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

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

February 24, 2014

VIA HAND-DELIVERY

Clerk of the Board
U.S. Environmental Protection Agency
Environmental Appeals Board
1201 Constitution Avenue, N.W.
WJC East Building, Room 3334
Washington, D.C. 20004

Re: Complainant Environmental Protection Agency's Brief in Opposition to Respondent Elementis Chromium Inc's Appeal; Docket No. TSCA-HQ-2010-5022

Dear Clerk of the Board:

Please find enclosed and served upon you for filing Complainant Environmental Protection Agency's Brief in Opposition to Respondent Elementis Chromium Inc's Appeal; Docket No. TSCA-HQ-2010-5022.

Sincerely,

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Enclosure

cc: John J. McAleese (by U.S. mail and email)
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Headquarters Hearing Clerk (by U.S. mail and email)
Honorable Susan L. Biro (by U.S. mail)

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
Respondent.	)	

COMPLAINANT ENVIRONMENTAL PROTECTION AGENCY'S BRIEF IN OPPOSITION TO RESPONDENT ELEMENTIS CHROMIUM INC'S APPEAL

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Complainant, the Director of the Waste and Chemical Enforcement Division, Office of Civil Enforcement, United States Environmental Protection Agency (EPA or the Agency), through counsel, respectfully submits this brief in reply to Respondent Elementis Chromium Inc's (Respondent's or Elementis') January 15, 2014 appeal brief. This matter involves the appeal of the March 25, 2011 Order (Order) and the November 12, 2013 Initial Decision issued by Chief Administrative Law Judge (ALJ) Susan L. Biro in the above-styled matter.

I. ISSUES PRESENTED FOR REVIEW

Respondent's appeal presents the following issues for review:

(1) Whether the Presiding Officer Correctly Ruled the TSCA Section 8(e) Requirement to Immediately Report Information that a Chemical Presents Substantial Risk of Injury to Health Is a Continuing Requirement, and therefore, the Claim Is Not Barred by the Statute of Limitations?

(2) Whether the Presiding Officer Correctly Held Elementis Violated TSCA Section 8(e) Because It Did Not Have Actual Knowledge that the Administrator Had Been Adequately Informed of Reportable Substantial Risk Information from an Industry Study?

II. STANDARD OF REVIEW

In an enforcement proceeding, the Environmental Appeals Board (Board or EAB) conducts a de novo review of the Presiding Officer's factual findings and legal conclusions. See 40 C.F.R. § 22.30(f) (the Board "shall adopt, modify, or set aside the findings of fact and conclusions of law or discretion" contained in an appealed initial decision); see also 5 U.S.C. § 557(b); In re Vico Constr. Corp., 12 E.A.D. 298, 312-13 (EAB 2005); In re Bricks, Inc., 11 E.A.D. 224, 226 (EAB 2003), aff'd, 426 F.3d 918 (7th Cir. 2005). The Board typically grants deference to an ALJ's determinations of witness credibility and factual findings based thereon because the ALJ is able to observe the witness' demeanor first-hand and is therefore in the best position to evaluate credibility. See In re J. Phillip Adams, CWA App. No. 06-06, slip op. at 12, 13 E.A.D. 310 (EAB 2007); In re Vico Constr. Corp., 12 E.A.D. at 313.

III. BACKGROUND

A. STATUTORY BACKGROUND

When Congress enacted TSCA in 1976 it directed that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures." See 15 U.S.C. § 2601(b)(1). Hence, Section 8 of TSCA authorizes EPA to require persons engaged in the manufacture, processing, and distribution in commerce of chemical substances and mixtures to keep certain records and report certain information. One of Section 8's most critical reporting requirements is Section 8(e), entitled "Notice to Administrator of substantial risks," which provides that:

> Any person who manufactures, processes, or distributes in commerce a 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, other federal agencies, state and local governments, public interest organizations, the chemical industry and the general public can use Section 8(e) data to further assess and understand potential human health and environmental risks associated with exposure to chemical substances. See EPA Section 8(e) website at http://www.epa.gov/oppt/tsca8e. Understanding potential risks associated with chemical substances and mixtures is an essential component of risk management efforts to reduce risks. Id.

The failure to report pursuant to Section 8(e) constitutes an unlawful act under TSCA Section 15(3)(B), 15 U.S.C. § 2614(3)(B), and is subject to a penalty of up to $25,000 per day, per violation, for each day that the violation continues, pursuant to TSCA Section 16(a), 15 U.S.C. § 2615(a). The Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890, as amended by the Debt Collection Improvement Act of 1996, Pub. L. 101-134, 110 Stat. 1321, raises the maximum civil penalty from $25,000 to $27,500 per day, per violation, for violations occurring between January 30, 1997 and March 15, 2004, inclusive, and to $32,500 per day, per violation, for violations occurring between March 16, 2004, and January 12, 2009, inclusive. 40 C.F.R. § 19.4; CX 104.

B. FACTUAL BACKGROUND

The Presiding Officer made detailed and extensive factual findings. (Initial Dec. at 6-32; see also Order on Compl't Mot. for Acc. Dec. on Liability and Resp't Req. for Oral Arg. at 11-13). The parties also stipulated to certain facts and exhibits before hearing. (Joint Exhibit (JX) 1; Transcript (Tr.) 7-8). Thus, many of the material facts in this case are undisputed. Respondent admitted that it is a manufacturer, processor and distributor in commerce of

hexavalent chromium-containing chemicals, including chromic acid, chromic oxide and sodium dichromate. (JX 1, ¶¶ 4, 6; Resp't Initial Post-Hearing Brief at 2; Resp't Memo. in Opp. to EPA Mot. for Acc. Dec. on Liability at 2, 4, 11 and Ex. A, ¶ 3 (Sworn Statement of Dr. Joel Barnhart); Ans. ¶¶ 9, 11-12). Elementis admitted that it has two main manufacturing facilities that produce chromium chemicals in the United States. (Ans. ¶¶ 6-8).

Respondent admitted that on October 8, 2002 it obtained an epidemiologic study of the risk of lung cancer mortality from occupational exposure to hexavalent chromium entitled, "Applied Epidemiology, Inc., Collaborative Cohort Mortality Study of Chromate Production Facilities, 1958 — 1998: Final Report," referred to here as the "Final Report." (CX 1; JX 1, ¶ 18; Ans. ¶¶ 24, 41). Elementis specifically admitted that Dr. Joel Barnhart, the then-Vice President-Technical of Elementis Chromium LP, received the Final Report on October 8, 2002. (JX 1, ¶¶ 12, 17; Ans. ¶ 42; CX 4). The parties stipulated that the Final Report found a statistically significant excess risk of lung cancer mortality in the study's highest cumulative exposure quartile (≥200 μg/L-years), which Respondent admitted constitutes substantial risk information.[1] (JX 1, ¶ 11; CX 1 at 18, 89-90; Tr. 737, 856-59, 880-81 (Dr. Mundt); see also Resp't Reply Brief at 2, 6; Resp't Initial Post-Hearing Brief at 2).

The Final Report's substantial risk conclusion that high cumulative exposures lead to lung cancer mortality is based on the statistically significant finding, but was derived from different exposure data than previous epidemiologic studies. The Final Report included only exposure data collected from chromate workers who had worked under no-lime or low-lime chromium production processes, thereby excluding exposure data from workers exposed to hexavalent chromium under high-lime processes. (CX 1 at 15, 43, 86, 111 (Table 7)). The Final

[1] Complainant uses the phrase "substantial risk information" to concisely state the Section 8(e) requirement to inform the Administrator of "information which reasonably supports the conclusion of substantial risk." See 15 U.S.C. § 2607(e).

Report also excluded exposure data collected from short-term workers. Id. at 15, 43-44, 86. In addition, the Final Report used two types of industrial hygiene data: urinary and air. Id. at 16, 47-51, 106 (Table 2). Moreover, the Final Report used two types of job exposures matrices: average exposure concentration and peak exposure index. Id. at 59-60. Finally, the Final Report used smoking data which included employee smoking history before and after the start of employment. Id. at 51-52, 83-84, 96).

Respondent admitted that it failed to immediately inform EPA of the Final Report, and that "Elementis chose not to submit the Report to EPA." (JX 1, ¶ 19; Resp't Memo. in Opp. to Compl't Mot. for Acc. Dec. on Liability at 2-3). Respondent repeatedly chose not to provide the report to EPA. During the early months of 2002, Dr. Barnhart received a draft of the Final Report and chose not to submit the draft to EPA after comparing it to an earlier EPA-funded study called the Gibb Study. (Tr. 968-69, 991 (Dr. Barnhart)). Dr. Barnhart received the Final Report on October 8, 2002, and again chose not to submit the report to EPA. Id. at 992; JX 1, ¶ 19. Elementis once again chose not to submit the report when a revised unpublished version of the report became available on April 7, 2003. (RX 14; see also JX 1, ¶ 20). Respondent admitted that it did not provide the Final Report to EPA until November 17, 2008, in response to an EPA subpoena. (JX 1, ¶ 20; Resp't Memo. in Opp. to Compl't Mot. for Acc. Dec. on Liability at 2).

C. PROCEDURAL BACKGROUND

Complainant filed a complaint against Respondent on September 2, 2010 for violation of TSCA Sections 8(e) and 15(3)(B) in the Matter of Elementis Chromium Inc., f/n/a Elementis Chromium, LP, Respondent, Docket No. TSCA-HQ-2010-5022. The Presiding Officer summarized the procedural history of the case. (Initial Dec. at 2-4; see also Order on Compl't

Mot. for Acc. Dec. on Liability at 1-2; EPA Initial Post-Hearing Brief at 6-8). We will not repeat the lengthy procedural history, but will describe the history since November 12, 2013, when the Presiding Officer issued an Initial Decision, in which Respondent was assessed a civil penalty of $2,571,800 for violating Sections 8(e) and 15(3)(B) of TSCA. (Initial Dec. at 92). On November 25, 2013, Respondent filed a Notice of Appeal. The parties concurrently filed a Joint Motion for Enlargement of Time and Revised Briefing Schedule on November 25, 2013. On December 5, 2013, the Board issued an Order Granting Joint Motion for Enlargement of Time and Revised Briefing Schedule. On January 15, 2014, Respondent filed its Appeal Brief.

IV. SUMMARY OF ARGUMENT

The instant case involves Elementis' violation of TSCA Section 8(e)'s mandatory data reporting requirement by failing to submit to EPA the Final Report, an industry study of the risk of lung cancer mortality from occupational exposure to hexavalent chromium, a highly toxic industrial chemical. Section 8(e) requires chemical manufacturers, processors and distributors such as Elementis to immediately inform EPA of information which reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health. EPA uses substantial risk information reported about chemical hazards in implementing the Agency's regulatory programs, disseminates 8(e) submissions to other federal agencies, and makes such information publicly available. EPA considers failure to comply with Section 8(e) to be one of the most serious TSCA violations because the data reported alerts the Agency to new information that may bear on EPA's chemical hazard/risk assessment and chemical control efforts. (CX 103 at 16, 26).

The Presiding Officer correctly ruled that the Section 8(e) disclosure requirement is continuing in nature. Respondent's Section 8(e) violation began once Elementis obtained the

Final Report in 2002, but the violation continued until the company actually provided the report to EPA in 2008 in response to an EPA subpoena. Respondent argues that EPA's Section 8(e) claim is barred by the general federal five-year statute of limitations at 28 U.S.C. § 2462 even though the Section 8(e) requirement to immediately report information that a chemical presents substantial risk is a continuing requirement. However, a substantial portion of Respondent's violation was within the five-year limitations period, and, under doctrine of continuing violations, Complainant's claim extends to 2002 when Elementis first obtained the Final Report.

Epidemiologic studies such as the Final Report are difficult, time-consuming, and expensive.[2] These constraints dictate that epidemiologic studies are not undertaken lightly, and the study which led to the 153-page Final Report is no exception. Elementis and other chromium chemical manufacturers invested approximately $500,000 and over four and a half years in this study to evaluate lung cancer mortality risks associated with hexavalent chromium exposure under conditions in four modernized chromium production plants in Germany and the United States. (Tr. 926 (Dr. Mundt); see also CX 33 (March 17, 1997); CX 1 at 41; RX 14 (April 7, 2003)). These manufacturers went to considerable efforts to re-construct past exposures for individual chromate workers by compiling and analyzing literally thousands of data points. See e.g., Tr. 654-55 (Dr. Mundt); CX 1 at 47-51, 59-64.

Elementis and the chromium chemicals industry commissioned such an extensive study because they believed at the time that the risk of lung cancer mortality from hexavalent chromium in modernized chromium production plants was unclear. See CX 1 at 18-19, 40-41. They undertook this study to determine whether the industry's revamped chromium production processes had reduced or eliminated this risk. (Tr. 648 (Dr. Mundt)). To further understanding

[2] See REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 564 (Federal Judicial Center & National Research Council of the National Academies, eds., The National Academies Press, 3rd ed. 2011).

of the risk of lung cancer mortality in modern plants, the Final Report's authors adjusted their methodologies to address what the industry considered to be uncertainties, flawed analyses and data gaps in earlier studies. Despite the fact the Final Report itself states that it "adds to a limited but very recent body of scientific studies," Respondent now wants this Board to accept the proposition that there is "absolutely no new information" in the Final Report which reasonably supports the report's conclusion of substantial risk. (CX 1 at 18; see also Resp't Appeal Brief at 10; Resp't Initial Post-Hearing Brief at 2, 9, 10).

Respondent does not dispute that the Final Report contains substantial risk information, and that Elementis repeatedly chose not to provide the report to EPA until it did so in response to an EPA subpoena in 2008. (JX 1, ¶ 11; Resp't Reply Brief at 2, 6; Resp't Initial Post-Hearing Brief at 2; see also Resp't Memo. in Opp. to Compl't Mot. for Acc. Dec. on Liability at 3 ("Dr. Barnhart and Elementis chose not to submit the Report to EPA . . . .") (emphasis added)). However, as an affirmative defense, Elementis claims that it was not required to submit the Final Report to EPA because it had actual knowledge that the Administrator had been adequately informed of the report's substantial risk information. Respondent premises its claim on the fact that the Final Report and an earlier EPA-funded study made similar statistically significant findings. However, the fact that both studies made similar findings does not mean that the Final Report does not contain new, reportable "information" which reasonably supports the report's conclusion that high cumulative exposures lead to lung cancer. In actuality, the Final Report's substantial risk conclusion was based on a statistically significant finding derived from different exposure data than previous studies. Consistent with Agency guidance, these data relate directly to the probability of the occurrence of lung cancer mortality from hexavalent chromium exposure in modern plants.

The evidence in the record shows, and the Presiding Officer properly held, that Respondent was required to provide the Final Report to EPA pursuant to Section 8(e) because it contains new substantial risk information not previously available to the Administrator. Respondent raises no arguments on appeal that warrant overturning the Presiding Officer's March 25, 2011 Order and November 12, 2013 Initial Decision. Elementis is liable for a civil penalty under TSCA Section 16(a), given that Respondent has not sustained its burden of proving its statute of limitations and affirmative defenses. Respondent did not raise any other issues on appeal. For the reasons set forth herein and in Complainant's Response to Respondent's Motion for Judgment on the Pleadings and Complainant's post-hearing briefs, Complainant respectfully requests that the Presiding Officer's Order and Initial Decision be affirmed and a Final Order be issued assessing a penalty of $2,571,800.

V. ARGUMENT

A. THE PRESIDING OFFICER CORRECTLY RULED THAT THE TSCA SECTION 8(e) DATA REPORTING REQUIREMENT IS A CONTINUING REQUIREMENT, AND, THEREFORE, COMPLAINANT'S CLAIM AGAINST ELEMENTIS WAS NOT BARRED BY THE STATUTE OF LIMITATIONS

In the first part of its appeal before the Board, Respondent contends that the Presiding Officer erred in ruling in a March 11, 2012 Order (Order) that the TSCA Section 8(e) data reporting requirement is a continuing requirement, and, therefore, Complainant's claim was not barred by the applicable statute of limitations. Elementis argues that Complainant's claim was barred by the general federal five-year statute of limitations even though the requirement to immediately report information that a chemical presents substantial risk is continuing in nature. But it is Respondent that errs in its contention. Respondent's failure to provide the substantial risk information at issue began immediately after Elementis' receipt of the Final Report, and the violation continued until Respondent actually provided the report to EPA. Under the continuing

violations doctrine, the claim extends back to 2002 when Elementis obtained the Final Report and failed to submit it to EPA, and a substantial portion of this continuing period of violation occurred within the five-year statute limitations. Therefore, the Presiding Officer correctly ruled that the Section 8(e) disclosure requirement is a continuing requirement and Complainant respectfully requests that the Board affirm the Presiding Officer's Order.

There is absolutely no support in TSCA for the assertion that Respondent's duty to provide substantial risk information to EPA ended as soon as Elementis failed to "immediately" provide the information. The statute provides that EPA be informed of substantial risk information as soon as possible and EPA's need for this information is not diminished by the fact that the submittal is late. Companies in the possession of substantial risk information have an ongoing duty to provide that information to EPA, a duty which is not discharged until the Administrator is adequately informed of the information. It makes no sense to read Section 8(e) to mean that the duty to provide the information to EPA is discharged the instant a company obtains substantial risk information. And yet, Respondent essentially argues that its duty to provide substantial risk information to EPA begins and ends immediately upon the company's receipt of such information.

1. Pursuant to the Continuing Violations Doctrine, the Statute of Limitations Period for EPA's Claim Did Not Begin to Run until Elementis Submitted the Final Report to EPA

Complainant does not dispute that the general federal five-year statute of limitations period in 28 U.S.C. § 2462 applies to TSCA enforcement actions such as this action. Claims generally "first accrue" on the date the violation first occurs. (Order at 6 (citing 3M Co. v. Browner, 17 F.3d 1453, 1462 (D.C. Cir. 1994))). However, there are exceptions to the general rule. Id. One of those exceptions is known as the "continuing violations doctrine," under which

the statute of limitations period does not begin to run until the illegal course of conduct is complete. Id. (citing Havens Realty Corp. v. Coleman, 455 U.S. 363, 380-81 (1982); In re Lazarus, Inc., 7 E.A.D. 318, 364 (EAB 1997)("the limitations period for continuing violations does not begin to run until an illegal course of conduct is complete"). The continuing violations doctrine generally involves "cases in which the original violation occurred outside the statute of limitations, but is closely related to other violations that are not time barred. In such cases recovery may be had for all violations . . . ." Hendrix v. Yazoo City, 911 F.2d 1102, 1103 (5th Cir. 1990).[3]

The Presiding Officer ruled, based on EAB precedent, that failure to submit Section 8(e)-reportable substantial risk information is a continuing violation. (Order at 2). The doctrine of continuing violations provides that "the limitations period for continuing violations does not begin to run until the illegal course of conduct is complete." Lazarus, 7 E.A.D. at 364. TSCA Section 16(a) provides that when a violation continues, for purposes of the penalty, each day is a separate violation. Under the continuing violations doctrine, EPA's claim extends to the original violation in 2002 when Elementis first obtained but failed to submit the Final Report to the Administrator. See Havens Realty Corp, 455 U.S. at 380-81; Yazoo City, 911 F.2d at 1103. Elementis failed to submit the report to EPA until 2008 and EPA filed its complaint in 2010, therefore, the violation continued within the statute of limitations period.

In ruling on Respondent's statute of limitations defense, the Presiding Officer applied the two-part test that the Board developed in In re Harmon Electronics, Inc., 7 E.A.D. 1 (1997), to determine whether the Section 8(e) requirement is a continuing obligation for statute of

[3] Some tribunals, including the Board, have appeared to use the term "continuing violations doctrine" to refer to any case where continuing violations extend into the period of limitations, while other courts have used the term solely to refer to the doctrine which allows the consideration of continuing claims which fall outside of the period of limitations. See generally James R. MacAyeal, The Discovery Rule and the Continuing Violations Doctrine as Exceptions to the Statute of Limitations for Civil Environmental Penalty Claims, 15 VA. ENVTL. L.J. 589 (1996).

limitation purposes. In Harmon, the Board first looked to the general language of the statute and the legislative history to determine whether the statute, or regulatory scheme, was "expected to give rise to continuing violations." Harmon, 7 E.A.D. at 22-23. Second, the Board looked at the specific alleged violations to determine whether they are continuing in nature in light of the statutory language and applicable implementing regulations. Id.

a. The Board has twice held that Congress contemplated continuing violations under TSCA

With respect to the first prong of the test, the Presiding Officer noted that the Board had twice determined since Harmon that TSCA and its legislative history contemplate and support the existence of continuing violations. (Order at 6; see also Lazarus, 7 E.A.D. at 318; In re Newell Recycling Co., Inc., 8 E.A.D. 598, aff'd Newell Recycling Co., Inc. v. EPA, 231 F.3d 204 (5th Cir. 2000)). In both cases, the Board held that TSCA's penalty provision, Section 16(a)(1), which authorizes penalties for each day of violation, provides "evidence that Congress contemplated the possibility of continuing violations of TSCA." See 15 U.S.C. § 2615(a)(1) ("[e]ach day such a violation continues shall, for purposes of this subsection, constitute a separate violation . . . ."); see also Order at 6 (citing Lazarus, 7 E.A.D. at 368; see also Newell, 8 E.A.D. at 614-15; Compl't Response to Resp't Mot. for J. on the Pleadings at 12-16 (describing how TSCA and its legislative history demonstrate that Congress intended for continuing violations under the statute). Thus, it is well-established that the language in TSCA's penalty provision allows for continuing violations under TSCA. Accordingly, the Presiding Officer moved to the second prong of the Harmon test, which requires an analysis of whether Section 8(e) imposes a continuing statutory reporting duty. (Order at 6).

b. The Presiding Officer correctly concluded that Section 8(e) imposes a continuing statutory reporting duty

The second prong of the Harmon test requires an analysis of the specific violations alleged in the complaint to determine whether they are continuing in nature. Harmon, 7 E.A.D. at 22-23. Section 8(e) states:

> Any person who manufactures, processes, or distributes in commerce a 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) (emphasis added). In applying the second prong of the Harmon test, the Presiding Officer ruled that the Section 8(e) disclosure requirement is continuing in nature for two reasons. First, "the term 'immediately' in Section 8(e) does not impose a 'temporal limitation,' which suggests that the obligation is continuing in nature." Second, "the statute provides that the obligation to inform is only discharged upon occurrence of a specific event, that is, providing the information." (Order at 8-9). Respondent argues that with the use of the word "immediately," the statutory language establishes a temporal component to compliance; if the report is not submitted immediately, then the violation is complete and it need not be submitted at all. (Resp't Appeal Brief at 18). However, this interpretation is contrary to both the language of the statute and Congress' intent when it drafted Section 8(e), which was to ensure the Agency received information from chemical manufacturers about the risks associated with chemicals. The term "immediately" evidences Congress' intent that the Agency be provided information as soon as possible, but it does not also provide an end to the obligation.

As the Presiding Officer reasoned, the Board has previously stated that when assessing whether a particular regulatory requirement is meant to be continuing in nature "'[w]ords and

phrases connoting continuity and descriptions of activities that are typically ongoing are indications of a continuing nature . . . [whereas] a continuing nature may be negated by requirements that must be fulfilled within a particular timeframe.'" See Order at 6 (citing Newell, 8 E.A.D. at 615-16). In Newell, the regulation at issue required that PCBs be disposed of either at an incinerator or a chemical waste landfill. See Newell, 8 E.A.D. at 616 (citing 40 C.F.R. § 761.60(a)(4)). The Board held that

> "the regulation on its face carries no temporal limitation. It does not, as we expressed in Lazarus, prescribe a 'requirement[] that must be fulfilled within a particular time frame.' On the contrary, nothing in the regulation remotely suggests that the obligation described is discharged or extinguished simply with the passage of time. Instead, the obligation is discharged only with the occurrence of a specified event – the proper disposal of PCB-contaminated soil at an incinerator or a chemical waste landfill. Until this occurs, compliance with the regulatory mandate has not been achieved, and the responsible party commits, each day, a violation . . . ."

8 E.A.D. at 617. Similarly, as the Presiding Officer found in this case, Section 8(e) does not contain a temporal limitation. (See Order at 7-8 (definition of "immediately" "reflects not a date certain but an imprecise relation in time, variable according to the facts and circumstances.")). Rather, the duty to inform the Administrator under Section 8(e) begins immediately and is not discharged until the company either submits the information to EPA or obtains actual knowledge that the Administrator has already been adequately informed of the information. Only the occurrence of one of these two "specified events" discharges the obligation. Id. at 9.

Based on the language of Section 8(e), the statutory provision is clear and unambiguous. The only reasonable interpretation of this language is that the mandatory duty to inform EPA under Section 8(e) begins "immediately"— as soon as a person subject to the reporting requirement obtains 8(e)-reportable information — and ends only when that person informs the

Administrator of the information.[4] Any other reading of the statute would be contrary to the language of Section 8(e) and would defeat the purpose of the reporting requirement which is to ensure that the Agency actually receives substantial risk information.[5] Therefore, the Presiding Officer correctly applied the Board's two-part test in ruling that the Section 8(e) disclosure requirement is a continuing requirement. (See Order at 6, 12).

Respondent argues that the Presiding Officer's consideration of the policy behind Section 8(e) improperly assessed "the consequences of an alleged failure to 'immediately inform.'" (Resp't Appeal Brief at 20). However, courts and administrative bodies, including the Board, regularly look to the purpose of a statute in deciding whether Congress contemplated continuing violations under that statute. See Reading Co. v. Koons, 271 U.S. 58, 61-62 (1926) (stating that the word "accrued" should be "interpreted in the light of the general purposes of the statute and its other provisions, and with due regard to those practical ends which are to be served by any limitation of the time within which an action must be brought"); see also Harmon at 25-26 (citing many cases that considered the purposes and legislative history of the statutes at issue in deciding whether the continuing violations doctrine applied). In the Order, the Presiding Officer looked to TSCA's legislative history and noted that "Congress intended to ensure that regulators received 'timely access to information regarding health and safety studies concerning chemicals covered by the Act' to avoid the situation where 'human health and the environment is protected only after serious injury has occurred.'" (Order at 11 (quoting S. Rep. No. 94-698, at 6, 8; as reprinted in 1976 U.S.C.C.A.N. 4491, 4496, 4498). The Presiding Officer determined that

[4] In regard to Respondent's second argument, an affirmative defense to the reporting requirement may be established if a person subject to Section 8(e) can prove that it had actual knowledge that the Administrator had already been adequately informed of the substantial risk information in question. As discussed below, the Presiding Officer determined that Elementis failed to establish its affirmative defense.

[5] See TSCA's statement of findings, policy, and intent, 15 U.S.C. § 2601; S. Rep. No. 94-698, at 6, 8; as reprinted in 1976 U.S.C.C.A.N. 4491, 4496, 4498; see also CX 103 at 21 ("[s]ome information such as TSCA § 8(e) information may affect the Agency's ability to initiate immediate action necessary to protect health and the environment").

Elementis' interpretation of the word "immediately" in the statute would frustrate this goal because "'a manufacturer could violate the reporting requirement without fear of punishment if it could successfully hide the evidence . . . for five years.'" Id. at 11 (quoting United States v. Advance Mach. Co., 547 F. Supp. 1085, 1090 (D. Minn. 1982)). Such an outcome would be contrary to congressional intent; both in the sense that it would encourage companies to withhold information and would fail to serve the intent of Section 8(e) which is that EPA receive substantial risk information as soon as possible in order to address any potential threats to human health or the environment. The Supreme Court has cautioned that "interpretations of a statute which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available." Griffin v. Oceanic Contractors, 458 U.S. 564, 575 (1982) (citing United States v. Am. Trucking Ass'n, Inc., 310 U.S. 534 (1940)).

Respondent further argues that the Agency "has interpreted TSCA Section 8(e) to mean that the required reporting must be performed within 30 days."[6] (Resp't Appeal Brief at 17-19). In the Order, the Presiding Officer noted that "such enforcement guidance is discretionary, and cannot add a definitive time limit to a statute where none exists." (Order at 8). In any case, a close reading of the guidance reveals that the Agency did not interpret "immediately" to mean that the obligation to report ends on day 31. The guidance is clear that the reporting timeframe was intended as a grace period for the regulated community to process an 8(e) submission to EPA to be consistent with the Paperwork Reduction Act (PRA) which provides that agencies should not require written responses in fewer than 30 days after receipt. (CX 67 at 7).

[6] EPA's guidance in effect at the time Elementis received the Final Report in October of 2002 only provided a 15 working day reporting period. See CX 17 at 2 (stating that a person will be deemed to have "'immediately informed' the Administrator if information is received by EPA not later than the 15th working day after the date the person obtained the information."). The reporting period in the guidance was not lengthened to 30 calendar days until June 2003; nine months after Elementis received the Final Report in October 2002. See CX 67 at 2.

In 1991, EPA put forth guidance on reporting 8(e) information that provided a more direct explanation of how the time window functions in relation to the duty to report and the term "immediately." EPA's TSCA Section 8(e) Reporting Guide from June 1991, which predates the 2003 shift from a 15- to a 30-day reporting period, states that "[a] person is considered to have discharged the Section 8(e) reporting obligation if the information is received at EPA . . . in writing within 15 working days after the person obtains the information." (CX 21 at 22). This statement, with the original document's emphasis on the word "if," confirms that the obligation to report under Section 8(e) is only discharged if the information is submitted to the Agency within the reporting period; in other words, where the information is not submitted to the Agency within that time frame then the obligation continues because it has not been discharged. There is absolutely no support in the guidance for the proposition which Respondent suggests: that the Section 8(e) reporting obligation can only be fulfilled within 30 days and disappears after the expiration of the 30 day period.

Further, EPA's Enforcement Response Policy (ERP) for TSCA Sections 8, 12, and 13 makes clear that the Agency has long considered the reporting requirement in Section 8(e) continuing in nature. The ERP, which has been in place since 1999, states that penalties for Section 8(e) violations are to be assessed on a per-day basis with no cap on the number of days for which a penalty can be assessed. (CX 103 at 12, 13, 23 ("[t]his ERP reflects the seriousness the Agency attaches to violations of TSCA Section 8(e) by not placing caps on the penalties assessed for these violations.")). In fact, under the ERP, Section 8(e) violations are the only per-day violations that are not subject to a cap. (See CX 103 at 13). As the Agency stated in the ERP, "[f]ailure to comply with the TSCA Section 8(e) reporting requirements can be the most serious violation of TSCA Section 8. These reports alert the Agency to new information which

may have a bearing on the Agency's chemical hazard/risk assessment and chemical control efforts." (CX 103 at 23). EPA's longstanding interpretation that Section 8(e) requirements are continuing violations is entitled to deference. Lazarus, 7 E.A.D. at 365 (citing United States v. McGoff, 831 F.2d 1071, 1084 n.22 (D.C. Cir. 1987)) ([I]n civil cases, an agency's interpretation regarding the continuing nature of requirements may receive deference in a court's determination of whether to apply the continuing violations doctrine to the statute of limitations."); see also Intermountain Ins. Serv. of Vail v. Comm'r, 650 F.3d 691, 707 (D.C. Cir. 2011) (suggesting that, in some circumstances, agency interpretations of statute of limitations trigger Chevron deference).

Respondent's assertion that its obligation to submit Section 8(e) information is discharged the instant it obtains the information but fails to report it is contrary to the language of the statute, the intent of Congress, and longstanding Agency policy. Therefore, the Board should uphold the Presiding Officer's Order.

c. The requirements at issue in the cases Respondent cites in its Appeal Brief are distinguishable from Section 8(e)

In its Appeal Brief, Respondent cites to three administrative and judicial cases which, it argues, analyzed requirements similar to those imposed by Section 8(e) and found that the continuing violations doctrine did not apply. (Resp't Appeal Brief at 21-26). Elementis' reliance on these cases is misplaced. For the reasons discussed below, the Section 8(e) data reporting requirement is distinguishable from the requirements analyzed in each of the cases Elementis cites.

First, Elementis relies on Lazarus in which the Board held that the obligation to prepare an annual PCB report was not a continuing violation because the obligation occurs "at a specific point in time." (See Resp't Appeal Brief at 22 (citing Lazarus, 7 E.A.D. at 379)). Elementis

argues that this annual requirement is similar to the Section 8(e) obligation to "immediately inform" because both require compliance "within a particular time frame." Id. However, the PCB annual reporting requirement in Lazarus required a separate report for each year, and thus each year a new reporting obligation arose. In contrast, the Section 8(e) reporting requirement is not a recurring obligation, but a continuous obligation to report a specific piece of information. Unlike the annual PCB requirement, which springs anew each year, the requirement to report immediately under Section 8(e) will never be overtaken or superseded by another reporting deadline.[7]

Elementis also discusses AKM LLC v. Sec'y of Labor, 675 F.3d 752 (D.C. Cir. 2012). (See Resp't Appeal Brief at 23). In that case, the D.C. Circuit held that an OSHA regulation which requires employers to record information about work-related injuries within seven calendar days of the injury is not subject to the continuing violations doctrine. See AKM, 675 F.3d at 758. Significantly, the Court was not looking at whether the OSHA recordkeeping requirement warranted an exception to the general federal five-year statute of limitations. Rather, the Court was evaluating OSHA's narrow argument that the Agency's five-year record retention requirement acted to extend the applicable six month statute of limitations:

> [i]n rejecting that argument, we express no opinion on whether some other violations . . . could . . . be extended by the continuing violations concept . . . . Instead, we simply conclude that the statutory language in Section 657(c) which deals with record-keeping is not authorization for OSHA to cite the employer for a record-making violation more than six months after the recording failure.

[7] Section 8(e) is more analogous to the PCB ban, which the Board also analyzed in Lazarus. That requirement states that "effective one year after January 1, 1977, no person may . . . use any [PCBs] in any manner other than in a totally enclosed manner." Lazarus at 38 (citing TSCA § 6(e)(2)(A)). With respect to that provision, the Board held that "[t]he statutory provision clearly evidences an intent to institute a PCB ban beginning on the first day of 1978 and to continue the ban every day thereafter." Id. Likewise, Section 8(e) requires that substantial risk information be reported to the Administrator as soon as it is obtained; an obligation which continues every day until the Administrator is informed of the information.

AKM, 675 F.3d at 755, 758. Elementis argues that two elements of the D.C. Circuit's decision in AKM apply in this case: (1) for a requirement to be considered a continuing violation it must be repeated during the limitations period, and (2) an "inaction" or "failure to right a past wrong" is not the sort of action that would extend the statute of limitations. AKM, 675 F.3d at 757-758. Neither of these points are applicable to the instant case.

As to the first point, Complainant has demonstrated that Section 8(e)'s reporting obligation begins the moment a person receives substantial risk information and continues unabated until that risk information is submitted to the Administrator or the person has actual knowledge that the Administrator has been adequately informed about the information. (See Order at 9; see also Compl't Response to Resp't Mot. for J. on the Pleadings at 16-20). A violation continues every day the Administrator is denied the information. This statutory provision is different from the situation in AKM where OSHA's claim was wholly dependent on a regulation established by the Secretary of Labor which purported to extend the statute of limitations.[8]

With respect to the second point, the Court in AKM did not hold that "inactions" could never give rise to continuing violations nor did the Court define "inactions" vs. "actions"; rather the Court was responding to an earlier D.C. Circuit decision which OHSA had misquoted. See AKM, 675 F.3d at 757-58. In fact, multiple courts have found that the continuing violations doctrine applies to environmental law violations that could arguably be categorized as "inactions."[9] The common theme in all these cases is that the "dangers created by the violations

[8] The court in AKM noted how absurd the result would be to adopt the Secretary of Labor's position, which would allow the Department of Labor to write a regulation that would effectively expand the statute of limitations "ad infinitum" by making the time period for keeping a record of each violation as long as the Department would like to have to bring an action based on that violation. AKM, 675 F.3d at 758.

[9] See Lutz v. Chromatex Inc., 718 F. Supp. 413, 422 (M.D. Pa. 1989) (finding the requirement in CERCLA Section 103 to "immediately notify" the National Response Center of a hazardous release from a vessel to be continuing in

persist." See AKM, 675 F.3d at 758 (stating that the government may "toll the statute of limitations on a continuing violations theory [where] the dangers created by the violations persist"). Failure to inform the Agency of substantial risk information under Section 8(e) denies the Agency "new information which may have a bearing on the Agency's chemical hazard/risk assessment and chemical control efforts." (CX 103 at 23). Additionally, failure to report under Section 8(e) can "affect the Agency's ability to initiate immediate action necessary to protect health and the environment." Id. at 21. Thus, the dangers created by a Section 8(e) violation persist until that information is submitted to the Agency.[10]

Finally, Respondent argues that United States v. Illinois Power Co., 245 F.Supp. 2d 951 (S.D. Ill. 2003) is "highly instructive" to the present matter. (See Resp't Appeal Brief at 25). Complainant disagrees. In that case, the district court found that failure to obtain a preconstruction permit under the Clean Air Act is not a continuing violation, nor are violations of the Clean Air Act's pre-construction notification and reporting obligations. Illinois Power Co., 245 F.Supp. 2d at 957-958. As Elementis notes, the Court reasoned that each of these requirements were "discrete violations that were complete at the time of construction." (Resp't Appeal Brief at 25 (citing Illinois Power Co., 245 F.Supp. 2d at 958)). Respondent argues that, like the Clean Air Act's preconstruction requirements, the company's obligation to "immediately inform" the Administrator of substantial risk information under Section 8(e) was "'complete' (as per EPA's guidance) 31 days after Respondent obtained the information." (Resp't Appeal Brief

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nature); Sasser v. Adm'r U.S. Envtl. Prot. Agency, 990 F.2d 127, 129 (4th Cir. 1993) (holding that each day unpermitted fill is not removed from a wetland constitutes an additional day of violation); Carr v. Alta Verde Indus., Inc., 931 F.2d 1055, 1062 (5th Cir. 1991) (finding that failure to obtain an NPDES permit is a continuing violation).

[10] The ongoing nature of the Section 8(e) reporting requirement is by itself enough to defeat Respondent's argument that its failure to submit the Final Report to EPA was simply the "failure to right a past wrong." In fact, the record contains substantial evidence that Elementis did not violate the requirement simply by neglect, but rather made a series of conscious, affirmative decisions not to submit the report to the Agency. (See Initial Dec. at 22, 24, 28; Resp't Memo. in Opp. to Compl't Mot. for Acc. Dec. on Liability at 3 ("Dr. Barnhart and Elementis chose not to submit the Report to EPA pursuant to TSCA Section 8(e)")).

at 25). Illinois Power is a single district court opinion which EPA believes to be wrongly decided and is inconsistent with EPA's position regarding whether these preconstruction requirements are continuing in nature. In any event, Respondent's argument ignores the fact that the court in Illinois Power placed great weight on the theory that the relevant requirements had a deadline: the requirements had to be completed before construction began.[11] There are no such deadlines that would act to cut short a Section 8(e) reporting obligation; here the only arguably temporal language — "immediately" — does not establish a deadline, or the end to an obligation, but rather a starting time. The obligation ends only upon submission of the information to the Administrator or actual knowledge that the Administrator has already been informed of that information.

Notwithstanding Elementis' focus on these three cases, other tribunals have determined that Section 8(e) and analogous statutes and regulations have imposed a continuing reporting duty. (See Order at 9-12 (citing Union Carbide Corp., EPA Docket No. TSCA 85-H-02, 1985 EPA ALJ LEXIS 13 (ALJ, October 3, 1985) (holding that Section 8(e) reporting requirement is continuous); United States v. Advance Machine Co., 547 F.Supp. 1085 (D.Minn. 1982) (holding that language identical to Section 8(e) in a Consumer Product Safety Commission regulation creates a continuing obligation); United States v. Canal Barge Co., 631 F.3d 347 (6th Cir. 2011) (holding that a violation of a regulation requiring vessels to "immediately notify" the Coast Guard of a hazardous condition was a continuing offense)). See also Compl't Response to

[11] The requirements at issue in the case read in relevant part: "[n]o major emitting facilities . . . may be constructed in any area to which this part applies unless . . . (1) a permit has been issued . . . ." 42 U.S.C. § 7475(a) (emphasis added); "[n]o stationary source . . . shall begin actual construction without a permit . . . ." 40 C.F.R. § 52.21(i)(1) (emphasis added); "[a]ny owner or operator subject to the provisions of this part shall furnish the Administrator . . . [a] notification of any physical or operational change to an existing facility . . . . This notice shall be postmarked 60 days or as soon as practicable before the change is commenced . . . ." 40 C.F.R. § 60.7 (emphasis added); "[w]ithin 60 days after achieving the maximum production rate . . . but not later than 180 days after initial startup of such facility . . . , the owner or operator of the facility shall conduct performance test(s) and furnish the Administrator a written report of the results of such performance test(s)." 40 C.F.R. § 60.8 (emphasis added).

Resp't Mot. for J. on the Pleadings at 20-24; Lutz v. Chromatex, Inc., 718 F.Supp. 413, 422 (M.D. Pa. 1989) (holding that failure to "immediately notify" National Response Center of a hazardous release from a vessel under CERCLA Section 103 is a continuing violation)).

2. Contrary to Respondent's Argument, the Discovery Rule Is Not at Issue In this Case

In an attempt to divert the Board from the proper analysis and direct it towards the recent Supreme Court decision in Gabelli v. Sec. and Exch. Comm'n, 133 S.Ct. 1216 (2013), Respondent blurs the distinction between two separate exceptions to the general rule of accrual: (1) the doctrine of continuing violations and (2) the discovery rule.[12] But the Board should not be confused by Elementis' attempt to recast Complainant's argument and distort the Presiding Officer's decision. Importantly, this matter involves an assertion by Complainant and a ruling by the Presiding Officer that the continuing violations doctrine applies to Section 8(e); not the discovery rule.

The doctrine of continuing violations is a distinct doctrine, long recognized by the Supreme Court and applied in numerous decisions by federal courts and the EAB in cases much like this one. See Havens Realty Corp. v. Coleman, 455 U.S. 363 (1982); Toussie v. United States, 397 U.S. 112 (1970); In re Harmon Electronics, Inc., 7 E.A.D. 1 (EAB 1997). As we have discussed above, this doctrine provides that "the limitations period for continuing violations does not begin to run until the illegal course of conduct is complete." Lazarus, 7 E.A.D. at 364. In contrast, the discovery rule is an equitable doctrine based on considerations often present in cases of fraud, where a plaintiff may not "discover" the fraud until long after it has taken place. This rule provides that the limitations period does not begin to run until the plaintiff discovers the violation. See 3M Co., 17 F.3d at 1460. Under the discovery rule a violation may have

[12] The D.C. Circuit ruled twenty years ago, in 3M Co., that the discovery rule is not applicable to TSCA enforcement actions. See 3M Co., 17 F.3d at 1460-63.

ended many years in the past, but the statute of limitations period does not begin to run until the plaintiff discovers the violation. But when the violation was "discovered" is not relevant to the continuing violations doctrine analysis.

Respondent argues that there are "remarkable similarities between the instant matter and the 'discovery rule' at issue in" Gabelli. Complainant strongly disagrees. Gabelli involved the applicability of the "discovery rule," a rule in which the statute of limitations does not run until the plaintiff discovers the claim, even if all of the alleged violations occurred outside the limitations period. This situation is completely different from the case at hand, in which the violation began outside of the five-year period but continued into the five-year period immediately preceding the filing of the complaint. Here, Elementis' failure to provide the Final Report to EPA lasted from when it first received a draft of the report in 2002 to when it submitted the report to the Agency in 2008 in response to a subpoena. As explained above, the Section 8(e) reporting requirement only makes sense if it is read to mean that Elementis' failure to submit this report was a continuing violation. Complainant is not arguing that the statute of limitations period was tolled until the Agency discovered the violation because of equitable considerations, but rather that the statute of limitations did not begin to run until the illegal course of conduct was complete, which was well within the limitations period.

Section 8(e) requires "information which reasonable supports the conclusion of substantial risk" be immediately submitted to the Agency unless the company has actual knowledge that the Administrator has already been adequately informed of that information. 15 U.S.C. § 2607(e). In other words, the obligation to report under the statute begins immediately upon receipt of reportable information and continues until either the company submits that information to the Agency or has actual knowledge that the Administrator has been adequately

informed of that information – the "illegal course of conduct" is not "complete" until one of these two events arise. See Lazarus, 7 E.A.D. at 364. As TSCA Section 16 provides, each day Respondent failed to submit the report is a new violation. 15 U.S.C. § 2615(a)(1) ("Each day such a violation continues shall . . . constitute a separate violation . . . ."). Thus, as the Presiding Office correctly held, the violation continues "as long as the information remains withheld from the Administrator." (Order at 9).

For the above reasons, the Presiding Officer correctly ruled in the Order that the Section 8(e) disclosure requirement is a continuing requirement and EPA's complaint against Elementis was not barred by the statute of limitations.

B. THE PRESIDING OFFICER CORRECTLY HELD THAT ELEMENTIS HAD A DUTY TO PROVIDE THE FINAL REPORT TO EPA UNDER TSCA SECTION 8(e) BECAUSE THE REPORT CONTAINS NEW INFORMATION WHICH REASONABLY SUPPORTS THE REPORT'S CONCLUSION THAT HEXAVALENT CHROMIUM PRESENTS A SUBSTANTIAL RISK OF INJURY TO HEALTH

Respondent also appeals the Initial Decision on the ground that the Presiding Officer incorrectly held that Elementis had a duty under TSCA Section 8(e) to provide to EPA the Final Report, an industry study of the risk of lung cancer mortality from hexavalent chromium exposure in modernized chromium production plants. (Resp't Appeal Brief at 2). Section 8(e) provides that:

> Any person who manufactures, processes, or distributes in commerce a 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). Elementis admitted that 1) it is a manufacturer, processor or distributor in commerce of hexavalent chromium, 2) it obtained the Final Report that contains substantial risk

information pertaining to hexavalent chromium, and 3) it failed to immediately submit the Final Report to EPA. (See Initial Dec. at 37-38; see also Order on Compl't Mot. for Acc. Dec. on Liability and Resp't Req. for Oral Arg. at 11-13). Thus, Respondent has admitted to facts deemed by the Presiding Officer to be sufficient to establish the three elements of Complainant's prima facie case for Section 8(e) liability against Respondent. (Initial Dec. at 37-38).

Specifically, Respondent appeals the Presiding Officer's denial of Elementis' affirmative defense that the company had actual knowledge that the Administrator had been adequately informed of the substantial risk information in the Final Report at the time the company obtained the report. (Resp't Appeal Brief at 10, 40-41). While largely ignoring the Presiding Officer's analysis and the Agency's Section 8(e) guidance, Respondent contends the Presiding Officer erred because: 1) the only substantial risk information in the Final Report is the report's "finding" that "there was a statistically increased risk of lung cancer seen in the highest quartile of cumulative exposures" in the study population; and 2) Elementis had actual knowledge that the Administrator had been adequately informed of the Final Report's finding given that an earlier EPA-funded study called the Gibb Study found that high cumulative exposures lead to lung cancer mortality.[13] Id. at 29, 40-42. Condensed to its simplest form, this is Respondent's affirmative defense. However, neither of these contentions is supported by the law or the evidence presented in this case.

Respondent's defense rests heavily on the testimony of Dr. Joel Barnhart, Elementis' then-Vice President-Technical. (Initial Dec. at 64 n.21). Dr. Barnhart testified that he compared

[13] Both parties use the word "high" to describe cumulative exposures in the Final Report's top quartile and the Gibb Study's top two quartiles. The word "high" is used in this brief only in comparison to the studies' remaining quartiles with relatively lower cumulative exposures, and should not be confused with the extremely high cumulative exposures found in chromate production plants before the change-over from high-lime to no-lime or low-lime processes. The record contains an explanation of these processes. (See Initial Dec. at 6-7 nn. 4 & 5 (citing RX 24 at 2; CX 1 at 26; CX 95 at 7-8)).

the draft Final Report and the EPA-funded Gibb Study with particular attention to the calculation of cumulative exposures, and chose not to submit the draft report to EPA. (Tr. 968-91 (Dr. Barnhart); Resp't Memo. in Opp. to Compl't Mot. for Acc. Dec. on Liability at 3). Dr. Barnhart again chose not to submit the report when he obtained the final version on October 8, 2002, and a revised unpublished version on April 7, 2003. Even though Dr. Barnhart was aware of Section 8(e)'s data reporting requirement, the company's top technical official paid scant attention to the reportability of the Final Report. Dr. Barnhart testified, "I don't know that I had actually ever read 8(e) or the guidance." (Tr. 990-91 (Dr. Barnhart)). The Presiding Officer did not find Dr. Barnhart's testimony credible, and neither should the Board. (See Initial Dec. at 78-88.)

Initially, before turning to the issue of whether Respondent was required to submit the Final Report, Complainant believes it is important to clarify the scope of the Section 8(e) data reporting requirement. Thus, in Section B.1 below, we explain that the Presiding Officer's ruling that the data reporting requirement applies broadly to information supporting a conclusion of substantial risk is consistent with the language of the statute, its legislative history, Agency guidance, and the scientific method. We then review in Section B.2 the evidence in the record that supports the Presiding Officer's ruling that the adverse effect of lung cancer from occupational exposure to hexavalent chromium in modernized chromium production plants had not been well-established at the time Elementis obtained the Final Report. Next we make clear in Section B.3 that the five specific examples identified by the Presiding Officer reasonably support the Final Report's conclusion that high cumulative exposures lead to lung cancer. Finally, in Section B.4, we summarize the evidence that supports the Presiding Officer's holding that Respondent was required to provide the Final Report to EPA pursuant to Section 8(e) because it contains new substantial risk information not previously known to the Administrator.

1. The Presiding Officer Correctly Ruled that the Section 8(e) Data Reporting Requirement Applies to Exposure Data in the Final Report

The Presiding Officer ruled that the Section 8(e) data reporting requirement imposes a broad duty on chemical manufacturers, processors and distributors such as Elementis to provide "information" which "reasonably supports" a conclusion of substantial risk of injury to health. Id. at 38-48, 64-72. As the Presiding Officer noted, "'information' in Section 8(e) is a broad term employed to keep the Agency as informed as possible about chemical risks." Id. at 48. Looking only at the language of the statute and ignoring longstanding Agency guidance interpreting Section 8(e), Elementis contends that the Presiding Officer "improperly . . . broaden[ed]" the scope of the duty by applying it to information other than a statistically significant finding. (Resp't Appeal Brief at 10). Elementis mistakenly posits that the Final Report's statistically significant finding is the "only" information which reasonably supports the report's substantial risk conclusion.[14] Id. at 30; Resp't Reply Brief at 2, 6. In challenging the Presiding Officer's determination, Respondent attempts to establish a narrow and unsupportable test for what information must be reported under Section 8(e) by limiting reportable information to the statistically significant finding. However, Respondent's myopic view of Section 8(e)-reportable information has no basis in the statute, its legislative history, Agency guidance, or the scientific method.

Section 8(e) provides that "[a]ny person who manufactures, processes, or distributes in commerce a 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

[14] Respondent has argued that the only substantial risk information in the Final Report is the report's statistically significant finding. But Elementis has also contended that the only substantial risk information is the report's actual conclusion that high cumulative exposures lead to lung cancer mortality. (Cf. Resp't Appeal Brief at 10, 30; Resp't Reply Brief at 2, 6 and Resp't Initial Post-Hearing Brief at 19). No matter which position Respondent advocates the Presiding Officer correctly determined that Section 8(e) imposes a broad data reporting duty, and Section 8(e)-reportable information is not limited to statistically significant findings or study conclusions. (Initial Dec. at 40, 44, 48, 72).

health or the environment shall immediately inform the Administrator of such information." 15 U.S.C. § 2607(e) (emphasis added). As the Presiding Officer observed, the term "information" in Section 8(e) is used without limitation as to the source (e.g., draft, interim or final reports) or nature (e.g., raw data, QA-certified data, findings of risk including statistically significant findings, study conclusions) of the information. (See Initial Dec. at 40 (citing CX 21 at 18 (Section 8(e)-reportable information can come from a "variety of sources"); CX 103 at 40-41)). Accordingly, Respondent's contention that the Final Report's statistically significant finding is the "only" substantial risk information in the report subject to the Section 8(e) data reporting requirement is contrary to the language of the statute. The legislative history also lends support to a broad rather than a narrow reading of the term "information" in Section 8(e). Congress could have mandated a limited reading of the term, but as the Presiding Officer pointed out, Section 8(e), as enacted, is based on the United States House of Representative's language that requires the reporting of substantial risk "information" and not merely findings of "risk" which was proposed in United States Senate language but not adopted. Id. at 41. Although Respondent dismisses the Presiding Officer's recitation of the legislative history, Elementis offers nothing to refute it. (See Resp't Appeal Brief at 33-34 n.11).

Additionally, Complainant established at hearing that the Agency has broadly interpreted the scope of the Section 8(e) data reporting requirement in Agency guidance since the inception of EPA's Section 8(e) reporting program. Both testimonial and documentary evidence showed that the Agency has long regarded Section 8(e) as a "critically important information gathering tool that serves as an 'early warning mechanism'" and one of TSCA's "most important health and safety data reporting provisions" given its "broad scope and nature." (Tr. 27 (Mr. Krasnic); CX 21 at 12; CX 24 at 2). Beginning with the issuance of the original guidance in 1978, the

Agency has interpreted Section 8(e) to require a chemical manufacturer, processor or distributor to "immediately report any evidence which 'reasonably supports'" the conclusion of substantial risk. (CX 17 at 3 (emphasis added). The Agency also has stated since 1978 that information from epidemiologic studies will often "reasonably support" a substantial risk conclusion. (CX 17 at 3 (emphasis added)). In addition, the Agency has long recognized that information which "reasonably supports" a study's conclusion of substantial risk is "not identical" to the conclusion itself. Id. at 5 (comment 6). The Agency has further stated for over two decades that Section 8(e)-reportable information includes "exposure information" and "exposure-related data," and that such exposure information "should not focus at all on whether the information is conclusive regarding the risk." (CX 21 at 13, 26-28). As Agency statements of policy on Section 8(e), the Presiding Officer properly accorded deference to the guidance. (See Initial Dec. at 39 (citing In re Methyl Tertiary Butyl Ether Prods. Liab. Litig., 559 F. Supp. 2d 424, 440 (S.D.NY 2008); Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944))).

Finally, Respondent's contention is not only contrary to the language of Section 8(e), its legislative history and Agency guidance, it is also inconsistent with evidence in the record explaining the scientific method in the field of epidemiology. Respondent contends that the only information it could possibly need to report is the Final Report's statistically significant finding of excess lung cancer risk in the highest cumulative exposure quartile. (Resp't Appeal Brief at 9, 29). Respondent's contention suggests that the only conceivably reportable data is for that quartile. However, expert testimony demonstrated at hearing that it is scientifically problematic to isolate the data from just one group such as the highest exposure quartile and consider only that data. (Initial Dec. at 58 (citing e.g., Tr. 565-66, 568 (Dr. Speizer)). The Presiding Officer gave considerable weight to the expert testimony of Dr. Frank Speizer, Edward H. Kass

Distinguished Professor of Medicine, Harvard Medical School, and Professor of Environmental Science, Harvard School of Public Health. Id. at 56-58; see also CX 90. Dr. Speizer explained,

> [i]n picking individual groups [quartiles] and looking at them separately, one is essentially in both cases throwing away 75 percent of the data . . . . If they [report authors] had proposed to measure only that subgroup, the study would be clearly under powered to make those measurements. And it would not probably have been done . . . . So I think the focus on the individual groups is simply misusing the data completely.

Id. at 46 (citing Tr. 544-46 (Dr. Speizer)). The Final Report's statistically significant finding alone without the entire data set would be meaningless to the Agency because EPA could not properly and adequately assess the information on which that finding was based. Importantly, the Agency's independent ability to verify or interpret the results of studies would be jeopardized in the absence of the complete underlying data if the Section 8(e) data reporting duty was to be construed narrowly as Respondent suggests, and it would undermine the purpose of Section 8(e).

In summary, the Presiding Officer correctly ruled that the Section 8(e) data reporting requirement applies broadly to all "information" —including exposure data— in the Final Report which "reasonably supports" the report's substantial risk conclusion. (Initial Dec. at 38-48, 72).

2. The Presiding Officer Correctly Ruled that the Adverse Effect of Lung Cancer from Hexavalent Chromium in Modern Plants Had Not Been Well-Established at the Time Elementis Obtained the Final Report

Section 8(e) provides an affirmative defense to a person subject to the statutory provision's broad data reporting requirement. Specifically, Section 8(e) requires a chemical manufacturer, processor or distributor to inform EPA of substantial risk information unless that person has "actual knowledge that the Administrator was already adequately informed" of the information. 15 U.S.C. § 2607(e). The Agency has interpreted this statutory language to mean that a person is not required to report substantial risk information if the "information . . . [i]s corroborative of well-established adverse effects already documented in the scientific literature .

. . ." (CX 17 at 3; see also CX 21 at 19). Although Respondent claims the Presiding Officer erred in determining what was "well-established" because the statute does not contain that language, Agency guidance has stated since 1978 that studies need not be reported if they contain information which corroborates "well-established" adverse effects. (Resp't Appeal Brief at 32 n.32). The Presiding Officer calls this the "'corroborative of well-established adverse effects' exception" to the reporting requirement. (Initial Dec. at 49-53). In applying the guidance, the Presiding Officer correctly ruled that the adverse effect of lung cancer from hexavalent chromium exposure at the four modernized plants in the Final Report had not been well-established. Id. at 6-10, 72. The Presiding Officer also correctly ruled that the full range of the dose-response relationship under modern plant exposure conditions had not been well-established.[15] Id. at 72.

In considering what was documented in the scientific literature at the time Elementis obtained the Final Report in 2002, the Presiding Officer noted that the chromium chemicals industry had instituted major changes to the chromium production process which have reduced historically high exposure levels since the 1950s and 1960s. Id. at 7-8. The evidence at hearing demonstrated that only limited studies have examined the question of whether the risk of lung cancer mortality from hexavalent chromium exposure persists under conditions in modernized chromium production plants. (CX 1 at 29-31). The purpose of these post-change studies was to determine whether the change-over from the old and outmoded high-lime processes to modern low-lime or no-lime processes had lessened the risk of lung cancer mortality from occupational

[15] A dose-response means that the greater the exposure, the greater the risk of disease; generally, higher exposures should increase the severity or incidence of disease. REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 603 (Federal Judicial Center & National Research Council of the National Academies, eds., The National Academies Press, 3rd ed. 2011).

exposure to hexavalent chromium to chromate workers.[16] The results of initial post-change studies from the 1970s and early 1990s were inconclusive according to both the scientists who conducted these studies as well as the Final Report's authors. (CX 1 at 29, describing as "not conclusive" 1979 Hayes et al. (RX 24 (Final Report reference #33)), 1991 Davies et al. (CX 22 (Final Report reference #21)) and 1993 Korallus et al. (CX 25 (Final Report reference #22)). The studies' lack of conclusiveness stemmed from various methodological limitations: (1) limited latency period to account for the lag between exposure and the onset of cancer;[17] (2) relatively small cohort size limiting the statistical power of a study;[18] (3) the absence of quantitative exposure data; and (4) the absence of data on confounding variables such as smoking.[19] Still more recent post-change studies done in the 1990s and 2000s were improved, but the Final Report's authors qualified the results of even these studies, which notably included the Gibb Study:

> It is tempting to attribute the apparent reduction of cancer risks suggested by most of the later epidemiological studies to improved workplace conditions and reduced exposure to [hexavalent chromium] compounds. Despite the improvements cited for the three more recent studies, the effects of methodological limitations remain unclear. . . .

Id. at 32. (emphasis added); see also CX 33 at 2, 5-6; CX 44 at 3-4. Although the Final Report identifies the Gibb Study as a more recent post-change study, the Final Report specifically flags

[16] The 1979 Hayes study is illustrative of the rationale of post-change studies: "[I]ts major purpose was to determine whether employment in a modernized factory had resulted in a reduction in the risk of lung cancer as compared to the risk for workers employed . . . in an old production factory." (RX 24 at 2, 8; see also CX 22 at 1; CX 25 at 1).

[17] Lung cancer is known as a long latency disease so a follow-up period in epidemiologic studies of at least 20 years is preferred. (Tr. 132-33 (Dr. Cooper), 302-03 (Dr. Clapp); Tr. 845-46 (Dr. Mundt)).

[18] A cohort refers to a group of people used in a scientific study who have something in common such as occupational exposure to hexavalent chromium. The size of the cohort needs to be sufficiently large for a study to have enough statistical power to detect risk. (Tr. 301-02 (Dr. Clapp)).

[19] A confounding variable refers to a variable which the researcher must control or eliminate so that it does not damage the internal validity of an experiment. In an epidemiologic study of the risk of lung cancer mortality from hexavalent chromium, it is important to control or eliminate smoking as a confounding variable because smoking is also known to cause lung cancer. (Tr. 195 (Dr. Cooper)).

the Gibb Study as one of the studies with "methodological limitations" whose effects "remain unclear." Id. at 32, referencing 1994 Pastides et al. (CX 26 (Final Report reference #39)), 2000 Gibb et al. (CX 62 (Final Report reference #33)) and 2003 Luippold et al. (CX 69 (Final Report reference #24) discussed at pages 29-30). Thus, Respondent's own report constitutes compelling evidence that the adverse effect of lung cancer from hexavalent chromium exposure in modernized chromium production plants had not been well-established given "methodological limitations" in the most post-change studies including the Gibb Study.

In summary, Respondent was required to provide the Final Report to EPA because the adverse effects of hexavalent chromium exposure in modernized chromate production plants had not been not "well-established" at the time Elementis obtained the report in 2002. Moreover, as we discuss below, Respondent was required to submit the Final Report to EPA because the Final Report contains specific examples of information which reasonably supports the report's substantial risk conclusion.

3. The Presiding Officer Correctly Ruled that the Final Report Contains Five Specific Examples of Information which Reasonably Support the Report's Substantial Risk Conclusion

The Presiding Officer identified five specific examples of information in the Final Report which reasonably support the report's substantial risk conclusion that high cumulative exposures lead to lung cancer. (Initial Dec. at 64-71). The Agency has interpreted the statutory language of a "substantial risk of injury to health" in Section 8(e) to mean that "the substantiality of a risk is the function of both [1] the seriousness of the effect and [2] the probability of the effect's occurrence (see Part V)." Id. at 42 (citing CX 17 at 1, 3; CX 21 at 13; see also Tr. 29-30 (Mr. Krasnic). With respect to the first prong, the Agency has determined that even a single "instance of cancer" in humans should be reported if the effect can be reliably ascribed to the chemical.

(Tr. 30 (Mr. Krasnic); CX 17 at 3). Cancer is an example of a human health effect "so serious" that relatively little weight is given to exposure; the mere fact the implicated chemical is in commerce constitutes sufficient evidence of exposure." (CX 17 at 2). There is no disagreement regarding the seriousness of the health effect of lung cancer from hexavalent chromium. (See Resp't Appeal Brief at 2; Resp't Initial Post-Hearing Brief at 29; Compl't Initial Post-Hearing Brief at 9, 17; RX 25). Moreover, in regard to the second prong, the Agency has equated the "probability" that an adverse effect will result from a defined exposure with "exposure potential." (CX 17 at 6 (comment 19)). Although Respondent asserts that the Presiding Officer erred in not explaining how the five examples reasonably support the Final Report's substantial risk conclusion, we will make clear below that each of these examples relate directly to the probability of the occurrence of lung cancer from hexavalent chromium exposure. (See Resp't Appeal Brief at 30-31).

Before turning to the specific examples, we note that Elementis and other chromium chemical manufacturers specifically designed the study that led to the Final Report to address industry criticisms of the EPA-funded Gibb Study. In this proceeding, Respondent extols the Gibb Study as the definitive epidemiologic study for establishing the risk of lung cancer mortality from hexavalent chromium exposure. (See id. at 32; Resp't Initial Post-Hearing Brief at 3). There is no question that EPA's Gibb Study had advanced the scientific understanding of the risk of lung cancer mortality from hexavalent chromium exposure due to its large cohort, numerous lung cancer deaths, extensive industrial hygiene data from air sampling, exposure measurements and estimates based directly on hexavalent chromium, and an analysis of smoking as a potential confounding variable. (See CX 62 at 10-11). However, these strengths were insufficient to immunize the Gibb Study from scathing industry criticism at the time of OSHA's

hexavalent chromium rulemaking.[20] (Tr. 1067 (Dr. Gibb)). Although Respondent now lauds the Gibb Study, Elementis and other manufacturers roundly criticized the Gibb Study in challenging the scientific basis for OSHA's revised permissible exposure limit and that agency's use of a linear dose-response model.[21] (Initial Dec. at 19-20; see also CX 96 at 2 (linear risk model can lead to a "serious overprediction" of estimated risk); CX 76 at 102-03). Chief among industry criticisms were: (1) the inclusion of short-term workers; (2) the appropriateness of extrapolating lifetime cumulative exposures from relatively short duration exposures; and (3) re-construction of exposures without characterizing peak exposures. (CX 65 at 4-7, 40-43; see also CX 70 at 17; CX 76 at 19-20). As we explain below, the Final Report addresses these industry criticisms of the Gibb Study.

a. Exposure data collected exclusively from modern plant workers reasonably supports the Final Report's substantial risk conclusion

The Presiding Officer correctly found that exposure data collected exclusively from modern plant chromate workers reasonably supports the Final Report's substantial risk conclusion. (Initial Dec. at 64-65). Exposure data are the consummate example of information which would reasonably support an epidemiologic study's conclusion of substantial risk. The evidence at hearing showed that the Final Report included only exposure data collected from workers who had worked under low-lime or no-lime chromium production processes, thereby

[20] Under the Occupational Safety and Health Act, OSHA is charged with setting a permissible exposure limit (PEL) for hexavalent chromium. 29 U.S.C. § 655(b)(5). In 1971, OSHA adopted a PEL of 52 $\mu g/m^3$ (micrograms per cubic meter of air). In 2006, OSHA lowered the PEL from 52 $\mu g/m^3$ to 5 $\mu g/m^3$. (CX 76 at 3). OSHA proposed a PEL of 1 $\mu g/m^3$ in 2004, but ultimately determined that 5 $\mu g/m^3$ was the lowest level that is both technologically and economically feasible as required by law. (Tr. 1108, 1112 (Ms. Edens); CX 70; CX 76 at 3).

With the new PEL of 5$\mu g/m^3$, OSHA estimated 10 to 45 excess lung cancer deaths per thousand chromate workers. (Tr. 1115 (Ms. Edens); CX 76 at 126). However, OSHA recognized that even with this ten-fold reduction, chromate workers exposed to concentrations lower than the new PEL may have "significant excess cancer risk." (CX 76 at 126). OSHA still expects approximately 4-22 excess lung cancer deaths per 1,000 workers who have 20 years of exposure, and 10-45 excess lung cancer deaths per 1,000 workers who have 45 years of exposure. Id.

[21] EPA and OSHA use a linear dose-response model which assumes risk of an adverse effect from a chemical starting at the lowest possible exposure in the absence of quantifiable exposure data. (Tr. 578 (Dr. Speizer)).

excluding exposure data from workers exposed to hexavalent chromium under high-lime processes. (CX 1 at 15, 43, 86, 111 (Table 7)). Respondent argues that information about risk from industrial processes does not constitute substantial risk information. (Resp't Appeal Brief at 33-34). But Respondent's argument misses the mark. The Final Report was purposefully designed to evaluate the risk of lung cancer mortality in modernized chromium production plants, and the report's substantial risk conclusion was derived from exposure data collected exclusively from chromate workers who worked in modern plants unlike previous post-change studies. (See CX 1 at 43, 86). In sum, the Final Report's exposure data collected from modern plant chromate workers both provide evidence and serve to reduce uncertainty about the probability of the occurrence of lung cancer from hexavalent chromium exposure among workers in modernized plants. (See CX 17 at 1, 3).

b. Duration of exposure data excluding data from short-term workers reasonably supports the Final Report's substantial risk conclusion

The Presiding Officer correctly found that duration of exposure data that excluded data collected from short-term chromate workers reasonably supports the Final Report's substantial risk conclusion. (Initial Dec. at 65-67). Duration of exposure data are an ideal example of information which would reasonably support an epidemiologic study's conclusion of substantial risk. The evidence at hearing showed that the Final Report excluded data collected from short-term workers in estimating duration of exposure. (CX 1 at 43). Respondent contends that the use of short-term workers in the study is only a difference in methodology. (Resp't Appeal Brief at 35). However, Respondent's contention is surprising given that Elementis and other manufacturers specifically criticized the inclusion of short-term workers in the EPA-funded Gibb Study, and even questioned the appropriateness of extrapolating lifetime cumulative exposures from relatively short duration exposures in the Gibb Study. (CX 65 at 4-7, 18, 38, 41, 47, 49; see

also CX 76 at 19-20; CX 70 at 17). An industry critique of the Gibb Study stated that the exposures of short-term workers may have been to "very high" concentrations of hexavalent chromium due to the fact that short-term workers are typically assigned to the worse and highest exposure jobs. (CX 65 at 18). It also stated that short-term workers are likely to have significant exposures from other jobs. Id. In addition, as Elementis' own report recognizes, short-term workers

> often have different baseline disease risks from long-term employees, and are less likely to have had occupational exposures that meaningfully influence their ultimate cause of death. Therefore their exclusion enhances the focus of the study on the most relevant employees and long-term exposures.

(Initial Dec. at 66 (citing CX 1 at 43)). Moreover, expert testimony at hearing questioned the biological relevance of the exposure assessment of short-term workers in the Gibb Study. Id. at 66 (citing Tr. 530-31, 1090, 1096-97 (Dr. Speizer)). Finally, "as compared to Gibb [Study] it [Final Report] provides a different dimension of that effect [lung cancer] in the sense that Gibb is not biased, but certainly is influenced by the presence of the short-term workers as a . . . significant fraction of the population. Id. at 58 (citing Tr. 1097 (Dr. Speizer)). Thus, in addressing one of Elementis' and the industry's key criticisms of the Gibb Study, the Final Report's exclusion of duration of exposure data collected from short-term workers both provide evidence and serve to reduce uncertainty about the probability of the occurrence of lung cancer mortality among chromate workers in modernized plants. (See CX 17 at 1, 3).

c. Urinary and air data used to estimate exposure reasonably supports the Final Report's substantial risk conclusion

The Presiding Officer correctly found that urinary and air data used to estimate exposure reasonably supports the Final Report's substantial risk conclusion. (Initial Dec. at 68-69). Exposure data epitomize information which would reasonably support an epidemiologic study's

conclusion of substantial risk. The evidence at hearing showed that the Final Report used both urinary and air data to estimate exposure. (CX 1 at 16, 106 (Table 2)). Respondent argues that the use of mixed urine and air exposure data does not reasonably support the Final Report's substantial risk conclusion even though there is "significant" evidence in the record, as the Presiding Officer noted, showing that urine data provides a better measure of how much hexavalent chromium actually gets inside the body. (Initial Dec. at 68-69 (citing Tr. 517-18 (Dr. Speizer) ("We call them exposures because they are what is in the air in contrast to dose, which actually gets into the lung. And that's why we use those two different terms."); Tr. 710-11 (Dr. Mundt) ("[T]he dose is the amount of material that's internalized and specifically reaches the target organ . . . . Urine has to reflect what's been internalized.")). Additional evidence in the record confirms the expert testimony on urine data. (CX 1 at 65 ("Dose represents the actual amount of toxin entering the body and reaching the target organ (lungs), whereas exposure reflects the amount of toxin present in the environment. This makes the urinary data appropriate for epidemiological assessment of the relationship between an indicator of dose and the occurrence of lung cancer."). As a result, the Final Report's combined urine and air exposure data both provide evidence and serve to reduce uncertainty about the probability of the occurrence of lung cancer mortality among chromate workers in modernized plants. (See CX 17 at 1, 3).

d. The analysis of peak exposures reasonably support the Final Report's substantial risk conclusion

The Presiding Officer correctly found the calculation of peak exposures reasonably supports the Final Report's substantial risk conclusion. (Initial Dec. at 69). Exposure data from the calculation of peak exposures are an excellent example of information which would reasonably support an epidemiologic study's conclusion of substantial risk. The evidence at

hearing showed the Final Report used job exposure matrices to re-construct past exposures by analyzing both average exposure concentration and peak exposures. (CX 1 at 59). Respondent contends that the use of job exposure matrices reveals "nothing of risk." (Resp't Appeal Brief at 37-38). Respondent's contention is astonishing because Elementis and other manufacturers specifically criticized the EPA-funded Gibb Study for re-constructing past exposures by estimating total cumulative exposures without characterizing peak exposures. (CX 65 at 5; see also CX 70 at 17; CX 76 at 19-20). Peak exposures (i.e., short-term, high intensity exposure) of hexavalent chromium could be an alternative cause of lung cancer, therefore, if not adequately considered it increases the uncertainty that cumulative exposure is the correct indicator of risk. The Final Report ruled out peak exposure as a more accurate indicator of risk than cumulative exposure. However, the fact that the Final Report characterized peak exposures suggests that Elementis and the other manufacturers were not entirely convinced that the Gibb Study's calculation of cumulative exposures had definitely answered the question of whether risk of lung cancer mortality persists in modernized plants. Importantly, the elimination of peak exposures as an alternative indicator of risk removes the doubt sowed by industry about substantial risk conclusions based solely on total cumulative exposure. In short, in addressing another of Elementis' and the industry's key criticisms of the Gibb Study, the Final Report's elimination of peak exposures as an indicator of risk both provides evidence and serves to reduce uncertainty about the probability of the occurrence of lung cancer mortality among chromate workers in modernized plants. (See CX 17 at 1, 3).

e. Robust data used to eliminate smoking as a lung cancer variable reasonably supports the Final Report's substantial risk conclusion

The Presiding Officer correctly found that the use of more robust data to eliminate smoking as a confounding variable reasonably supports the Final Report's substantial risk

conclusion. (Initial Dec. at 70-71). Exposure data related to smoking is a perfect example of information which would reasonably support an epidemiologic study's conclusion of substantial risk. The evidence at hearing showed that the Final Report used extensive data to eliminate smoking as a confounding variable, which the report's authors considered a strength. (CX 1 at 51-52, 96). Respondent contends that smoking had no effect on the Final Report's substantial risk conclusion and, therefore, smoking information cannot possibly reasonably support the report's conclusion. (Resp't Appeal Brief at 39). This is an absurd contention because failing to adequately control for smoking can completely undermine any findings of lung cancer risk from hexavalent chromium exposure because smoking causes lung cancer too. Expert testimony at hearing demonstrated the importance of eliminating smoking as a confounding variable in studies of the risk of lung cancer from hexavalent chromium. (Tr. 195 (Dr. Cooper), 533 (Dr. Speizer), 698-99 (Dr. Mundt)). Respondent's own report acknowledges that most epidemiologic studies have largely ignored the role of smoking as a confounding variable because smoking data have been unavailable. (CX 1 at 31). Although both the Final Report and the Gibb Study controlled for smoking in their analyses to account for smoking as a potential confounder, the Final Report had more robust smoking data than the Gibb Study. The fact that Elementis and other manufacturers went to the expense of compiling more complete smoking data suggests that they were not convinced that the Gibb Study had definitely ruled out smoking as a potential confounder. Hence, the use of more robust data to eliminate smoking as a confounding variable both provides evidence and serves to reduce uncertainty about the probability of the occurrence of lung cancer mortality among chromate workers in modern plants. (See CX 17 at 3).

In summary, the evidence at hearing demonstrated that the five specific examples of information identified by the Presiding Officer in the Final Report reasonably support the

report's substantial risk conclusion and, therefore, Respondent was required to provide the Final Report to the Administrator pursuant to Section 8(e).

4. The Presiding Officer Properly Held that the Final Report Contains New Substantial Risk Information Not Previously Known to the Administrator, and, therefore, Elementis Was Required to Provide the Report to EPA

Having established that the five examples identified by the Presiding Officer reasonably support the Final Report's substantial risk conclusion that high cumulative exposures lead to lung cancer, the only remaining issue is whether Elementis had actual knowledge that the Administrator was adequately informed of the substantial risk information in Final Report. Respondent argues that it was not required to provide the Final Report to EPA because the report contains no new substantial risk information given that the earlier EPA-funded Gibb Study had identified an excess risk of lung cancer mortality at comparatively lower exposures. (Resp't Appeal Brief at 10; Resp't Initial Post-Hearing Brief at 2, 9 ("nothing new"), 10 ("absolutely no new information")). However, the evidence in the record showed, and the Presiding Officer properly held Respondent was required to provide the Final Report to EPA because the report contains new substantial risk information not previously known to EPA. (Initial Dec. at 72).

Contrary to Respondent's argument, the overwhelming evidence in the record shows that the Final Report contains new substantial risk information to estimate exposure potential, which directly addresses the Agency's definition of substantial risk in Agency guidance. (See CX 17 at 1, 3). The Presiding Officer gleaned from the extensive testimony of Respondent's own expert and the Final Report's primary author, Dr. Mundt, as well as her exhaustive review of the 153-page report, that the Final Report contains new exposure data. (Initial Dec. at 53-55, 64-72). Determining Dr. Mundt's expert testimony to be "thoughtful" and "credible" and his opinions "insightful," the Presiding Officer noted Dr. Mundt's testimony as well as other statements about

the value of the exposure data compiled for the Final Report. Id. at 53, 55 (citing Tr. 871, 879 ("rich data resource [] not fully exploited")), 938-939 (Dr. Mundt); CX 74 at 5 ("The data obtained . . . represent a valuable resource for documenting control of [hexavalent chromium] exposures, and for future investigations of potential health effects."). The Presiding Officer also noted Dr. Speizer's testimony about the value of the exposure data in the Final Report in "adding important information to our understanding of the dose response . . . relationship between exposure to these chemicals and the [adverse] outcome of lung cancer." Id. at 56-58 (citing Tr. 1085 (Dr. Speizer)). We summarize the evidence in the record that supports the Presiding Officer's holding below.

In an argument which pervades Respondent's discussion of examples (a), (c) and (d) of the substantial risk information in the Final Report, Elementis contends that the report contains no new substantial risk information because the Final Report and the Gibb Study's substantial risk conclusions are based on a single "common point of information," namely, high cumulative exposure levels. (Resp't Appeal Brief at 32). There is no disagreement that the Final Report and the Gibb Study used total cumulative exposure, and that that is a commonly accepted metric in epidemiologic studies. However, Respondent's contention merely re-states its position that the only substantial risk information in the Final Report is the report's statistically significant finding, which the Presiding Officer soundly rejected. (Initial Dec. at 44-48, 72). Importantly, as Dr. Speizer cautioned, "[Y]ou have to be careful about what goes into [total cumulative exposure]" in terms of "the basis for defining years of exposure" [duration of exposure] and "the monitoring of exposure" [exposure].[22] (Tr. 525 (Dr. Speizer)).

[22] Total cumulative exposure is a combination of years worked in the environment (duration of exposure) and the quantification of what is in the environment (exposure). (Tr. 512, 514-15 (Dr. Speizer)). Duration of exposure is derived from re-construction of employee work histories, and employment records are generally more complete and reliable than exposure data. Id. at 518-19. In contrast, exposure is derived from re-construction of historical

a. The Final Report contains new substantial risk information because the report's conclusion was derived from exposure data collected solely from modern plant chromate workers

The Presiding Officer correctly found, based on evidence in the record, that the Final Report contains new substantial risk information about exposure potential under the reduced exposure conditions in modernized plants. (Initial Dec. at 64-65). The Presiding Officer cited evidence of the Final Report's use of exposure data collected from chromate workers who had worked solely with modern no-lime or low-lime chromium production processes, thereby excluding data from workers exposed to hexavalent chromium under the old and outmoded high-lime processes. Id. at 64 (citing CX 1 at 43, 86). Additional evidence in the record buttresses the Presiding Officer's finding. (See, e.g., CX 1 at 15 ("All employees (n = 1518) included in the [Final Report] study worked one year or more in plants using [modern] low- or no-lime chromium production processes. Such a selection of the study cohort eliminates employees of high lime production processes . . . ."), 29 ("Employees with a history of pre-change exposure . . . were excluded."), 86 ("The study cohort is restricted to employees who have no prior experience working in a high lime process . . . ."), 111 (Table 7) (High-lime exposure exclusions by plant)).

Additionally, the Presiding Officer cited evidence of the Gibb Study's use of exposure data collected from chromate workers who had worked during the 1950s under outmoded high-lime processes in the plant's older facilities which were not phased out until 1960. (Initial Dec. at 64-65) (citing CX 62 at 1; RX 24 at 2; CX 20 at 2 ("New production facilities were constructed in 1950 and 1960; however, the old facility continued to operate until 1960.")). The Presiding Officer also noted Dr. Barnhart's use of the term "high-lime" to describe the Baltimore

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exposure measurements, and industrial hygiene data are expensive to collect and may be less complete than work histories. Id. at 519.

plant's old facilities examined in the Gibb Study. (Initial Dec. at 65 (citing CX 95 at 8). Additional evidence in the record supports the Presiding Officer's finding. (See, e.g., RX 24 at 3 (Table 2), 8 ("To include workers who had been employed for varying and possibly long periods of time in the industry prior to [modernization] would have confounded this issue."); CX 1 at 30 ("Unfortunately, [Gibb Study] did not evaluate separately lung cancer risk for those who worked exclusively in the new facilities, although the second new facility opened in 1960."), 86 ("All four plants had been studied previously, but each of these studies included employees exposed to high lime processes . . . ."). In short, the evidence at hearing showed that the Final Report used only exposure data to calculate total cumulative exposures from chromate workers who were exposed to hexavalent chromium under modern no-lime or low-lime chromium production processes, but the Gibb Study used exposure data from workers exposed under the old and outmoded high-lime chromium production processes.

b. The Final Report contains new substantial risk information about estimating the duration of exposure because the report excluded data from short-term chromate workers

The Presiding Officer correctly found, based on evidence in the record, that the Final Report contains new substantial risk information about estimating exposure potential from duration of exposure data that excluded data from short-term workers. (Initial Dec. at 65-68). The Presiding Officer cited evidence that the Final Report used duration of exposure data collected from long-term chromate workers by excluding data from short-term workers. Id. at 66 (citing CX 1 at 43)). Additional evidence in the record supports the Presiding Officer's finding. (See, e.g., CX 1 at 15 ("All employees (n = 1518) included in the study worked one year or more in plants using low- or no-lime . . . processes."), 30 ("[O]ver half worked less than six months, and 42% worked less than 90 days."), 43-44 ("Employees . . . with less than one year of

employment in modern plants" were excluded.), 86 ("This study [included] . . . 1,518 employees who worked for at least one year at one of the four . . . facilities in Germany and the United States."), 111 (Table 7 (Worked less than one year exclusions by plant))).

Additionally, the Presiding Officer cited evidence that the Gibb Study used extensive duration of exposure data collected from short-term chromate workers. (Initial Dec. at 66 (citing CX 62 at 2; Tr. 1030-31 (Dr. Gibb); CX 1 at 30)). Additional evidence in the record supports the Presiding Officer's finding. See CX 1 at 94 ("[A] very large proportion of the employees had very short duration of employment."); CX 70 at 17 ("Gibb et al. included workers regardless of duration of employment, and the cohort was heavily weighted by those individuals who worked less than 90 days."). Thus, the evidence at hearing demonstrated that the Final Report used duration of exposure data collected only from long-term chromate workers to estimate total cumulative exposures, but the Gibb Study extrapolated total cumulative exposures from relatively short duration exposures because that study was heavily weighted toward workers with less than one year of total employment.

c. The Final Report contains new substantial risk information about estimating exposure because the report used both air and urine data

The Presiding Officer correctly found, based on evidence in the record, that the Final Report contains new substantial risk information about estimating exposure potential from the use of combined air and urine data. (Initial Dec. at 68-69). The Presiding Officer cited evidence that the Final Report used both urinary and air data to estimate total cumulative exposures. Id. at 68 (citing CX 1 at 16, 106 (Table 2) (12,000 urine samples)). Additional evidence from the Final Report supports the Presiding Officer's finding. (See CX 1 at 47-51, 55-57). The Presiding Officer also cited evidence that the Gibb Study used only air data to calculate total cumulative exposures. (Initial Dec. at 68 (citing CX 62 at 3 (70,000 airborne measurements))). The record

contains additional evidence from the Gibb Study that supports the Presiding Officer's finding. (See CX 62 at 4, 5). As a result, the evidence at hearing showed that the Final Report estimated exposure potential using two types of industrial hygiene data, urinary and air, but the Gibb Study used only air data.

d. The Final Report contains new substantial risk information about estimating exposure because the report analyzed peak exposures

The Presiding Officer correctly found, based on evidence in the record, that the Final Report contains new substantial risk information about estimating exposure potential using a peak exposure index. (Initial Dec. at 69-70). The Presiding Officer cited evidence that the Final Report analyzed two types of exposures: total cumulative exposure (average exposure concentration) and peak exposure. Id. at 69 (citing CX 1 at 59). Additional evidence in the record explains the reason for analyzing peak exposures. (CX 1 at 16 ("Estimates of peak exposure values were also derived for each cohort member to determine whether peak exposure might predict lung cancer risk better than simple cumulative exposure.")). The Presiding Officer also cited evidence that the Gibb Study analyzed only a single type of exposure: average exposure concentration. (Initial Dec. at 69 (citing CX 62 at 3-4). In sum, the evidence at hearing showed that the Final Report analyzed both total cumulative exposures and peak exposures to estimate exposure potential, but the Gibb Study only analyzed average exposure concentration.

e. The Final Report contains new substantial risk information about estimating exposure because the report had robust smoking data to eliminate smoking as a variable in causing lung cancer mortality

The Presiding Officer correctly found, based on evidence in the record, that the Final Report contains new substantial risk information about estimating exposure potential from robust smoking data to eliminate smoking as a variable in causing lung cancer mortality. Id. at 70-71. The Presiding Officer cited evidence that the Final Report had superior smoking data to the Gibb

Study. Id. at 71 (citing CX 1 at 51-52, 122-23 (Tables 18, 19)). Additional evidence in the record supports the Presiding Officer's finding. (See, e.g., CX 1 at 51 ("[I]nformation collected including smoking status, age began smoking, number of cigarettes or cigars smoked per day, grams of pipe tobacco smoked per week and the year the employee quit smoking."), 96 (Strengths of this Study: "Finally, we were able to obtain and incorporate basic smoking information as a potential confounding variable, on a large majority of the cohort.")).

Additionally, the Presiding Officer cited evidence from the Gibb Study and an industry critique of the Gibb Study that it "did not have robust smoking information." (Initial Dec. at 71 (citing CX 62 at 11; CX 65 at 5-6)). Additional evidence in the record confirms the Presiding Officer's finding. (See, e.g., CX 62 at 3 ("Smoking status (yes/no) as of the beginning of employment was identified . . . from company medical records."), 5 ("[S]moking status was reported as of date of first employment."), 10 (Table IX) ("Yes/No for 91% of cohort at time of first employment"), 11 ("The measure of smoking in the current study was yes/no at the time of beginning employment. Such a measure does not provide information on the amount smoked or the number of individuals who smoked at the time of employment and who subsequently quit or the number of nonsmokers who became smokers.")). Hence, the evidence at hearing showed that the Final Report estimated exposure potential using robust smoking data including employee smoking history before and after the start of employment, but the Gibb Study only used smoking data limited to declaration of smoking status at the start of employment.

In closing, the Presiding Officer correctly found that the Final Report's new exposure data, when combined with the fact that lung cancer is an adverse effect of hexavalent chromium, is subject to the Section 8(e) data reporting requirement. Expert testimony demonstrated that the scientific understanding of health effects from chemical exposure is based on the accretion of

knowledge from information data in "[m]ultiple studies done by multiple investigators" in peer reviewed journals. (Initial Dec. at 55-56 (citing Tr. 477 (Dr. Clapp), 1064-1068 (Dr. Gibb); see also Tr. 939 (Dr. Mundt); CX 74 at 5). Data are important in adding additional information to reduce uncertainty about the hypothesis that the linear dose-response curve continues at lower exposure levels. Id. at 58 (citing Tr. 1093-94, 1097 (Dr. Speizer)). Even studies that replicate conclusions using different methods and populations "[r]educe uncertainty." Id. at 57 (citing Tr. 556) (Dr. Speizer)). The Presiding Officer noted Dr. Speizer's explanation of what constitutes "corroboration" in the field of epidemiology. Id. at 57 (citing Tr. 552 ("It really is important that you actually have different investigators working on different populations. And that's not corroboration. That's adding information to the scientific base.") (emphasis added)). Additionally, the Presiding Officer noted Dr. Speizer's example of the Surgeon General's 1964 advisory on smoking as the culmination of "dozens, if not hundreds of studies . . . ." Id. Moreover, the Presiding Officer specially noted Dr. Gibb's OSHA testimony, "[y]ou can't focus on one or two studies" in "determining whether there is a risk," but "[y]ou look at all of the studies, and then you make a determination." Id. at 61 (citing CX 97 at 148).

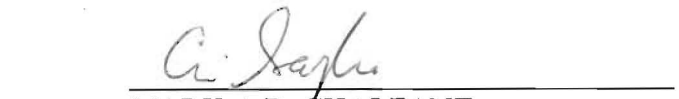
VI. CONCLUSION

Respondent bore the burden of proving by a preponderance of the evidence that the Section 8(e) requirement to immediately report information that a chemical presents substantial risk of injury to health is not a continuing requirement, and, therefore, EPA's claim is barred by the statute of limitations 40 C.F.R. § 22.24; In re Methyl Tertiary Butyl Ether Prods. Liab. Litig., 559 F. Supp. 2d at 434-35. The Presiding Officer correctly ruled that the Section 8(e) disclosure requirement is a continuing requirement, and, therefore, EPA's claim was not barred by the statute of limitations. Additionally, Elementis bore the burden at hearing of proving that,

when the company obtained the Final Report on October 8, 2002, Elementis had "actual knowledge that the Administrator had been adequately informed" of the information which reasonably supports the report's conclusion that high cumulative exposures lead to lung cancer. The Presiding Officer properly held that Respondent was required to provide the Final Report to EPA pursuant to Section 8(e) because the report contains new substantial risk information not previously known to the Administrator. Therefore, the Presiding Officer correctly concluded as a matter of law that Respondent had not sustained its burden of proving its affirmative defense by a preponderance of the evidence, and Elementis is, therefore, liable for a civil penalty under TSCA Section 16(a). Complainant respectfully requests that the Board affirm the Presiding Officer's March 25, 2011 Order and November 12, 2013 Initial Decision.

Respectfully submitted,

Date: February 24, 2014



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CERTIFICATE OF SERVICE

I certify that the foregoing *Complainant Environmental Protection Agency's Brief in Opposition to Respondent Elementis Chromium Inc's Appeal* in Docket No. TSCA-HQ-2010-5022, dated February 24, 2014, was sent this day in the following manner to the addresses listed below:

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