

**UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR**

IN THE MATTER OF:)
)
)
Elementis Chromium Inc.,)
f/k/a Elementis Chromium, LP)
)
Respondent.)
)
)
_____)

Docket No. TSCA-HQ-2010-5022

COMPLAINANT’S INITIAL POST-HEARING BRIEF

Complainant, the United States Environmental Protection Agency (Complainant, EPA or the Agency) respectfully submits its Initial Post-Hearing Brief pursuant to the Presiding Officer’s Post-Hearing Scheduling Order.

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Agency Documents

Occupational Exposure to Hexavalent Chromium; Final Rule, 71 Fed. Reg. 10,100 (Feb. 28, 2006) [CX 76]	40
U.S. Environmental Protection Agency, Memorandum, <u>Penalty Policy Supplements Pursuant to the 2004 Civil Monetary Penalty Inflation Adjustment Rule</u> (June 5, 2006) [CX 104]	46
U.S. Environmental Protection Agency, <u>Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12, and 13</u> (March 31, 1999) [CX 103]	45, 47, 48, 49, 50, 51, 52, 53, 56
U.S. Environmental Protection Agency, <u>Guidelines for Carcinogen Risk Assessment</u> (July 1999) [CX 61]	40
Guidelines for the Assessment of Civil Penalties Under Section 16 of the Toxic Substances Control Act; PCB Penalty Policy, 45 Fed. Reg. 59,770 (Sept. 10, 1980) [CX 102]	46, 47, 48, 49, 50, 53, 54, 55, 56
U.S. Environmental Protection Agency, <u>Health Assessment Document for Chromium</u> , EPA-600/8-83-14F (1984) [RX 25]	9, 10, 17, 18, 19, 21, 22, 30
Notification of Substantial Risk Under Section 8(e), 43 Fed. Reg. 11,110 (March 16, 1978) [CX 17]	14, 37, 51
U.S. Environmental Protection Agency, <u>Toxicological Review of Hexavalent Chromium (CAS No. 18540-29-9): In Support of Summary Information on the Integrated Risk Information System (IRIS)</u> (August 1998)	9, 17, 18, 19, 21, 22, 30
U.S. Environmental Protection Agency, <u>TSCA Section 8(e) Reporting Guide</u> (June 1991) [CX 21]	2, 37, 45, 49

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Other Sources

Applied Epidemiology, Inc., <u>Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998: Final Report</u> (Sept. 27, 2002) [CX 1]	9, 10, 11, 17, 18, 20, 24, 25, 26, 28, 29, 31, 32
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EPA Integrated Risk Information System web page (Coke oven emissions (CASRN 8007-45-2))	44
F. Speizer, Curriculum Vitae [CX 90]	36
Government of Canada, Priority Substances List Assessment Report - Chromium and its Compounds (1994) [RX 29]	9, 17
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Int'l Agency for Research on Cancer, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Lyons, France (Supp. 7 1987) [RX 26] 9, 17

J. Barnhart, Comments of Elementis Chromium LP dated December 31, 2004 regarding Proposed Rule for Occupational Exposure to Hexavalent Chromium, Docket H054A EX. 45-1 [CX 95] 40

J. Barnhart, Curriculum Vitae [RX 8] 10

J. Barnhart, Hearing Testimony dated January 3, 2004 [sic] submitted on behalf of Chrome Coalition regarding Proposed Rule on Occupational Exposure to Hexavalent Chromium, Docket H054A EX. 45-1 [CX 96] 40

K.S. Crump, Evaluation of Epidemiological Data and Risk Assessment for Hexavalent Chromium, prepared for Occup. Health and Safety Admin. (1995) [RX 35] 17

Minutes of Chrome Coalition Ad Hoc PEL Committee - Special Meeting with ChemRisk, dated February 13, 1996 [CX 27] 30

R.S. Luippold et al., Lung cancer mortality among chromate production workers, 60 OCCUP. ENVIRON. MED. 451 (2003) [CX 69] 21, 24, 25, 26, 27, 43

REFERENCE GUIDE ON EPIDEMIOLOGY, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (Federal Judicial Center & National Research Council of the National Academies eds., The National Academies Press, 3rd ed. 2011) 17, 20

T.F. Mancuso & W.C. Hueper, Occupational Cancer and Other Health Hazards in a Chromate Plant: A Medical Appraisal, I. Lung Cancer in Chromate Workers, IND. MED. AND SURG. 20, 358 (1951) [RX 20] 21

T.F. Mancuso, Chromium as an Industrial Carcinogen: Part I, AM. J. IND. MED. 31, 129 (1997) [RX 31] 21

T.F. Mancuso, Chromium as an Industrial Carcinogen: Part II. Chromium in Human Tissues, AM. J. INDUS. MED. 31, 140 (1997) [RX 30] 21

T.F. Mancuso, Consideration of Chromium as an Industrial Carcinogen, Int'l Conf. on Heavy Metals in the Env't, Toronto, Ontario 343 (1975) [CX 16] 21

U.S. Dept. of Health and Human Services, Agency for Toxic Substances and Disease Registry, Toxicological Profile for Chromium (1993) [RX 28] 9, 17

W. Machle & F. Gregorius, Cancer of the Respiratory System in the U.S. Chromate-producing Industry, PUB. HEALTH REP. 63, 1114 [RX 18] 17

I. QUESTIONS PRESENTED

1. Whether EPA Has Met Its Burden of Persuasion to Prove that Respondent Failed to Immediately Inform the Administrator of the Final Four Plant Report as Required by TSCA Section 8(e), When Respondent Has Admitted or Stipulated to Each Element of Complainant's Prima Facie Case?

2. Whether Respondent Has Failed to Meet Its Burden of Persuasion to Establish Its Statutory Affirmative Defense Under TSCA Section 8(e), When the Final Four Plant Report Contains New Information to Quantify the Carcinogenic Effects of Hexavalent Chromium Under Long-term, Low-intensity Exposure Conditions that the Administrator Had Not Been Adequately Informed of at the Time Respondent Obtained the Report in 2002?

3. Whether EPA's Proposed Penalty of \$2,338,000 Is Appropriate Under TSCA Section 16(a)(2)(B), When It Was Calculated in Accordance with the Statutory Penalty Criteria?

II. SUMMARY OF THE ARGUMENT

Hexavalent chromium is one of the most toxic chemical compounds used in the industrial workplace. Workers in many different occupations are exposed to this highly toxic substance. For over a century, hexavalent chromium has been linked with the increased risk of lung cancer mortality at high exposure levels. But the carcinogenic potency of hexavalent chromium at the low levels of exposure found in modern chromate production plants has been hotly disputed. The report at issue in this case, obtained by Respondent Elementis Chromium, Inc. (Elementis) in 2002, was commissioned by the chromate industry to better quantify the carcinogenic effects of hexavalent chromium at low exposure levels in modern plants. This report, referred to here as the Final Four Plant Report, shows elevated lung cancer mortality risk from occupational exposure to hexavalent chromium under long-term, low-intensity exposure conditions. Yet

Elementis, a major domestic manufacturer and distributor of chemicals containing hexavalent chromium compounds, did not turn the Final Four Plant Report over to EPA until the Agency specifically requested the report in a 2008 subpoena. It is Elementis's six-year delay in submitting the Final Four Plant Report to the EPA Administrator that is the impetus for this action to enforce the Toxic Substance Control Act (TSCA)'s mandatory reporting duty for manufacturers and distributors to timely disclose new information about chemical hazards.

Pursuant to section 8(e) of TSCA, Elementis has a duty to immediately submit to the Agency any information it obtains which reasonably supports the conclusion that hexavalent chromium presents a substantial risk of injury to health. Section 8(e) is a "critically important information gathering tool that serves as an 'early warning' mechanism for keeping the Agency and others apprised of new-found serious chemical hazards and/or exposures" CX 21 at 12 [1991 EPA 8(e) Reporting Guide]. Because this statutory provision is intended to protect human health, violations of TSCA section 8(e) are treated as serious violations.

Elementis violated TSCA section 8(e)'s mandatory reporting requirement when it failed to immediately submit to EPA the report it obtained in 2002 showing elevated risk of lung cancer mortality from hexavalent chromium exposure under long-term, low-intensity exposure conditions. Elementis has admitted or stipulated to all three elements of a prima facie case of section 8(e) liability: 1) that it is subject to TSCA as a person who manufactures or distributes in commerce a chemical substance or mixture; 2) that it obtained information which reasonably supports the conclusion that hexavalent chromium presents a substantial risk of injury to health; and 3) that it did not immediately inform the EPA Administrator of such information. Thus, EPA has proven a prima facie case against Respondent for its failure to timely inform the Agency of the 2002 Final Four Plant Report.

Having established the prima facie case, Respondent's liability turns on whether TSCA section 8(e)'s statutory affirmative defense operates to relieve Elementis from its obligation to report. Section 8(e) provides that a person is required to immediately submit substantial risk information to the Administrator "unless such person has actual knowledge that the Administrator has been adequately informed of such information." 15 U.S.C. § 2607(e). At hearing, Respondent failed to meet its burden of proving by a preponderance of the evidence that it had actual knowledge that the EPA Administrator had been adequately informed of the information in the Final Four Plant Report.

Although the carcinogenicity of hexavalent chromium was well-recognized at the time of the Final Four Plant Report, the carcinogenic potency of hexavalent chromium under long-term, low-intensity exposure conditions was not well-established in 2002. Long-term, low-intensity exposures are of prime interest to the Agency for estimating the carcinogenic potency of a chemical for human health risk assessments. Many epidemiological studies link hexavalent chromium to lung cancer. But, at the time of the Final Four Plant Report, limitations in prior studies resulted in inadequate exposure data to fully quantify carcinogenic effects under long-term, low-intensity exposure conditions.

The Final Four Plant Report authors in the report itself as well as Respondent's testifying expert, Dr. Herman Gibb, acknowledged the limited availability of exposure data for quantifying the carcinogenic potency of hexavalent chromium. Dr. Gibb testified at hearing that there were three exposure data sets, only two of which existed at the time of the Final Four Plant Report. Considerable testimony was devoted to comparing what the 2000 EPA-funded Gibb et al. study, one of the three studies cited by Dr. Gibb, and the Final Four Plant Report contribute to the scientific understanding of the carcinogenic potency of hexavalent chromium. While both the

Gibb et al. study and the Final Four Plant Report found elevated risk of lung cancer mortality from hexavalent chromium exposure, these findings are based on markedly different exposure conditions reflecting the intensity or concentration of exposure and the duration of work exposure.

The Gibb et al. study's finding of elevated lung cancer mortality risk is based on short-term, high-intensity exposure conditions; in contrast, the Final Four Plant Report's finding is based on long-term, low-intensity exposure conditions. The different exposure conditions in the Gibb et al. study and the Final Four Plant Report are evident from the duration of work exposure in the respective study cohorts. The Gibb et al. study cohort's duration of work exposure is, on average, only 3.1 years, with a median duration of less than five months, but the duration for the Final Four Plant Report cohort is, on average, 8 to 12 years. In light of the comparable cumulative exposure levels in both studies and the short duration of work exposure reported in the Gibb et al. study, the Final Four Plant Report necessarily must have a lower intensity of exposure than the Gibb et al. study to result in the same cumulative exposure levels over a longer period.

In summary, EPA has proven Elementis's liability under TSCA section 8(e) and Respondent has failed to establish its statutory affirmative defense. Based on the plain language of the statute, the Final Four Plant Report contains new information about the elevated risk of lung cancer mortality from hexavalent chromium exposure. As such, this new information is not corroborative of previously available information. Thus, Respondent could not have had actual knowledge that the Administrator had already been informed of that information. Consequently, EPA is entitled to judgment against Elementis for its violation of TSCA section 8(e). Moreover, the Agency's proposed civil penalty of \$2,338,000 is appropriate. The proposed civil penalty

was calculated in accordance with the statutory factors set forth in TSCA section 16 and appropriately considers the importance the Agency attaches to non-reporting violations under TSCA section 8(e), the potential harm that could result from such violations, and the fact that Respondent's violation did not disrupt the Agency's ability to address situations involving potential imminent hazards.

III. STATEMENT OF THE CASE

A. Statutory Framework

Section 8(e) of TSCA imposes a mandatory statutory reporting duty as follows:

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). Failure to report pursuant to section 8(e) constitutes an unlawful act under TSCA section 15(3)(B), which states it is unlawful for any person to fail or refuse to submit reports, notices, or other information required by TSCA, and subjects the person to the assessment of civil penalties for each day of the violation, pursuant to TSCA section 16. 15 U.S.C. §§ 2614(3)(B), 2615.

TSCA section 2(b) establishes three general federal policies with respect to chemical substances and mixtures in U.S. commerce, "that—

[A]dequate 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;

[A]dequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and

[A]uthority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.”

15 U.S.C. § 2601(b).

B. Procedural Background

On September 2, 2010, Complainant filed a Complaint and Notice of Opportunity for Hearing against Elementis pursuant to TSCA section 16(a), 15 U.S.C. § 2615(a), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (“Consolidated Rules of Practice”), 40 C.F.R. Part 22. The Complaint alleges that Respondent violated TSCA section 8(e), 15 U.S.C. § 2607(e), by failing to immediately inform the EPA Administrator of substantial risk information it obtained on October 8, 2002, that Respondent’s violation was continuing in nature, and that Respondent’s violation constitutes an unlawful act under TSCA section 15(3)(B), 15 U.S.C. § 2614(3)(B). (Compl. at 9, ¶¶ 49-2.) On October 4, 2010, Respondent filed an Answer and Affirmative Defenses to the Complaint. In its Answer, Respondent admitted many of the essential allegations set forth in the Complaint. (Ans. at 2-5.) Respondent also asserted five affirmative defenses. *Id.* at 6-7.

On December 15, 2010, Respondent filed a Motion for Judgment on the Pleadings seeking an order dismissing the Complaint with prejudice on the ground that the TSCA section 8(e) claim is time-barred by the general federal five-year statute of limitations at 28 U.S.C. § 2462. (Resp’t Mot. for J. on the Pleadings ¶¶ 5, 7.) On January 7, 2011, Complainant filed its response requesting that Respondent’s Motion for Judgment on the Pleadings be denied in its entirety. (Compl’t Mot. in Response to Resp’t Mot. for J. on the Pleadings.) On January 24,

2011, Respondent filed its reply to Complainant's response. (Resp't Reply Mem. of Law in Support of Resp't Mot. for J. on the Pleadings.) On March 28, 2011, the Presiding Officer issued an order denying Respondent's Motion for Judgment on the Pleadings. (Order on Resp't Mot. for J. on the Pleadings.)

On April 7, 2011, Respondent filed a Motion Requesting the Presiding Officer to Recommend Interlocutory Review of the March 28, 2011 Order by the Environmental Appeals Board. (Resp't Mot. Requesting the Pres. Officer to Recommend Interl. Review.) Complainant filed a response in opposition on April 14, 2011. (Compl't Response to Resp't Mot. Req. the Pres. Officer to Recommend Interl. Review.) The Presiding Officer denied the motion on April 27, 2011. (Order Denying Resp't Mot. for Interl. Appeal.) On April 28, 2011, the Presiding Officer issued a Prehearing Order. (Prehearing Order.)

On April 28, 2011, Complainant filed a Motion for Accelerated Decision on Liability. (Compl't Mot. for Acc. Dec. on Liability.) On May 13, 2011, Respondent filed a Memorandum in Opposition to Complainant's Motion for Accelerated Decision on Liability. (Resp't Memo. in Opp. to Compl't's Mot. for Acc. Dec. on Liability.) Complainant filed a reply on May 24, 2011. (Compl't Reply to Resp't Memo. in Opp. to Compl't Mot. for Acc. Dec. on Liability.) On June 1, 2011, Respondent filed a Request for Oral Argument on Complainant's Motion for Accelerated Decision on Liability. (Resp't Req. for Oral Arg. on Compl't Mot. for Acc. Dec. on Liability.) Complainant filed a response on June 10, 2011, and Respondent filed a reply on June 16, 2011. (Compl't Response to Resp't Req. for Oral Arg. on Compl't Mot. for Acc. Dec. on Liability; Resp't Reply to Compl't Response to Resp't Req. for Oral Arg. on Compl't Mot. for Acc. Dec. on Liability.) On August 8, 2011, the Presiding Officer denied Complainant's Motion

for Accelerated Decision and Respondent's Request for Oral Argument. (Order on Compl't Mot. for Acc. Dec. and Resp't Req. for Oral Argument.)

On June 10, 2011, Complainant filed its Initial Prehearing Exchange. (Compl't Initial Prehearing Exch.) Respondent filed its Initial Prehearing Exchange on June 30, 2011. (Resp't Initial Prehearing Exch.) Complainant filed a Rebuttal Prehearing Exchange on July 15, 2011. (Compl't Rebuttal Prehearing Exch.) On August 22, 2011, the Presiding Officer issued a Notice of Hearing and Scheduling Order scheduling a hearing to be held in Washington, D.C. commencing on December 12, 2011. (Notice of Hearing and Scheduling Order.)

The parties filed a Joint Set of Stipulated Facts, Exhibits and Testimony on November 10, 2011. (Joint Set of Stip. Facts, Exs., and Test.) On November 18, 2011, Respondent filed a Prehearing Brief. (Resp't Prehearing Brief.) Complainant filed an Unopposed Motion to Supplement Complainant's Prehearing Exchange on December 6, 2011; the Presiding Officer granted the motion that same day. (Compl't Unopposed Mot. to Supp. Compl't Prehearing Exch.; Order Granting Unopposed Mot. to Supp. Compl't Prehearing Exch.) The parties filed a Joint Set of Stipulated Exhibits and Expert Qualifications on December 8, 2011. (Joint Set of Stip. Exs. and Expert Quals.)

A hearing was held before Chief Administrative Law Judge, Susan L. Biro, in Washington, D.C., on December 12–14, 2011. On December 21, 2011, the Presiding Officer issued a Post-Hearing Scheduling Order. (Post-Hearing Scheduling Order.) On January 30, 2012 Complainant filed a Joint Motion to Conform Transcript to Actual Testimony pursuant to 40 C.F.R. § 22.25. (Joint Mot. to Conform Transcript to Actual Testimony.) The Presiding Officer granted the joint motion on February 1, 2012. (Order Granting Joint Mot. to Conform Transcript to Actual Testimony.)

C. Factual Background

Elementis Chromium Inc. (Elementis) and its predecessors have been manufacturing chromium chemicals for over 35 years. (Joint Set of Stip. Facts, Exs., and Test. ¶ 5.) Elementis is a manufacturer and distributor in commerce of chemical substances, including chromic acid, chromic oxide, and sodium dichromate. *Id.* at ¶¶ 4, 6; see also CX 8, 9 [Inventory Update Reporting Filings]. Chromic acid and sodium dichromate are hexavalent chromium compounds. (Ans. ¶ 18.) Respondent has two main manufacturing facilities that produce chromium chemicals in the United States, including one that was owned by Elementis at the time the company obtained the report at issue in this case. *Id.* at ¶¶ 6, 8.)

Hexavalent chromium has been linked to lung cancer since the late 1800s. See generally, RX 25 [1984 EPA Cr Health Assessment]; RX 26 [1987 IARC Monograph]; RX 27 [1990 IARC Monograph]; RX 28 [1993 ATSDR CrVI Toxicological Profile]; RX 29 [1994 Environment Canada Report]; CX 53 [1998 EPA CrVI Toxicological Review]. In the 1950s and 60s, the chromate industry instituted manufacturing process changes and industrial hygiene controls with the expectation that these improvements would reduce worker exposure to dust containing hexavalent chromium compounds, thereby reducing their risk of developing lung cancer from hexavalent chromium exposure. CX 1 at 1, 26-27 [FFPR]; see also Tr. at 653, 656 (Mundt). In 1984, EPA classified hexavalent chromium as a human carcinogen. RX 25 [1984 EPA Cr Health Assessment].

In or about 1998, the Industrial Health Foundation (IHF) Chromium Chemicals Health and Environmental Committee initiated a multi-plant epidemiological study of 1,518 employees from four chromium chemicals production facilities, two located in the United States and two in Germany. (Joint Set of Stip. Facts, Exs., and Test. ¶¶ 7-10.) This study, referred to as the Final

Four Plant Report, sought to investigate whether the lower levels of hexavalent chromium exposure resulting from process changes the industry implemented in the 1950s and 60s had successfully reduced workers' risk of developing lung cancer. See CX 3 at 18, 52 [1999 FFPR Revised Protocol]; see also CX 3 at 51 [FFPR Revised Protocol—Peer Review Comments]; Tr. at 653 (Mundt). Commissioned over a decade after EPA first classified hexavalent chromium as a human carcinogen in 1984, the Final Four Plant Report had a total cost of approximately \$500,000. See generally, RX 25 [1984 EPA Cr Health Assessment]; Tr. at 913-14, 926 (Mundt).

Dr. Joel Barnhart, Vice President—Technical for Elementis, played a key role in overseeing the development of the Final Four Plant Report through his involvement in various industry organizations. (Tr. at 955-959 (Barnhart); Ans. ¶¶ 25, 26, 31-34; CX 6 at 6, 8 [Subpoena Response (Barnhart)]; RX 8 [Barnhart CV].) At the time the Final Four Plant Report was undertaken, only a small number of epidemiological studies had evaluated the lung cancer mortality risk from hexavalent chromium exposures in modern chromate plants, which are lower than in older plants. CX 1 at 27-32, 86 [FFPR]; Tr. at 653 (Mundt); Tr. at 1090 (Speizer). As of the late 1990s, the limited scientific literature suggested that the lower exposures characteristic of the modern chromate production process had reduced lung cancer mortality risk; however, on the whole, as noted by the authors of the Final Four Plant Report, there was not sufficient exposure data to draw this conclusion. CX 1 at 15, 29 [FFPR].

At the time Respondent obtained the Final Four Plant Report in 2002, only two epidemiological studies (Mancuso (1975, 1997); Gibb (2000)) contained exposure data sets that could be used for risk estimation in human health risk assessments. (See Tr. at 1065-66 (Gibb).) A third study (Luippold (2003)) containing an exposure data set became available after

Respondent obtained the Final Four Plant Report. Id. Each of these studies had limitations that affect the interpretation of the results, including, for example: (1) method and timing of exposure measurements; (2) small study cohort size; (3) lack of or incomplete smoking data; and (4) inclusion of short-term workers in the study cohort. See Table 1 below. One of the key limitations in the Gibb et al. study was the inclusion of short-term workers. (See Tr. at 150-51, 157 (Cooper).) The authors of the Final Four Plant Report eliminated this limitation by excluding short-term workers from the Final Four Plant Report study cohort. CX 1 at 15, 43 [FFPR]; Tr. at 721 (Mundt); Tr. at 1030-31 (Gibb).

Both the Final Four Plant Report and the Gibb et al. study show an elevated risk of lung cancer mortality with increased exposure to hexavalent chromium. (Joint Set of Stip. Facts, Exs., and Test. ¶ 11; CX 1 at 98 [FFPR]; Tr. at 729, 737, 742 (Mundt); Tr. at 94, 164 (Cooper); Tr. at 538 (Speizer) and CX 1 at 93 [FFPR]; Tr. at 868 (Mundt); Tr. at 148-50 (Cooper).) These studies' respective findings are based on different exposure conditions. (Tr. at 165 (Cooper); Tr. at 541-43 (Speizer).) The Gibb et al. study's finding is based on short-term, high-intensity exposure conditions; the Final Four Plant Report's finding is based on long-term, low-intensity exposure conditions. (Tr. at 165, 243-44 (Cooper); Tr. at 541-43 (Speizer).) In the Gibb et al. study, the average duration of work exposure is 3.1 years, with a median duration of less than five months. CX 62 at 6 [Gibb (2000)]; Tr. at 142-43 (Cooper); Tr. at 533-534 (Speizer). In contrast, the average duration of work exposure in the Final Four Plant Report is 8 to 12 years. (Tr. at 158 (Cooper); see also CX 1 at 113 [FFPR].) The long-term, low-intensity exposure conditions examined in the Final Four Plant Report are of prime interest to the Agency for human health risk assessment. (Tr. at 153 (Cooper).)

Elementis's representative, Dr. Barnhart, received the Final Four Plant Report from IHF on or about October 8, 2002. (Joint Set of Stip. Facts, Exs., and Test. ¶¶ 17, 18.) Elementis did not submit the report to EPA until November 17, 2008, in response to an EPA subpoena. *Id.* at ¶¶ 17-20.

IV. ARGUMENT

A. EPA Has Proven the Elements of a Prima Facie Case of TSCA Section 8(e) Liability against Respondent.

1. EPA Has the Burden of Persuasion to Prove the Basic Elements of a Prima Facie Case.

Section 22.24(a) of the Consolidated Rules of Practice provides that Complainant has the burdens of presentation and persuasion to prove the elements of a prima facie case. 40 C.F.R. § 22.24(a). To prevail in a TSCA section 8(e) case, Complainant must show by a preponderance of the evidence that:

- a) Respondent is a person who manufactures or distributes in commerce a chemical substance or mixture;
- b) Respondent obtained information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment; and
- c) Respondent failed to immediately inform the EPA Administrator of such information.

15 U.S.C. § 2607(e). As the Presiding Officer observes in the Order on Complainant's Motion for Accelerated Decision and Respondent's Request for Oral Argument, the Respondent does not dispute that Complainant has proven each of the three elements. (Order on Compl't Mot. for Acc. Dec. and Resp't Req. for Oral Arg. at 11-13.)

2. Respondent Has Conceded that EPA Has Proven a Prima Facie Case.
 - a. Respondent is a person who manufactures or distributes in commerce a chemical substance or mixture.

For purposes of TSCA section 8(e), Respondent is a person¹ who manufactures or distributes in commerce a chemical substance or mixture. Respondent admits in its Answer that it has two main manufacturing facilities that produce chromium chemicals in the United States, one of which was owned by Elementis at the time of the Final Four Plant Report. (Ans. ¶¶ 6, 8.) Respondent also stipulated to the fact that it manufactures chromium chemicals, including chromic acid (CASN 7738-94-5), chromic oxide (CASN 1308-38-9) and sodium dichromate (CASN 10588-01-9). (Joint Set of Stip. Facts, Exs., and Test. ¶¶ 4, 5; see also Ans. ¶¶ 9, 12.) Additionally, Respondent stipulated that it distributes in commerce chromium chemicals, including chromic acid, chromic oxide and sodium dichromate. (Joint Set of Stip. Facts, Exs., and Test. ¶ 6; Ans. ¶¶ 11, 12.) Moreover, Respondent admits in its Answer that chromic acid and sodium dichromate are hexavalent chromium compounds. (Ans. ¶ 18.)

As the Presiding Officer states in the Order on Complainant's Motion for Accelerated Decision and Respondent's Request for Oral Argument, "there is no dispute that, at all times relevant hereto, Respondent is and was a 'person who manufactures, processes, or distributes in commerce a chemical substance or mixture,' and as such, was and is subject to the requirements of Section 8(e). 15 U.S.C. § 2607(e)." (Order on Compl't Mot. for Acc. Dec. and Resp't Req.

¹ EPA TSCA section 8(e) guidance broadly defines "person" to include "any natural person, corporation, firm, company, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government." CX 67 at 9 [2003 EPA 8(e) Guidance]. Elementis Chromium Inc. is a corporation. As a corporation or other business entity, Respondent meets the definition of a person.

for Oral Arg. at 12.) Thus, Complainant has established the first element of a section 8(e) violation.

- b. Respondent obtained the Final Four Plant Report which reasonably supports the conclusion that hexavalent chromium presents a substantial risk of injury to health.

Respondent obtained the Final Four Plant Report on October 8, 2002, thereby triggering its duty to report to the EPA Administrator pursuant to TSCA section 8(e). As admitted in its Answer and later stipulated to, Dr. Joel Barnhart, Vice-President–Technical of Elementis Chromium, obtained the Final Four Plant Report from the Industrial Health Foundation (IHF) on or about October 8, 2002. (Joint Set of Stip. Facts, Exs., and Test. ¶¶ 16, 17, 18; Answer ¶¶ 24, 41, 42; see also CX 6 at 15 (10.a.), 16 (10.c.) [2008 Elementis Subpoena Response].) Dr. Barnhart’s receipt of the Final Four Plant Report is documented in an electronic mail message dated October 8, 2002. CX 4 [2002 IHF Transmittal Email]; see also Joint Set of Stip. Facts, Exs., and Test. ¶¶ 12, 17-18.

The Final Four Plant Report shows elevated risk of lung cancer from occupational exposure to hexavalent chromium. The Agency considers reports showing any instance of cancer to be substantial risk information. CX 17 at 3 [1978 EPA 8(e) Guidance]; Tr. at 30 (Krasnic). In filings before this Court, Respondent does not dispute that the Final Four Plant Report contains information which reasonably supports the conclusion that hexavalent chromium presents a substantial risk of injury to health. (See Resp’t Memo. in Opp. to Compl’t Mot. for Acc. Dec. on Liability at 11-14; see also Joint Set of Stip. Facts, Exs., and Test. ¶ 11.)

As the Presiding Officer states in the Order on Complainant’s Motion for Accelerated Decision and Respondent’s Request for Oral Argument, because Respondent has admitted that it obtained the Final Four Plant Report and that the report contains information which reasonably

supports the conclusion that hexavalent chromium presents a substantial risk of injury to health, Complainant has established the second element of a section 8(e) violation. (Order on Compl't Mot. for Acc. Dec. and Resp't Req. for Oral Arg. at 12.)

- c. Respondent failed to immediately inform the Administrator of the Final Four Plant Report.

Respondent failed to immediately inform the EPA Administrator of the Final Four Plant Report, as required by TSCA section 8(e). Respondent stipulated that it did not submit the Final Four Plant Report to EPA at the time it obtained the report on or about October 8, 2002. (Joint Set of Stip. Facts, Exs., and Test. ¶ 19.) Respondent further stipulated that it did not submit the Final Four Plant Report to EPA until November 17, 2008, when it did so in response to a TSCA subpoena from EPA. Id. ¶ 20. As the Presiding Officer states in the Order on Complainant's Motion for Accelerated Decision and Respondent's Request for Oral Argument, because "Respondent has acknowledged that it failed to 'immediately' inform the Administrator of the information in the Final [Four Plant] Report, this third and final element of Complainant's prima facie case is also established." (Order on Compl't Mot. for Acc. Dec. and Resp't Req. for Oral Arg. at 13.)

- B. Respondent Has Not Established its Statutory Affirmative Defense Under TSCA Section 8(e).

1. Respondent Has the Burden of Persuasion to Establish its Statutory Affirmative Defense.

Respondent has raised the statutory affirmative defense pursuant to TSCA section 8(e).² (Ans. at 6-7.) This statutory provision provides that a person is required to immediately submit

² The Presiding Officer previously observed that Respondent alleged this defense as its first, second and third affirmative defenses in the Answer, but they collectively comprise the statutory affirmative defense made available to it in TSCA section 8(e). (Order on Compl't Mot. for Acc. Dec. and Resp't Req. for

substantial risk information to the EPA Administrator “unless such person has actual knowledge that the Administrator has been adequately informed of such information.” 15 U.S.C. § 2607(e). Respondent has the burden of proving by a preponderance of the evidence that it had “actual knowledge that the Administrator ha[d] been adequately informed of such information” at the time it obtained the Final Four Plant Report in 2002. See 40 C.F.R. § 22.24(a); see also Order on Compl’t Mot. for Acc. Dec. and Resp’t Req. for Oral Arg. at 11; In re Methyl Tertiary Butyl Ether Products Liab. Litig., 559 F. Supp. 2d at 424, 435 (S.D.N.Y. 2008).

2. Respondent Has Failed to Meet Its Burden of Persuasion Because the Final Four Plant Report Contains Substantial Risk Information Not Known to the Administrator in 2002.

Respondent has not proven by a preponderance of the evidence that it had actual knowledge that the EPA Administrator had been adequately informed of the substantial risk information contained in the Final Four Plant Report at the time Respondent received the report in 2002. The link between hexavalent chromium exposure and lung cancer in humans is undisputed. However, the carcinogenic effects of hexavalent chromium under long-term, low-intensity exposure conditions were not well-established in 2002. The Final Four Plant Report contains new information about the elevated risk of lung cancer mortality from hexavalent chromium exposure under long-term, low-intensity exposure conditions, which are of prime interest to EPA for risk assessment.³ Consequently, Respondent cannot meet its burden.

Oral Arg. at 13 n.5.) Consequently, the Presiding Officer ruled that these affirmative defenses will be treated as a single affirmative defense. Id.

³ EPA uses risk assessment to characterize the nature and magnitude of health risks to humans from chemicals at relatively low exposure levels in environmental settings such as workplaces. (Tr. at 110 (Cooper).) EPA human health risk assessments involve four steps: (1) hazard identification; (2) dose-response assessment; (3) exposure assessment; and (4) risk characterization. CX 61 at 11 [1999 EPA Draft Cancer Guidelines]; see also Tr. at 104-11 (Cooper). Dose-response assessment is the most relevant to this case.

- a. The carcinogenicity of hexavalent chromium was well-recognized at the time of the Final Four Plant Report; however, the carcinogenic effects under long-term, low-intensity exposure conditions were not well-established in 2002.

The record is replete with reports classifying hexavalent chromium as a human carcinogen based on its carcinogenicity. See generally, RX 25 [1984 EPA Cr Health Assessment]; RX 26 [1987 IARC Monograph]; RX 27 at 214 [1990 IARC Monograph]; RX 28 [1993 ATSDR CrVI Toxicological Profile]; RX 29 [1994 Environment Canada Report]. “Carcinogenicity” is used in epidemiology to describe the ability or tendency of a chemical to cause cancer in humans. In 1984, EPA classified hexavalent chromium as a human carcinogen in its health assessment for chromium relying upon qualitative judgments about the degree of evidence for carcinogenicity provided by the available data on hexavalent chromium. RX 25 [1984 EPA Cr Health Assessment]; see also RX 35 at 2 [1995 OSHA/Crump White Paper]. The Agency confirmed its classification of hexavalent chromium as a human carcinogen in its toxicological review for hexavalent chromium in 1998. CX 53 [1998 EPA CrVI Toxicological Review]; see also Tr. at 116-17 (Cooper). The risk of lung cancer mortality has been linked⁴ to occupational exposure to hexavalent chromium since the first case reports were documented in 1890 and 1911, and the first epidemiological study of chromate production plant workers in the

⁴ Epidemiologists refer to this as the “association” between exposure to a chemical agent and the development of disease. REFERENCE GUIDE ON EPIDEMIOLOGY, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 552-53 n.7 (Federal Judicial Center & National Research Council of the National Academies eds., The National Academies Press, 3rd ed. 2011), available at [http://www.fjc.gov/public/pdf.nsf/lookup/SciMan3D01.pdf/\\$file/SciMan3D01.pdf](http://www.fjc.gov/public/pdf.nsf/lookup/SciMan3D01.pdf/$file/SciMan3D01.pdf). The primary author of the Final Four Plant Report, Dr. Mundt, and his fellow investigators state in the report that “the published literature demonstrates a consistent association between hexavalent chromate exposure and respiratory cancer.” CX 1 at 40 [FFPR]. Dr. Mundt testified at hearing that “it’s been known for decades” that there is an association between occupational exposure to hexavalent chromium and lung cancer. (Tr. at 916 (Mundt).)

United States was published in 1948. CX 1 at 27 [FFPR]; RX 18 [Machle et al. study]. In short, the carcinogenicity of hexavalent chromium was well-recognized at the time of the Final Four Plant Report. (Tr. at 117, 139-40 (Cooper); Tr. at 1034, 1061 (Gibb); RX 25 [1984 EPA Cr Health Assessment]; CX 53 [1998 EPA Toxicological Review].)

What was not well-established at the time of the Final Four Plant Report was the extent of carcinogenic risk from hexavalent chromium under long-term, low-intensity exposure conditions. (Tr. at 150-51 (Cooper); see also Tr. at 521-22, 573 (Speizer).) In the 1950s and 60s, the chromate industry instituted manufacturing process changes and improved industrial hygiene controls. CX 1 at 15, 25-26 [FFPR]. These developments led to lower exposure levels than the historic exposure levels documented in early epidemiological studies that established the linkage between hexavalent chromium exposure and lung cancer mortality resulting in the classification of hexavalent chromium as a human carcinogen. (Tr. at 127-128 (Cooper); Tr. at 1090 (Speizer); Tr. at 653 (Mundt).) Importantly, with respect to the scientific literature demonstrating the linkage between hexavalent chromium exposure and lung cancer mortality, Dr. Kenneth Mundt and his fellow investigators state in the Final Four Plant Report:

[t]he change to no-lime or low-lime processes in the chromium chemicals industry [and the concomitant decline in exposures] . . . renders [the] extensive literature unrepresentative of [the risk of lung cancer mortality from hexavalent chromium exposure under] current exposure conditions.

CX 1 at 40-41 [FFPR] (emphasis added); see also Tr. at 653 (Mundt); CX 2 at 10 (“obsolete”) [FFPR Draft Protocol]; CX 3 at 16 (“unrepresentative”) [FFPR Revised Protocol]. Respondent’s expert witness and the principal author of the Final Four Plant Report, Dr. Mundt, stated at hearing that he agreed with this statement. (Tr. at 918 (Mundt).)

- (1). Limitations in prior studies resulted in inadequate exposure data to fully quantify carcinogenic effects under long-term, low-intensity exposure conditions as of 2002.

Although the classification of hexavalent chromium is supported by many epidemiological studies linking hexavalent chromium exposure to lung cancer, limitations associated with prior studies resulted in inadequate exposure data to fully estimate carcinogenic potency at the time of the Final Four Plant Report study.⁵ (Tr. at 124-25 (Cooper).) The term “carcinogenic potency” is used in epidemiology to describe a chemical’s capacity to cause cancer at varying levels of exposure. Determining the carcinogenic potency of a chemical entails the quantification of risk at different levels of exposure. (Tr. at 114 (Cooper).) This quantification of risk allows decision makers to make regulatory and cleanup decisions based on an evaluation of the level of risk for specific exposures. (Tr. at 114 (Cooper).)

The limited availability of exposure data sets for hexavalent chromium at the dose-response assessment step of the risk assessment process is widely acknowledged by EPA, the authors of the Final Four Plant Report, and the parties’ respective experts. RX 25 at 205 [1984 EPA Cr Health Assessment]; CX 53 at 48 [1998 EPA CrVI Toxicological Review]; CX 1 at 27

⁵ Epidemiologic studies are used for hazard identification as well as dose-response assessment. Typically, many epidemiological studies are relied upon to establish the carcinogenicity of a chemical. (Tr. at 97, 115-16, 124 (Cooper).) However, relatively few studies provide adequate exposure data for use in dose-response assessment. (Tr. at 97, 115-16, 124 (Cooper).) As Dr. Cooper explained at hearing:

[T]here are relatively few studies that provide that level of [exposure] detail that you really want to see in order to do this kind of [dose-response] evaluation.

....

[I]n my experience, as I said, I might review 20 studies that provide information on the risk -- cancer risk of a chemical, but of those 20 maybe one has that kind of exposure information that you need to do this kind of quantitative evaluation.

(Tr. at 115-16 (Cooper).) Hexavalent chromium is no exception. CX 53 at 48 [1998 EPA CrVI Toxicological Review].

[FFPR]; Tr. at 1065-66 (Gibb); Tr. at 139-40 (Cooper). EPA's risk assessment expert, Dr.

Cooper, testified at hearing about the limited availability of exposure data sets for dose-response assessment:⁶

Well, at the time this [Gibb] study was developed which would have been in the 1990s, it was clearly established that chromium is a carcinogen, but at the same time, as I mentioned, the amount of exposure information that we [EPA] had that we could use for exposure response modeling, the number of studies available that had that kind of information was relatively small. It still is relatively small and what the Agency was using was that Mancuso study from 1975 with exposure measures from 1949 that were applied to the 1930s.

(Tr. at 139-40 (Cooper) (emphasis added).) As Dr. Cooper stated, there were limited exposure data sets at the time of the Final Four Plant Report.⁷

⁶ Dose response assessment is "the quantitative evaluation of the relationship between [the] specific exposure level and the specific degree of risk between an exposure and a disease" and depends upon the availability of studies that have adequate measures of exposure. (Tr. at 107 (Cooper); see also CX 61 at 79 [1999 EPA Draft Cancer Guidelines].) In other words, dose-response assessment is an attempt to quantify the relationship between a specific exposure level (dose) and the disease (response). A dose-response relationship means that the greater the exposure, the greater the risk of disease; generally, higher exposures should increase the incidence (or severity) of disease. REFERENCE GUIDE ON EPIDEMIOLOGY, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 603 (Federal Judicial Center & National Research Council of the National Academies eds., The National Academies Press, 3rd ed. 2011).

⁷ The authors of the Final Four Plant Report recognize in the report the limited availability of exposure data sets:

Reliable quantitative risk estimates of the well recognized association between occupational exposure to hexavalent chromium compounds and lung cancer have been unavailable until very recently, precluding the establishment of scientifically based workplace and environmental exposure limits.

CX 1 at 15 [FFPR]. Similarly, the Final Four Plant Report's authors state in the report:

Numerous case reports and epidemiological studies have examined the effects of chromate production exposures on workers' health; however, reports quantitatively estimating individual hexavalent exposure levels, at least until very recently, have been scarce.

Id. at 27 (emphasis added). The authors cite two examples for the proposition that there was limited availability of exposure data sets, namely, the 2000 Gibb et al. study and the 2003 Luippold et al. study.

Respondent's expert, Dr. Gibb, testified that only three exposure data sets have been relied upon for dose-response assessment for hexavalent chromium. (Tr. at 1065 (Gibb).) As Dr. Gibb stated:

We've had multiple studies demonstrating that hexavalent chromium is carcinogenic. Not so many studies looking at the dose response, but there have been three done, I think that on which dose response assessments have been based for hexavalent chromium, the first being Mancuso, which is what we used originally.

(Tr. at 1065-66 (Gibb) (emphasis added).) The three cohort studies⁸ Dr. Gibb referred to in his testimony are: 1) Mancuso (1975, 1997); 2) Gibb et al. (2000); and 3) Luippold (2003). (Tr. at 1065-66 (Gibb); see also RX 20 [Mancuso (1951)]; CX 16 [Mancuso (1975)]; RX 31 [Mancuso (1997-Part I)]; RX 30 [Mancuso (1997-Part II)]; CX 62 [Gibb et al. (2000)]; CX 69 [Luippold (2003)].)

The first of the epidemiological studies referred to by Dr. Gibb in his testimony is the Mancuso study of occupational cancer and other health effects from exposure to chromium. (Tr. at 1065-66 (Gibb).) Starting in 1951, this study investigated a study cohort of 332 workers at a chromate production plant in Painesville, Ohio. CX 16 at 4 [Mancuso (1975)]; RX 31 at 1, 3 [Mancuso (1997-Part I)]; see also RX 30 at 1 [Mancuso (1997-Part II)]. EPA relied upon exposure data from Mancuso's 1975 update of the study to estimate the carcinogenic potency of hexavalent chromium in its 1984 health assessment for chromium and its updated 1998 toxicological review for hexavalent chromium. (Tr. at 124-25 (Cooper); RX 25 at 205-06 [1984 EPA Cr Health Assessment] ("Mancuso's data [are] used as the main data base for estimating the carcinogenic potency of hexavalent chromium."); CX 53 at 48 [1998 EPA CrVI Toxicological

Id. at 27, 101 n. 23, 24. However, the later study was in press at the time the 2002 Final Four Plant Report. Id.

⁸ In cohort studies, a group of "exposed" and "non-exposed" individuals are identified and studied over time to determine differences in disease occurrence. CX 61 at 32 [1999 EPA Draft Cancer Guidelines].

Review].) Although the Agency considered the Mancuso exposure data set to be the “best available data” at the time of the 1984 health assessment and the 1998 toxicological review, Mancuso’s exposure data set was widely viewed as having limitations that must be considered in interpreting the study’s results. (Tr. at 124-25 (Cooper); Tr. at 1022-23 (Gibb).) EPA states in both its 1984 health assessment for chromium and its 1998 toxicological review for hexavalent chromium that Mancuso’s exposure data set was “limited but adequate” for use in risk estimation. RX 25 at 205 [1984 EPA Cr Health Assessment]; CX 53 at 48 [1998 EPA CrVI Toxicological Review]. Moreover, the Agency observes in the toxicological review that “several important uncertainties in the potency estimate result from the use of the Mancuso [exposure] data [set] for the dose-response estimation.” CX 53 at 56 [1998 EPA CrVI Toxicological Review].

The testimony of the parties’ respective experts about the Mancuso exposure data set mirrors EPA’s general statements in the 1984 health assessment and the 1998 toxicological review. Both of Complainant’s experts, Drs. Cooper and Speizer, and Respondent’s expert, Dr. Gibb, testified at hearing about limitations in Mancuso’s exposure data set for dose-response assessment. (Tr. at 122, 125 (Cooper); Tr. at 529 (Speizer); Tr. at 1022-23 (Gibb).) In one example, Dr. Gibb remarked that Mancuso measured exposures for total chromium rather than hexavalent chromium. (Tr. at 1022 (Gibb).) In a second example, Dr. Cooper and Dr. Gibb recognized that Mancuso utilized exposure measurements that were not concurrent with work history. In particular, Dr. Cooper observed that Mancuso relied upon exposure measurements taken in 1949 to estimate exposures in the 1930s when the plant opened. (Tr. at 122, 125, 140 (Cooper).) Similarly, Dr. Gibb described how Mancuso had relied upon exposure estimates done in 1949 while Mancuso’s cohort was defined as having begun employment between 1931 and

1937. (Tr. at 1022-23 (Gibb); see also CX 62 at 10 (Table IX) [Gibb (2000)].) In yet a third example, Dr. Gibb noted that no smoking data were available for the workers in the Mancuso cohort. (Tr. at 1022 (Gibb).) The 2000 EPA-funded Gibb et al. study identifies an identical set of limitations in the Mancuso exposure data set for dose-response assessment. CX 62 at 2 [Gibb (2000)]. In Dr. Gibb's view, "there was limitations, but that was the best data we had" at the time of the 1984 health assessment. (Tr. at 1023 (Gibb).)

The second study referenced by Dr. Gibb is a 2000 EPA-funded study of lung cancer mortality and clinical irritation referred to here as the Gibb et al. study. CX 62 at 1 [Gibb (2000)]; Tr. at 165 (Cooper); Tr. at 1034-35 (Gibb). This study investigated a combined study cohort of approximately 2,300 workers at a chromate production plant in Baltimore, Maryland. CX 62 [Gibb (2000)]; Tr. at 141 (Cooper); Tr. at 529 (Speizer). EPA funded the 2000 Gibb et al. study to augment Mancuso's limited exposure database for dose-response assessment. (Tr. at 139-40 (Cooper); Tr. at 1061 (Gibb).) Dr. Cooper stated that at the time of the Gibb et al. study, "there's clearly the recognition that newer, better data that could be used to evaluate the dose response between chromium exposure and risk of lung cancer would be a valuable asset to the Agency." (Tr. at 140 (Cooper). Dr. Gibb explained that the Gibb et al. study was undertaken to improve dose-response assessment for hexavalent chromium. (Tr. at 1068 (Gibb) ("It was done so that we had -- we, the EPA, had a better dose response analysis for hexavalent chromium.")) In particular, he stated that the study was conducted "[b]ecause it could provide much more detailed exposure information than we [the Agency] had before." (Tr. at 1061 (Gibb); see also Tr. at 1068 (Gibb).) Building upon Mancuso's research, the EPA-funded Gibb et al. study made

progress in developing a more complete exposure database for dose-response assessment.⁹ (Tr. at 139-40 (Cooper); see also CX 62 at 2 [Gibb (2000)].)

While the EPA-funded Gibb et al. study advanced the development of quantitative exposure data, it also has limitations. For example, the Gibb et al. study's smoking data were derived from a yes/no survey conducted at the beginning of workers' employment, which the report itself acknowledges. CX 62 at 10 [Gibb (2000)]. As a result, information about workers' smoking habits over the course of their employment was not available. More importantly, in another example, short-term workers comprise a "large proportion" of the study cohort. (Tr. at 142-43, 150-51 (Cooper); Tr. at 1097 (Speizer).) Specifically, 990 of 2,357 workers had worked for short periods. (Tr. at 529-30 (Speizer); CX 62 at 1-2, 10 (Table IX-Cohort (Size)) [Gibb (2000)].) Fifty percent of the study cohort had worked less than five months, and an even higher percentage of the cohort had worked less than one year. (Tr. at 143, 150-151 (Cooper); Tr. at 529-30, 534, 547 (Speizer); see also CX 69 at 6 [Luippold (2003)].) In fact, Dr. Gibb readily acknowledged at hearing that he purposely included workers who had been employed less than 90 days to examine the risk of lung cancer mortality to short-term workers. (Tr. at 1030-31 (Gibb).) Moreover, the Final Four Plant Report authors in the report identified this limitation in the Gibb et al. study. CX 1 at 94 [FFPR] ("A large proportion of the employees had very short duration of employment.").

The third study referenced by Dr. Gibb in his testimony is the Luippold et al. study, which was not available until early 2003 after Elementis obtained the Final Four Plant Report. The Luippold et al. study investigated a cohort of 493 workers at the same chromate production

⁹ Key differences between the Mancuso and Gibb et al. studies are summarized by the authors of the Gibb et al. study. CX 62 at 10 (Table IX) [Gibb (2000)]. The Gibb et al. study had a larger study cohort, more lung cancer deaths, and smoking information for most of the cohort than the Mancuso study. Id.

plant in Painesville, Ohio, that was the subject of Mancuso's study. CX 69 at 1-2 [Luippold (2003)]; Tr. at 1066 (Gibb). This study reiterates EPA's prior statements about the limited availability of exposure data to estimate the carcinogenic potency of hexavalent chromium: "Despite the available evidence of the carcinogenicity of Cr(VI), most epidemiological studies to date have not adequately characterised [sic] exposures to allow for quantitative risk assessment." CX 69 at 1-2 [Luippold (2003)] (emphasis added). In remarking on the "very few studies" that have quantitatively characterized exposure, the Luippold et al. study states, "Cr(VI) has long been known to cause lung cancer and, as expected, this report supplies yet more evidence. However, there has been considerable uncertainty regarding the dose-response relation between Cr(VI) and lung cancer." Id. at 6 (emphasis added).

As in the case of the Mancuso and Gibb et al. studies, the Luippold et al. study has limitations. For example, the Luippold et al. study has a small study cohort of 493 workers compared to the 2,357-member cohort for the Gibb et al. study and the 1,518-member cohort for the Final Four Plant Report. Cf. CX 69 at 1, 2 [Luippold (2003)] and CX 62 at 1, 3 [Gibb (2000)]; Tr. at 1066 (Gibb) ("Luippold was much smaller than my [Gibb et al.] study."); CX 1 at 15 [FFPR]. In another example, while the Luippold et al. study's exposure assessment represents a "major improvement" in methodology, the study has an absence of personal monitoring data, sparse industrial hygiene area measures in the 1940s, and gaps in work history for some cohort members. CX 69 at 6 [Luippold (2003)]. In still another example, data gaps exist for some members of the Luippold et al. cohort, including missing dates of birth and unknown vital status. Id. In yet another example, information on potential confounders, such as smoking, was also limited and precluded the study investigators' ability to assess their effects. Id. Smoking data for the cohort was not sufficiently complete for use in the analysis because

only 35% of the study cohort was represented and available data from annual surveys administered to employees was limited to the years 1960 to 1965. Id.

The Luippold et al. study also describes limitations in both the Mancuso and Gibb et al. studies. See generally, CX 69 [Luippold (2003)]. Ms. Luippold¹⁰ and her fellow investigators note that Mancuso's study has been criticized for using total chromium as a measure to estimate exposures to hexavalent and trivalent chromium. Id. at 1-2. Moreover, the Luippold et al. study identifies limitations in the Gibb et al. study. Id. at 1-2, 6. Specifically, Ms. Luippold and her fellow investigators observe that "SMRs [standardized mortality ratios] are presented by quartile of exposure, resulting in few data points from which to understand dose-response relation for lung cancer." Id. at 2. Ms. Luippold and her colleagues also emphasize that the Gibb et al. study includes a "very high fraction" of short term workers, with more than half of the cohort working less than six months, and 40% working less than 90 days. Id. at 1-2, 6 [Luippold (2003)]. We quote at length from the Luippold et al. study about the inclusion of short-term workers:

Although the Baltimore [Gibb] cohort is considerably larger than this Painesville [Luippold] cohort (2357 versus 492 workers, respectively), very short term workers were included in the Baltimore cohort, including some that were reported to have no exposure. More than half of the Baltimore cohort worked less than six months, and 990 workers (42%) worked less than 90 days. In fact, only 589 (25%) worked two or more years. In contrast, over half (54%) of the cohort from the Painesville plant worked six or more years in the plant. Unlike the Baltimore study, Painesville employees with less than one year of employment were excluded from the current study. Lifestyle factors may differ considerably for short term employees, and other (unmeasured) occupational exposures may be more likely to exist. Short term workers may have different risk profiles than longer term workers.

¹⁰ Listed as an author under epidemiologists, Ms. Luippold participated in the design, conduct, and reporting of the Final Four Plant Report. CX 1 at 3 [FFPR].

Id. at 6 (emphasis added). The limitations in the Gibb et al. study noted by Ms. Luippold and her fellow investigators parallel the limitations that were the subject of expert testimony by Drs. Cooper and Speizer. (Tr. at 150-154 (Cooper); Tr. at 529-31 (Speizer).)

In sum, only two exposure data sets existed at the time the study which culminated in the Final Four Plant Report became available in 2002 (Mancuso (1997), Gibb (2000)); a third was not published until the year after Elementis obtained the 2002 Final Four Plant Report (Luippold (2003)). Table 1 below summarizes the limitations in the three epidemiological studies referenced by Dr. Gibb as discussed above.

Table 1 Summary of Limitations in Studies Cited by Dr. Gibb			
Limitation	Mancuso	Gibb (2000)	Luippold (2003)
Method and timing of exposure measurements	Tr. at 122, 125 (Cooper) (Non-concurrent exposure measurements) Tr. at 1022-23 (Gibb) (Total chromium, non-concurrent exposure measurements)		CX 69 at 6 [Luippold (2003)]
Small study cohort size	CX 16 at 4 [Mancuso (1975)] CX 42 at 3-4 [Mancuso (1997-Part I)]		Tr. at 1066 (Gibb)
Lack of or incomplete smoking data	Tr. at 1022 (Gibb)	CX 62 at 10 (Table IX), 11 [Gibb (2000)]	CX 69 at 6 [Luippold (2003)]
Inclusion of short-term workers in cohort		Tr. at 142-43 (Cooper) Tr. at 1097 (Speizer) Tr. at 1030-31 (Gibb) CX 62 at 10 [Gibb (2000)] CX 1 at 94 [FFPR] CX 69 at 6 [Luippold (2003)]	

As Table 1 shows, each of the studies cited by Dr. Gibb has limitations for fully assessing the dose-response relationship.

Importantly, the Final Four Plant Report addresses limitations that must be considered in interpreting the results of the Mancuso and Gibb et al. studies. Unlike the Mancuso study, the Final Four Plant Report differentiates exposures by the form of chromium (e.g., hexavalent chromium) rather than only for total chromium, and exposure measurements were taken concurrently with worker exposures. See generally, CX 1 [FFPR]. At hearing, Dr. Speizer, EPA's expert¹¹ and the principal investigator of a cohort study of the risk of lung cancer from diesel exhaust involving 50,000 railroad workers, commended Dr. Mundt's exemplary efforts to collect exposure data for the Final Four Plant Report's quantitative exposure assessment. (Tr. at 495, 1085 (Speizer).) Dr. Speizer stated that he was "even more impressed with Dr. Mundt's work" after listening to the Final Four Plant Report's lead author's detailed description of the exposure assessment, including the collection of exposure data and the construction of job exposure matrices involving 114 job locations. (Tr. at 1084 (Speizer); see also Tr. at 1032 (Mundt); CX 1 at 53-56 [FFPR].) Moreover, the Final Four Plant Report addresses an important limitation in the former study cited by not only Complainant's experts but also Ms. Luippold, specifically, the inclusion of a high percentage of short-term workers that greatly shortened the average duration of work exposure in the Gibb et al. study. (Tr. at 157 (Cooper) ("So that issue of short-term duration, at least defined as less than a year, would not be a part of this [FFPR] analysis."))

¹¹ Respondent stipulated to Dr. Speizer as an expert in the fields of pulmonary medicine, chronic disease epidemiology including lung cancer, and environmental epidemiology including air pollutants. (Joint Set of Stipulated Exs. and Expert Quals. at 2.)

- b. The Final Four Plant Report Contains New Quantitative Exposure Data that the Administrator Had Not Been Adequately Informed of at the Time Respondent Obtained the Report in 2002.

During the years leading up the Final Four Plant Report there was “growing interest in the possible health effects of chromium at lower exposure levels.” CX 1 at 18 [FFPR] (emphasis added). The study for the Final Four Plant Report was conducted to augment the limited exposure data sets available in an effort to ascertain whether the risk of lung cancer mortality from hexavalent chromium exposure persists under modern chromate plant exposure conditions. (Tr. at 131, 156 (Cooper).) Designed to capture and analyze additional hexavalent chromium exposure data, the Final Four Plant Report contains new exposure data to quantify the risk of lung cancer mortality from hexavalent chromium exposure at low levels of exposure in modern plants. (Tr. at 94-95, 205 (Cooper); Tr. at 509-10 (Speizer).) As such, the Administrator had not been adequately informed of the information in the Final Four Plant Report at the time Respondent obtained the report in 2002.

The authors of the Final Four Plant Report describe the aim of the Final Four Plant Report in the protocol for the study: “The central goal of this study is to evaluate the possible cancer mortality risks associated with hexavalent chromium exposure in the ‘post-change’ environment.”¹² CX 3 at 18 [FFPR Revised Protocol]. Similarly, in the authors’ own words:

¹² In peer review comments on the draft protocol for the study, Dr. Harvey Checkoway, a national expert in the field of occupational epidemiology and author of one of the field’s leading textbooks, reflects on the purpose of the study for the Final Four Plant Report:

The [Final Four Plant Report] investigators are proposing an epidemiologic cohort mortality study to address the potential risks related to chromate exposures in industrial facilities where exposure levels have been reduced technologically. The focus of this study would be on risks for lung cancer, for which associations with occupational exposures to hexavalent chromates are well established. Insofar as existing evidence for a lung cancer hazard is largely based on studies in facilities with high dust exposures (from addition of lime in calcining operations), the results of the study could shed light on risks related to much lower levels that typify modern processes.

This study has been designed to describe the cause-specific mortality patterns of employees engaged in the manufacture of chromium chemicals in the years since substantial changes in the production processes (i.e., the reduction or elimination of lime) were implemented to reduce risks to employee health.

Id.; see also CX 3 at 52 (Final Four Plant Report will “address an important occupational health issue—potential lung cancer risks associated with chromate exposures at levels lower than have been implicated previously.”) [FFPR Revised Protocol-Peer Review Comments]. Thus, the Final Four Plant Report was not intended to determine whether hexavalent chromium is carcinogenic. (See Tr. at 916 (Mundt).) The classification of hexavalent chromium as a human carcinogen had long since resolved that issue. See generally, RX 25 [1984 EPA Cr Health Assessment]; CX 53 [1198 EPA CrVI Toxicological Review]. Rather, the study for the Final Four Plant Report was designed to generate new exposure data for quantitatively estimating the carcinogenic potency of hexavalent chromium at low exposure levels in modern plants.¹³ CX 3 at 18 [1999 FFPR Revised Protocol]; see also Tr. at 163 (Cooper).

CX 3 at 51 [FFPR Revised Protocol—Peer Review Comments] (emphasis added); see also Tr. at 888 (Mundt). Moreover, Dr. Checkoway states, “The scientific value of this study will no doubt be determined by the ability to investigate dose-response relations for lung cancer....” CX 3 at 51 [FFPR Revised Protocol—Peer Review Comments]. As Dr. Checkoway’s peer review comments illustrate, the fundamental purpose of the study was to ascertain whether elevated risk of lung cancer persists under modern plant exposure conditions by analyzing the dose-response relationship at low levels of exposure through quantitative exposure assessment.

¹³Assessing the carcinogenic potency of hexavalent chromium was a principal focus of the Chrome Coalition, an industry trade association chaired by Dr. Barnhart of Elementis Chromium (formerly, American Chrome and Chemicals). Even before embarking in the late 1990s on the epidemiological study that culminated in the Final Four Plant Report, the Chrome Coalition retained a consulting firm to review and critique epidemiological studies for dose-response assessment. See CX 27 at 2 [Chrome Coalition Ad Hoc PEL Committee Minutes (February 13, 1996)] (“Coalition’s primary concern in requesting a proposal was to concentrate on the cancer potency.”).

- (1). The Report shows elevated risk under long-term, low-intensity exposure conditions.

The Final Four Plant Report examines the risk of lung cancer mortality at low exposure levels under substantially different exposure conditions than the Gibb et al. study. The 2000 EPA-funded Gibb et al. study shows elevated risk of lung cancer mortality from occupational exposure to hexavalent chromium. CX 1 at 93-94 [FFPR]; Tr. at 868 [Mundt]; Tr. at 148-49 (Cooper). Likewise, the 2002 Final Four Plant Report shows increased lung cancer mortality risk. (Joint Set of Stip. Facts, Exs., and Test. ¶ 11; CX 1 at 98 [FFPR]; Tr. at 729, 737, 742 (Mundt); Tr. at 94, 164 (Cooper); Tr. at 539 (Speizer).) Both the Gibb et al. study and the Final Four Plant Report document a “pattern” of increasing risk of lung cancer mortality with increasing occupational exposure to hexavalent chromium. (Tr. at 190, 240, 253-54 (Cooper).) However, these findings are based on different exposure conditions. (Tr. at 165 (Cooper); Tr. at 541-43 (Speizer).) The Gibb et al. study’s finding is based on short-term, high-intensity exposure conditions. (Tr. at 165, 243-44 (Cooper); Tr. at 541-42 (Speizer).) In contrast, the Final Four Plant Report’s finding is based on long-term, low-intensity exposure conditions. (Tr. at 165, 243-44 (Cooper); Tr. at 541-42 (Speizer).) Because the findings of elevated risk of lung cancer mortality in these studies are based on substantially different exposure conditions, the Final Four Plant Report contains new information of which the Administrator had not been adequately informed.

The markedly different exposure conditions in the Gibb et al. study and Final Four Plant Report are evident from the duration of work exposure in the respective study cohorts. (Tr. at 244 (Cooper).) The Gibb et al. study itself reports the average duration of work exposure to be 3.1 years. CX 62 at 6 (Table II: Total Group Work Years = 3.1 years) [Gibb (2000)]; see also Tr. at 142-43 (Cooper); Tr. at 533-34 (Speizer). However, the median duration of work exposure is

less than five months. (Tr. at 142-43 (Cooper); Tr. at 534 (Speizer).) In contrast, the average duration of work exposure in the Final Four Plant Report is 8 to 12 years. (CX 1 at 113 (Table 9) (Duration of exposure: 7.8 (Corpus Christi) to 12.4 (Castle Hayne)) [FFPR]; see also Tr. at 158 (Cooper).) Thus, the Gibb et al. study cohort was exposed to a much shorter duration of work exposure than the Final Four Plant Report cohort.

At hearing, there was extensive testimony about exposure levels in the Gibb et al. study and the Final Four Plant Report. These studies used a cumulative exposure metric, a standard tool of measurement in epidemiological studies of lung cancer. (Tr. at 143-144, 163 (Cooper); Tr. at 1038 (Gibb); Tr. at 688 (Mundt).) Cumulative exposure is calculated using two factors: 1) exposure intensity or concentration (amount); and 2) duration of work exposure (time component). (Tr. at 143-45 (Cooper).) The equation for calculating cumulative exposure based on these two factors is written as follows:

$\text{Amount} \times \text{Time Component} = \text{Cumulative Exposure}$

This equation can also be expressed as written below:

$\begin{array}{c} \text{Exposure Intensity or Concentration (Amount)} \\ \times \\ \text{Duration of Work Exposure (Time Component)} \\ = \text{Cumulative Exposure} \end{array}$

As these equations indicate, cumulative exposure is the product of two factors, exposure intensity or concentration and duration, which are multiplied to calculate cumulative exposure.

Id. As such, cumulative exposure reflects the underlying exposure conditions, that is, the combination of exposure intensity or concentration and the duration of work exposure.

Both the Gibb et al. study and the Final Four Plant Report report elevated risk of lung cancer mortality at comparable cumulative exposure levels. (Tr. at 177 (Cooper).) However, these cumulative exposure levels were calculated using different values for the two factors;

namely, the Final Four Plant Report has a longer duration of work exposure than the Gibb et al. study. (Tr. at 143, 158 (Cooper).) Thus, without a lengthy explication of the relative intensity or concentration of exposure in these studies, the Final Four Plant Report necessarily must have a lower intensity of exposure than the Gibb et al. study to result in the same cumulative exposure level over a longer period.¹⁴ Consequently, the comparable cumulative exposure levels reported in the Gibb et al. study and the Final Four Plant Report represent different exposure conditions. (Tr. at 244 (Cooper).)

Dr. Glinda Cooper, an expert in the field of epidemiology¹⁵ and experienced EPA risk assessor, gave two compelling examples of how differences in the intensity or concentration of exposure and the duration of work exposure can manifest themselves even when the cumulative exposure level is the same. First, drawing on an example from the field of epidemiology of “pack years” based on cigarette smoking history, she explained how the same cumulative exposure level can be derived differently depending upon the values for the factors, intensity or concentration and amount. In this example, Dr. Cooper roughly equated the Gibb et al. study with smoking two packs per day (amount) over three years (time component) and the Final Four Plant Report with smoking one pack per day (amount) over 20 years (time component). (Tr. at 145, 270-71 (Cooper).) Like the Gibb et al. study, the former represents a

¹⁴ This is simply a matter of solving for the missing variable in the equation for calculating cumulative exposure:

$\text{Cumulative Exposure} \div \text{Duration of Work Exposure (known variable)}$ $= \text{Intensity or Concentration of Exposure}$

(Tr. at 171 (Cooper).)

¹⁵ Respondent stipulated to Dr. Cooper as an expert in the field of epidemiology. (Joint Set of Stipulated Exs. and Expert Quals. at 1.)

higher exposure level over a shorter period, while the latter, like the Final Four Plant Report, represents a lower exposure level over a longer period. (Tr. at 145, 270-71 (Cooper).)

Second, using an occupational example, Dr. Cooper explained that a cumulative exposure level measured in chromium of 100 micrograms per cubic meter-years ($\mu\text{g}/\text{m}^3\text{-years}$) can be derived either from exposure to 200 $\mu\text{g}/\text{m}^3$ (amount) over six months (time component), or 5 $\mu\text{g}/\text{m}^3$ (amount) over 20 years (time component). (Tr. at 146 (Cooper).) As this occupational example shows, the same cumulative exposure level can be calculated from different exposure conditions represented by the amount and time component factors. In the instant case, although the Gibb et al. study and the Final Four Plant Report have comparable cumulative exposure levels, the studies' respective cumulative exposure levels were calculated differently due to differences in the values for the factors for the time component and, by extension, the amount.

Dr. Frank Speizer, one of the nation's most accomplished and recognized epidemiologists and lung cancer researchers, testified about the relationship between high short-term exposures and clinical irritation from hexavalent chromium exposure. (Tr. at 530, 1090-91 (Speizer).) Based on his experience as a pulmonologist in treating and researching diseases of the respiratory system and his review of the nasal irritations and other acute phenomena described in an article authored by Dr. Gibb from the Gibb et al. study, Dr. Speizer concluded that it was likely that the "kinds of acute irritations and phenomena" [from hexavalent chromium exposure] that workers suffered likely related to "much higher" short-term exposures. (Tr. at 530, 1091 (Speizer); see also RX 6 at 8 [Gibb CV] (citing "HJ Gibb, PSJ Lees, P. Pinsky, BC. Rooney, Clinical findings of irritation among chromium chemical production workers," 38 AM. J. IND. MED. 127-31 (2000).) Dr. Gibb acknowledged at hearing that hexavalent chromium is a "very irritating substance." (Tr. at 1033 (Gibb).)

Dr. Cooper also testified about the importance of long-term, low-intensity exposures when conducting human health risk assessments:

Well, this is a scenario that is of prime interest to the Agency, because what we're interested in is lifetime exposures to . . . relatively low levels of exposure and what would be the chronic risks associated with that type of exposure.

And the other reason – the reason that – particularly in this study that this arises is because although we've assumed that these two scenarios that I drew out of 20 years breathing air at 5 micrograms per cubic meter and a half a year breathing air at 200 micrograms per cubic meter, in the modeling that's done in this [Gibb] study those two scenarios are treated the same in terms of what you would predict their risk would be.

And the question that arises is are those two scenarios the same? We assume they are. It's a reasonable assumption, but you're always looking for data that would support that assumption. You're looking for new information that you can use to verify that assumption. In a situation like this where it's such an important question given what a large proportion of this study was a short-term duration kind of experience.

(Tr. at 153-54 (Cooper); see also Tr. at 262 (Cooper).) As Dr. Cooper emphasized, the Agency is especially interested in long-term, low-intensity exposures for risk assessment. In addition, Dr. Cooper questioned the generalizability of the results of an epidemiological study involving short-term duration exposures. (Tr. at 150-51 (Cooper).) In particular, she expressed wariness about generalizing the results of a study such as the Gibb et al. study to long-term, low-intensity exposures. (Tr. at 153-54 (Cooper).) She testified that the design of the Final Four Plant Report avoided the problems introduced by including short-term workers in the Gibb et al. cohort because the report's cohort is "limited to workers who had worked for at least a year." (Tr. at 157 (Cooper); see also Tr. at 538 (Speizer).)

In addition, Dr. Speizer testified at hearing about the biological plausibility of the results of the Gibb et al. study due to cohort's short duration of work exposure. (Tr. at 1097 (Speizer); see also Joint Set of Stip. Exs. and Expert Quals. at 2.) In testifying about biological plausibility, he drew upon his medical background as a pulmonologist as well as his extensive experience in

chronic disease epidemiology, including lung cancer. CX 90 [Speizer CV]. Importantly, Dr. Speizer questioned the biological plausibility of the results of the Gibb et al. study:

It is very hard from a biological perspective to anticipate or expect that the risk of lung cancer might be related to exposures of less than six months. It just is, from what we know about cigarette smoking, yes, you know, you can have eight years of exposure to cigarette smoking and get lung cancer 20 years later. But five months of exposure, it's very hard to anticipate you would expect to see any risk of lung cancer from that exposure.

(Tr. at 531 (Speizer) (emphasis added).) A prolific researcher steeped in chronic disease epidemiology and lung cancer, Dr. Speizer emphasized that the duration of exposure is critical to the induction of lung cancer. (See Tr. at 527, 531 (Speizer) (“[W]e know that particularly for lung cancer that there is a long latency period between the onset of exposure and the development of clinical disease [lung cancer].”); see also Tr. at 132 (Cooper).) Respondent proffered no comparable testimony from an expert in pulmonary medicine or chronic disease epidemiology to contradict or even dispute Dr. Speizer’s testimony. (Joint Set of Stip. Exs. and Expert Quals. at 2.) Thus, Dr. Speizer’s expert testimony regarding the biological plausibility of the results of the Gibb et al. study stands uncontested in the record.

In short, the Final Four Plant Report’s finding of elevated lung cancer risk is based on substantially different exposure conditions than the Gibb et al. study. The record is clear and unambiguous that the Final Four Plant Report’s finding of elevated risk under long-term, low-intensity exposure conditions differs from the Gibb et al. study’s finding based on short-term, high-intensity conditions. Thus, the Final Four Plant Report contains new exposure information to quantify the risk of lung cancer mortality under long-term, low-intensity exposure conditions.

- (2). The Report is not corroborative of previously available information because it contains new information.

TSCA section 8(e) expressly requires the reporting of information which reasonably supports the conclusion of substantial risk of injury to health except where a person has actual knowledge that the EPA Administrator already has been informed adequately of such information. The term “substantial risk” found in section 8(e) is not defined by statute. See 15 U.S.C. § 2607(e); Tr. at 28 (Krasnic). Beginning in 1978, EPA issued a series of guidance documents to clarify inter alia the scope of the reporting requirement. (Tr. at 28-29 (Krasnic); CX 17 [1978 EPA 8(e) Guidance]; CX 21 [1991 EPA 8(e) Reporting Guide]; CX 67 [2003 EPA 8(e) Guidance].) The 1991 Section 8(e) Reporting Guide¹⁶ states that a person need not submit certain substantial risk information:

WHAT INFORMATION IS NOT REPORTABLE UNDER SECTION 8(E)?

There are several kinds of information about which the Agency considers itself to be adequately informed already for the purposes of Section 8(e) of TSCA. For example, information that otherwise meets the criteria for Section 8(e) reporting need not be submitted if the information meets one or more of the following criteria:

....

- (5) is corroborative (in terms of, for example, route of exposure, dose, species, time to onset, severity, species [sic], strain, etc.) of a **well-established** adverse effect.

It is important to note, however, that information that newly identifies a serious toxic effect **at a lower dose level** for example, or **confirms a serious effect that was previously only suspected**, is **not** considered by EPA to be corroborative and should be reported under Section 8(e) of TSCA.

CX 21 at 19 [1991 EPA 8(e) Reporting Guide]; see also Tr. at 34-36 (Krasnic).

¹⁶ EPA issued revised guidance in 2003, after the period began for Complainant’s TSCA section 8(e) violation, which contains a similar provision regarding corroborative information. CX 67 at 11 [2003 EPA 8(e) Guidance]; see also Tr. at 36-37 (Krasnic).

This case turns on whether the Final Four Plant Report contains new substantial risk information. Complainant established at hearing that the Final Four Plant Report contains new information for three key reasons. First, the Final Four Plant Report is not corroborative of a well-established adverse effect, specifically, lung cancer, from occupational exposure to hexavalent chromium where there is long-term duration of exposure, the first component of long-term, low-intensity exposure conditions. Without repeating the argument above in its entirety, the Gibb et al. study examines short-term, high-intensity exposure conditions. (Tr. at 142-43 (Cooper); Tr. at 541-43 (Speizer).) But the Final Four Plant Report examines long-term, low-intensity exposure conditions, which are of prime interest to EPA for risk assessment. (Tr. at 153, 244 (Cooper); Tr. at 541-43 (Speizer).) In particular, Dr. Speizer explained that the Final Four Plant Report contains new information because its finding is based on different exposure conditions than the Gibb et al. study, namely, long-term, low-intensity exposure conditions:

As compared to [the] Gibb [et al. study] it [Final Four Plant Report study] provides a different dimension of that effect in the sense that [the] Gibb [et al. study] is not biased, but certainly is influenced by the presence of the short-term workers as a bulk of the – or as a significant fraction of the population.

(Tr. at 1097 (Speizer).) As discussed above, the inclusion of a high percentage of short-term workers manifests itself in the Gibb et al. study's substantially shorter average duration of work exposure. Thus, the Final Four Plant Report's finding of elevated risk of lung cancer mortality based on long-term duration of exposure does not corroborate the Gibb et al. study's finding of elevated risk based on short-term duration of exposure.

Second, the Final Four Plant Report is not corroborative of the well-established adverse effect of lung cancer from occupational exposure to hexavalent chromium at low exposure intensity, the second component of long-term, low-intensity exposure conditions. At hearing, Dr. Speizer testified at length about why the Final Four Plant Report contains new information at

low exposure levels. (Tr. at 521-22, 1087-97 (Speizer).) Dr. Speizer's knowledge of hexavalent chromium exposure levels dates back over 30 years to the first time he wrote about the lung cancer risk of hexavalent chromium, based on Mancuso's early work, as a contributor to Harrison's Principles of Internal Medicine, one of the two leading textbooks worldwide for medical students. (Tr. at 501, 520 (Speizer).) Dr. Speizer began by explaining what was known about the carcinogenic potency of hexavalent chromium at high exposure levels at the time of the Final Four Plant Report: "At high exposure levels, [hexavalent chromium] produces a fairly substantial risk. In that sense, the potency was believed to be pretty high." (Tr. at 521 (Speizer).) He then compared what was known about the carcinogenic potency at high exposure levels with actual scientific knowledge about potency at low exposure levels:

I don't think as the exposures were reduced we're so sure how potent the chemical was -- is. So I think yes, it was considered pretty well settled that it was a potent chemical. However, at low exposure levels, it was assumed to be linear dose response but it is not clear that we knew how potent it would be at the lower levels.

(Tr. at 521-22 (Speizer) (emphasis added).) Dr. Speizer observed that "as you move down the exposure level, the certainty about both the potency and the magnitude of risk . . . was essentially unknown I think." (Tr. at 522 (Speizer) (emphasis added).) Similarly, Dr. Cooper noted the implications of an absence of exposure data at low exposure levels and emphasized the importance of new exposure data:

When there is a lack of data at lower exposure levels, there is more uncertainty about the risk assessment process. And that's why any new information about risk at lower levels than what was known previously adds so much new information that the EPA can use in its risk assessments because it's providing new information about an area of response that we didn't have before.

(Tr. at 110-11 (Cooper).) Importantly, Dr. Speizer concluded that the carcinogenic potency of hexavalent chromium at the low exposure levels characteristic of modern chromate production plants was not well-established at the time of the Final Four Plant Report. (Tr. at 522 (Speizer).)

In assessing cancer risk from known human carcinogens such as hexavalent chromium, EPA, as a matter of Agency policy, assumes a linear dose-response relationship by default in the absence of exposure data. CX 61 at 25 [1999 EPA Draft Cancer Guidelines]; Tr. at 578 (Speizer). EPA's use of the linear default approach for hexavalent chromium is premised on the chemical substance having the potential to cause lung cancer at all exposure levels consistent with the Agency's cancer guidelines. CX 61 at 25 [1999 EPA Draft Cancer Guidelines]. This linear default approach to assessing risk is considered generally conservative of public health. Id. at 87. With respect to the linear default approach, Dr. Speizer stated, "[i]t was hypothesized that there would be risk but we didn't know the magnitude and then we certainly didn't have much certainty about that risk." (Tr. at 522 (Speizer).)

The use of the linear default approach for hexavalent chromium by EPA and its sister agency, the Occupational Safety and Health Administration (OSHA) has been roundly criticized by the chromate industry, including well after the Final Four Plant Report became available in 2002. (Tr. at 1110-11 (Edens); see also CX 95 at 95 ("We [Elementis] believe that use of a linear relative risk model can lead to a serious overprediction in estimated risks especially when it is based on effects at very high exposure levels.") [2004 Elementis Comments on OSHA Proposed Rule for Occupational Exposure to Hexavalent Chromium]; CX 96 at 2 ("The possibility of a threshold-like effect in the relationship between exposure to Cr(VI) and lung cancer suggests that the studies on chromate production workers should not be relied on to establish the PEL [Permissible Exposure Limit] Use of a linear risk model can lead to a serious overprediction [of] estimated risk.") [2006 Elementis (Barnhart) OSHA PEL Testimony]; CX 76 at 102 ("OSHA's [linear] model assumes that the risk associated with a cumulative exposure resulting from long-term, low-level exposure is similar to the risk associated with the

same cumulative exposure from briefer exposures to higher concentrations, and that a linear relative risk model adequately describes the cumulative exposure-response relationship OSHA received a variety of comments regarding the uncertainties associated with using the [linear] risk model based on the Gibb and Luippold cohorts to predict risk to individuals exposed over a working lifetime to low levels of CrVI Some commentators suggested that a nonlinear or threshold exposure-response model is an appropriate approach to estimate lung cancer risk from Cr(VI) exposures.”) [2006 OSHA Final Rule.] Dr. Mundt, the Final Four Plant Report’s principal investigator, acknowledged at hearing, “There’s a lot of interest in certain compounds like hexavalent chromium that there may well be a threshold above which exposures are more harmful, and not necessarily what you accumulate over years and years.”). (Tr. at 717-18 (Mundt).) The controversy over whether hexavalent chromium has a linear as opposed to a non-linear or threshold dose-response relationship underscores the importance of new exposure data in supporting EPA’s linear default approach for dose-response assessment.

Moreover, Dr. Speizer explained that, although EPA had used a linear default approach for hexavalent chromium, the only exposure data sets available to the Agency examine exposure levels “five to ten times higher” than modern chromate plant exposure levels. (Tr. at 1090 (Speizer).) In particular, he contrasted the high exposure levels in older studies such as Mancuso’s upon which EPA’s 1984 health assessment for chromium and its 1998 toxicological review for hexavalent chromium are based with the exposure levels examined in the Gibb et al. study and the Final Four Plant Report:

[W]hat we do know from these two studies, Gibb’s and the Mundt [Final Four Plant Report] study, is that these [exposures levels] are, in theory anyway, all below the levels that were all done up until 1984 [health assessment], 1998 [toxicological review], values that EPA had.

(Tr. at 1087 (Speizer).) In view of this sharp contrast in hexavalent chromium exposure levels, Dr. Speizer explained how the EPA-funded Gibb et al. study and the Final Four Plant Report contribute to the scientific understanding:

[T]he Gibb study importantly puts a marker in this region [lower exposure levels] that means that a degree of certainty about what's going on at this lower level has been added to our database.

However, the Gibb's data suffers in my mind from having to deal with the fact that . . . he [Gibb] included a number of people – a substantial number of people with short-term exposure Anyway, he's reduced the uncertainty about our hypothesis that there's a linear dose response curve by some degree.

(Tr. at 1090-91 (Speizer).) In comparing the relative contributions of the Gibb et al. study and the Final Four Plant Report, Dr. Speizer emphasized the importance of the results of the later study:

The Mundt [Final Four Plant Report] study, I believe, adds to that [Gibb et al. study] information considerably because it is I still believe a significant dose response within the whole population.

. . . .

I think it contains certainly additional information. It helps reduce the uncertainty about what we hypothesize as the linear dose response curve.

. . . .

[The Final Four Plant Report] provides information that increases the certainty about the hypothesis that the linear dose response curve continues at lower levels.

(Tr. at 1091, 1093-94, 1097 (Speizer).) Dr. Speizer concluded, "I believe it [Final Four Plant Report] does provide additional and new information about the risk of [lung cancer mortality at] low levels of exposure." (Tr. at 510 (Speizer).) He also stated that the Final Four Plant Report contains a "very valuable resource of data which has the potential . . . of adding important information to our understanding of the dose response-exposure response relationship" (Tr. at 1085 (Speizer).) Thus, the Final Four Plant Report's finding of elevated risk of lung cancer

mortality based on low-intensity exposure does not corroborate the Gibb et al. study's finding of elevated risk based on high-intensity exposure.

Third, the Final Four Plant Report is not corroborative of a well-established adverse effect under long-term, low-intensity exposure conditions because of the scarcity of studies containing exposure data sets for dose-response assessment. Of the three studies referenced by Dr. Gibb, it is undisputed that the first study by Mancuso contains limited exposure data dating to the 1940s, well before the chromate industry implemented manufacturing process and industrial hygiene changes in the 1950s and 60s resulting in lower hexavalent chromium exposure levels. (Tr. at 122, 125, 140 (Cooper); Tr. at 1022-23 (Gibb).) Consequently, only two of the studies cited by Dr. Gibb had been conducted recently, and one of those studies –the 2003 Luippold et al. study– had not been published at the time the Final Four Plant Report became available in 2002. See CX 69 [Luippold (2003)]. For all intents and purposes, the Gibb et al. study was the only recent study with an exposure data set available at the time of the Final Four Plant Report. As discussed above, the Gibb et al. study examines fundamentally different exposure conditions than the Final Four Plant Report.

Even Respondent's expert, Dr. Gibb, only cited a single example where one epidemiological study was sufficient for dose-response assessment. (Tr. at 1064 (Gibb).) The exclusive example cited by Dr. Gibb concerns a "very large" study of the risk of cancer from coke oven emissions initiated by the University of Pittsburgh in 1962. Id.; see also C. K. Redmond, Cancer Mortality Among Coke Oven Workers, 52 ENVIRON. HEALTH PERSPECTIVES 67, 68 (1983), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1569361/pdf/envhper00458-0072.pdf>. Publicly available information about coke oven emissions studies in EPA's Integrated Risk Information

System indicates that the University of Pittsburgh study cohort exceeds 59,000 workers. See EPA Integrated Risk Information System web page: <http://www.epa.gov/iris/subst/0395.htm> (Coke oven emissions (CASRN 8007-45-2). The Agency's Integrated Risk Information System references dose-response information from the University of Pittsburgh's Lloyd-Redmond cohort data assembled by Mazumdar et al. (1975) and sorted by Land (1976). Id. In comparison to the 2,357-member Gibb et al. study cohort, the "largest" of the three hexavalent chromium studies referenced by Dr. Gibb in his testimony, the initial study conducted by the University of Pittsburgh (Lloyd et al.) has a cohort of 59,000 workers with an additional number of workers in a University of Pittsburgh follow-up to the study (Redmond et al.) which expanded the cohort even more. (Tr. at 1058, 1066 (Gibb) ("largest" study); Cf. CX 62 at 1, 3 [Gibb (2000)] and EPA Integrated Risk Information System profile for coke oven emissions; see also C. K. Redmond, supra.) Thus, Dr. Gibb's isolated example involving a study cohort of more than 59,000 workers far exceeds the size of Mancuso's as well as the later Gibb et al. and Luippold et al. cohorts, and thus is not analogous.

In short, the Final Four Plant Report is not corroborative of other epidemiological studies of lung cancer mortality risk from hexavalent chromium exposure which existed at the time Elementis obtained the report in 2002. The Final Four Plant Report contains new information about the elevated risk of lung cancer mortality from hexavalent chromium under long-term, low-intensity exposure conditions. This new information clearly distinguishes the Final Four Plant Report from the Gibb et al. study. The former study examines the risk of lung cancer mortality under long-term, short-intensity exposure conditions while the later examines risk under short-term, low-intensity exposure conditions. Moreover, although the Luippold et al. study does examine long-term, short-intensity exposure conditions, it was not published until

2003 and could not have been available as a publication in the open scientific literature to Elementis or the EPA Administrator in 2002. See CX 21 at 19 [1991 EPA 8(e) Reporting Guide]. As such, the Final Four Plant Report is not corroborative of other epidemiological studies known to the Administrator as of 2002. Consequently, Respondent has failed to meet the burden of persuasion to establish its statutory affirmative defense.

C. EPA's Proposed Penalty of \$2,338,000 Is Appropriate Because It Is in Accordance with the Statutory Penalty Criteria Established in TSCA section 16(a)(2)(B).

TSCA section 8(e) requires the immediate reporting of information which “reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment.” 15 U.S.C. § 2607(e) (emphasis added). On its face, this statutory provision ensures that EPA receives information relating to human health risks from chemical substances as soon as such information is obtained by the manufacturers, processors or distributors of such chemical substances. Because non-reporting violations under TSCA section 8(e), especially those involving human health data, can severely limit the Agency's ability to address substantial risks to health and the environment from chemical exposures, they are considered serious violations under TSCA. See CX 103 at 23, 25-26 [1999 TSCA Enforcement Policy (ERP)]. Respondent's failure to submit the Final Four Plant Report to the EPA Administrator immediately upon receipt had the potential to undermine the Agency's ability to fully assess human health risk from hexavalent chromium exposure under long-term, low-intensity exposure conditions. In accordance with TSCA section 16, EPA's proposed penalty of \$2,338,000 takes into account the seriousness of Respondent's violation along with each of the other statutory penalty criteria.

TSCA section 16(a)(1) authorizes the assessment of civil penalties for violations of TSCA section 15, 15 U.S.C. § 2614, in an amount not to exceed \$25,000 for each day of the violation. 15 U.S.C. § 2615(a)(1). The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, requires EPA to adjust penalties to account for inflation. EPA's Civil Monetary Penalty Inflation Adjustment Rule raised the maximum civil penalty that may be assessed under TSCA to \$27,500 per day, per violation for violations occurring between January 30, 1997 and March 15, 2004; \$32,500 per day, per violation for violations occurring between March 16, 2004 and January 12, 2009; and \$37,500 per day, per violation for violations occurring after January 12, 2009. See 40 C.F.R. Part 19; CX 104 [2006 EPA Penalty Inflation Adjustment Memo.].

Although Respondent's TSCA section 8(e) violation carries a maximum statutory penalty of \$69 million, EPA proposed a penalty of \$2,338,000 in accordance with the penalty criteria established in TSCA section 16(a)(2)(B). The statutory penalty criteria require EPA to take into account the nature, circumstances, extent, and gravity of the violation alleged, as well as Respondent's ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. 15 U.S.C. § 2615(a)(2)(B); see also Tr. at 590-591 (Ellis).

In 1980, the Agency published in the Federal Register a document entitled Guidelines for the Assessment of Civil Penalties Under Section 16 of the Toxic Substances Control Act; PCB Penalty Policy ("Guidelines"). See CX 102 [1980 Guidelines]. The Guidelines set forth a general policy for the assessment of penalties, with the understanding that regulation-specific penalty policies would be developed separately using the approach set forth in the Guidelines. CX 102 at 2 [1980 Guidelines]. The applicable regulation-specific penalty policy in this case is

the Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12, and 13 (“TSCA ERP”). See CX 103 [1999 TSCA ERP]; Tr. at 591, 595 (Ellis).

Together, the Guidelines and the regulation-specific policies, such as the TSCA ERP, ensure that penalties assessed under TSCA section 16 are “assessed in a fair, uniform, and consistent manner; that the penalties are appropriate for the violation committed; that economic incentives for violating TSCA are eliminated; and that persons will be deterred from committing TSCA violations.” CX 102 at 2 [1980 Guidelines]; see also Tr. at 592, 596 (Ellis).

1. The Proposed Gravity-Based Penalty of \$2,338,000 Was Calculated in Accordance with the Statutory Penalty Criteria Set Forth in TSCA Section 16(a)(2)(B) and Applicable EPA Penalty Policies.

The Guidelines establish a two-stage approach to the calculation of civil penalties: first, a “gravity-based penalty” (GBP) is determined, and second adjustments to the gravity based penalty are made. CX 102 at 2 [1980 Guidelines]. Calculation of the GBP takes into account the statutory factors of “nature,” “extent,” and “circumstances.” Id. These factors, specific to the type of violation, are incorporated into a penalty matrix which is used to determine the appropriate GBP. Id. In this case, Respondent’s violation was a straight forward TSCA section 8(e) violation. Thus, EPA’s proposed GBP of \$2,338,000 was calculated in accordance with the penalty matrix developed pursuant to the statutory factors in TSCA section 16. Nothing in the circumstances surrounding Respondent’s violation justified any upward or downward adjustments to the GBP.

The first step in calculating a GBP under the Guidelines and TSCA ERP is to define the “nature” of the violation. The “nature” factor refers to the type of requirement that was violated. CX 102 at 3 [1980 Guidelines]. The Guidelines define three categories of “nature”: chemical

control; control-associated data gathering; and hazard assessment. Id. Chemical control regulations are those aimed at minimizing the risk presented by a chemical substance; control-associated data gathering regulations are the recordkeeping and reporting requirements associated with chemical control regulation; and hazard assessment requirements are those “used to develop and gather the information necessary to intelligently weigh and assess the risks and benefits presented by particular chemical substances, and to impose chemical control requirements when appropriate.” Id. at 3; see also Tr. at 593 -594 (Ellis).

All of the recordkeeping and reporting requirements discussed in the TSCA ERP fall under the “nature” category of “hazard assessment.” CX 103 at 12 [1999 TSCA ERP]. The Agency uses the information submitted under TSCA section 8 to evaluate the potential risks associated with the manufacture, process, distribution, and use of specific chemical substances. Id. at 21. When information is not timely submitted under TSCA section 8(e), such as in the instant case, the Agency’s ability to initiate immediate action necessary to protect human health and the environment is affected. Id. at 18.

The second step in calculating a GBP under the Guidelines and TSCA ERP is to define the “circumstances” of the violation. The “circumstances” factor reflects the probability that the assigned “extent” of harm will actually occur. CX 102 at 4 [1980 Guidelines]; CX 103 at 21 [1999 TSCA ERP]. In a penalty calculation, the “circumstances” factor is measured through the assignment of one of six levels. Levels 1 and 2 are considered high, levels 3 and 4 are medium, and levels 5 and 6 are low. CX 102 at 4 [1980 Guidelines]; CX 103 at 21-25 [1999 TSCA ERP]. The probability of harm is assessed “based on the risk inherent in the violation *as it was committed.*” CX 102 at 4 [1980 Guidelines]. A violation which presented a high probability of harm at the time it was committed will be penalized at a higher circumstance level, even if the

predicted harm did not end up occurring. Id. As noted in the Guidelines, “[t]he theory is that violators should be penalized for the violative conduct, and the ‘good’ or ‘bad’ luck of whether or not the proscribed conduct *actually* caused harm should *not* be an overriding factor in penalty assessment.” Id. For the reporting rules discussed in the TSCA ERP, including TSCA section 8(e), the potential harm speaks to the Agency’s ability to assess hazards and risks to human health and the environment. CX 103 at 21 [1999 TSCA ERP].

TSCA section 8(e) is a “critically important information gathering tool” that allows EPA and others to receive information relating to new-found serious chemical hazards and/or exposures from chemical substances as soon as that information is received by the manufacturers, processors, or distributors of those chemical substances. See CX 21 at 12 [1991 EPA 8(e) Reporting Guide]. Thus, the Agency considers non-reporting violations under TSCA section 8(e) to be extremely serious violations. See CX 103 at 22, 23 [1999 TSCA ERP]. For that reason, non-reporting violations under TSCA section 8(e) are considered Level 1 violations, for which a penalty is assessed on a per day basis with no cap on the total number of days for which a penalty can be assessed. CX 103 at 12, 23, 34 [1999 TSCA ERP]. When information is not timely submitted, the Agency is forced to proceed with chemical assessment, priority setting, and regulation development without crucial information or, in some cases, without the knowledge that such information even exists. CX 103 at 22 [1999 TSCA ERP]; Tr. at 597-598 (Ellis).

Pursuant to the Guidelines and TSCA ERP, Respondent’s TSCA section 8(e) violation is a Level 1 violation. As clearly stated in the Guidelines, that the Agency has not yet had the opportunity to use the information contained in the Final Four Plant Report is not a justification for lowering the penalty. Rather, the “circumstances” portion of the penalty calculation turns on

the probability that the harm may occur. See CX 102 at 4 [1980 Guidelines]. A violator should not be rewarded for its good luck that the potential harm from its violation was not realized. In this case, it is nearly impossible to know what EPA might have done with the information in the Final Four Plant Report had the Agency received it in 2002. The Agency's default penalty calculation formula actually takes a conservative approach in that it assumes that a TSCA section 8(e) violation did not disrupt the Agency's ability to address situations involving potential imminent hazards. Had the Agency determined that its ability to address an imminent hazard had been impaired, the penalty would have been calculated at the much higher statutory maximum. See CX 103 at 15–16 [1999 TSCA ERP].

The third and final step in calculating the GBP under the Guidelines and TSCA ERP is to define the “extent” of the violation. This factor refers to the extent of potential harm to EPA's hazard/risk assessment process caused by a violation. CX 103 at 25 [1999 TSCA ERP]. “Extent” is broken into three levels: major; significant; and minor. CX 102 at 3 [1980 Guidelines]. Major extent violations are those with the potential for serious damage to human health or major damage to the environment; significant extent violations are those with a potential for significant damage to human health or the environment; and minor extent violations are those with a potential for lesser damage to human health or the environment. Id. For hazard assessment data-gathering regulations, the “extent” of harm considers the goals of the given hazard assessment regulation and the types of harm it is designed to prevent. Id. at 4. As discussed in the TSCA ERP, in the case of recordkeeping and reporting rules, harm is defined as the inability of the Agency to carry out its risk assessment responsibilities under TSCA. CX 103 at 25 [1999 TSCA ERP].

In examining the extent of potential harm, the Agency considers the type of information that is the subject of the violation. Data related to human effects or human exposure is treated differently from animal data or information pertaining to environmental effects. CX 103 at 14, 25 [1999 TSCA ERP]; Tr. at 599 (Ellis). Under the TSCA ERP, violations of TSCA section 8(e) which involve human data are considered “major” in extent, while violations of 8(e) involving animal or aquatic studies, environmental monitoring, or workplace monitoring (non-invasive human monitoring) are considered “significant” in extent. CX 103 at 14, 25-26 [1999 TSCA ERP]. Because the Final Four Plant Report involves human health effects data, Respondent’s failure to submit that report to the Agency is appropriately categorized as “major” in extent.

Pursuant to the TSCA ERP, Respondent’s violation is a Level 1, “major” extent violation which carries a base penalty of \$27,500 for that portion of the violation that occurred on or before March 15, 2004, and \$32,500 for the portion that occurred after March 15, 2004. Although Respondent obtained the Final Four Plant Report on October 8, 2002, EPA used October 29, 2002 as the first day of violation for purposes of calculating the GBP because EPA’s guidance at the time of the violation allowed for a 15 working day “grace period.” See CX 17 at 2 [1978 EPA 8(e) Guidance]. The violation ended on November 16, 2008; the day Respondent submitted the Final Four Plant Report to the Agency in response to a subpoena.¹⁷ (Tr. at 602 (Ellis).) Because TSCA section 8(e) violations do not have a cap on the number of days for

¹⁷ Publication of the U.S. and German data separately did not operate to cut short the violation period. In 2003, EPA clarified its TSCA section 8(e) guidance to note that substantial risk information need not be reported to the Agency under section 8(e) if it can be “obtained in its entirety” from one of a number of enumerated sources, including scientific publications. CX 67 at 11 [2003 EPA 8(e) Guidance] (emphasis added). The Final Four Plant Report was never published in its entirety; instead, the study was bifurcated and the re-analyses of the U.S. and German data were published separately. Published separately, the two studies lack the statistical power of the full Final Four Plant Report to detect the risk of lung cancer under long-term, low-intensity exposure conditions and at low levels of exposure. (Tr. at 1083-84 (Speizer) (“[B]ecause [U.S. and German] populations are split the precision of any of the estimates is reduced simply because of smaller sample sizes.”).)

which a penalty may be assessed, EPA is entitled to assess penalties for every day of the violation. The TSCA ERP notes that

[f]ailure to comply with the TSCA §8(e) reporting requirements can be the most serious violation of TSCA §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. This ERP reflects the seriousness the Agency attaches to violations of TSCA §8(e) by not placing caps on the penalties assessed for these violations.

CX 103 at 23 [1999 TSCA ERP]. Assessment of a per day penalty for the full period of violation is consistent with both section 16(a)(1) of TSCA, which provides for penalties to be assessed for each day of the violation, and with the Presiding Officer’s ruling that TSCA section 8(e) violations are continuing in nature. (See Order on Resp’t Mot. for J. on the Pleadings at 12 (March 25, 2011).)

As noted above, the Respondent’s violation did not disrupt the Agency’s ability to address situations which involve potential imminent hazard, substantial endangerment situations or unreasonable risks. Therefore, the Agency used the formula which provides for a substantial reduction in the per day penalty assessment for a TSCA section 8(e) violation after the first day of violation. Pursuant to the TSCA ERP, the applicable penalty formula for determining the gravity based penalty in this matter is as follows:

$$\text{Base Penalty} + \frac{(\text{Number of Days of Violation} - 1)}{30} \times \text{Base Penalty}$$

CX 103 at 15-16 [1999 TSCA ERP]. As explained in the TSCA ERP, the “Base Penalty” in the formula represents the first day of the violation. Because Respondent’s violation spanned two different time periods affected by the inflationary rule, the GBP was calculated as follows:

First phase: October 29, 2002 – March 14, 2004 = 503 days

$$27,500 + \frac{(503-1) \times 27,500}{30} = \underline{\$487,667}$$

30

Second phase: March 15, 2004 – November 16, 2008 = 1,708 days

$$(1708) \times 32,500 = \underline{\$1,850,333}$$

30

The final gravity based penalty for this action is \$2,338,000, which is equal to the sum of the two phases. (See Tr. at 603-604 (Ellis).)

2. The Circumstances Surrounding Respondent's Violation Do Not Warrant Any Upward or Downward Adjustments to the Gravity-Based Penalty.

Pursuant to the Guidelines and the TSCA ERP, after the Agency calculated the GBP it considered whether any adjustments to the GBP were warranted. While the GBP is focused on the nature, circumstances, and extent of the violation, the adjustment criteria consider factors specific to the violator itself, such as: ability to pay, effect of the GBP on ability to continue in business, any history of prior violations, the degree of culpability, and such other matters as justice may require. CX 102 at 5 [1980 Guidelines]; CX 103 at 9 [1999 TSCA ERP]. As discussed further below, the circumstances surrounding Respondent's violation did not warrant any upward or downward adjustments to the GBP.

Under TSCA, the "culpability" factor requires an assessment of the violator's knowledge of the particular TSCA requirement, the degree of the violator's control over the violative condition, and the attitude of the violator. CX 102 at 5 [1980 Guidelines]. With respect to the violator's knowledge of the particular TSCA requirement, under the Guidelines, a violator can be held fully culpable even if it had no knowledge of a particular regulatory requirement where it

does know that the particular substance it was dealing with was hazardous. Id. The Guidelines recognize that culpability reductions for lack of knowledge are rare, noting that a “reduction in the penalty based on lack of knowledge could only occur where a reasonably prudent and responsible person in the violator’s position would not have known that the conduct was hazardous or violative of TSCA.” Id. Culpability also includes consideration of the degree of control the violator had over the violation. In situations where the violator may be less than fully responsible for the violation’s occurrence a reduction in the GBP may be warranted. Id.

In this case, although Respondent’s representative, Dr. Barnhart, claims not to have actually read TSCA section 8(e) or the guidance, he did admit at hearing to having a general understanding that there was a reporting requirement. (Tr. at 990-991 (Barnhart).) There is no dispute that the chemicals Respondent manufactures, chromic acid, chromic oxide and sodium dichromate, toxic substances are regulated by TSCA. Respondent admits that two of these chemicals, chromic acid and sodium dichromate are hexavalent chromium compounds, which are “highly” carcinogenic substances. (Ans. ¶ 18; Tr. at 1033 (Gibb) (“[O]n a pound for pound basis, hexavalent chromium was the most carcinogenic substance that we [EPA] did a dose response assessment on, at least for the known human carcinogens.”).) That Respondent’s representative, a long-time senior manager for a major chemical manufacturer, misunderstood the reporting requirement does not justify a reduction in the GBP.¹⁸ Furthermore, the fact that

¹⁸ Mr. Barnhart, a vice president for Elementis, testified that he had not actually read TSCA section 8(e) or the guidance, but that he “understood that if something new came out that was significant, showing an adverse effect that was especially unexpected or much greater than expected, that there was a reporting requirement for it.” (Tr. at 990-91 (Barnhart).) This is a misunderstanding of the section 8(e) reporting requirement; this statutory provision requires the reporting of substantial risk information of which the Administrator has not already been adequately informed. Neither section 8(e) nor the guidance requires that the information be “especially unexpected” or “much greater” than expected; the reporting requirement is triggered by any new substantial risk information, no matter how different it is from previously known information.

other companies received the Final Four Plant Report at the same time as Respondent does not justify a reduction in the GBP. Each company had an independent obligation to report the information contained in the Final Four Plant Report unless that company had actual knowledge that the Administrator had already been adequately informed of that information. Respondent has provided no evidence that it had reason to believe another company had reported the Final Four Plant Report to EPA. Thus, Respondent is fully responsible for the violation's occurrence and no reduction to the GBP for culpability is warranted.

The Guidelines also allow for consideration of the Respondent's "attitude." The following factors are considered in assessing a violator's attitude: whether the violator is making "good faith" efforts to comply with the appropriate regulations; the promptness of the violator's corrective actions; and any assistance given to the Agency to minimize any harm to the environment caused by the violation. CX 102 at 5 [1980 Guidelines]. In this case, Respondent did not submit the Final Four Plant Report to EPA until it was required to do so in response to an EPA-issued TSCA subpoena. (Tr. at 602, 604, 625-26 (Ellis).) The Agency does not consider compliance through a mandatory response to a subpoena the type of "good faith" effort that would justify a downward adjustment in the GBP for attitude.

TSCA section 16 also requires the Agency to consider the Respondent's "ability to pay" and "effect on ability to continue to do business." 15 U.S.C. § 2615(a)(2)(B). These are listed as two separate factors in the statute; however, because the distinctions between the two are so narrow the Agency treats the two as a single factor. CX 102 at 7 [1980 Guidelines].) Generally, at the time the Agency files the complaint it presumes the violator has the ability to pay the civil penalty. Id. If the violator raises the issue of inability to pay in its answer or in the course of settlement discussions, the Agency will conduct an ability to pay analysis to determine a more

appropriate penalty. Id. In this case, subsequent to calculating the proposed penalty EPA investigated Respondent's ability to pay by consulting the company's Dun & Bradstreet report in addition to financial data available on Elementis's website. The information found through those inquiries indicated no concerns regarding Respondent's ability to pay the GBP. (Tr. at 605-06 (Ellis).) Nor has Respondent claimed an inability to pay the proposed penalty. Id. at 606.

Other factors the Agency considers when assessing whether any adjustments to the GBP are warranted include: economic benefit from non-compliance; history of prior violations; voluntary disclosure; and government clean-up costs. See 15 U.S.C. § 2615(a)(2)(B); see also CX 102 at 5 [1980 Guidelines]; see also CX 103 at 18-20 [1999 TSCA ERP].) In this case, Respondent's violation did not result in any government clean-up costs; the Respondent did not voluntarily disclose its violation; and the Agency identified no history of prior TSCA violations. Any economic benefit Respondent gained through its violation is assumed to be minimal and accurately captured through the GBP. (Tr. at 605 (Ellis).)

The GBP of \$2,338,000 was calculated in accordance with the statutory penalty criteria set forth in TSCA section 16(a)(2)(B) as well as the Agency's interpretation of the statutory penalty criteria as memorialized in the Guidelines and TSCA ERP. Because the Agency determined none of the statutory or guidance adjustment factors apply to Respondent's violation, the final proposed penalty is \$2,338,000.

V. CONCLUSION

For the foregoing reasons, Complainant respectfully requests that an order be entered in Complainant's favor finding Respondent liable as a matter of law for its continuing violation of section 8(e) of TSCA and imposing a civil penalty in the amount of \$2,338,000.

Respectfully submitted,

03.16.2012
Date

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