beyond What Was Stipulated, Chief Judge Biro Failed to Identify What In The Final Four Plant Report Constituted Reportable Risk Information.

Having correctly set herself this task, however, Chief Judge Biro never makes specific and concrete findings of what she considers to have been the information within the Final Four Plant Report that meets all elements of the statutory requirements, other than the Final Four Plant Report's finding of increased risk for high cumulative exposure populations. The sum of her specific conclusions on this point are found at page 48:

> The only SRI therein, Respondent argues, is "a statistically significant excess of lung cancer deaths above the expected number of lung cancer deaths, but only in the highest cumulative exposure group." After examining the Final Report's 153 pages, 19 tables and 24 figures, and in light of the meaning of SRI in TSCA Section 8(e) as established above and in the record, I cannot agree with Respondent. Having addressed the question of what constitutes TSCA Section 8(e) SRI, the following discussion will address Respondent's defense that the Agency's own guidance exempt the Final Report SRI from reporting.

Opinion at 48.

The difficulty, however, is that the preceding pages to this conclusion can be parsed at length and nowhere can be found a statement of the specific pieces of information in the Final Four Plant Report that lead her to her conclusion, *i.e.* that she cannot agree with Elementis. In turn, this makes her claim that she has "addressed the question of what constitutes SRI" incorrect. At most, Chief Judge Biro completed the first step of the analysis – she identified a risk the Final Four Plant Report identified -- "the instance of cancer." Opinion at 42. But beyond that, at no point did Chief Judge Biro identify what specific information in that Report "substantially supports the conclusion that the risk is present," beyond that which Elementis acknowledged – the information that showed a statistically significant cancer risk for the most highly exposed workers. To be sure, Chief Judge Biro acknowledged that Elementis argued that the only SRI was the evidence of risk in the highest exposure category. But her only specific

findings are in the negative, in the passage above, stating she rejects the Elementis claim, having read the report. This amounts to nothing more than "trust me, it's there, I've read the report and all its attachments." That is not enough and thus her decision must be reversed.[9]

3. The Information Cited By Chief Judge Biro In the Final Four Plant Report Was Not Information Reasonably Supporting the Conclusion That Hexavalent Chromium Presents a Substantial Risk of Injury to Human Health.

Somewhat oddly, having failed in the earlier section of her opinion to identify precisely what "information" the Final Four Plant Report presented that "reasonably supported" a conclusion of increased risk (other than the acknowledged risk of cancer in the highest exposure group), Chief Judge Biro then, at a later point, cites to five "specific examples" of SRI which she relies on in finding that the Final Four Plant Report is not "corroborative" of the Gibb Study. Before turning to each of those specific categories, we note several global points that apply to each. First, it was incorrect for Chief Judge Biro to analyze whether the Final Four Plant Report

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[9] Admittedly Chief Judge Biro spends multiple pages discussing testimony related to the importance in epidemiology of "statistical significance" as well as the testimony from various experts about how scientific information accretes. There was also testimony, reviewed by Chief Judge Biro, regarding how the underlying raw data might be later used ("fully mined"). But, of course, TSCA § 8(e) does not require the reporting of "important" information, or useful information, or "mineable" information. And, significantly, at no point in this portion of her discussion (Opinion at 38-48) does Chief Judge Biro quote any witness testimony in which the witness says "the Final Four Plant Report substantially supports a conclusion" that there is a cancer risk of any degree, other than the acknowledged risk from high cumulative exposures. This again highlights her failure to identify and explain what information was in the Report that constituted SRI beyond the information of higher risk at the highest exposure level.

Given that this section of her opinion, ultimately, does not identify particular information that she believes satisfies the TSCA § 8(e) requirements, Elementis does not, at this point, see further utility in examining at length Chief Judge Biro's discussion, except for the following point. Elementis notes that Chief Judge Biro has provided a discussion related to her conclusion that a statistical analysis need not yield results that meet standards of statistical significance in order to still satisfy the statute's requirements that the information "reasonably support the conclusion of substantial risk." Given that, in the absence of "statistical significance", it cannot be determined that a particular statistical result was from something other than raw chance. Tr. at 853 (Mundt). Chief Judge Biro's construction of the statute on this particular point cannot be correct. For example, there was no evidence or no claim from any of the government's experts that they would themselves support a risk finding as "reasonably supported" by statistical results that lack statistical significance. Such a result, or even a result that shows weak statistical significance, cannot be, as a matter of sound statutory construction, information that "reasonably supports" that a "substantial risk" exists. Nor did any witness claim, as a matter of fact, that this would be a reasonable claim to make.

simply was "corroborative" of the Gibb Study. The correct analysis is whether the serious effect identified in the Final Four Plant Report was corroborative of the serious effect identified in the Gibb Study. As Chief Judge Biro acknowledged in the Initial Decision, and what had been indisputably established at the hearing, both the Gibb Study and the Final Four Plant Report found a serious adverse effect, namely a statistically significant elevated risk of lung cancer for workers at the higher cumulative exposure range. Therefore, because the Gibb Study, which was an EPA study, had been completed several years before the Final Four Plant Report, the serious effect identified in the Final Four Plant Report corroborated what had been found in the Gibb Study.[10] In fact, as Chief Judge Biro found, the Gibb Study even found a statistically significant elevated risk at lower cumulative exposures that the Final Four Plant Report. Thus, even though the two studies had differences, which Chief Judge Biro analyzed in substantial detail, those differences do not alter the common point of information that each study reported that related to risk – the finding that, at certain cumulative exposure levels, a statistically significant increased rate of lung cancer can be observed, which in turn could reasonably support the conclusion that exposure to hexavalent chromium presents substantial risk.

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[10] At the hearing, there was much attention and effort devoted to discrediting or limiting the force of the Gibb Study and its conclusions, as if it should have been known to all in the early 2000's that Gibb was not to be regarded as trustworthy or as if it was a study that all would immediately be able to recognize as defective in certain critical respects. That hindsight approach, of course, belies the contemporaneous record, which was clearly that the Agency itself considered the Gibb Study consequential and definitive – as evidenced by the fact that EPA funded the study and, when its results were revealed, chose to give Dr. Gibb a major award based upon it. Tr. at 1027 (Gibb). The award indicated that the Gibb Study was "the most significant and detailed study of the lung cancer and clinical irritation risks from chromium ever conducted. Tr. at 1027 -1028 (Gibb). Moreover, the attack in hindsight is far afield of what the statute directs – the statute permits a manufacturer not to report information of substantial risk already known to the Administrator. Clearly that calls for an analysis on what is known – or thought to be known – at the time Elementis received the Final Four Plant Study. It does not require, and does not permit, the Agency to later step forward with a collection of experts who then seek to critique the first study and suggest that flaws or weaknesses that they now see in this earlier Gibb Study mean that the Gibb Study did not give the Agency the information the Gibb Study so clearly did.

This approach of allowing an inquiry into the soundness of Dr. Gibb's study is tied to a related error of law by Chief Judge Biro - in considering whether the Final Four Plant Report needed to be reported, she determined that she was authorized to assess whether the risk was "well established," Opinion at 60, and, if not well-established, that the second report had to be provided. But, of course, "well-established" is not language found in the statute - it is only necessary that the Agency know of the information that can reasonably support the conclusion of risk.

Second, Chief Judge Biro's detailed discussions of whether each of the five SRI examples she identifies is corroborative of Gibb puts the cart before the horse, as it assumes – without ever demonstrating -- that each of those "examples of SRI" (*i.e.*, examples that meet the full TSCA definition of information that must be reported) meets all of the TSCA § 8(e) requirements. But as examination of those examples show, none even qualifies as "SRI" because none of the pieces of information she points to actually meet all the required elements to be SRI -- i.e. that the information 'reasonably supports" the "conclusion" that "hexavalent chromium presents a substantial risk of injury to human health."

The first specific example that Chief Judge Biro cites is that the Final Four Plant Report looked at modern conditions and "presents a more accurate assessment of risk to workers in a modern chromate plant environment where low-lime and no-lime processes are utilized." As a basis for establishing that "this more accurate assessment" in turn qualifies as SRI, her explanation fails. First, the sentence itself reveals that Chief Judge Biro is focused on the risk associated with an industrial production process (low-lime and no-lime), not a risk from the chemical or substance, hexavalent chromium. Thus, on that basis alone it fails to meet TSCA § 8(e)'s requirements, which apply to reporting information of risks from a "substance or mixture," not production processes.

Second, there is no dispute that the plants analyzed in the Final Four Plant Report were different from the plant analyzed in the Gibb Study. However, nothing in that difference constitutes information reasonably supporting a conclusion that hexavalent chromium presents a substantial risk of injury to human health.[11] In fact, it supports no conclusion whatsoever and

[11] Chief Judge Biro's failure to describe how this, or any other of her five examples, "reasonably supports" a finding of risk, also helps illustrate that her discussion of legislative history (Opinion at 40-41) is equally beside the point in focusing on whether it is the "risk" or the "information" to be reported. As her own discussion notes, both the Senate and House versions of the TSCA legislation included the requirement that, for any report to be required,

Chief Judge Biro never links that difference to a finding of risk from the chemical. Indeed, the fact that the difference itself has no necessary relationship to risk is nicely illustrated by the Four Plant Study. As the Final Four Plant Report reported, for three of the four exposure quartiles (*i.e.*, those less than 200 ug/L-years) "there was no excess mortality from lung cancer," CX 1 at 90, *i.e.* even with different plants under review, no information to reasonably support a finding of risk was developed for the vast majority of workers studied.

Finally, the difference in workers being studied was addressed through each study author conducting the study and reporting his findings through the common metric of total cumulative exposure, which in turn is the accepted best proxy for understanding risk from hexavalent chromium. Tr. at 431 (Clapp); Tr. at 495, 524 and 1085 (Speizer). Indeed, that is the very reason why the cumulative exposures of the workers are determined – so that the experience of the workers can be compared based on what is thought to be the relevant common characteristic for determining risk – the total cumulative exposure. Thus, again, while different plants were studied, the information the studies presented was brought to a common currency when it was time to try and provide information on risk – and that common currency was total cumulative exposure. Consequently, the two reports do not differ meaningfully with respect to the actual information that can reasonably support a finding of substantial risk.

As her second example of SRI in the Final Four Plant Report, Chief Judge Biro points to the Gibb Study's inclusion of short-term workers, whereas the Final Four Plant Report excluded them. As with the first example – the difference in plants – Chief Judge Biro does not explain how the exclusion of certain workers is a piece of information that reasonably supports a finding

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the information must "reasonably support" a conclusion that the substance at issue poses a risk. It is that modifier which sets the bounds of what information triggers reporting and also sets the bounds of what must be reported – only that information that reasonably supports a conclusion of substantial risk.

of risk – the textual statutory requirement for this to be "SRI" in the first instance. Thus, she is simply wrong that it is SRI at all.

And, again, even with this difference, each study ultimately reported its findings in similar terms – findings of increased incidence of cancer at higher cumulative exposure levels. As discussed above, both studies used cumulative exposure as the prime indicator of worker exposure; consequently the differences in methodologies between the two studies do not affect the ability to compare their findings. Therefore, although Final Four Plant Report excluded short-term workers from its analysis, its finding of an elevated risk for workers in the highest quartile of cumulative exposure (regardless of how long those workers worked) was consistent with the same finding in the Gibb Study.

In an apparent attempt to address this point, particularly in an attempt to distinguish the Final Four Plant Report as not simply "corroborative," Chief Judge Biro quotes various pieces of testimony and evidence suggesting that different researchers, including EPA's retained experts in this case, would not choose to include short term workers in such a study. *See, e.g.*, Opinion at 66. That may be so, but the fact remains that the Gibb Study did include them, and the only risk information that the Gibb Study reports is reported in terms of whether there are excess cases of lung cancer given various cumulative exposure levels. Thus, the information it provides that "reasonably supports" a finding of substantial risk is presented through exactly the same metric – cumulative exposure to hexavalent chromium – as was used in the Four Plant Study. In sum, while Chief Judge Biro may have identified a difference between the studies but not one that is legally relevant under TSCA Section 8(e)'s express terms.

The third example of "substantial risk information" Chief Judge Biro identifies as distinguishing the Final Four Plant Report from the Gibb Study is its use of urine and air data to

generate calculations of cumulative exposure, whereas the Gibb Study only used air data. As with all the other examples, the difference in data is not information that satisfies TSCA's requirements to be reported. The simple use of mixed urine and air data does not, in itself, do anything to demonstrate that the "urine/air" data reasonably supports a finding of risk. Here again, Chief Judge Biro's conclusion that this difference creates SRI that is not "corroborative" fails on the preliminary point that it is not SRI at all – "corroborativeness" need never even be reached.

As to corroborativeness, again, it is undeniable that the two studies used different data sets and, in some instances, types of data from which they derived their cumulative exposure estimates. But, because both studies reported their findings based on the same measure – cumulative exposure to hexavalent chromium – and because they reported findings of risk only in terms of increased cancer incidence given certain exposure levels, they are not different in terms of whether the Final Four Plant Report provides information of risk of which the Agency was previously unaware. In fact, when compared, the Gibb Study actually suggests greater risk from hexavalent chromium because it found increased cancer (compared to the cancer rates in general populations) at exposure levels lower than the Final Four Plant Report. Thus the Final Four Plant Report was entirely "corroborative."[12]

The next example of "distinct SRI" provided by Chief Judge Biro in the Initial Decision is the job exposure matrix ("JEM") details provided in the Final Four Plant Report. According to Chief Judge Biro, because the Final Four Plant Report "provides such detailed information on

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[12] Chief Judge Biro also grounds her legal conclusion that the air/urinary data constitutes SRI by pointing to certain charts that report the dose exposure as calculated through use of the urine data. But even a cursory examination of those charts shows that this is all they report – *i.e.* they report levels of exposure in various plants at various years. Those same charts report nothing about cancer rates associated with those doses. *See, e.g.*, Final Four Plant Report, Figures 1 & 2 CX 1 at 124, 125 (cited in Opinion at 69). Thus, the charts themselves cannot constitute information "reasonably supporting" a conclusion of risk because no "risk" -- *i.e.*no cancer incidence rate of any kind, whether high, low or normal – is reflected on the charts.

what has been shown to be a critical part in occupational risk assessment studies," it is "distinguishable" from the Gibb Study and thus "potentially important to the field, particularly in modern plants." Opinion at 70. But this ignores what the JEM is, and the limited role it plays. The JEM is simply the tool by which the cumulative exposure of each worker in the study is calculated. Tr. 515 – 519 (Mundt). Descriptions of how a JEM was constructed – *i.e.* how the study authors decided to associate certain exposure levels with certain job functions and the cumulative exposure that could thereby result depending on time spent in various jobs -- as well as the actual JEMs developed are merely isolated steps toward developing information regarding whether there is a reasonable basis to conclude substantial risk exists. Had Chief Judge Biro focused on the statutory requirement for what constitutes SRI, she would have recognized that the JEMs information cannot be, standing alone, SRI because it is developed only as a tool to further analysis – on its own it reveals nothing of risk.

Indeed, the portion of her opinion discussing the JEM information contains two telling passages illuminating both the error of Chief Judge Biro's analysis as to the JEM information and the more general mindset and approach that produced errors as to all of the five categories. First, Chief Judge Biro indicates at one point "[t]he JEM details constitute 'information' about the substantial risk of lung cancer from exposure to hexavalent chromium." Opinion at 70. Similarly, she indicates her belief that "the Final Report's lengthy discussion of its JEM details could potentially be very important to the field, particularly in modern plants." *Id.* But, of course, this is not the inquiry the statute dictates – it is not enough that the "information" in question be "about" the risk of lung cancer to constitute SRI. Rather it must be information that "reasonably supports" the conclusion that there is a substantial risk from a substance. Nor, similarly, is it enough simply to conclude that the information could be "important" to a field of

study. Information can be "important" for many different reasons to scientists and practitioners and even to the regulatory agencies, but Congress has not set the bar at general "importance" -- it set the bar at the clear requirement that to be reportable the information must "reasonably support" a conclusion of substantial risk. And while this tendency to substitute a test of importance or usefulness or difference for the actual statutory requirements is most starkly conveyed in the JEM analysis, it is an error that pervades all of Chief Judge Biro's analysis of her five examples.

As to the JEM information and the "corroborativeness" question – whether the JEM information was new to the Agency – the answer again is "no." First, the notion of using a JEM in an occupational epidemiological exposure study was not groundbreaking – to the contrary it was well known as the established methodology in field, including well-known to EPA (EPA's knowledge is most readily evidenced by the fact that Dr. Gibb, when still himself employed at EPA, used the JEM approach in his own study). CX 62 at 4. Thus, while the Final Four Plant Report and the Gibb Study are based on different plants, utilized different data sets, different data types, and were written in different ways, the Final Four Plant Report did not represent a new type of information simply by incorporating a JEM as a step in developing the study analysis. Similarly, while the Final Four Plant Report authors may have undertaken different efforts to construct the JEM for the plants and may have explained their steps in great measure and detail this does not change -- and cannot change -- the fact that the efforts to construct a JEM and a description of those efforts was only for purposes of developing cumulative exposure estimates that could, in turn, then be used to assess comparative cancer rates for the exposed and unexposed. It is only the reported results of this comparison that provides information that can

reasonably support a conclusion of substantial risk. And on this dimension, the Final Four Plant Report did simply corroborate the earlier Gibb Study.

Finally, as her fifth and final category of SRI, Chief Judge Biro states that the Final Four Plant Report "presented risk information on workers that more accurately accounted for their smoking history as a confounder," and because the "Gibb Study did not have robust smoking information," Opinion at 70, the Final Four Plant Report does not corroborate the findings of the Gibb Study. As with the other four categories, however, Chief Judge Biro misses the mark by failing to attend to the statute's actual requirements. Her analysis on the smoking point consists exclusively of comparing what the two studies did to control for smoking as a potential confounder of the results. Opinion at 70. As can readily be seen, the whole of her discussion is comparative, with no effort to explain how the Final Four Plant Report's explanation of what the authors did as to smoking data makes that smoking discussion "information that substantially supports a conclusion of risk." In fact, both studies found that smoking had no effect on the ultimate findings with regard to exposure to hexavalent chromium, and both reports ultimately found risk associated with certain cumulative exposure levels, unlinked to the presence or absence of smoking data.

Given this, it is unsurprising that Chief Judge Biro did not closely link her analysis on smoking to showing that the statutory requirements were met -- there was no way to do so. But this is a fundamental failure. Given that there is not, and could not be a way of reasonably concluding that the smoking differences supported a finding of substantial risk from chromium exposure, the smoking information is not SRI. Because it was not SRI to begin with, it thus should never have been subject to the further "corroboration" analysis – the same error made with respect to the prior four.

But even assuming the corroboration analysis Chief Judge Biro conducted to compare the Gibb Study and the Final Four Plant Report was appropriate, the analysis was deficient for the same reasons expressed for the other categories. The only corroboration that must exist is between the information that supports the conclusion that the hexavalent chromium presents a substantial risk of injury to human health, and in each study this information was the reported correlation of high cumulative exposure with increased risks of cancer. Whether one study had better smoking data is not relevant to this analysis. But as far as the analysis of whether the substantial risk findings in the Final Four Plant Report corroborate the substantial risk finding in the Gibb Study, the fact that smoking was determined not to impact the findings is irrelevant.

4. Elementis Had Knowledge that EPA Was Aware that Hexavalent Chromium Presented a Substantial Risk of Injury to Human Health.

While Chief Judge Biro made no express findings on the final element of the TSCA § 8(e) inquiry – apparently because she concluded that the Gibb Study did not make the Agency aware of the risk information in the Final Four Plant Report – Elementis notes for sake of completeness that if Chief Judge Biro's conclusions are rejected, the record is clear that Elementis had knowledge of EPA's awareness of the Gibb Study and knew that the Gibb Study made the Agency aware of the cancer risk associated with certain cumulative exposure levels. *See, e.g.*, Opinion at 21-22 (describing Dr. Barnhart testimony that he knew the Gibb Study at the time he received the Final Four Plant Report, knew EPA was aware of it because EPA funded the study, and conducted comparison of the two studies to confirm whether the Final Four Plant Report showed risk at cumulative exposure levels different than Gibb). Thus, this element of the TSCA Section 8(e) requirements is also satisfied.

While this case must ultimately turn on the statute's text and the requirements it imposes, one final point bears noting here. Chief Judge Biro's opinion generally reflects a concern that

any "tilt" in reading the statute should be in the direction that, she believes, will result in more, rather than less material being presented to the Agency. But even assessing this case from that perspective, the result Chief Judge Biro reaches in this case will frustrate, rather than contribute to achieving that. In this case, one has an industry group voluntarily undertaking a study, paying substantial sums for an expert to undertake the work, ceding control over the methods to be used in the study, and allowing the author final control over whether, where and how to publish the results. To be met, in that situation and where the Study only serves to confirm what the Agency already knew through its own study, with a penalty of the size proposed here can only serve to dissuade industry from undertaking such studies in the future given the high risks involved. It will thus ultimately stunt, rather than expand, the sum of information available to the Agency and the scientific community.

In sum, Section 8(e) of TSCA, as supported by EPA's guidance to the regulated community, unambiguously provides that information reasonably supporting a conclusion that a chemical substance presents a substantial risk of injury to human health does not have to be reported to EPA if it corroborates the same finding already known to EPA. The record in this matter sets forth overwhelming evidence that EPA knew for many years, and certainly before the Final Four Plant Report was provided to Elementis, that high cumulative exposure to hexavalent chromium presented an increased risk of lung cancer. Therefore, although the Final Four Plant Report may have contained different, useful, even important information for the scientific community or for OSHA, Elementis was not required to provide it to EPA under Section 8(e) of TSCA. The analysis by Chief Judge Biro of the differences between the Final Four Plant Report and the Gibb Study are irrelevant to the analysis of whether the Final Four Plant Report was to be reported by Elementis under TSCA 8(e). The only analysis that mattered is whether

Elementis knew that the Final Four Plant Report's conclusion that high cumulative exposure to hexavalent chromium presented an increased risk of lung cancer was known to EPA. Because Elementis proved by a preponderance of the evidence that EPA was fully aware of this risk associated with hexavalent chromium and that Elementis knew EPA was so aware, there was no violation of Section 8(e) of TSCA.

VI. CONCLUSION

WHEREFORE, Elementis Chromium Inc. respectfully requests that the Environmental Appeals Board dismiss the Complaint with prejudice for having been filed beyond the applicable statute of limitations, or, in the alternative, issue an order that Elementis did not violate Section 8(e) of TSCA by not immediately submitting the Final Four Plant Report to EPA.

VII. ALTERNATIVE FINDINGS OF FACT

1. Elementis Chromium Inc. ("Respondent") is a manufacturer and distributor of chemical substances, including chromic acid, chromic oxide, and sodium dichromate.

2. Respondent and its predecessors have been manufacturing and distributing chromium chemicals for more than 35 years.

3. From at least 1984 to 2003, Respondent was a member of the Industrial Health Foundation (the "IHF"), an industry-based organization.

4. From at least 1984 to 2003, Respondent was a member of the IHF's Chromium Chemicals Health and Environmental Committee (the "Chromium Committee").

5. From 1984 until 2003 when IHF was dissolved in bankruptcy, Dr. Barnhart, who was Vice President ~ Technical for Respondent, served as a representative of Respondent on the IHF Chromium Chemicals Health and Environmental Committee.

6. As of 1998, in addition to Respondent's representatives, representatives of two other companies, Bayer AG ("Bayer") and Occidental Chemical Corporation ("Occidental"), were members of the Chromium Committee.

7. In or about 1998, the Chromium Committee entered into an agreement with Applied Epidemiology Inc. which called for Applied Epidemiology to conduct an epidemiology study (the Four Plant Study") involving two chromium chemicals manufacturing plants located in the United States (Castle Hayne, North Carolina,

which was owned by Occidental, and Corpus Christi, Texas, which was owned by Respondent), two chromium chemicals manufacturing plants located in Germany owned by Bayer (Leverkusen and Uerdingen, Germany) and one chromium chemicals manufacturing plant in the United Kingdom owned by Respondent (Eaglescliffe, England).

8. In 1999, the Eaglescliffe, England chromium chemicals manufacturing plant was eliminated from the epidemiology study because it became apparent that the data from that plant would not be compiled in time to be included in the study.

9. The Four Plant Study was designed to be a mortality study of employees who had worked in the plants for at least one year, and who had started working after each of the plants had implemented various production changes designed to reduce exposures to hexavalent chromium.

10. Dr. Kenneth Mundt was a principal of Applied Epidemiology and the lead epidemiologist for the Four Plant Study.

11. Each cohort member was followed for vital status as of December 31, 1998.

12. In early 2002, Dr. Mundt submitted a draft of Applied Epidemiology's report on the Four Plant Study to the Chromium Committee for review and comment.

13. Dr. Barnhart received the draft in early 2002.

14. In reviewing the draft, and through prior conversations he had had with Dr. Mundt, Dr. Barnhart realized that the Four Plant Study identified an elevated risk of lung cancer from cumulative exposure to hexavalent chromium for the highest cumulative exposure quartile (~200 μg/L-years) using standardized mortality ratio analysis.

15. This finding was the only finding in the draft report that showed any substantial risk associated with hexavalent chromium.

16. Through standard data conversion methods, Dr. Barnhart compared the mean of the cumulative exposure quartile at which the Four Plant Study had found an elevated risk with the findings of a study conducted by Dr. Herman Gibb and others which had been published in 2000 in the American Journal of Industrial Medicine (the "Gibb Study").

17. The Gibb Study was an epidemiology study of chromate workers at a chromium chemicals manufacturing facility in Baltimore.

18. Like the Four Plant Study, the Gibb Study found an elevated risk of lung cancer for workers exposed to hexavalent chromium.

19. The Gibb Study found a statistically significant increased risk of lung cancer in workers who had much lower cumulative exposures or doses of hexavalent chromium than that found by the Four Plant Study.

20. Based on his comparison of the Gibb Study and the draft report on the Four Plant Study, Dr. Barnhart determined that the Four Plant Study did not provide any new information regarding the substantial risk associated with hexavalent chromium.

21. Dr. Barnhart also knew that Dr. Gibb was employed by EPA at the time the Gibb Study was published and that EPA had funded the Gibb Study.

22. Because the Four Plant Study did not identify a substantial risk associated with hexavalent chromium not already identified by the Gibb Study, and because he knew that EPA had the Gibb Study, Dr. Barnhart did not report the finding of the Four Plant Study regarding the increased risk of lung cancer in the highest cumulative exposure quartile to EPA.

23. On October 8, 2002, Dr. Mundt emailed the "final" copy of the report entitled Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998: Final Report ("Final Four Plant Report") dated September 27, 2002 to the IHF.

24. Marianne Kaschak of the IHF e-mailed the Final Four Plant Report to Dr. Barnhart on October 8, 2002.

25. Dr. Barnhart reviewed the Final Four Plant Report and did not identify any significant changes to the findings from the draft he received in early 2002.

26. Pursuant to EPA's guidance, if Elementis was required to provide the Final Four Plant Report to EPA pursuant to Section 8(e) of TSCA, it should have been provided to EPA on or before November 7, 2002.

27. Neither Occidental nor Bayer provided the Final Four Plant Report to EPA.

28. The date that is 5 years after November 7, 2002 is November 7, 2007.

29. On June 30, 2009, EPA and Elementis entered into the first of a series of Tolling Agreements to toll the running of the limitations period.

30. EPA commenced this enforcement action on September 2, 2010.

31. Respondent provided the Final Four Plant Report to EPA on November 17, 2008 in response to a subpoena.

VIII. ALTERNATIVE CONCLUSIONS OF LAW

1. Respondent manufactures and distributes in commerce hexavalent chromium, a chemical substance.

2. To the extent that Respondent was required to provide the Final Four Plant Report to EPA pursuant to Section 8(e) of TSCA, Elementis was required to provide the Report to EPA no later than November 7, 2002.

3. A failure to report under Section 8(e) of TSCA would be a violation of Section 15(3)(B) of TSCA and would have occurred at least as of November 7, 2002, because EPA has claimed "immediate" to be within 30 days for the purposes of Section 8(e).

4. Failure to report under Section 15(3)(B) of TSCA is not a continuing violation.

5. Pursuant to 28 U.S.C. § 2462, any enforcement action pursuant to Section 15(3)(B) of TSCA must be commenced within 5 years of the alleged violation.

6. EPA did not commence this action within 5 years after the alleged violation occurred, and therefore the action must be dismissed with prejudice.

Alternative Conclusions of Law:

2. When Respondent received the Final Four Plant Report on October 8, 2002, it obtained information which reasonably supports the conclusion that exposure to hexavalent chromium presents a substantial risk of injury to health or the environment.

3. Respondent was not required by Section 8(e) of the Toxic Substances Control Act, 15 U.S.C. § 2607(e), to immediately inform the Administrator of such information because Respondent had actual knowledge that the Administrator had been adequately informed of such information.

Respectfully submitted,

/s/

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CERTIFICATE OF SERVICE

I, John J. McAleese, III, hereby certify that on this 15th day of January, 2014, I served a copy of the foregoing Appeal Brief on the following:

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