UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Elementis Chromium Inc.,	)	**Docket No. TSCA-HQ-2010-5022**
f/k/a Elementis Chromium, LP,	)	
	)	
Respondent.	)	

INITIAL DECISION

Pursuant to Section 16 of the Toxic Substances Control Act, 15 U.S.C. § 2615, a penalty in the amount of $2,571,800 is hereby imposed against Respondent Elementis Chromium, Inc., f/k/a Elementis Chromium, LP, for noncompliance with Sections 8(e) and 15(3)(B) of the Toxic Substances Control Act, 15 U.S.C. § 2607(e) and § 2614(3)(B).

DATED: November 12, 2013

PRESIDING OFFICER: Chief Administrative Law Judge Susan L. Biro

APPEARANCES:

For Complainant:

Mark A.R. Chalfant, Esq.
Environmental Protection Agency
1595 Wynkoop Street (8ENF-L)
Denver, CO 80202
(303) 312-6117

Erin K. Saylor, Esq.
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
WJC Building: MC 2249A
Washington, DC 20460
(202) 564-6124

For Respondent:

John J. McAleese, III, Esq.
(Formerly Morgan, Lewis & Bockius, LLP)
1735 Market Street, Suite 700
Philadelphia, PA 19103
(215) 979-3892

Ronald J. Tenpas, Esq.
Morgan, Lewis & Bockius, LLP
1111 Pennsylvania Avenue, N.W.
Washington, DC 20004
(202) 739-5435

I. PROCEDURAL HISTORY

On September 2, 2010, Rosemarie A. Kelley ("Complainant"), Director of the Waste and Chemical Enforcement Division, Office of Civil Enforcement, United States Environmental Protection Agency ("EPA" or "Agency"), filed a Complaint and Notice of Opportunity for Hearing ("Complaint") pursuant to Section 16(a) of the Toxic Substances Control Act ("TSCA"), 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, set forth at 40 C.F.R. Part 22 ("Rules of Practice"), against Elementis Chromium, LP ("Respondent" or "Elementis Chromium")).[1] The Complaint alleges in a single count that Respondent violated TSCA Sections 8(e) and 15(3)(B), 15 U.S.C. § 2607(e) and § 2614(3)(B), respectively, by failing to immediately inform EPA's Administrator of substantial risk information it obtained on October 8, 2002, via receipt of a report entitled "Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998 – FINAL REPORT" ("Final Report"). The Complaint did not propose a specific penalty amount for the alleged violation.

On October 4, 2010, Respondent filed its Answer and Affirmative Defenses to Complaint and Notice of Opportunity for Hearing ("Answer" and "Ans."). Therein, Respondent admitted that Dr. Joel Barnhart, its then-Vice President, received the Final Report on October 8, 2002 (Ans. ¶ 42). Respondent denied, however, that it did not immediately inform the Administrator of substantial risk information allegedly contained in the Final Report (Ans. ¶ 49). Further, Respondent listed multiple affirmative defenses in its Answer, including the assertion that, at the time Respondent received the Final Report, EPA was adequately informed of the information described therein, or at least was aware of information indicating an increased risk of cancer among certain workers with high levels of exposure in chromium processing plants, and that Respondent had actual knowledge that EPA was so informed. Ans. at 6-7. Respondent also asserted that Complainant's claim was barred by the applicable statute of limitations, and that Complainant's own published guidance and interpretation of law stated that TSCA Section 8(e) did not require the information contained in the Final Report to be disclosed to it. Ans. at 7.

On October 13, 2010, the undersigned was designated to preside over this matter. Shortly thereafter the parties were offered the opportunity to participate in an Alternative Dispute Resolution ("ADR") process before a neutral Administrative Law Judge. Both parties accepted the offer, and on November 9, 2010, the undersigned issued an order designating Administrative Law Judge Spencer T. Nissen to serve as the neutral in the parties' ADR process.

On December 15, 2010, Respondent filed a Motion for Judgment on the Pleadings raising a statute of limitations issue. Judge Nissen terminated the ADR process on January 7, 2011, and on that same day, Complainant filed a Motion in Response to Respondent's Motion for Judgment

[1] The caption of the case was later amended to reflect Respondent's name change to "Elementis Chromium Inc." *See* Order on Respondent's Motion for Judgment on the Pleadings, n.1 (Mar. 25, 2011); *see also* Joint Exhibit ("JX") 1, Joint Set of Stipulated Facts, Exhibits and Testimony (Nov. 10, 2011).

on the Pleadings. On January 10, 2011, the undersigned was (re)designated to preside over the hearing in this matter. By Order dated March 25, 2011, the undersigned denied Respondent's Motion for Judgment on the Pleadings, finding that the TSCA Section 8(e) disclosure requirement is continuing in nature, and therefore, the claim was not barred by the applicable statute of limitations.

Thereafter, on April 7, 2011, Respondent filed a Motion Requesting the Presiding Officer to Recommend Interlocutory Review of the March 25, 2011 Order by the Environmental Appeals Board. Complainant filed a Response in opposition on April 14, 2011, and the undersigned denied the Motion by Order dated April 27, 2011. The following day a Prehearing Order was issued establishing various prehearing filing requirements and deadlines.

On April 28, 2011, Complainant filed a Motion for Accelerated Decision on Liability and Memorandum in Support. On May 18, 2011, Respondent filed a Memorandum in Opposition to Complainant's Motion for Accelerated Decision on Liability ("R's AD Opp.") and on June 1, 2011, a Request for Oral Argument on Complainant's Motion for Accelerated Decision on Liability. The undersigned issued an Order on Complainant's Motion for Accelerated Decision and Respondent's Request for Oral Argument ("AD Order") on August 8, 2011, denying Respondent's request for oral argument. The undersigned also held in the AD Order that although the prima facie elements of a Section 8(e) violation had been shown, the Motion must be denied because there were "genuine issues of material facts regarding whether in October 2002 or at some later point, Respondent had actual knowledge that the Administrator had been adequately informed of the Final Report's substantial risk information." AD Order at 17. The AD Order stated that Respondent would have an opportunity at the hearing to prove its affirmative defense by a preponderance of the evidence.

By Notice of Hearing and Scheduling Order dated August 22, 2011, the undersigned scheduled the hearing and set additional prehearing filing deadlines. On November 10, 2011, the parties filed a Joint Set of Stipulated Facts, Exhibits and Testimony. On December 6, 2011, Complainant filed an Unopposed Motion to Supplement Complainant's Prehearing Exchange, and the undersigned granted the Motion. On December 8, 2011, the parties filed a Joint Set of Stipulated Exhibits and Expert Qualifications.

The hearing in this matter was held in Washington, D.C., beginning on December 12, 2011.[2] In support of the violation, Complainant initially offered the testimony of six witnesses: Toni Krasnic, a chemist with EPA's Existing Chemicals Branch in the Office of Pollution Prevention and Toxics; Frederic Arnold, a chemical engineer in EPA's Office of Pollution Prevention and Toxics;[3] Dr. Glinda Cooper, a senior epidemiologist with EPA's National Center for Environmental Assessment (NCEA); Dr. Richard Clapp, Professor Emeritus at Boston

[2] Citations herein to the transcript of the hearing will appear as follows: "Tr. [page]."

[3] Mr. Arnold's testimony was limited after the undersigned sustained an objection made by Respondent's counsel. Tr. 66.

University School of Public Health; Dr. Frank Speizer, Edward Kass Distinguished Professor of Medicine, Harvard Medical School, and Senior Consulting Physician at the Brigham and Women's Hospital; and Anthony Ellis, a case development officer in EPA's Waste and Chemical Enforcement Division in the Office of Civil Enforcement. Tr. 24-25, 61, 64, 67, 70, 274, 276, 488, 492, 586-87. Respondent offered initially for its defense the testimony of three additional witnesses: Dr. Kenneth Mundt of Environ International Corporation; Joel Barnhart, Vice President, Technical, at Elementis Chromium; and Dr. Herman Gibb of Tetra Tech. Tr. 633-34, 941-42, 946, 1010-11. For its rebuttal case, Complainant recalled Dr. Speizer and called Amanda Edens, Deputy Director of the Directorate of Standards and Guidance at the Occupational Health and Safety Administration (OSHA). Tr. 1080, 1098-99. For its surrebuttal case, Respondent recalled Dr. Barnhart. Tr. 1166. In addition, a total of 120 exhibits were offered and admitted into evidence, specifically Complainant's exhibits ("CX") 1-9, 16-17, 19-41, 43-74, 76-104, 98 revised; Respondent's Exhibits ("RX") 6-8, 12-14, 18-21, 23-33, 35; and Joint Exhibits ("JX") 1 and 2, respectively, the Joint Set of Stipulated Facts, Exhibits and Testimony filed on November 10, 2011 and the Joint Set of Stipulated Exhibits and Expert Qualifications filed on December 8, 2011. Tr. 7-8, 629-31, 1079.

A copy of the hearing transcript was received by the hearing clerk on December 20, 2011. By Post-Hearing Scheduling Order issued December 21, 2011, the undersigned set briefing deadlines. On January 30, 2012, the parties filed a Joint Motion to Conform Transcript to Actual Testimony, including a List of Transcript Corrections. The Joint Motion was granted by Order dated February 1, 2012, and the List of Transcript Corrections was incorporated. Complainant filed an Initial Post-Hearing Brief on March 16, 2012, and Respondent filed an Initial Post-Hearing Brief on April 16, 2012. On May 1, 2012, Complainant filed a Reply Brief, and on May 16, 2012, Respondent filed a Reply Brief. With the latter filing, the record closed.

II. APPLICABLE LAW

A. Liability

TSCA Section 15(3)(B), "Prohibited acts," provides in pertinent part:

> It shall be unlawful for any person to–
> * * *
> (3) fail or refuse to . . . (B) submit reports, notices, or other information . . . as required by this chapter or a rule thereunder . . . .

15 U.S.C. § 2614(3)(B).

TSCA Section 8(e) provides:

> (e) Notice to Administrator of substantial risks

> 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). The Agency has not issued any regulations specifically implementing TCSA Section 8(e). However, EPA has published several policy documents intended to clarify the Agency's interpretation of Section 8(e).

Just over one year after TSCA went into effect, the Agency published a "Statement of interpretation and enforcement policy" regarding Section 8(e). 43 Fed. Reg. 11110 (Mar. 16, 1978) ("1978 Policy Statement"); CX 17. Thirteen years later, the Agency issued a TSCA Section 8(e) Reporting Guide. 56 Fed. Reg. 28458 (June 20, 1991) ("1991 Reporting Guide"); CX 21.

In 1993, EPA solicited public comment on "certain refinements to EPA's policy concerning the mandatory reporting of information under section 8(e)," including "the circumstances under which certain information need not be reported." 58 Fed. Reg. 37735 (July 13, 1993) ("1993 Notice"); CX 24 at 1. The deadline for comments to the 1993 Notice was later extended (58 Fed. Reg. 46970 (Sept. 3, 1993)), and then comments were again solicited in 1995. 60 Fed. Reg. 14756 (Mar. 20, 1995).

In 2003, the Agency published "a single reference source for the TSCA section 8(e) policy and guidance," having considered comments to the 1978 Policy Statement and EPA's proposed changes to that document. 68 Fed. Reg. 33129 (June 3, 2003) ("2003 Guidance"); CX 67 at 1. Most recently, in 2005, the Agency announced that a question and answer page for Section 8(e) had been created on EPA's website, located at: www.epa.gov/oppt/tsca8e ("2005 Q&A"). 70 Fed. Reg. 2162 (Jan. 12, 2005); CX 78.

B. Penalty

TSCA Section 16, "Penalties," provides:

> (1) Any person who violates a provision of section 2614 or 2689 of this title shall be liable to the United States for a civil penalty in an amount not to exceed $25,000 for each such violation. Each day such a violation continues shall, for purposes of this subsection, constitute a separate violation of section 2614 or 2689 of this title.
> * * *
> (2) [ ] (B) In determining the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or

> violations and, with respect to the violator, 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). The Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890, as amended by the Debt Collection Improvement Act of 1996, Pub. L. 101-134, 110 Stat. 1321, compelled the Agency to raise the maximum civil penalty from $25,000 to $27,500 per day, per violation, occurring between 1997 and March 15, 2004, and to $32,500 per day, per violation, occurring between March 16, 2004, and January 12, 2009. 40 C.F.R. § 19.4; CX 104.

III. FACTUAL BACKGROUND

Respondent Elementis Chromium Inc., formerly known as Elementis Chromium LP, is a New Jersey Corporation. JX 1 ¶¶ 1-3; Tr. 942. For more than 35 years, Respondent has been manufacturing and distributing chromium chemicals. JX 1 ¶¶ 4-6. In 2004, Elementis described itself as "the only U.S. manufacturer of basic hexavalent chromium chemicals, sodium dichromate and chromic acid" and the manufacturer of "the largest volume of these chemicals worldwide." CX 95 at 2. It has owned chromium manufacturing plants in North Carolina, Texas, and Eaglescliffe, England. Tr. 942-43, 954; Compl. ¶¶ 6-8; Ans. ¶¶ 6-8.

Chromium (Cr), a complex and transition metal, and its compounds are used to provide color for paint, prevent decay, resist soiling, preserve wood, inhibit corrosion and tan leather. CX 1 at 20; RX 24 at 1. It exists principally in its trivalent (Cr(III)) and hexavalent (Cr(VI)) oxidation states, the latter of which is most relevant here. CX 1 at 20. Lime was traditionally and liberally used in the processing of chromate compounds, which produced chemically-laden dust and residue to which workers in chromium manufacturing plants were exposed.[4] *Id.* at 26.

Studies in epidemiology and other literature published in the United States have long documented the relationship between occupational exposure to chromates and cancer. CX 62 at 2; CX 1 at 28; CX 22 at 1; CX 70 at 14; CX 76 at 13-15; CX 79 at 1; CX 16 at 1-2; RX 21 at 21. Sixty-five years ago, in 1948, the first epidemiological study of U.S. chromate production workers was published. RX 18 at 2. Medical doctors Machle and Gregorius studied a group of

[4] Historically, in chromate chemical production, lime, chromite ore and soda ash were part of a finely milled mixture that was roasted to produce sodium monochromate and a complex mixture of chromium containing compounds as well as aluminum, iron, silicate and others. RX 24 at 2; RX 21 at 22-23. The monochromate was then separated from the residue material by a water leaching process and the leachate was converted into a crystalline sodium dichromate. *Id*. Other chromium-bearing products and by-products are produced by treatment and recovery from the primary process. *Id*.

1,445 workers from seven U.S. high-lime[5] chromium production plants (including plants in Baltimore, Maryland, and Painesville, Ohio), who had worked in the plants in the 1930s and 40s, some of whom had first been exposed to chromates decades earlier.[6] RX 18 at 2, 5. They found an "excessive rate for cancer of the bronchi and lungs" for all age groups of workers studied and in all plants except one. RX 18 at 7-8. Looking further into exposures at the Baltimore plant during this early period, Anna Baetjer, Sc.D. of Johns Hopkins University, studied lung cancer patients at Baltimore hospitals who had worked in chromium production. RX 19. Baetjer's study, published a couple of years later in 1950, confirmed the conclusions of Machle and Gregorius. RX 19 at 11-12.

In 1951, the Painesville, Ohio plant cohort, which Machle and Gregorius had also studied, was reviewed by Dr. Mancuso of the Ohio Department of Health and Dr. Hueper of the National Cancer Institute, who found that the lung cancer mortality rate among those who worked for periods in the 1930s and 40s was approximately fifteen times higher than the rate for the local county population.[7] RX 20 at 6; 21 at 21; CX 53 at 14. At hearing, Dr. Glinda Cooper, Senior Epidemiologist at the EPA's National Center for Environmental Assessment, testified that for the Mancuso cohort, there were no exposure level measurements for the early time period studied, so Mancuso used 1949 exposure levels of 200 $\mu g/m^3$ (micrograms per cubic meter of air) to estimate exposure measurements to Cr(VI) for the 1930s and 40s. Tr. 122-23, 125. Out of the extensive database of studies, "that was the best that we had available for doing qualitative dose response modeling and I think everyone recognizes the limitations . . . with what was available," she said. Tr. 125. The early studies of Mancuso and others, Dr. Cooper opined, "found quite strikingly increased risk of lung cancer among the workers in these older facilities" with risk ratios "up to 20 times higher" than in the general population or comparison groups. Tr. 120.

In 1951, the U.S. Public Health Service published a report presenting the clinical and environmental findings of an investigation to determine the present health status of chromate workers and evaluate the effects of the working environment on their health. RX 21 at 11. The investigation included six plants and 1,200 workers. *Id*. Based upon the findings, the report

---

[5] "High-lime" refers to a ratio of lime to ore of 0.5 or more to 1. CX 1 at 26; CX 95 at 7-8. A "low-lime" or "no-lime" process generally refers to plants using a lime to ore ratio of 0.1 or less. CX 95 at 8.

[6] Lung cancer is known as a long latency disease, i.e., "[i]t takes a long time from initial exposure to the subsequent diagnosis or in this case death due to the disease," so a follow-up period in epidemiology studies of at least 20 years is preferred. Tr. 133-134; 302-303, 845-846; CX 1 at 86.

[7] In 1975, Dr. Mancuso, then a Research Professor at the University of Pittsburgh, published an update to his 1951 study with Hueper which followed the Painesville, Ohio, plant cohort (1931-1937) through 1974 and confirmed the high lung cancer risk from exposure to all forms of chromium. CX 16.

recommended implementation of measures to reduce chemically-laden dust, including the design or redesign of equipment, the use of personal protection devices, ventilation, and routine air analysis. RX 21 at 12.

To their credit, chromium manufacturers in both the United States and abroad supported the aforementioned studies and, in light of the results thereof, altered their manufacturing processes to improve the work environment. RX 21 at 14-15, 23. As a result, Dr. Cooper testified, by 1970 there was in operation a new generation of chromate production plants "in terms of the degree of control of exposures, the kind of industrial hygiene measures" to control dust, "as well as other kinds of changes in the processes that led to much lower levels of exposure." Tr. 127. For example, the Baltimore chromium production plant featured in the Machle and Gregorius and Baetjer studies was re-designed in 1951 and 1960 in order to "obtain improvements in process technique and in environmental control of exposure to chromium bearing dusts." RX 24 at 2. Similarly, in 1958 and 1964 respectively, the Bayer company converted its chromium plants in Leverkusen and Uerdingen, Germany from a high-lime to no-lime production processes. CX 1 at 32; CX 25 at 1; CX 1 at 35. In 1971, Occidental Chemical Corporation opened a new plant in Castle Hayne, North Carolina, built with a low-lime process design, which was intended to replace the Painesville plant and another in New Jersey. CX 1 at 38. In addition, a chromium plant in Corpus Christi, Texas, employed a high-lime chromate production process from 1962 until 1980, when American Chrome and Chemicals ("AC&C") acquired it and converted it to a no-lime facility. CX 1 at 37.

The federal government also responded to worker health concerns. In 1971, shortly after the passage of the Occupational Safety and Health Act, OSHA adopted a general industry permissible exposure limit ("PEL") of 1 mg/10 m^3 CrO_3 (1 milligram chromium trioxide per 10 cubic meters air) in the workplace, which corresponds to a ceiling concentration (the maximum permissible concentration at any time) of 52 $\mu g/m^3$ (microgram per cubic meter of air) for chromium hexavalent (Cr(VI)). CX 70 at 8; CX 76 at 5. In 1975, the National Institute of Occupational Safety and Health ("NIOSH") published criteria for a recommended standard for occupational exposure to "carcinogenic" hexavalent chromium of a 10-hour time-weighted average of 1 $\mu g/m^3$. RX 23; CX 70 at 8.

In light of these changes, 30 years after Machle and Gregorius' original study, Johns Hopkins researchers Hayes, Lilienfeld, and Snell designed a study to "determine whether the improvements in the technology of production resulted in a decreased mortality experience for plant employees," by looking at the health of Baltimore chromium plant workers who had been hired between 1945 and 1974. RX 24 at 2. The Hayes et al. study published in 1979 concluded that the plant's new facilities "had not totally eliminated the excess risk of lung cancer" and "the question of excess risk in the low exposure group must still be considered open." RX 24 at 8.

In 1981, a follow-up to an earlier study was published in the British Journal of Industrial Medicine by Alderson, Rattan and Bidstrup, researchers from the United Kingdom's Institute of Cancer. CX 19. Of the three plants studied in this report, one in Eaglescliffe, England, had

transitioned to a no-lime process by 1961. CX 19 at 2. The other two facilities studied, however, were either high-lime throughout the study or started out as high- and later converted to low-lime. *Id*. Alderson et al. included workers who had worked for at least one year between 1948 and 1977, and found, among other interpretations, that the longer the employee worked, the greater the risk of lung cancer, but "that the introduced [process] modifications have been associated with an appreciable decrease in risk of lung cancer." CX 19 at 1, 7.

In 1984, EPA published a Health Assessment Document for Chromium, designed to "represent an interpretive summary of relevant studies" and to "serve as a scientific data base for regulatory decision making by the agency." RX 25 at 16. In its assessment, EPA acknowledged that "epidemiologic studies of chromate production workers have demonstrated an association of exposure to chromium compounds with respiratory cancer." RX 25 at 26. Further, "[u]sing the IARC [International Agency for Research on Cancer] classification scheme, the level of carcinogenic evidence available for the combined animal and human data would place hexavalent chromium (Cr VI) compounds into Group 1, meaning that there is decisive evidence for the human carcinogenicity of those compounds." RX 25 at 27. The assessment relied primarily on the Mancuso findings from the Painesville cohort study. RX 35 at 30; Tr. 124-25.

In 1985, the Baltimore chromium plant closed. That same year, OSHA researchers Braver, Infante and Chu published a study based upon the Baltimore plant data from the Hayes et al. study. CX 20. According to Dr. Cooper, Braver et al. "estimated the exposures in the 1940s [and 50s] in the Baltimore plant were on the level of about 400 micrograms [of chromium] per cubic meter, so again quite high." Tr. 124. Significantly, Braver et al. found that their results "suggest a potential excess risk of death from lung cancer among U.S. workers exposed to [even] the current permissible exposure limit (PEL) for hexavalent chromium of 52 $\mu g/m^3$ because such workers could accumulate exposures [ ] similar to those associated with excess risk in Hayes et al's cohort." CX 20 at 1.

In 1990, the IARC, part of the World Health Organization, published a monograph update on chromium risks, stating in conclusion: "Chromium[VI] *is carcinogenic to humans* (Group 1)." RX 27 at 215; *see also* RX 26 (1987) at 166. In 1995, OSHA published an Evaluation of Epidemiological Data and Risk Assessment for Hexavalent Chromium, recognizing six sets of epidemiological data as reliable bases for quantitative risk assessment of hexavalent chromium[8]: the Mancuso cohort (Painesville, Ohio), the Hayes/Braver cohort (Baltimore, Maryland), and four other cohorts in Norway, Sweden, and Russia. However, OSHA concluded in its evaluation that the Mancuso and Hayes/Braver cohorts provide the "best data currently available." RX 35 at 3-13, 53.

Over time, research on "post-process change plants" continued to be studied, e.g., by

---

[8] "Quantitative risk assessment" is the characterization of the potential adverse health effects of human exposures to environmental hazards through reliance on numerical results. National Research Council, *Risk Assessment in the Fed. Gov't: Managing the Process* 18 (1983), *available at* http://www.nap.edu/openbook.php?record_id=366&page=18.

Davies, Easton and Bidstrup in 1991 who looked at three UK plants including Eaglescliffe (CX 22), Korallus, Ulm and Steinmann-Steiner-Haldenstaett in 1993 who studied two German plants, Leverkusen and Uerdingen (CX 25), and Pastides, Austin, Lemeshow, Klar and Mundt in 1994 who studied the Castle Hayne plant (CX 26). Tr. 127. Dr. Cooper emphasized that the exposures in these plants were "so much lower" than those studied in the older literature. Tr. 127-28. The authors recognized "that these plants represented new plant conditions," Dr. Cooper averred. Tr. 130-31. The question the researchers sought to answer with the advantage of the passage of time was "whether the risks that were observed among workers in the older plants would also be seen in the workers in the newer plants, or whether there would be a change in that observation of risk in relationship to the lower exposures that were now present in these new plants." Tr. 131.

Davies et al.'s 1991 study was an update of the English three-plant cohort studied by Alderson and Bidstrup, where researchers distinguished between "early," "pre-change," and "post-change" workers in the cohort. CX 19, 22. The authors found evidence that suggested that the cancer risk for chromate production workers was limited to cancers of the lung, nose and nasal sinuses. CX 22 at 14. The report also found that for two of the three plants studied, "[t]he mortality results for postchange workers fail to show excess deaths." CX 22 at 13. The study further reads: "It is clear that the risk has diminished for postchange workers, but it is not possible to distinguish whether the decline in the risk is attributable to the introduction of low-lime and no-lime processes or to general reductions in exposure to chromate." *Id*.

Korallus et al. studied 1,417 workers from the two German plants in Leverkusen and Uerdingen who had worked more than one year, and categorized them by date of hire: 1903-1947, 1948-1957, and 1957-1987. CX 25 at 3 (1993). Dr. Cooper estimated that the average exposures to workers in these plants ranged from 12-73 $\mu g/m^3$. Tr. 137. The study "confirms the distinct reduction in BC [bronchial carcinoma] mortality in the post-change cohort compared with the pre-change cohort." CX 25 at 8.

Pastides et al., in a study published in 1994 and sponsored by Occidental Chemical Corporation, looked at the Castle Hayne plant (built in 1971) where the average exposure to hexavalent chromium (Cr(VI)) of the 398 workers studied was less than 5 $\mu g/m^3$, Dr. Cooper explained. Tr. 138; CX 26 at 6-7. The study found that employees at this newer facility did not have an elevated risk of developing cancer. *Id*. However, the study acknowledged that it was limited and that its failure to detect an increased risk "must be interpreted in light of the limited period of follow-up and the modest study size." CX 26 at 12. OSHA wrote in 2004 in its proposed rule on occupational exposure to hexavalent chromium, that the "North Carolina cohort is still relatively young and not enough time has elapsed to reach any conclusions regarding lung cancer risk and Cr(VI) exposure." CX 70 at 20.

In July 1993, the Oil, Chemical, and Atomic Workers International Union and the Public Citizen's Health Research Group ("Public Citizen") petitioned OSHA to issue an emergency temporary standard to lower the PEL for Cr(VI) to 0.5 $\mu g/m^3$ as an 8-hour time-weighted average. Upon review, OSHA agreed that there was evidence of increased cancer risk from

exposure to Cr(VI) at the existing PEL, but found that the available data did not show the "grave danger" required to support imposition of an emergency temporary standard. CX 76 at 5. Therefore, the Agency denied the request, but began preliminary analyses and a very extended rulemaking process in anticipation of issuance of a new lower industry standard. *Id*.

Naturally, the chromium industry trade groups were very interested in OSHA's efforts to update the PEL for hexavalent chromium and particularly what data the Agency would be relying on to establish a new PEL. At all times relevant to this proceeding, the not-for-profit Industrial Health Foundation ("IHF") served as administrator to two such groups, the Chromium Chemicals and Health and Environmental (or Health, Safety and Environmental) Committee ("Chromium Chemicals Committee"), and the Chrome Coalition,. Tr. 952; CX 71 at 2.

The members of the Chromium Chemicals Committee included Elementis Chromium, Bayer, and Occidental Chemical, among other international corporations. Tr. 953-54. Elementis at that time owned two chromium facilities, the British Chrome & Chemicals facility in Eaglescliffe, England, and the AC&C facility in Corpus Christi, Texas. *Id*. The Chromium Chemicals Committee member meetings served the purpose of "trying to make sure that the company understood recent developments in chromium chemicals." *Id*. The Chromium Chemicals Committee was comprised of various subcommittees, e.g., the Management Committee, Environmental Committee, Epidemiology/Human Effects Committee, and Toxicology Committee. Tr. 956. From 1987 until IHF filed for bankruptcy in 2003, Respondent's Vice-President – Technical, Dr. Joel Barnhart, served as Chairman of the Environmental Committee. Tr. 953, 956-58; CX 30 at 1.

The Chrome Coalition, also administered by IHF, was a separate, "broad spectrum" U.S.-based group composed of companies and trade organizations that had an interest in chromium, not necessarily chromium chemicals. Tr. 958-59. During much of the Coalition's existence (approximately 1986-2004), Dr. Barnhart served as its Chairman. Tr. 959.

Dr. Barnhart testified at hearing that in anticipation of the redesigned German plants closing (the Uerdingen plant closed in 1992, and the Leverkusen Plant closed in 1999), a Chromium Chemicals Committee member had suggested that the exposure data at the plants be collected and a mortality update completed. Tr. 961; CX 1 at 33. Other company representatives agreed, and the idea was discussed at meetings as set forth below.

At a February 13, 1996, special meeting of the Chrome Coalition's ad hoc PEL Committee, Dr. Barnhart "stated that the purpose of [the] meeting was to meet with the scientific principals specific to the proposal for critiquing OSHA risk assessment techniques and its standard-setting process relative to a proposed Cr^{+6} PEL." CX 27 at 1 (meeting minutes). In a document produced in association with this meeting titled, Discussions and Recommendations, it is stated that the "driving force" of OSHA's current actions related to the hexavalent chromium PEL "is the Mancuso study." CX 28 at 1. The document continues:

For the past several years we have expected that the study being conducted at

> Johns Hopkins University of the former workers at the Baltimore chromium chemicals plant . . . would provide a better database than Mancuso. This study [of the Baltimore plant] was commissioned by EPA and we know that OSHA is planning to use the findings in this study as the basis for setting a new [PEL].

Id.[9]

At the meeting, one attendee suggested that "the Coalition may wish to approach the regulators, with a program designed to fill a 'data gap,' thus entering into a data gap agreement, to forestall the rulemaking." CX 27 at 2. Another attendee responded to that idea with skepticism, stating that OSHA was already so far along in the process. *Id*. It was proposed that in addition to "[d]eveloping an anti-Mancuso manuscript," a consultant firm could "review and critique all the other relevant epidemiological studies, adding weight to the effort of convincing OSHA not to go forward with what they presently have." *Id*. at 2-3. After the consultants departed the meeting, two proposals were discussed: "It was concluded that [Firm A] will provide information for the record; [Firm B], on the other hand, affords an opportunity to build for future regulatory impact." *Id*. at 3.

In an April 1996 memorandum concerning "Recent Activities of the Chrome Coalition OSHA/PEL Ad Hoc Committee," a Coalition member wrote:

> For the past two years, we have been engaged in fighting the activity of OSHA in their promulgation of a new [PEL] for chromium. OSHA wants to lower the PEL in the area of 0.5 ug/m^3 from the current 0.1 mg/m^3. [ ] It is the intention of the Chrome Coalition to refute/influence OSHA's decision making. Should the final PEL be as low as OSHA would like, the Chrome industry, both producers and users, will suffer severely and similarly to what is happening with cadmium.

CX 29 at 1.

In the minutes of a meeting of the IHF Environmental Committee held six months later in October 1996, it was reported that members recognized OSHA's movements towards development of a new PEL, which included OSHA's call for "information linking current exposure control measures in use at the time of sampling" from which to help it develop

---

[9] There is evidence to suggest that Dr. Barnhart drafted this memorandum, although the authorship is not explicitly stated in the document (CX 28), in the parties' description of the document (JX 1 at 6), or anywhere else in the record. First, the minutes of the meeting that the memorandum summarizes state: "Within the next few weeks, Dr. Barnhart will prepare a summary of activities proposed by ChemRisk which will be sent to the ad hoc committee for consideration and approval." CX 27 at 3. Complainant's Exhibit 28, the memorandum, is addressed to the Chrome Coalition Ad Hoc PEL Committee (CX 28 at 1), summarizes the activities proposed by ChemRisk (CX 28 at 2-3), and otherwise appears to match the description in the meeting minutes of what Dr. Barnhart was tasked with when the meeting concluded.

technological feasibility conclusions. CX 30 at 2. The group also noted one member's efforts to "conceptualiz[e] and develop[] an 'industry friendly' standard for Cr^{+6}" for use as rebuttal when OSHA published its proposed standard, as well as the development of an "advocacy mechanism" for "lobbying appropriate Administration principals when OSHA sends the proposed standard to the OMB [U.S. Office of Management and Budget]." CX 30 at 2-3. Dr. Kenneth Mundt, who would later author the Final Report at issue here, was an invited guest at this meeting. CX 30 at 1. The next day, the IHF Management Committee held a meeting, and the minutes report that Dr. Barnhart briefed the Committee on the hexavalent chromium PEL issue discussed at the Environmental Committee meeting and mentioned that a consultant, Dr. Mundt, had been invited to that meeting. CX 31 at 2, 5.

Dr. Kenneth Mundt started his career in academia, working at the University of Massachusetts' School of Public Health for ten years after he completed his Ph.D. in epidemiology in 1990. Tr. 634-35; RX 7. From 1991 to 2003, Dr. Mundt served as President and founder of Applied Epidemiology, Inc. ("Applied"), which merged in 2003 with ENVIRON Health Sciences. RX 7; Tr. 635. He participated as a researcher in the limited Pastides et al. study of the Castle Hayne facility published in 1994 mentioned above. The parties in this matter stipulated to Dr. Mundt's expertise in the fields of epidemiology and assessment of human health risk associated with exposure to hexavalent chromium. JX 2 at 2; RX 7. Regarding the Chromium Chemicals Committee, Dr. Mundt testified, "it became clear that the IHF companies were interested in conducting an epidemiological study that would combine all of the small studies and look specifically at more recent workplaces, where some of the efforts to reduce exposures had been implemented for a sufficiently long time to begin to look to see whether the risks had reduced at all." Tr. 648. Dr. Mundt stated that he and the companies' representatives "discussed the merits of putting together an epidemiological study." Tr. 649. In initial talks, there was "a question of whether they were ready to go forward with an update of their plants, and if so, how would this work, because we had different companies involved . . . different processes, different time periods." Tr. 651. Once they decided to move forward, Dr. Mundt developed a proposal and presented it to the committee on behalf of Applied. Tr. 652.

Dated March 17, 1997, Applied's draft proposal begins by stating that since process changes were implemented at chromate plants, studies of workers employed at these post-change plants "have demonstrated to date no consistently elevated mortality risks." CX 33 at 2. Further:

> It remains unclear, however, whether the absence of significantly elevated cancer risks can be attributed to improved workplace conditions and reduced exposure to hexavalent chromium compounds, or reflects methodological limitations of the studies such as inadequate latency periods due to relatively short follow-up periods and low statistical power due to small cohorts.
> * * *
> Although the published literature demonstrates a consistent association between hexavalent chromate exposure and respiratory cancer, the change to no-lime or low-lime processes in the chromium chemicals industry renders this extensive literature obsolete.

CX 33 at 5-6, 9. The proposal further states that no post-change cohort studied up until that time had included more than 500 employees, that the average follow-up among the studies was 25 years, and the average number of deaths from respiratory cancer was only five. CX 33 at 10. Applied stated in the proposal that it was the intention of Dr. Mundt and Dr. Tritschler, his colleague at Applied, to study and update cohorts from six "post-change" plants using a job exposure matrix ("JEM") (tool linking individual work histories and mortality experience to plant exposure environments), conduct a standardized mortality ratio ("SMR") analysis (a comparison of observed cases to expected cases from a reference population), and account for workers' smoking history, among other things. CX 33 at 3, 12.

At hearing, Dr. Mundt testified that at the time the proposal was made, "there really was an eagerness to know whether the high risks that has been documented in the literature since the 50's were attenuated at all, with all of the changes, and there were various types of industrial hygiene engineering and process changes throughout these plants, and they were different at different times." Tr. 653. "[C]ollectively," he noted, "there was agreement that over time, exposures had declined," so they decided to track the exposures and mortality data of only those employees who worked in the facilities after efforts had been made to reduce exposures. Tr. 648, 653-55. Dr. Mundt presented the draft proposal at a special session of the IHF Epidemiology/Human Effects Subcommittee meeting on April 16, 1997. CX 34 at 2. Applied completed a second draft proposal on October 21, 1997, and presented it to the Epidemiology/Human Effects Subcommittee the next day. CX 36-37.

By this time in 1997, Mancuso had published another update of his study on the Painesville cohort, finding in part, a "magnitude of the occurrence of occupational cancer in this relatively small cohort of workers demonstrates the potential and necessity of identifying the causes of occupational cancer and their prevention" and that "[t]he true nature of the range and magnitude of occupational and environmental cancer remains unknown." RX 30; RX 31 at 10-11.

On October 23, 1997, the IHF Environmental Subcommittee met and Dr. Barnhart updated attendees as to recent activities surrounding OSHA's PEL development:

> This summer the Public Citizen Health Research Group initiated a new threat to OSHA requesting that OSHA immediately issue a Notice of Proposed Rulemaking (NPRM) to reduce the PEL[10] . . . . The Chrome Coalition is continuing a dialogue with OSHA and is planning to meet with them in November. Dr. Barnhart and Ms. Jackson met with them approximately three

[10] In 1997, Public Citizen had petitioned the U.S. Court of Appeals for the Third Circuit to compel OSHA to complete the rulemaking it initiated in 1993 that would lower the hexavalent chromium PEL. CX 76 at 5. The Appeals Court found that OSHA was not unreasonably delaying the rulemaking and dismissed the petition. *Id.*; *Oil, Chem. and Atomic Workers Union and Public Citizen Health Research Group v. OSHA*, 145 F.3d 120 (3d Cir. 1998).

> weeks ago at which time OSHA did indicate a willingness to acknowledge biologically based information and alternative risk assessment models. OSHA is using the 1997 Mancuso papers to update its risk assessment.

CX 38 at 2. That November, Applied completed its study Proposal, which reflected its intention at that time to study workers from six plants, two British, two German (Leverkusen and Uerdingen), and two American (Castle Hayne and Corpus Christi). CX 40 at 9-18. The Proposal stated that by combining employees from the six plants owned by four companies using similar research methods into a single set of analyses it would create "in essence an ideal meta-analysis," with enhanced statistical power due to the larger combined cohort and improved exposure assessment reducing exposure misclassification and subsequent bias. *Id*. at 5. The study would also take into account the confounding role of smoking in evaluating respiratory cancer risks. *Id*.

On November 12, 1997, the Chrome Coalition met with OSHA representatives. CX 41. In a memo to the Chromium Chemicals Committee about what was discussed, Dr. Barnhart added his reflections:

> It seems to me that these developments open several possibilities for us to influence the proposed rule.
>
> 1. If OSHA is going to do a quick analysis of the Johns Hopkins data [from the Baltimore plant workers] and call it the definitive study we certainly should make an effort to be involved and consider announcing that we are doing an even more extensive study.

CX 41 at 2.

On February 24, 1998, Applied completed a Revised Proposal, in which it was noted that one of the British plants would be excluded (it was only a no-lime facility for only eight years, and had been closed for thirty years). CX 44 at 1, 8. Applied gave a short review of the studies that had been produced at that time and their limitations:

> Occupational exposure to hexavalent chromate in dust produced in high-lime kiln manufacturing processes has been associated with elevated risk of respiratory cancers. This epidemiological finding . . . led the chromate chemicals industry to modify production to no-lime (or low-lime) processes and to improve other plant hygienic measures. Epidemiological studies of cohorts employed after process changes or employed in newer plants using the improved processes have demonstrated to date no consistently elevated mortality risks, including mortality due to respiratory cancers. [ ] The relatively small study sample sizes and short follow-up periods of these studies resulted in a limited ability of these studies to clarify the relationship, if any, between modern occupational chromate exposures and cancer in general, and respiratory cancers in particular.

> This proposal describes a methodology for updating the same cohorts in a standardized manner so that the data may be combined validly . . . .

CX 44 at 3. And later:

> Among more recent studies of employees in plants using low-lime or no-lime processes, no significant elevations in cancer risk have been seen (Davies . . . Korallus . . . Pastides . . .). It remains unclear, however, whether the absence of significantly elevated cancer risks can be attributed to improved workplace conditions and reduced exposure to hexavalent chromium compounds, or reflects methodological limitations of the studies such as inadequate latency periods due to relatively short follow-up periods and low statistical power due to small cohorts.

CX 44 at 7. *See also* CX 44 at 16 ("the studies had limited statistical power . . . primarily due to the modest sample sizes, and relatively short follow-up periods").

On April 4, 1998, Applied and IHF executed an agreement for Applied's consulting services. CX 45 at 2-6; CX 46. The agreement stipulated that the final report would be completed by December 1, 2000, and that the total cost would be $299,040. CX 45 at 44, 46. In May 1998, Applied and Elementis executed a separate agreement for Applied's services in identifying, compiling and processing all data in Elementis' possession for contribution to the main IHF project. CX 49 at 2-7. Applied would be paid an additional $46,480 for these services. *Id*. at 8.

In a letter dated July 24, 1998, the then-Chairman of the IHF Chromium Chemicals Committee, Bruce Norman, wrote a letter to an OSHA authority, announcing "the initiation of a major epidemiological study of health effects associated with employment in the basic chromate chemicals production industry," which "will be the most extensive study undertaken to date" in this area. CX 52 at 1. Mr. Norman continued:

> By following similar protocols for each of the plants, the results can be combined to greatly improve the statistical power and consequently the usefulness of the study.
> * * *
> Whereas current risk assessment is based on limited information from plants operating 50 years ago this study will provide a comprehensive database for risk assessment of plants operating to modern standards.

Id.

In August 1998, EPA published its Toxicological Review of Hexavalent Chromium ("Review"), the purpose of which was "to provide scientific support and rationale for the hazard identification and dose-response assessment in IRIS," the Agency's Integrated Risk Information

System, "pertaining to chronic exposure to Cr(VI)." CX 53 at 1, 5. Dr. Herman Gibb, then Assistant Center Director at the EPA National Center for Environmental Assessment, was part of the Agency's internal review team for the Review. CX 53 at 6; RX 6 at 3. The Review classified hexavalent chromium as a "Known Human Carcinogen." CX 53 at 38. The Review further states:

> Results of occupational epidemiological studies of chromium-exposed workers are consistent across investigators and study populations. Dose-response relationships have been established for chromium exposure and lung cancer.
> * * *
> There are many epidemiologic studies demonstrating that hexavalent chromium (CrVI) is a potential human carcinogen, but few provide adequate exposure data for use in risk estimation.

CX 53 at 38, 48.

At a meeting of the IHF Management Committee on October 8, 1998, Mr. Norman informed attendees that "a letter had been sent to OSHA, EPA . . . alerting them to the initiation of the epidemiology study." CX 54 at 2. Also discussed was EPA's IRIS update, and the "concern that EPA continues to use the Mancuso data, therein clouding the carcinogenicity issue regarding Cr^{+6} and Cr^{+3}." CX 54 at 5.

In correspondence with another member of IHF in early 1999, Dr. Barnhart outlined the main points of a conversation he had with Dr. Mundt about the study and Dr. Mundt's idea to explore a number of different potential relationships between the data. CX 56 at 2. Dr. Barnhart commented:

> This may give us evidence to argue that biologically plausible relationships other than cumulative lifetime exposure to Cr + 6 should be considered. As we have seen in the past, even a negative relationship between cancer rate and exposure can lead to a significant cancer potency factor if a linear dose response model is assumed and the upper bound of the statistical uncertainty is used. Having a large enough cohort to explore a number of relationships was the big advantage we discussed of having a unified study rather than a meta analysis.

Id. That same year, the Eaglescliffe plant was eliminated from the study because it became apparent that the data from that plant would not be compiled in time to be included in the study. JX 1 ¶ 8.

On March 20, 2000, a study of 2,357 workers employed at the Baltimore plant between 1950 and 1974 conducted by EPA's Dr. Gibb and others (Lees, Pinsky, and Rooney) was published in the American Journal of Industrial Medicine ("Gibb Study"). Tr. 139, 1035; CX 62 at 1. Dr. Gibb, whom the parties have stipulated is an expert in epidemiology and in particular, assessment of risk associated with exposure to hexavalent chromium, said at hearing that it is the

"largest study done to date." Tr. 1066; JX 2 at 2; RX 6 at 3. For his work, Dr. Gibb won an EPA Scientific and Technological Achievement Award in 2002, which according to Dr. Gibb, recognized the study as "the most significant and detailed study of the lung cancer and clinical irritation risks from chromium ever conducted." RX 6 at 17; Tr. 1027-28.

To conduct his Study, Dr. Gibb had arranged a cooperative agreement between EPA and Johns Hopkins University to collect data on exposure at the Baltimore plant and update the Hayes cohort. Tr. 1029-30. Allied Chemical Company, the owner of the Baltimore plant, which had been torn down in 1985, agreed to the study proposal and by consent provided the data that Dr. Gibb and his colleagues requested. Tr. 1031, 1062. The database that they "discovered," Dr. Gibb stated at hearing, "did a lot of things that the Mancuso database didn't do." Tr. 1029-30. For example, the Gibb study only included plant employees who had begun working after August 1, 1950, because at that time "[t]hey essentially built a new plant . . . so they reduced a lot of the exposures that they had in the previous plant." Tr. 1030. The Gibb study also included in the cohort workers who had worked in the plant for less than ninety days, which the Hayes study had not done. Tr. 1030-31. Whereas Hayes had followed the cohort through 1977, Gibb and his colleagues followed the cohort through 1992. Tr. 1031. They created a JEM with 114 job titles, and factored in the time the subjects spent working in different parts of the plant, to calculate their cumulative exposures. Tr. 1032. The average length of follow-up was 30 years, which in Dr. Cooper's opinion is "very long." Tr. 142, 1033. However, the study's average duration of exposure for each worker was only 3.1 years, which Dr. Cooper notes is that low because all workers were included in the study, even those that worked a day or a month. Tr. 142. In defending his decision to include short-term workers in the study, Dr. Gibb explained that because hexavalent chromium is extremely carcinogenic and a "very irritating substance," he thought they would be able to examine the risk with even very short periods of exposure. Tr. 1033-34. Dr. Cooper testified that the study was designed to obtain "newer, better data that could be used to evaluate the dose response between chromium exposure and risk of lung cancer" because the number of studies available at that time for exposure response modeling "was relatively small" and based on data from a long time ago. Tr. 140. Nevertheless, the Agency has not used the study to update its risk assessment. Tr. 1034-35, 1077.

Dr. Gibb presented his study at an IHF meeting in 1996 and at a National Academy of Sciences meeting in 2000, shortly before it was published. Tr. 1035-36. "OSHA knew that the study was going on[], NIOSH knew the study was going on," Dr. Gibb stated. Tr. 1036. OSHA, the industry, and Public Citizen all tried to obtain the data underlying the Gibb Study before the study was completed. *Id*. After the study was published, Gibb et al. did provide the data to "whomever asked." Tr. 1037.

At the time, the carcinogenicity of hexavalent chromium had been "well established for a long time," acknowledged Dr. Gibb. Tr. 1034. What his study showed was that cumulative hexavalent chromium exposure was associated with an increased lung cancer risk, while trivalent chromium was not, and that these results were not confounded by smoking status. Tr. 1037; CX 62 at 1. The study "offers the best quantitative evidence to date of the relationship between hexavalent chromium exposure and lung cancer." CX 62 at 1-2. Further, as stated in the Gibb

Study itself:

> The current study confirms the elevated lung cancer risk from hexavalent chromium exposure observed in other studies and presents the best opportunity to date of evaluating the lung cancer exposure-response relationship from exposure to hexavalent chromium.
> * * *
> As can be seen, the current study, in comparison with the Mancuso study, had a larger cohort, more lung cancer deaths, and has smoking information for most of the cohort. [ ] . . . the ambient measures or estimates of exposure were concurrent with the work history and are of hexavalent chromium directly, not derived from other measures. Furthermore, the cumulative exposure groups in the current study represent lower exposures than those of the Mancuso study, providing better risk estimates at these lower levels of exposure, an important consideration for quantitative risk assessment.

CX 62 at 10.

Dissatisfied with the Gibb study, the Chrome Coalition hired Exponent to review and critique "the methods and findings" of the Gibb Study. CX 65 at 8; CX 76 at 19. Exponent's Critique of Two Studies by Gibb et al. ("Critique"), was submitted to OSHA as part of a larger package from the Coalition in June 2002 (before the publication of the proposed rule). CX 65 at 2; CX 76 at 19; JX 1 at 10. The Critique listed several findings, including the following:

> For several reasons, it has been concluded that the methods used to measure airborne Cr(VI) in the Baltimore plant likely underestimated Cr(VI) exposures.
> * * *
> . . . the exposure reconstruction did not characterize peak exposures, which would be the most meaningful dose metric for assessing irritation effects.
> * * *
> The Cr(III) exposure estimates are based on measures of total chromium and Cr(VI) in rafter dust, collected several years after the plant was closed, and correlated to measure levels of Cr(VI) in airborne samples. These exposure estimates are not reliable for many reasons.
> * * *
> . . . the impact of short-term workers in this cohort could be substantial. The analysis should be reevaluated without the data from short-term workers to determine their effect on the conclusions.
> * * *
> The authors present smoking-adjusted risk estimates from the Cox regression models; however, the authors did not control for smoking in the standardized mortality ratio (SMR) analysis, and the results could be substantially biased.
> * * *
> . . . Baltimore reference rates should have been used in the SMR analysis. . . . [A]

> smaller number of expected deaths are generated when using death rates from the state of Maryland . . . .
> * * *
> The value of these data for quantitative cancer risk assessment seems to be overstated. . . . CIs [Confidence Intervals] for relative risks . . . with smoking included . . . were not presented. Thus, it is difficult to assess the precision of those risk estimates. The SMRs, which are typically used for cancer risk assessment, were not adjusted for smoking. The utility of these data for cancer risk assessment would be substantially improved if the SMRs were adjusted for smoking. Finally, the appropriateness of extrapolating lifetime cumulative exposures . . . from relatively short duration exposures (e.g., 2 years), is highly questionable and not generally considered an acceptable risk assessment practice.
> * * *
> In summary, the findings of this study should be judged cautiously because of the many uncertainties in the information presented. In particular, risk estimates for lung cancer at the lower levels of cumulative Cr(VI) exposure may be inaccurate for several reasons and should not be relief upon for health risk assessment.
> * * *
> Ultimately, a reevaluation of the raw data should enable a more accurate and complete analysis of the dose-response relationship from these data.
> * * *
> It would be far more appropriate to assess the risks of lung cancer based on a subset of these data, focused on the longer-term workers (e.g., those with at least 1 year of tenure), than to extrapolate the Gibb et al. findings to occupational standards designed to protect against exposures for an occupational lifetime. The findings at the lower dose levels are highly questionable and extrapolation of the risks due to short-term exposures to long-term cumulative exposures is not scientifically defensible.
> * * *
> . . . it is inappropriate to conclude that these data provide a "strong" dose-response relationship. While these data do present an opportunity for improved quantitative cancer risk assessment, further data analysis and more complete data presentation are required to ensure confidence in the findings.

CX 65 at 4-7, 41, 43. In later reviewing Exponent's critique, OSHA concluded that despite the many limitations and questionable accuracy of some measures, "[t]he Gibb study is one of the better cohort mortality studies of workers in the chromium production industry. The quality of the available industrial hygiene data . . . makes the Gibb study particularly useful for risk assessment." CX 76 at 20 (OSHA's Final Rule, 2006).

In the early months of 2002, Dr. Barnhart received a draft report of IHF's four plant study from Dr. Mundt. Tr. 968-69. Dr. Mundt also sent his study to the report's reviewers and to others at IHF. Tr. 702. The study showed that those post-change plant workers who fell into the highest (fourth) quartile of exposure, i.e. those with exposure greater than 200 micrograms per

liter years, had a statistically significant increase in cancer risk, essentially double that of the general population. Tr. at 737. Dr. Barnhart testified that "within the first few days of getting the draft," he considered the following:

> Well, I thought about what it showed. And it showed information that there wasn't adverse effect other than lung cancer. The lung cancer effect was fairly small in the overall group. But then there weren't many lung cancer deaths anyhow. And so the statistics wouldn't be that good. And I thought about how this kind of fit into what other studies had shown.
> * * *
> Since the cumulative exposures were in terms of chromium in urine, I had to think about how that related to the chromium in air, which was of interest.[11] We certainly knew of OSHA at the time and EPA had shown an interest in the past of that. So there hadn't been much discussion over the years about chromium in urine although some people had looked at biological exposure indices for chromium. So anyhow I had to try to understand how this fit in with what had been known. And since fairly recently, at least in my mind fairly recently at that point, the Gibb et al. study had been published and it had been done with cumulative exposures in air and in the same sort of thing but air, well– and I don't remember now if I wrote it down on a little piece of paper or whether I just did it in my head, did a little calculation on that highest exposure group to try to understand where it fit into especially the Gibb publication.

Tr. 971-72, 983-84. Dr. Barnhart testified that he knew the Gibb Baltimore Plant Study well at the time he received the draft of the four plant study, and knew that EPA had knowledge of the Gibb Study because Dr. Gibb worked for EPA and EPA had funded the study. Tr. 984-86. "[W]here you can, you try – I try to go back to what the governments know." Tr. 985.

> So I went back into the paper and I found this .77 [air to urine] conversion number[12] . . . . I figured that would be as good a number as any. . . . I decided

---

[11] Personal air samples were available at all four plants, but the German plants had very few, and only after 1986. CX 1 at 47, 55. The German plants had primarily biomonitoring data, especially chromium in urine and blood. *Id*. at 50, 56. The U.S. plants had no biomonitoring data and relied on extensive air monitoring data. *Id*. at 51, 56. Applied elected to "summarize the average air concentration in U.S. plants in terms of urine concentration equivalents for use in the JEMs" because urine data were more abundant and "because urine data are presumably a better measure of dose," meaning the actual amount of toxin entering the body and reaching the target organ. *Id*. at 65. The Final Report states: "This makes the urinary data appropriate for epidemiological assessment of the relationship between an indicator of dose and the occurrence of lung cancer." *Id*.

[12] Applied decided to use a factor of 0.77 for converting air measurements to urine measurements (continued...)

> well probably, for all the values above 200, 250 might be a good number to use. And using the .77, it would come out to be 325 when you divided out.
> * * *
> So then I compared it to what kind of numerically similarly treated data was easily available at that [time] to me. . . . [S]ince the Gibb[] study was readily available, I pulled it out and looked at it.

Tr. 980-81. After making some calculations with the Gibb Study data points, Dr. Barnhart determined that "a cumulative dose of 225 micrograms per cubic meter years was the high exposure group in the Gibb Study. . . . And so I thought well, this data falls in the same range more or less as the Gibb data." Tr. 982-83. He continued:

> And so that's why I thought that it was – had the same sort of effect and the same sort of cumulative dose range, recognizing that especially in the Four Plant Study, there was a lot of assumptions made.
> * * *
> . . . I was at a point there where I felt well, there is a similar sort of effect over a roughly similar sort of exposure range. And so it's kind of what you might expect more or less with all the uncertainties built in.

Tr. 983. Dr. Barnhart testified that when he "did this real rough comparison with the Gibb information," he did not think Applied's draft study "showed something that was so much different[,] that it was showing [something] that was completely unexpected or was an effect that was much severer than what had been expected before." Tr. 991. Further, Dr. Barnhart alleged: "I don't know that I had actually ever read [TSCA §] 8(e) or the guidance but I 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. 990-91. As such, Elementis Chromium decided not to submit a copy of the draft of the four plant study to EPA at that time.

On August 22, 2002, OSHA published a request for information in the Federal Register seeking "data, comments, and information on issues relevant to occupational exposure to hexavalent chromium (CrVI), including: Significant epidemiological . . . studies; the relationship between occupational exposures to CrVI and the development of adverse health effects . . . ." CX 66 at 1. Acknowledging the Gibb Study, OSHA asked the public whether that study adequately characterizes risk, and why. *Id*. at 3. OSHA also stated therein: "OSHA is especially interested in studies of occupational exposure that quantify exposure data and control for important confounding variables, have good statistical power, and are well conducted." *Id*. OSHA set a November 22, 2002, deadline for comments. *Id*. at 1.

---

[12](...continued)
because it was "the only one available in the literature that pertains to chronic exposure scenarios" and the estimates they were producing on their own "were not very different from this published value." CX 1 at 66.

In September 2002, before the Final Report was completed, Dr. Mundt presented the exposure assessment method and the preliminary results to the Congress on Epidemiology in Occupational Health at a conference in Barcelona, which "many, many occupational epidemiologists attend." Tr. 704. Dr. Mundt described presenting at the conference as "a little bit of a sales job, and a little bit of a testing of the waters on how our exposure assessment would be received by the community at large." Tr. 707. He explained to the approximately 200 attendees "how we got the exposure data information, and how we tried to harmonize" the air and urine measurements. Tr. 704-5, 12; RX 13 (slides on presentation). It became clear to Dr. Mundt that although "they were impressed with the heroic effort expended . . . collectively the group wasn't satisfied that that was the most valid way to make use of these data." Tr. 705. Dr. Mundt continued: "As much as that was the goal from the beginning of the first proposal, that it didn't make sense to force those data together where there were so many differences between the German workers and the U.S. workers." *Id*. There was a great amount of attention at that time in the epidemiological community on "careful exposure reconstruction," because "[i]t had not been done uniformly at all in other epidemiological studies . . . ." Tr. 712. Dr. Mundt testified that there was an understanding that there were only three lung cancer deaths from the U.S. plants, "so separating them off was no loss of information, . . . it wouldn't change the overall impact, and it would free us from all the heavy assumptions, and all the imprecision of the [air/urine] conversion factor . . . and [we] could focus on where we knew there were real risks in the most highly exposed German workers." Tr. 713. This conference was "the first time that those SMRs [standardized mortality ratios] by quartile exposure were published." Tr. 715.

At some point before presenting the Final Report to the IHF Chromium Committee, Dr. Mundt informed Dr. Barnhart that in Barcelona, he received "a lot of feedback from other people in his field questioning whether it was proper to combine the air values from the U.S. facilities with the urine data from the German facilities because of the difficulty of coming up with a conversion from one to the other as well as there being some differences in the facilities . . . themselves, the way they were built, and the way they were operated was somewhat different." Tr. 988. Dr. Mundt told Dr. Barnhart that people questioned "whether it was right" to conduct the study the way it was conducted, and that the study may need to be split into two groups if it is meant to be published. Tr. 988-90. At the hearing, Dr. Mundt testified that deciding whether to combine the German and U.S. data was a "basic question [since] the very first review of the protocol." Tr. 708. "[G]iven the predictable heterogeneity or differences between U.S. and Germany, should this really be put together. . . . [B]ut if you don't do that, you don't have enough numbers. So, it was kind of always a battle between putting them together and compromising validity, or separating them, preserving validity but losing precision in the power of the analysis." *Id*. Dr. Mundt explained: "[T]here is a relationship between . . . chromium in air and chromium in urine. It's just that there's not a perfect correlation between those two." Tr. 676. "I can't say that at the end of the day, we were able to do it well . . . [w]e did the best we could." *Id*.

On October 8, 2002, four and a half years after the study began, Dr. Mundt e-mailed the Final Report on the four plant study, dated September 27, 2002, to an IHF employee, who that day forwarded it on to Dr. Barnhart and others. JX 1 ¶ 17; RX 12 at 1; CX 4 at 1. It has been stipulated that Respondent obtained the Final Report "[o]n or about October 8, 2002." JX 1 ¶ 18.

While the Final Report contained the analysis of all four plants' data, in Dr. Mundt's cover e-mail to the IHF employee, he states:

> One common suggestion from multiple reviewers was to present the results of the German and American plants separately! I agree, and will propose at our meeting next week that we consider submitting three manuscripts from this project: an overall methods paper, a German plant study results paper, and a brief report on the American plants.
> * * *
> The lung cancer results poster drew some discussion, mainly regarding the possible threshold effect. . . . In any case, we have eased up on the threshold language in the report, and leave the interpretation more to the reader.[13]

RX 12 at 1. Dr. Barnhart testified, "I didn't see anything in it that was dramatically different than what I had seen in the draft as far as the information." Tr. 992. Again, Respondent chose at that point to not submit the Final Report to EPA. JX 1 ¶ 19.

> The Executive Summary of the 2002 Final Report reads, in part:
>
> This report presents the results of an epidemiological mortality study of the combined employees of four modern chromium chemical production facilities, including two plants in Germany and two in the United States. All employees (n = 1518) included in the study worked one year or more in plants using low- or no-lime chromium production processes. . . . Each cohort member was followed for vital status as of December 31, 1998, the end of the study follow-up period. A total of 157 deaths . . . were identified . . . .
> * * *
> Individual exposure estimates were derived using a [JEM], in which all personal

---

[13] The "threshold effect" of a chemical substance is the level of exposure to the chemical that a worker could be exposed to each work day for his whole working life without experiencing adverse health effects. Tr. 861-62. In its Final Rule, OSHA notes that when Exponent re-analyzed the Gibb cohort, it "found that lung cancer rates associated with exposures around 0.045 mg/m3-years Cr(VI) and below were not significantly elevated in some analyses," suggesting a threshold. CX 76 at 103. OSHA asserts, however, that such result is due to a fault of the study "rather than a threshold or nonlinearity in exposure-response," and notes that Dr. Gibb agrees. *Id*. at 103. After further addressing Exponent's and the Chrome Coalition's suggestions that a threshold might be present, OSHA concludes (*Id*. at 104-105):

> OSHA recognizes that, like most epidemiological studies, neither the Luippold nor the Gibb cohort provides ideal information with which to identify a threshold or detect nonlinearities in the relationship between Cr(VI) exposure and lung cancer risk, and that it is important to consider other sources of information about the exposure-response relationship at very low levels of Cr(VI) exposure.

industrial hygiene data are pooled by job category and calendar year for each individual working in the same job categories. Because urinalysis date were the best available exposure indicators for a majority of the study cohort, air monitoring data for the remaining employees (i.e., two U.S. plants) were converted to urine equivalents for the exposure analyses. A total of nearly 20,000 exposure measures were available and incorporated into the exposure assessment. Estimates of peak exposure values were also derived for each cohort member to determine whether peak exposure might predict lung cancer risk better than simple cumulative exposure.

* * *

Standardized mortality ratios (SMR) and 95% confidence intervals (CI) were calculated for specific causes of death and for all causes combined. Overall mortality experience for the cohort was somewhat lower than expected (SMR = 0.94; 95% CI: 0.80-1.10) based on appropriate United States and German reference rates.

* * *

For no specific category of cause of death was the SMR meaningfully increased except for cancers of the respiratory system (SMR = 1.59; 95% CI: 1.04-2.33), and more specifically for cancers of the lung (SMR = 1.66; 95% CI: 1.08-2.46), based on 25 observed and 15 expected cases using national reference rates.[14]

* * *

We evaluated relationships among cumulative exposure, peak exposure, age, and smoking status using logistic regression modeling. Generally, we found increased odds of lung cancer death for the higher exposure groups, relative to the low exposure group. This pattern persisted in models adjusted for age and smoking

---

[14] In plain language, the SMR, or standardized mortality ratio, is a ratio that reflects the difference between the number of cases of something (deaths, in this case) that were actually observed or reported, and the number of expected cases. Tr. 726. For example, if 10% of an exposed population developed a particular disease, and in a reference or control population, 5% developed the disease, the ratio is 10 divided by 5, or 2, meaning in general terms that there was a doubling of the risk in the exposed group compared to the control group. Tr. 99-101 (an SMR of 1 means that the risk is the same in both populations; generally, the higher the SMR, the greater the association). The confidence interval ("CI") is the researcher's attempt to account for a "margin of error;" a 95% confidence interval would account for a margin of error of 0.05 or 5%, and shows "the likelihood of seeing a result 95 times out of 100, if you repeated that study, given the level of variability that you saw in that study." Tr. 102, 183, 728. Here, the SMR of 1.59 is the midpoint of the 95% CI set by the authors of the study, 1.04-2.33, "so we can conclude that . . . 1.59 is not likely due to chance." Tr. 728. The SMRs of 1.59 and 1.66 noted here indicate that there were 59% more cases of death due to respiratory cancer and 66% more cases of death due to lung cancer in the cohort of modern chromium plant workers tested than in the referenced state populations. Tr. 728-31. Because the lower end of the 95% CI for both cancers listed here are above 1, the results could be said to show that "there is an indication of an increased risk of lung cancer." Tr. 729.

status, suggesting an independent role of higher versus lower chromium exposure on lung cancer death.

Consistent with other recent studies attempting to quantitatively assess occupational chromium exposure and lung cancer, this study demonstrates a modest overall increase in risk among exposed cohort members, largely limited to those in the highest exposure categories (i.e., =200 µg/L-years, or peak score = 24).

The last several years have witnessed growing interest in the possible health effects of chromium compounds at lower exposure levels. The United States Environmental Protection Agency (EPA) has repeatedly indicated its intentions to issue a new ruling concerning chromium. Current EPA guidelines indicate a unit risk for inhalation of hexavalent chromium of 1.2 x 10 per mg/m^3. This estimate was generated from Mancuso's study of a pre-change cohort, that used a single industrial hygiene area survey to estimate exposures. The EPA cites several uncertainties in using the Mancuso data, and others have criticized the study for its methodological limitations and assumptions.

* * *

This study adds to a limited but very recent body of scientific studies of occupational exposure to chromium compounds that attempts to quantitatively characterize chromium chemical exposure and subsequently quantify the risks associated with these exposures. As with the other recent studies, **this study is intended to help fill the critical gap in the published literature on which a scientifically sound risk assessment for hexavalent chromium may be based. Though all of these recent studies, including the present one, suffer from methodological limitations (especially sample size and data on potentially confounding factors such as smoking), they represent the best available scientific evidence of the relationship between chromium exposure and human lung cancer risk.**

CX 1 at 15-19 (internal citations omitted) (emphasis added). Further, the authors of the four plant study commented on the Gibb Study:

A recent update of the Baltimore, MD cohort initially studied by Hayes et al also provided the methodological improvements of an extensive exposure assessment and use of smoking data in multivariate analysis. [description of report omitted].

Unfortunately, this recent report did not evaluate separately lung cancer risk for those who worked exclusively in the new facilities, though the second new facility opened in 1960. The number of employees employed exclusively in these new facilities was also not provided; however, the earlier report by Hayes et al indicated 509 employees had initial hire dates between 1960 and 1974. Additionally, the Gibb cohort included many very short-term employees; over half

worked less than six months, and 42% worked less than 90 days.

CX 1 at 30 (internal footnotes omitted).

There is substantial testimony and documentary evidence in the record describing the approach to the four plant study and the Final Report results; only a brief recapitulation will be presented here. For each facility, Applied created a job exposure matrix ("JEM"), Dr. Mundt explained, "so that each and every worker in each facility had his or her work history linked to every one of the jobs they ever held over time . . . ." Tr. 680. Dr. Mundt explained further: "We worked every individual through their entire work history through this matrix, and gave every worker a cumulative exposure based on that precise process." Tr. 682. The authors tracked down the workers to follow-up on their mortality status (whether they were dead or alive). Tr. 685-91. Then the first step in putting these data together was to conduct an SMR analysis, which helps answer a "critical question," "[i]s there any evidence that the deaths among this group are increased relative to a non-exposed general population." Tr. 691-92. For the U.S. plants, the authors used North Carolina and Texas reference rates, depending on where the worker lived, and for the German plants, the authors used rates from North Rhine-Westphalia, the state in which the plants were located. Tr. 693-94. In the Final Report, using the SMR analysis, the authors saw "a small increase in . . . excess lung cancer risk." Tr. 697. For cancer generally, the numbers do not "meet the threshold of statistical significance." Tr. 726-27; *see* CX 1 at 115. The 95% confidence interval for the SMR of 1.15 ranges from .87 to 1.49 and therefore "says we can't rule out chance," Dr. Mundt testified. *Id*. When it comes to respiratory system cancers, however, there were 26 cases when only 16 were expected, suggesting 10 excess cases, and an SMR of 1.59 with the 95% confidence interval ranging from 1.04 to 2.33. CX 1 at 115; Tr. 728. Dr. Mundt explained, "so we can conclude that that 1.59 is not likely due to chance." Tr. 728. Overall, Dr. Mundt stated, the SMR analysis presented in Table 11 "is not showing any differences from what's expected in the general population with the possible exception of the respiratory or trachea bronchus and lung cancers." Tr. 730.

To "see if that blip of an excess of lung cancers was just random," Applied divided the cohort of workers into quartiles, and found that the only evidence of an elevated lung cancer risk was "isolated to the most highly exposed subset of that cohort . . . greater than 200 microgram[s] per liter urine chromium." Tr. 697-98. To test whether workers' smoking habits confounded the results, Dr. Mundt and his team wanted to utilize a proportional hazards model, which permits the stratification of the data by variables like smoking, however there were not enough cancer cases for the model to run. Tr. 699-700. Instead, they used a logistic regression model, which was not the "proper tool," Dr. Mundt admitted, but it did show that the risk in the highest exposure category did not "go away" when smoking was factored into the model. Tr. 700-01, 735, 756. At the hearing, Dr. Mundt surmised that in the end the total cost of the four year study was "about $500,000." Tr. 926.

Before the close of the submission period for the OSHA rulemaking, Dr. Barnhart had the impression that Dr. Mundt "was going to split the cohort into the German workers and the U.S. workers, and publish the papers on each of the groups." Tr. 1167-68. As to why he did not

submit the Final Report to the OSHA rulemaking team in response to the published request, Dr. Barnhart explained, "I didn't because I believed that OSHA would consider publications in a peer reviewed journal more strongly than an industry-sponsored non-peer reviewed study, so I was hoping that – and anxious for the publications to be available in time to be useful for the rulemaking." Tr. 1167. However, when requested to fund publication of the study, IHF declined and Applied undertook the publication work at its own expense. At hearing, Dr. Barnhart suggested that a "misunderstanding" between him and Dr. Mundt or Dr. Mundt and "other people in the company" led to that result. Tr. 927-29, 1006-07.

It was not until after Applied had decided to split the German results from the U.S. results that itd discovered an "error in the algorithm of the software" that it had used for the 2002 Final Report's analyses. Tr. 736. Applied re-ran each analysis with the correction made, and released the revised Final Report on April 7, 2003. *Id.*; RX 14. Again, Elementis chose at that time not to submit the Final Report to EPA.

Dr. Barnhart testified that when he received the revised 2003 Report, he looked to see what was different from the 2002 Report, and, he said, "the only thing that really caught my eye was the lowest exposure group, the SMR had changed from being above one to below one," which indicated to him at the time that the risk was lower for that group. Tr. 993-94. However, according to Dr. Mundt, the main difference in the studies "was an intensification of the estimated risk in the German cohort where the exposures and the cases occurred." Tr. 923. "[T]he U.S. study was uninformative." *Id.*

Subsequently, Dr. Mundt received a call from an epidemiologist at the U.S. Office of Management and Budget who wanted literature on hexavalent chromium "in preparation for OSHA's review of the literature to propose or to establish a new exposure limit for hexavalent chromium" and "asked if there were any way we could move these papers into publication . . . ." Tr. 928-31. Dr. Mundt provided her with a copy of the Final Report in early 2004. Tr. 931.

On October 4, 2004, OSHA proposed an 8-hour time-weighted average PEL of 1$\mu g/m^3$. (one microgram of hexavalent chromium per cubic meter of air). CX 70 at 1; Tr. 1108. OSHA set January 3, 2005, as the due date for comments, and stated that it was seeking "comment on all relevant issues, including health effects, risk assessment, significance of risk determination, technological and economic feasibility, and the provisions of the proposed regulatory text." CX 70 at 1-2. Further:

> In its preliminary assessment of risk, OSHA has relied primarily on two epidemiologic cohort studies of chromate production workers to estimate the lung cancer risk to workers exposed to Cr(VI) [Baltimore/Gibb and Painesville/Luippold]. Are there any other studies that you believe are better suited to estimating the risk to exposed workers; if so, please provide the studies and explain why you believe they are better.
> * * *
> The preliminary quantitative risk assessment relies on two (Gibb and Luippold)

> cohort studies in which most workers were exposed [to] higher Cr(VI) levels than the PEL proposed by OSHA, for shorter durations that a working lifetime exposure. The risks estimated by OSHA for lifetime exposure to the proposed PEL, therefore, carry the assumption that a cumulative exposure achieved by short duration exposure to higher Cr(VI) air levels . . . leads to the same risk as an equivalent cumulative exposure achieved by longer duration exposure to lower Cr(VI) exposure . . . . OSHA preliminarily finds this assumed exposure equivalency to represent an uncertainty in the estimates of risk but does not have information that indicates this uncertainty introduces serious error in its predictions of risk. Does the OSHA exposure-response assessment based on the higher [levels] and/or shorter durations experienced by the Gibb and Luippold cohorts lead to a serious underprediction or overprediction in estimated risks for the occupational exposure scenarios of interest to OSHA? Please provide any data to support your rationale.

CX 70 at 2-3. The proposed PEL document also requested job category and job category-specific exposure information, asked for details on the technical changes put into effect at plants, asked about air monitoring data and indications of peak levels, and more. CX 70 at 3. About the Gibb Study, the proposed rule reads:

> Despite the potential methodological limitations of the Gibb Study, this is one of the better cohort mortality studies of workers in the chromium production industry. The quality of the available industrial hygiene data and its characterization as 'typical/usual' makes the Gibb study useful for risk assessment.

CX 70 at 18.

Respondent submitted comments to OSHA on December 31, 2004, which were prepared by Dr. Barnhart. CX 95. In the comments, Dr. Barnhart indicated that Elementis Chromium was "especially concerned about the very low proposed PEL of 1μg/m^3, stating that it did not "believe that the available toxicological data or worker exposure experience justifies a value this low." *Id*. at 2. The comments neither discussed, referenced, nor attached the Final Report. The following month, in preparation for a public hearing on the proposed PEL, the Chrome Coalition submitted an outline of Dr. Barnhart's testimony to OSHA. CX 96. In both of these documents, Dr. Barnhart criticizes the information upon which OSHA relied in creating its proposed PEL; for example, the latter reads:

> OSHA's basis for revising the PEL . . . is based in large part on the reports of elevated risk of lung cancer for workers exposed to Cr(VI), especially those exposed during the period of 1930-1970 in the chromate chemicals production industry.
> * * *
> It is very unlikely that the types of exposures and the compounds to which

> workers were exposed in the chromate production industry in the 1930s through the 1970s are representative of the current exposures to Cr(VI) in either this or other industries.

CX 96 at 2. Dr. Barnhart reiterated the criticism that exposure values used in the Gibb Study were "artificially lower" due to a number of factors, causing an "underestimation of the cumulative lifetime exposures" at the Baltimore plant. CX 96 at 3. Dr. Barnhart concludes: "OSHA is strongly encouraged to collect additional data and reassess its analysis of risk, cost and technical feasibility before proceeding any further with this rulemaking." CX 96 at 4. Again, no mention was made of the four plant study described in the Final Report.

On February 1, 2005, OSHA held an informal public hearing on the proposed rule on hexavalent chromium. CX 97 (hearing transcript). Dr. Gibb presented testimony as one of two expert witnesses. *Id*. at 100-149. Ms. Edens served on the hearing panel in her role at that time as Director, Office of Chemical Hazards – Metals. *Id*. at 2.

In April 2005, part of the Final Report results (U.S. plants only) was finally published by Luippold, Mundt, Dell and Birk in the Journal of Occupational and Environmental Medicine ("U.S. Results Paper"). CX 74. The paper reported that "[l]ung cancer mortality was 16% lower than expected, with only three lung cancer deaths (3.59 expected)." CX 74 at 1, 3. Further: "The absence of an elevated lung cancer risk may be a favorable reflection of the postchange environment. However, longer follow-up allowing an appropriate latency for the entire cohort will be needed to confirm this conclusion." CX 74 at 1, 5. Still, the authors write, "[t]he data obtained . . . represent a valuable resource for documenting control of Cr(VI) exposures, and for future investigations of potential health effects." CX 74 at 5. In response to the paper, Dr. Mundt testified, someone affiliated with Public Citizen in a letter to the editor of an online journal and in a book accused him of having separated the Final Report results into two papers "because there was a result in the four plant study that was just a regression result that was uncomfortable for me or my client and that they were trying to make me make it go away . . . ." Tr. 933-34. Dr. Mundt said he tried to explain to his critic why Applied split the report into two papers, but that he published his criticisms anyway. Tr. 934.

By letter dated June 29, 2005, approximately two months after OSHA's revised deadline for submitting post-hearing comments on its proposed PEL, Public Citizen sent Ms. Edens, in her capacity as an OSHA official, the Final Report. Tr. 1116; CX 73. No one had mentioned the study during the "rulemaking record," Ms. Edens testified. Tr. 1117. OSHA did not reopen the record upon receipt of the Final Report because, she said, so far along in the process, "it wouldn't really have materially altered sort of the decision at hand, which was trying to determine what was technologically and economically feasible." Tr. 1120. Ms. Edens continued explaining: "And, therefore, being under a court order and not wanting to reopen the record unless it was absolutely necessary, we decided that we would not reopen the record." *Id*.

Before OSHA's Final Rule was published, Dr. Mundt provided her with a prepublication copy of the paper presenting the German plants-only results. Tr. 1135-36; CX 79 at 1 (published

in 2006 in the Journal of Occupational and Environmental Medicine) ("lung cancer risk was elevated only in the highest exposure group"; "[t]hese data suggest a possible threshold effect") ("German Results Paper"). Because Applied merged with Environ International Corporation in 2003, both the U.S. Results Paper and the German Results Paper are attributed to Environ. Tr. 635.

On February 28, 2006, OSHA published its Final Rule, establishing an 8-hour time-weighted average PEL of 5 micrograms of hexavalent chromium (Cr(VI)) per cubic meter of air ($5\mu g/m^3$). CX 76 at 2; Tr. 1112-13 (Ms. Edens recalled, "we determined that five was actually the lowest feasible level for industry," paying particular attention to "technologic feasibility"). With this new PEL, OSHA expects 40-145 fewer worker deaths from lung cancer every year. CX 76 at 206. Nevertheless, with the new permissible exposure level, OSHA still expects to see approximately 4-22 excess lung cancer deaths per 1,000 workers who have 20 years of exposure, and 10-45 excess lung cancer deaths per 1,000 workers who have 45 years of exposure. CX 76 at 126.

OSHA discussed at length in the Final Rule the studies that it reviewed to determine the new PEL. In support of its reliance on the Gibb Study, OSHA wrote that it "does not believe that the inclusion of short term workers in the Gibb cohort is a source of substantial uncertainty in the Agency's risk estimates." CX 76 at 81. OSHA also addressed "a new epidemiological study conducted by Environ, Inc. [Applied/Mundt] for the [IHF], about which the agency had received several comments." *Id*.

> These commenters suggested that OSHA should use these cohorts to model risk of lung cancer from low exposures to Cr(VI). Unfortunately, the public did not have a chance to comment on this study because documents related to it were submitted to the docket after the time period when new information should have been submitted. However, OSHA reviewed the study and comments that were submitted to the docket. Based on the information submitted, the Agency does not believe that quantitative analysis of these studies would provide additional information on risk from low exposures to Cr(VI).

Id. When OSHA refers to "studies" here, Ms. Edens clarified, it means the U.S. Results Paper and a prepublication version of the German Results Paper. CX 76 at 82; Tr. 1123-24; CX 74; CX 79. Apparently, the Society of the Plastics Industry had "requested that OSHA obtain and evaluate the German study as 'new and available evidence which may suggest a higher PEL than proposed [$1\mu g/m^3$]'" and "could form the basis for an exposure threshold." CX 76 at 82. OSHA rejects the notion that a threshold could be found in the German paper results. *Id*. Instead of relying on the German cohort, OSHA states, it "has relied upon a larger, more robust cohort study for its risk assessment," the Gibb Baltimore plant cohort. *Id*.

The Final Rule refers to how OSHA obtained a copy of the Final Report (Ms. Edens confirmed at hearing that the Final Report is labeled in the Final Rule as "48-1-2," and the prepublication copy of the German Results Paper is labeled as "48-4"). Tr. 1129; CX 76 at 82.

Further, in regard thereto it states -

> The results of the recent German post-change cohort showed that excess lung cancer mortality occurred among chromate-exposed workers in plants exclusively using a no-lime production process. (**Ex. 48-4** [German Results Paper]). Like the Gibb cohort, the German cohort was exposed to average full-shift Cr(VI) exposures well below the previous PEL of 52 [micrograms per cubic meter] but without the possible contribution from the more carcinogenic calcium chromate (**Exs. 48-1-2** [Final Report]; Ex. 7-91). OSHA believes the elevated lung cancer mortality in these post-change workers are **further evidence** that occupational exposure to the less carcinogenic water-soluble Cr(VI) present a lung cancer risk.

CX 76 at 101 (emphasis added).

Respondent never did voluntarily submit the Final Report to EPA. JX 1 ¶¶ 19, 20. EPA only obtained a copy of the Final Report from Respondent on November 17, 2008, in response to a subpoena it had issued to Respondent for documents and information on August 22, 2008. CX 81; JX 1 ¶ 20; CX 82 at 6.

IV. ARGUMENTS

A. Complainant's Initial Post-Hearing Brief

Complainant first states in its Initial Post-Hearing Brief ("EPA Brief") that it has met its burden of proving, and Respondent has not disputed, the prima facie elements of a TSCA Section 8(e) claim. EPA Brief at 12-15; *see* Order on Complainant's Motion for Accelerated Decision and Respondent's Request for Oral Argument (Aug. 8, 2011) ("AD Order").

Complainant then argues that Respondent has not established the statutory affirmative defense in TSCA Section 8(e), which would be that at the time Respondent obtained a copy of the Final Report, Respondent had "actual knowledge that the Administrator [of EPA] has been adequately informed of such information." EPA Brief at 15-45; 15 U.S.C. § 2607(e); 40 C.F.R. § 22.24(a); *In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, 559 F. Supp. 2d 424 (S.D.N.Y. 2008). Respondent cannot prove this, Complainant argues, because "at the time of the [Final Report], limitations in prior studies resulted in inadequate exposure data to fully quantify carcinogenic effects under long-term, low-intensity exposure conditions," which were the exposure conditions of the workers in the Final Report. EPA Brief at 3. At the time, the only other study of hexavalent chromium exposure in modern plants, the Gibb Study, revealed an elevated lung cancer mortality risk based on short-term, high intensity exposure conditions. *Id.* at 4, 16-28. Complainant argues that the difference between the studies in terms of the duration of worker exposure (Gibb Study average, 3.1 years; Final Report average, 8-12 years), means that the cumulative exposures found in the studies, while "comparable," must have been calculated with significantly different values for exposure intensity (because cumulative exposure =

exposure intensity x duration of work exposure). *Id*. at 31-34. Furthermore, the Gibb Study has important limitations, for which Complainant and its witnesses question the "biological plausibility" of its findings, and which the authors of the Final Report recognized and attempted to account for in their study. *Id*. at 27-28, 35-36.

Next, Complainant refutes any assertion that the Agency's TSCA Section 8(e) guidance justified Respondent not submitting the Final Report, because, it argues, in October 2002, the Final Report was not "corroborative" of previously available information. EPA Brief at 37; CX 17, CX 21, CX 67. Complainant proclaims that the Final Report contains new information because, at the time, (1) the risk of lung cancer from occupational exposure to hexavalent chromium was not well-established when there was *long-term duration of exposure*; (2) nor was the same effect well-established at *low exposure intensity*; and (3) there was a "scarcity of studies containing exposure data sets for dose-response assessment." EPA Brief at 37-45. As to the third point, Complainant discounts the Mancuso study because its data is from the 1940s, well before the process changes that the Gibb Study and Final Report were designed to address, among other reasons. *Id*. at 43. Complainant also discounts the Luippold Study because it was not published until 2003, and the Gibb Study, for the reasons already stated. *Id*.

Finally, Complainant argues that the appropriate penalty to be imposed on Respondent is $2,338,000, taking into account the statutory factors in TSCA Section 16(a)(2)(B), the Agency's Guidelines for the Assessment of Civil Penalties Under Section 16 of the Toxic Substances Control Act; PCB Penalty Policy ("1980 Guidelines"), and the Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12, and 13 ("Penalty Policy"). EPA Brief at 45-46; 15 U.S.C. § 2615(a)(2)(B); CX 102; CX 103. Using the Penalty Policy in particular, Complainant states that the "nature" of the violation is "hazard assessment," which are those that are "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." EPA Brief at 48; CX 102 at 3, 12. Non-reporting violations under TSCA are a Level 1 on the "circumstances" spectrum (the most serious level), Complainant argues, because "[w]hen 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." EPA Brief at 49; CX 103 at 12, 22-23, 34. Third, the "extent" of Respondent's violation, Complainant argues, is major, which is the level assigned under the Penalty Policy to TSCA Section 8(e) violations involving data related to human effects or exposure. EPA Brief at 50; CX 102 at 3; CX 103 at 14, 25. Using these assignments, Complainant calculated a penalty for the days beginning October 29, 2002, through March 14, 2004, at the rate applicable at the time, and a penalty for the period beginning March 15, 2004 through November 16, 2008, at the newer rate. EPA Brief at 53. Added together, these total $2,338,000. *Id*. Complainant found no aggravating or mitigating circumstances based on the factors of ability to pay, effect of penalty on violator's ability to continue in business, any history of prior violations, degree of culpability, or any other matter that justice may require. *Id*. at 53; CX 102 at 5; CX 103 at 9.

B. Respondent's Initial Post-Hearing Brief

Respondent argues in its Initial Post-Hearing Brief ("Respondent's Brief") that the only "substantial risk information" in the Final Report is "the finding that there was a statistically significant increased incidence of lung cancer in the plant employees who had been exposed to high cumulative levels of hexavalent chromium." Respondent's Brief at 2, 13. Because this same finding had been established before the Final Report was completed, in studies that had been known to EPA, namely the Gibb Study, there was no new information about risk in the Final Report. *Id*. In fact, Respondent argues, the Gibb Study showed risk from hexavalent chromium exposure at even lower exposure levels than risk was shown in the Final Report. *Id*. at 3, 22. The Final Report "did not identify a significant new risk associated with hexavalent chromium, rather it just found risk where it was already known to exist based on the previously-conducted Gibb Study." *Id*. at 23 (emphasis in original). Respondent states that when Dr. Barnhart received a draft of the Final Report, he compared the findings with those of the Gibb Study, and determined that the Final Report data "falls in the same range more or less as the Gibb data." Tr. 983; Respondent's Brief at 24. Dr. Barnhart also knew that EPA knew about the Gibb Study because it was funded by EPA, Respondent argues, and so Dr. Barnhart "correctly concluded that EPA was already adequately informed of this risk." Respondent's Brief at 25.

Respondent argues that whatever differences Complainant finds in the calculation of cumulative exposure between the studies (long-duration, low-intensity v. short-duration, high-intensity), the fact remains that "it is cumulative total exposure that is relevant in assessing risk, and identical cumulative exposures can result from multiple exposure scenarios." *Id*. at 5, 31-33. As to cumulative exposure, the Final Report "provided no information that Gibb had not already established," specifically, a statistically significant increase in lung cancer mortality in the group of workers exposed to the highest levels of hexavalent chromium. *Id*. at 5, 10.

Respondent also disputes Complainant's characterization of the Final Report exposure conditions as "long-term" and "low-intensity." *Id*. at 16, 38-41. Respondent states, "the only place . . . where any such information is even referenced for an individual cohort member is in Figure 24," which "clearly demonstrates that the term of employment . . . is not uniformly 'long-term,' as EPA has incorrectly stated, but rather varies greatly, as would be expected." *Id*. at 15-16, 31 ("the cohort . . . included a wide range of exposures from short-term exposures to very long-term exposures, as well both high-intensity exposures and low-intensity exposures"), 36-38; CX 1 at 113 (Table 9), 147 (Figure 24); CX 62 at 6 (Table II). Respondent further argues that Complainant cannot show a correlation of the actual risk information in the Gibb Study and Final Report to the high long-duration/low-intensity or short-duration/high-intensity values that Complainant claims are important. Respondent's Brief at 30. Respondent asserts, "EPA's position relies not on what the [Final Report] actually reports or what the Gibb Study reports but on what EPA believes it might be read to suggest based on further manipulation, evaluation and interpretation." *Id*. at 31. Plus, Respondent argues, there will always be differences between cohorts; under Complainant's view, "it will be impossible for any occupational epidemiological exposure study not to demonstrate new risk, as every time that risk will have, by assumption, emerged in a different context that the Agency regards as significant under TSCA 8(e)." *Id*. at

33.

Respondent argues that under both the 1978 Policy Statement and the 1991 Guidance, the Final Report does not have to be submitted to the Agency. Respondent's Brief at 26-30; CX 17, CX 21. Specifically regarding the exemption applicable to information that is corroborative in terms of "route of exposure, dose, species, time to onset, severity, species," etc., Respondent discounts Dr. Clapp's testimony that the time to onset was different between the studies, arguing that such comparison is "impossible" because "neither study analyzed" time to onset. Respondent's Brief at 28-29. Regarding the 1991 Guidance language that reads, "information that newly identifies a serious toxic effect at a lower dose level . . . is not considered by EPA to be corroborative," Respondent concludes that the opposite, information that identifies a toxic effect at a higher dose level, *is* corroborative and therefore exempted from the reporting requirement. *Id*. at 29 (emphasis in original).

Finally, Respondent attacks Complainant's reliance on the Penalty Policy for its proposed penalty calculations, stating that the following circumstances should be reflected in the penalty if there is one imposed at all:

> (1) even if reportable, the information is of so little consequence that not a single regulatory action has resulted or is contemplated based on information in the [Final Report], (2) even if reportable, the failure to report was clearly made in a good-faith belief that the information was only corroborative and not new; and (3) even if mistaken, the conclusion that the [Final Report] is not exempted was a reasonable one, i.e. this presents, at best for the Agency, an exceedingly close case by which it has barely established a violation and it would be unfair to treat this case on equal-footing with more significant and obvious violations.

Respondent's Brief at 48-49. Respondent states further, "if a violation occurred at all, it must have been by the barest of margins and in a circumstance where, at best for EPA, reasonable scientific and regulatory minds might disagree." *Id*. at 50.

C. Complainant's Reply Brief

In its Reply Brief ("EPA Reply") Complainant objects to Respondent's characterization of intensity and duration of exposure as being irrelevant to the more important measure in epidemiology, cumulative exposure. EPA Reply at 3. "As Respondent acknowledges," Complainant states, "comparable cumulative exposure levels can be based on different combinations of intensity and duration of exposure." *Id*. at 4. Complainant continues:

> The cumulative exposure in the [Final Report's] overall cohort is based on a longer duration of exposure than the [Gibb Study's] overall cohort. Thus, the [Final Report's] overall cohort necessarily must have a lower intensity of exposure than the [Gibb Study's] overall cohort to have the same cumulative exposure over a longer period. Consequently, the [Final Report] contains new

information . . . .

Id. (citations omitted). Complainant also takes issue with Respondent's conclusion that the only substantial risk information in the Final Report is its finding of an elevated risk at the highest cumulative exposures. *Id*. at 6-7. Citing its experts' testimony at hearing, Complainant argues that "the trend in the overall study cohort is the most appropriate use of all of the data in an epidemiological study" and focusing on one exposure group is "not consistent with the purpose of the study." *Id*.

Complainant admits that the Gibb Study "found increased risk at statistically significant, lower cumulative exposure levels than the [Final Report]," but argues that looking at statistical significance "over practical significance" provides limited information in evaluating epidemiological data. *Id*. at 7-8. Furthermore, TSCA Section 8(e) guidance does not contemplate a test for reportability based on statistical significance. *Id*. at 8. Even if Respondent argues that the trends are comparable between the two studies, Complainant answers that the cohorts are still different enough to show "new" information in the Final Report. *Id*. at 8-9.

As to Respondent's assertion that both the Final Report and the Gibb Study studied a range of short-term and long-term workers, Complainant responds by pointing out that Respondent in part relies on Figure 24 of the Final Report, which reports only the exposures of the 25 workers who had died from lung cancer. *Id*. at 11. More relevant, Complainant urges, are the average exposures for the Final Report, 8-12 years, and for the Gibb Study, 3.1 years. *Id*. In response to the allegation that Complainant manipulated the Final Report's data in order to make its case, Complainant explains that "EPA evaluated the reportability of the [Final Report] based on averages (means), a commonly used descriptive statistic," and that "a basic approximation of the exposure conditions in both the [Gibb Study] and the [Final Report] overall cohorts may be obtained using average duration values directly reported in these studies." *Id*. at 12.

Finally, as to the penalty calculations, Complainant states that it did consider the fact that the Agency has not yet had the opportunity to use the information in the Final Report, and therefore calculated the penalty using a formula that yielded a lower number than it could have been. *Id*. at 14; CX 103 at 12-13. Complainant also challenges Respondent's characterization of Dr. Barnhart's determination not to submit the Final Report as made in good faith and in interpretation of the statute and guidance, when Dr. Barnhart testified that he did not know if he ever read TSCA Section 8(e) or any guidance. EPA Reply at 15-16; Tr. 990-91. Also, Complainant states that it did consider whether it had any evidence of Respondent hiding the Final Report from the regulators; if there had been any such evidence, the penalty could have been raised by 25%, but there was none, so the penalty was not raised. EPA Reply at 16; CX 102 at 5.

D. Respondent's Reply Brief

In its Reply Brief ("Respondent's Reply"), Respondent states:

> TSCA 8(e) does not require a manufacturer to speculate, interpolate or otherwise guess as to what an EPA scientist or outside reviewer may do with a report to further extrapolate risk from it, or based on the fact that such individuals may think the information useful or interesting.

Respondent's Reply at 1. Instead, Respondent argues, to determine reportability under TSCA Section 8(e), Respondent here was only required to look at the "content of the [Final Report] within its four corners, not through further Agency manipulation, analysis and expert opining," for any new risk information. *Id*. at 6.

Answering Complainant's position that duration and intensity of exposure are related to cumulative exposure, and therefore, relevant to the consideration of what new substantial information is present in the Final Report, Respondent argues that there is no evidence that those metrics were correlated to the risk, nor even assessed at all in the Final Report. *Id*. at 3. Even "read forwards and backwards," Respondent asserts, the Final Report does not contain "a determination that substantial risk from hexavalent chromium was associated with long-term, low-intensity exposure." *Id*. at 7. And in response to Complainant's argument that looking at "trend" is more important than individual exposure groups, Respondent argues that the trend of risk associated with exposure to hexavalent chromium was nothing new. *Id*. at 4.

Respondent argues that Congress established a clear standard for reporting in an effort to balance public benefits and reporting burdens. *Id*. at 9. The manufacturer, distributor, or processor must decide if there is substantial risk information in studies that they obtain, and they are not required to consult with leading epidemiologists before they do so. *Id*. at 13. Respondent argues that the information Respondent obtained here was organized in quartiles, and so the quartile information should be the only information from the Final Report tested for reportability under TSCA Section 8(e). *Id*. at 15.

V. DISCUSSION

It has already been established in this matter that at all times relevant to the claims at issue, Respondent has been subject to the requirements of TSCA Section 8(e), having manufactured and distributed in commerce chemical substances or mixtures, specifically chromic acid, chromic oxide and sodium dichromate. JX 1 ¶¶ 4-6; Ans. ¶¶ 6-9, 11-12; AD Order at 11-12. Second, it has been established that on October 8, 2002, Respondent, through then-Vice President Dr. Joel Barnhart, obtained information "which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment," or as it shall be termed herein, "Substantial Risk Information" ("SRI"). JX 1 ¶¶ 17-18; AD Order at 12; Ans. ¶¶ 24, 41-42; R's AD Opp. at 11-15 (identifying what Respondent argues is the "only Substantial Risk Information" in the Final Report). Third, it has been found and stipulated that Respondent did not provide the Final Report to EPA until more than six years later, on November 17, 2008, in response to a subpoena issued by EPA, and that Respondent therefore did not "immediately" inform the Administrator of the SRI. JX 1 ¶¶ 19-20; AD Order at 12-13; *see*

Order on Respondent's Motion for Judgment on the Pleadings.

The prima facie elements of a TSCA Section 8(e) violation having been so established, Respondent bore the burden at the hearing of proving by a preponderance of the evidence that when it obtained the Final Report, it had "actual knowledge that the Administrator ha[d] been adequately informed" of the SRI in the Final Report. 40 C.F.R. § 22.24; *MTBE*, 559 F. Supp. 2d at 434-35.[15] To prevail under a preponderance of the evidence standard, a party must demonstrate that the facts it seeks to establish are more likely than not to be true. *Smith Farm Enterprises, LLC*, CWA Appeal No. 08-02, 2011 EPA App. LEXIS 10, 14 (EAB, Mar. 16, 2011) ("A factual determination meets the preponderance of the evidence standard if the fact finder concludes that it is more likely true than not.") (citing *Julie's Limousine & Coachworks, Inc.*, 11 E.A.D. 498, 507 n.20 (EAB 2004); *Lyon County Landfill*, 10 E.A.D. 416, 427 n.10 (EAB 2002), *aff'd*, No. Civ-02-907, 2004 WL 1278523 (D. Minn. June 7, 2004), *aff'd*, 406 F.3d 981 (8th Cir. 2005); *Bullen Cos., Inc.*, 9 E.A.D. 620, 632 (EAB 2001)). I find that Respondent did not meet this burden, and therefore, is liable for violating TSCA Section 8(e) and subject to civil penalties.

There is no dispute that the only excess cases of lung cancer reported by the Final Report in the SMR analyses were within the highest exposure category. *See* JX 1 ¶ 11; CX 1 at 15-19, 94, 98, 118 (Table 14); Tr. 737, 741, 856-59, 880-81 (Dr. Mundt); 164, 239, 253-254 (Dr. Cooper). There is also no dispute that the Gibb Study showed statistically significant risk at lower cumulative exposures than the Final Report. Tr. 434-36, 439-40, 476 (Dr. Clapp); 1045-46, 1075 (Dr. Gibb); 1097-98 (Dr. Speizer); EPA Reply at 7; Respondent's Reply at 14. Third, no party disputes the fact that the two studies show the same general trend, i.e., that as exposure increases, so does cancer risk. Tr. 148-50, 164, 190, 240 (Dr. Cooper; *see* CX 99); 329, 446 ("Q [Counsel for Respondent]: So both Gibb and the Modern Four Plant revealed the trend that you referred to of higher exposure greater risk. A [Dr. Clapp]: Yes."); EPA Brief at 2; *see also* Tr. 451, 476 (Dr. Clapp); 544, 549 (*see* CX 99), 566 (Dr. Speizer); 869-70 (Dr. Mundt). However, the preponderance of the evidence shows that despite these commonalities, the Final Report nonetheless presents new SRI about occupational hexavalent chromium exposure, as will be discussed below.

A. What is TSCA Section 8(e) "Substantial Risk Information"?

Resolution of this matter requires initially determining what in the Final Report constitutes "information which reasonably supports the conclusion that [a] substance or mixture presents a substantial risk of injury to health or the environment," or Substantial Risk Information ("SRI"). 15 U.S.C. § 2607(e). Respondent argues that the only SRI in the Final Report was a single "[f]inding" – "that there was a statistically increased risk of lung cancer seen in the highest quartile of cumulative exposures within the studied cohort." Respondent's Reply

[15] It is recognized that the words "such information" in the affirmative defense language of Section 8(e) incorporate and reference "information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment," or "substantial risk information." 15 U.S.C. § 2607(e).

at 5-6. Because the earlier Gibb Study had identified an excess risk of lung cancer at comparatively lower exposures, EPA already knew about all that constituted SRI in the Final Report, Respondent argues. *Id*. at 14-16. The present task, therefore, is to compare the SRI in the Final Report to that of the Gibb Study.

The Agency has issued no regulations defining SRI under TSCA Section 8(e) that could help make this determination. However, as mentioned above, since TSCA Section 8(e) took effect in 1977, EPA has published several policy documents intended to clarify the Agency's interpretation of the statutory provision, including the 1978 Policy Statement (CX 17), the 1991 Reporting Guide (CX 21), the 2003 Guidance (CX 67), and the 2005 Q&A (CX 78). Guidance documents issued by the Agency are not binding, but may be persuasive; they "may be considered for their 'power to persuade' when a court interprets a statute." *MTBE*, 559 F.Supp. 2d at 440 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

These guidance documents, the evidence in the record, TSCA legislative history, and the common dictionary meaning of the words in the phrase, "information which reasonably supports the conclusion that [a] substance or mixture presents a substantial risk of injury to health or the environment," are examined below so as to determine what in the Final Report constitutes SRI. 15 U.S.C. § 2607(e).

i. "Information"

"Information" is defined as follows:

> **1 :** the communication or reception of knowledge or intelligence **2 a** (1) **:** knowledge obtained from investigation, study, or instruction (2) **:** INTELLIGENCE, NEWS (3) **:** FACTS, DATA **b :** the attribute inherent in and communicated by one of two or more alternative sequences or arrangements of something [ ] that produce specific effects **c** (1) **:** a signal or character (as in a computer system or computer) representing data (2) **:** something (as a message, experimental data, or a picture) which justifies change in a construct (as a plan or theory) that represents physical or mental experience or another construct **d :** a quantitative measure of the content of information; *specif*: a numerical quantity that measures the uncertainty in the outcome of an experiment to be performed . . . .

Webster's Ninth New Collegiate Dictionary 620 (Frederick C. Mish et al. eds., 9th ed. 1990). And also as this:

> **2 :** something received or obtained through informing: as **a :** knowledge communicated by others or obtained from investigation, study, or instruction **b :** knowledge of a particular event or situation **:** INTELLIGENCE, NEWS, ADVICES <latest ~ from the battle front> <securing ~ about conditions in the upper atmosphere> <~ bureau> **c :** facts or figures ready for communication or use as distinguished from those incorporated in a formally organized branch of

knowledge **:** DATA <reliable source of ~> . . . .

Webster's Third New International Dictionary 1160 (Philip Babcock Gove et al. eds., 2002) ("*Webster's Third*"). These definitions indicate that the meaning of the term "information" is not limited to only an important or new conclusion or finding. Instead, the definitions convey that "information" has a much broader meaning that can include facts, figures, data, intelligence, knowledge, as well as findings, summations and conclusions. While "news" is included in the definition, it in no way limits the use of the word to meaning only surprising or unexpected data, facts, etc.

About where this "information" typically is found, the 1991 Reporting Guide explains:

> TSCA Section 8(e)-reportable information can come from a variety of sources including, but not limited to **draft, interim or final written reports (including study reports, letters, telegrams, telex reports) or verbal reports (received at meetings or by phone) that involve observations (including preliminary observations)** from, for example, controlled or uncontrolled: (1) human or animal studies/events (including but not limited to studies/events that involve high dose levels or non-routine routes of exposure) . . . .
>
> The evidence that offers reasonable support for a conclusion of substantial risk need not be complete nor definitive but should provide a **plausible link** between 1) an observed serious effect and one or few chemicals . . . or 2) a specific product/activity and a previously unrecognized exposure to a chemical that is known or reasonably anticipated to cause serious adverse health or environmental effects.

CX 21 at 18 (emphasis added).

One of the Agency's guidance documents on penalty, EPA's Enforcement Response Policy for [TSCA] Sections 8, 12 and 13 ("ERP") (effective June 1, 1999), lends further support to a broad reading of "information." CX 103. The ERP states that examples of Section 8(e) violations could include the failure to report "information from a spill incident," "a study showing human health effects," and even any "reportable information" that was omitted from a study that the company had earlier submitted to EPA. CX 103 at 40-41. The Agency's 1993 Notice explains: "The **broad scope and nature** of TSCA section 8(e) makes it one of the most important health and safety data reporting provisions under TSCA." CX 24 at 2 (emphasis added). Thus, the Agency's own interpretation of what "information" means in 8(e) is that it includes much more than just a finding of risk or particular conclusion from a study or event.

This is also evident from the legislative record leading up the passage of TSCA. First, the ways in which the language of the TSCA bill changed in committee is insightful. In March 1976, the Senate passed S. 1349, Section 8(e) of which provided:

> Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture, and any liability insurer of such person, who obtains information which supports the conclusion that such substance or mixture causes or contributes to an unreasonable risk of injury to health or the environment **shall immediately inform the Administrator of such risk** unless such person has reason to believe that the Administrator has been adequately informed of such **risk**.

Toxic Substances Control Act, S. 3149, 94th Cong. § 8(e), 122 Cong. Rec. 8304, 8311 (1976) (as passed by Senate, Mar. 26, 1976) (emphasis added). The House passed S. 3149 in August of that year with amendments; Section 8(e) read therein 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 causes or significantly contributes to a substantial risk 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**.

Toxic Substances Control Act, S. 3149, 94th Cong. § 8(e), 122 Cong. Rec. 27,205, 27,213 (1976) (as passed by H.R., Aug. 23, 1976) (emphasis added). The Senate bill would have only required covered persons to submit any finding of "risk" to the Administrator unless he or she had already been informed of the "risk," not the underlying "information" that supports the risk existing. Conversely, the House version would require the submission of "information" that reasonably supports the existence of a risk, unless the Administrator has been informed of "such information." Ultimately, the final version of Section 8(e) resembles the House bill. P. Law. No. 94-469, 90 Stat. 2027 (1976) (codified at 15 U.S.C. § 2607). If Congress had chosen the more narrow and *conclusory* word "risk," it would have lent support to Respondent's argument. Instead however, the provision seeks the submission of the broader item, "information."

Likewise, the legislative history of other subparts of TSCA Section 8 shows that Congress wrote these provisions to ensure the Agency would have access to *more* information on chemical risks as opposed to less. In the Conference Report issued jointly by Senate and House leaders in committee on the proposed bills, there are no informative comments from the conferees as to how or why they agreed on the final language of Section 8(e). H.R. Rep. No. 94-1679, at 81 (1976) (Conf. Rep.). However, as to Section 8(c), which as proposed required manufacturers, etc., to retain "records of significant adverse reactions . . . for five years," the conferees notably carved out a more cautious rule for occupational hazards, and identified an interest in liberally retaining information: "The conferees recognize the **special dangers** presented to persons who are exposed to substances on a daily basis; therefore, records of adverse **occupational** effects must be retained for **thirty years**. . . . Because the ultimate significance of adverse reactions is difficult to predict, **the conferees intend that the requirement to retain records err on the side of safety**." *Id*. at 81 (emphasis added). As to Section 8(d), which, as proposed, directed the Administrator to promulgate rules requiring the submission of health and

safety studies, the Report states:

> As with the provision concerning adverse reactions, **the conferees emphasize the importance of gaining information which errs on the side of too much rather than too little.** Of course, the Administrator is to avoid imposing unnecessary or overly burdensome reporting requirements. [However] [i]n cases where test results are submitted, **supporting data and the sources for such data must be included**.

Id. at 30, 81 (emphasis added).[16] While the comments on Sections 8(c) and 8(d) do not specifically address Section 8(e), they do provide insight to lawmakers' interest at the time in the Agency having access to as much "information" as possible about chemical risks, particularly in the occupational context. Moreover, they indicate an intent that regulated entities be required to submit the underlying "supporting data" and data sources relating to chemical risks, and not simply communicate the fact that a "risk" exists.

ii. "Substantial Risk"

"Substantial" is defined as:

> **1 a :** consisting of, relating to, sharing the nature of, or constituting substance **:** existing as or in substance **:** MATERIAL . . . **b :** not seeming or imaginary **:** not illusive **:** REAL, TRUE . . . **c :** being of moment **:** IMPORTANT, ESSENTIAL . . . **3 a :** having good substance . . . **b :** having a solid or firm foundation **:** soundly based **:** carrying weight <a ~ argument> <~ evidence> **4 a :** being that specified to a large degree or in the main <a ~ victory> <a ~ lie> **b :** of or relating to the main part of something

Webster's Third at 2280. *See also United States v. Pizano*, 403 F.3d 991, 996 (8th Cir. 2005) (noting "substantial" is "a word whose meaning varies depending on its legal context.").

The 1978 Policy, echoed by the 1991 Reporting Guide, provides that "the substantiality of a risk is the function of both the seriousness of the effect and the probability of its occurrence (see Part V)." CX 17 at 1; CX 21 at 13. Part V sets forth the Agency's determination that "[a]ny instance of cancer" in humans is an effect "so serious" as to constitute a substantial risk regardless of the probability of its occurrence. CX 17 at 2-3; Tr. 30. Respondent concedes that the Final Report identified an "instance of cancer" and therefore, substantial risk. Respondent's Brief at 27.

---

[16] As will be reiterated below, no evidence or argument was submitted to the record showing that the reporting provision imposes unnecessary or overly burdensome requirements as are warned against here.

iii. "Reasonably Supports the Conclusion of Substantial Risk"

The 1978 Policy advises:

> [The Administrator] emphasizes that "reasonably supports the conclusion" of substantial risk is **not identical to a conclusive demonstration** of substantial risk. **The former typically occurs, and must be reported, at an earlier stage.**
> * * *
> A person is not to delay reporting until he obtains conclusive information that a substantial risk exists, but is to immediately report ***any evidence*** which "reasonably supports" that conclusion. **Such evidence will generally not be conclusive as to the substantiality of the risk; it should, however, reliably ascribe the effect to the chemical.**

CX 17 at 1, 3 (emphasis added). The Policy continues:

> Information from the following sources concerning the effects described in Part V will often "reasonably support" a conclusion of substantial risk. Consideration of corroborative information before reporting can only occur where it is indicated below.
>
> (1) *Designed, controlled studies.* In assessing the quality of information, the respondent is to consider **whether it contains reliable evidence ascribing the effect to the chemical**. **Not only should final results from such studies be reported, but also preliminary results from incomplete studies where appropriate**. Designed, controlled studies include:
>
> (I) In vivo experiments and tests.
> (ii) In vitro experiments and tests. Consideration may be given to the existence of corroborative information, if necessary to reasonably support the conclusion that a chemical presents a substantial risk.
> (iii) **Epidemiological studies.**
> (iv) Environmental monitoring studies.

CX 17 at 3 (emphasis added).

The 1991 Guide provides, in pertinent part:

> The decision-making process for Section 8(e)-reportability should focus primarily on whether the toxicity or exposure information offers reasonable support for a conclusion or substantial risk under the criteria described above, but **should not focus at all on whether the information is conclusive regarding the risk**. A decision to report information to the Agency under Section 8(e) should not involve exhaustive health and/or environmental risk assessments of the subject chemical(s).

CX 21 at 13-14 (emphasis added).

In line with the Agency's position that toxicity or exposure information does not have to be "conclusive" about a risk to be SRI, there is no evidence that Congress intended Section 8(e) to mandate the reporting of "statistically significant" study results only. Nor would that make sense in terms of the nature of risk assessment in epidemiology, as evidence produced in this matter shows. For example, while addressing comments made about his Baltimore study at the OSHA hearing on the hexavalent chromium PEL, Dr. Gibb, in rejecting the suggestion that a "threshold" might exist in his findings, explained that excess risk may exist even when no "statistically significant" excess risk is shown:

> Another comment was that . . . below a particular cumulative exposure . . . no lung cancer risk was observed. The argument was made that, well, this suggest that there may have been a threshold. Having been a risk assessor for a number of years, and having dealt with that argument many times, there is always some point at which you cannot statistically detect an excess risk. I mean, it relates to the power of the size of the group to be able to see that risk. . . . There has to be the data to support it. So saying that below a particular cumulative exposure means that there wasn't a statistically significant excess risk, doesn't mean that a risk does not exist. The risk can still be there, although you may not be able to detect it.

CX 97 at 108-09. And later during the hearing:

> DR. LURIE: Is there any question in your mind that the risk of lung cancer from hexavalent chromium might extend below even those quartiles in which you found statistical significance?
>
> DR. GIBB: Sure. I think that's quite possible.

Id. at 129-130. Dr. Cooper was asked about this issue at the present hearing and stated a similar opinion:

> Q . . . Is it necessary for a finding in an occupational epidemiology study to be . . . statistically significant in order for it to be important?
>
> A [Dr. Cooper] No, I don't think that's true.
>
> Q And why is that?
>
> A [Dr. Cooper] Well, again, one of the issues when you're evaluating a study is that the statistical significance of that study, is driven, in such a large part, by the size of the study.

> So in the context, for example, of an occupational study, where there's a limited number of observations into smaller and smaller groups, for example, as you look at . . . three or four levels of exposures, then quite often there's really little expectation that individual results for individual groups within that larger study would be statistically significant.
>
> So what you look for is the pattern of results that you're seeing across exposures, rather than the statistical significance of any individual estimate from one particular group within a study.

Tr. 263-64. Dr. Mundt agreed that there can be value in a study regardless of the authors' findings of statistical significance:

> JUDGE BIRO: So whether or not the conclusions would be statistically significant, the data itself, the raw data, has a significant value in the field?
>
> THE WITNESS [Dr. Mundt]: Absolutely. Yet, to be discovered or fully mined.

Tr. 938-39. Dr. Speizer echoed these comments on statistical significance while discussing Complainant's Exhibit 99, which was produced by Dr. Cooper with help from Dr. Clapp specifically for use in this proceeding. Tr. 179; 318. The exhibit presents in a graphic the relationship between the mean cumulative air exposures to hexavalent chromium in quartiles from the 2003 Final Report and the Gibb Study, and the SMR of the workers' lung cancer mortality and that of an external referent group. *Id.*; CX 99.[17] Dr. Speizer opined:

---

[17] Both parties stipulated to the authenticity and admissibility of Complainant's Exhibits 98, 99 and 100. JX 1 at 13. Complainant's Exhibit 99, "a comparison . . . of the results, in terms of . . . the relative risk of lung cancer in the two sets of data," received at least some favorable treatment at the hearing in terms of its accuracy. Tr. 179; *see, e.g.*, Tr. 906-907 (Dr. Mundt believes CX 99 is an accurate representation of the Final Report results); 1044 (Dr. Gibb stated that CX 99 fairly represents the results of his study and of the Final Report); *see also* Respondent's Brief at 22. However, I do not find Complainant's Exhibits 98 and 100 to be useful, after consideration of the lengthy expert testimony at hearing and upon their close examination, because of the serious doubts raised as to their accuracy and reliability.

What Dr. Cooper illustrated in Complainant's Exhibit 98, essentially, is the difference between exposure in the Baltimore Plant historically, regardless of study, and in the four plants studied by Applied as presented in the Final Report. Ultimately, I do not find CX 98 useful due to the conflicting opinions about its accuracy and the confusion about what it shows. *See, e.g.,* Tr. 1047-48 (Dr. Gibb: the measurements presented as coming from the Gibb Study in CX 98 "were not used at all in our study," but come instead from the Braver Study, and were obtained by the Baltimore City Health Department's testing of "hot spots," and therefore, are elevated); 1050-52 (Dr. Gibb: to characterize the measurements represented by the bars labeled for the German

(continued...)

> The study has been designed, empowered, to look at the overall effect in the total population. In picking individual groups [quartiles] and looking at them separately, one is essentially in both cases throwing away 75 percent of the data.
> * * *
> If they had proposed to measure only that subgroup, the study would be clearly under powered to make those measurements. And it would not probably have been done.
> * * *
> So I think the focus on the individual groups is simply misusing the data completely. **If you look at the four plant study at the first two groups, there's a tenfold, almost a tenfold difference between lower and upper bounds of the confidence level. That means that somewhere in that range is what the real risk is and we don't know what the risk is in that range.**
> * * *
> The fact that the highest group turned out to be significant could be - - it's gratuitous. It doesn't help me understand what the trend is. The trend is mostly what's in all of the data and that's what we should be using. That's true for both

---

[17](...continued)
plants in CX 98 as average exposure is "disingenuous"); 1051 (Dr. Gibb: the most objectionable part of CX 98 is the sentence about exposures being "2 to 5 times higher" at the Baltimore plant; it is "just not true" and "grossly misleading"); 897 (Dr. Mundt: the blue bars purporting to represent the average air concentrations at the German plants in CX 98 are "not at all" accurate); 902-904 (Dr. Mundt: the title of the graph on CX 98 is "incomplete" and the comparison presented is "misleading"); 404-405 (Dr. Clapp: CX 98 "is what it is[,] . . . a representation of the years for which there are air measurements in the German plants;" not a representation of the average exposures for all workers during their employment); 409-412 (Dr. Clapp: examination established that the reader would "have to go to the footnote" and then to the Braver study to not be confused by the heading about what is presented in CX 98); 219 (Dr. Cooper defended CX 98: "what I was trying to do was pull together all the information I could find on exposures in the Baltimore plant"); 190 (Dr. Cooper sees evidence of a "healthy worker effect"); 175-77, 221 (Dr. Cooper admitted to using Braver data in the table on the bottom of CX 98, in part because exposures in the 1950s were "the most relevant time period" for the Gibb Study; she doesn't know why the Gibb Study authors didn't include useful information that she had to calculate to insert in the graph); *see also* Respondent's Brief at 46-47.

Because there are similar problems with Complainant's Exhibit 100, it has not been used in this determination. *See*, *e.g.*, Tr. 254-56 (Dr. Cooper admitted using the mean from the Gibb Study instead of the median to determine data points in CX 100, because she thought it was a typographical error in Gibb Study); 1054-56 (Dr. Gibb responded: "That's not a typo," therefore, the top graph of CX 100 is "misleading;" the bottom graph represents "an apples and oranges comparison" (logistic regression data and proportional hazards data), which is "an inappropriate comparison"); 249 (Dr. Cooper believes it *is* appropriate); 700, 749, 753 (Dr. Mundt casts doubt on the usefulness of the logistic regression results, and later calls them "very, very imprecise").

the Gibb study and the four plant study.

Tr. 544-46 (emphasis added); CX 99. Also, Dr. Clapp explained:

> Q Is it necessary for something to be statistically significant for it to be considered informative by epidemiologists?
>
> A [Dr. Clapp] No.
>
> Q And why is that?
>
> A [Dr. Clapp] Well, the relationship is what's most important, and that's to say, for example, in this example the relative risk or the [SMR], that's the focus of an epidemiological investigation. And **the statistical test is, as I said, a mathematical calculation that says how likely it is that that finding was due to chance**. So, the statistical test is [–] it's actually a convention. Some journals require that it be done, but **it's not the focus of epidemiologic investigation**.

Tr. 321 (emphasis added).[18] *See also* CX 76 at 113 (OSHA in its PEL Final Rule: "The fact that

---

[18] *See also* CX 91 (Sir Austin Bradford Hill (President, Section of Occupational Medicine, Royal Society of Medicine), *The Environment and Disease: Association or Causation?*, 58(5) Proc. of the Royal Soc'y of Med. 295, 289 (1965), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1898525/pdf/procrsmed00196-0010.pdf.) at 5:

> What I do not believe – and this has been suggested – is that we can usefully lay down some hard-and-fast rules of evidence that *must* be obeyed before we accept cause and effect. . . . [T]he fundamental question [is] is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect?
> * * *
> No formal tests of significance can answer those questions. Such tests can, and should, remind us of the effects that the play of chance can create, and they will instruct us in the likely magnitude of those effects. Beyond that they contribute nothing to the 'proof' of our hypothesis.

See also Allen v. United States, 588 F. Supp. 247, 416 (D. Utah 1984) (citing Hugh D. Young, *Statistical Treatment of Experimental Data* 131-32 (Carnegie Inst. of Technology, 1962), *available at* http://nhn.nhn.ou.edu/~johnson/Education/Juniorlab/TEXT/Statistical TeatmentofData-HughDYoung-All.pdf), *rev'd* 816 F.2d 1417 (10th Cir. Utah 1987):

> The scientific papers and reports will often speak of whether a deviation from the expected numbers of cases is "statistically significant," supporting a hypothesis of

(continued...)

an upward trend in lung cancer risk with Cr(VI) exposure duration fails to meet a statistical confidence of 95 percent does not mean the relationship does not exist.").

Based on these explanations (from both parties' witnesses), if TSCA Section 8(e) only covered "statistically significant" risk information, in practical terms that might mean that only studies of extremely large cohorts would have the statistical power to show a risk important enough to be reported. That is clearly not the appropriate reading of "*information* which *reasonably supports* the conclusion that [a] substance or mixture presents a substantial risk" in TSCA Section 8(e), as the above analysis demonstrates. "Information" in Section 8(e) is a broad term employed to keep the Agency as informed as possible about chemical risks. To the extent Respondent relies on "statistical significance" as the hallmark of SRI to support its argument that one finding is the only SRI in the Final Report, that argument must fail.

Respondent asks the undersigned to look "at the content of the Final Four Plant Report within its four corners." Respondent's Reply at 6. The only SRI therein, Respondent argues, is "a statistically significant excess of lung cancer deaths above the expected number of lung cancer deaths, but only in the highest cumulative exposure group." Respondent's Brief at 17 (emphasis in brief). After examining the Final Report's 153 pages, 19 tables, and 24 figures, and in light of the meaning of SRI in TSCA Section 8(e) as established above and in the record, I cannot agree with Respondent. Having addressed the question of what constitutes TSCA Section 8(e) SRI, the following discussion will address Respondent's defense that the Agency's own guidance exempts the Final Report SRI from reporting.

---

[18](...continued)

> causation, or whether the perceived increase is attributable to random variation in the studied population, i.e., to chance. The mathematical tests of significance commonly used in research tend to be stringent; for an increase to be considered "statistically significant," the probability that it can be attributed to random chance usually must be five percent or less ($p = 0.05$). In other words, if the level of significance chosen by the researcher is $p = 0.05$, then an observed correlation is "significant" if there is 1 chance in 20 – or less – that the increase resulted from chance. . . . The cold statement that a given relationship is not "statistically significant" cannot be read to mean "there is no probability of a relationship." Whether a correlation between a cause and a group of effects is more likely than not – particularly in a legal sense – is a different question from that answered by tests of statistical significance, which often distinguish narrow differences in degree of probability.

See also Charles Seife, *The Mind-Reading Salmon: The True Meaning of Statistical Significance*, Scientific American, Aug. 2011, *available at* http://www.scientificamerican.com/article.cfm?id=the-mind-reading-salmon ("The *p*-value puts a number on the effects of randomness. . . . A long-standing convention in many scientific fields is that any result with a *p*-value below 0.05 is deemed statistically significant. An arbitrary convention, it is often the wrong one.").

B. The "Corroborative of Well-Established Adverse Effects" Exception

The following excerpt from the 1965 address to the Royal Society of Medicine by the President of the Society's Occupational Medicine Section provides a useful perspective for answering the questions of when a health risk is "well-established" and when an epidemiological report can be deemed "corroborative" of that risk. CX 91; CX 17 at 3; CX 21 at 19.

> With many alert minds at work in industry today [1965] many an environmental association may be thrown up. Some of them on the customary tests of statistical significance will appear to be unlikely to be due to chance. Nevertheless whether chance is the explanation or whether a true hazard has been revealed may sometimes be answered only by a repetition of the circumstances and the observations.
>
> Returning to my more general example, the Advisory Committee to the Surgeon-General of the United States Public Health Service found the association of smoking with cancer of the lung in 29 retrospective and 7 prospective inquiries [studies as of 1964]. The lesson here is that broadly the same answer has been reached in quite a wide variety of situations and techniques. In other words we can justifiably infer that the association is not due to some constant error or fallacy that permeates every inquiry. And we have indeed to be on our guard against that.
>
> [D]ifferent results of a different inquiry certainly cannot be held to refute the original evidence; yet the same results from precisely the same form of inquiry will not invariably greatly strengthen the original evidence. I would myself put a good deal of weight upon similar results reached in quite different ways . . . .

Id. at 2-3.

i. Pre-2002 Guidance

The 1978 Policy states as follows:

> Information need not be reported if it:
> * * *
> (c) Has been published in the scientific literature and referenced by the following abstract services: (1) Agricola, (2) Biological Abstracts . . . .
> (d) **Is corroborative of well-established adverse effects** already documented in the scientific literature and referenced as described in (c) above . . . .

CX 17 at 3 (emphasis added). Though the 1978 Policy does not further define "corroborative" or "well-established," the Agency later elaborated in the 1991 Reporting Guide:

> 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 of 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 (emphases in exhibit and added); Tr. 33-34.

The Agency acknowledged in its 1993 Notice that "[t]he statutory language of section 8(e) and the section 8(e) interpretive documents issued to date require the exercise of a certain degree of judgment in determining the section 8(e) reportability of information." CX 24 at 2. The Notice defines "corroborates" in the 1978 Policy to mean "that the information **essentially duplicates and/or confirms** an existing and **well-documented understanding** of a serious adverse effect of a particular chemical substance or mixture." CX 24 at 5 (emphasis added). Further, the 1993 Notice states:

> EPA has correctly received, and expects to continue to receive, substantial risk reports that show adverse effects of a more serious degree or of a different kind than are already established. In other words, the Agency expects subject persons to immediately consider reporting information on serious toxic effects (including, but not limited to cancer . . .) if, for example: such effects are substantially more serious in terms of the severity of the effects . . . ; occur within a significantly shorter time frame following exposure; occur via a different route of exposure; occur at a significantly lower dose or concentration; or occur in a different species, strain, or sex.

Id. (emphasis added).

ii. Post-2002 Guidance

The 2003 Guidance reveals, among other things, that "the Agency is expanding the types of information that it believes need not be reported under section 8(e)," e.g., draft and final reports made available to the public by other Federal agencies, and information obtained from

news publications.[19] CX 67 at 2, 5. The 2003 Guidance should be applied prospectively, it

[19] Respondent's counsel pointed out at hearing that the 1978 Policy Statement and the 2003 Guidance differ in one important regard on the issue of "corroborative" information. Tr. 45-50. The 1978 Policy, which was available to Respondent in 2002, reads:

> Note that: (i) The effects outlined below should not be reported if the respondent has actual knowledge that the Administrator is already informed of them.
>
> (ii) Information respecting these effects can be obtained either directly, by observation of their occurrence, or inferred from designed studies as discussed in Part VI.

CX 17 at 2-3. During his cross-examination of Anthony Krasnic, the Agency's witness from the FIFRA program office, counsel read aloud the revisions made to this "Note" by the 2003 Guidance:

> Q . . . And it says "Note that the information on the effects outlined below should not be reported, (i) if the Respondent has actual knowledge that the Administrator is already [ ] informed of them; ***or*** (ii) information respecting these effects can be obtained either directly by observation of their occurrence or inferred from designed studies as discussed in part six." Again, an epidemiologic study is a design study. Correct?
>
> A [Mr. Krasnic] Correct.
>
> * * *
>
> Q But this is the guidance that EPA writes to the regulated community. It says, there is two, at least in this provision, there is [sic] two reasons why the regulated community shouldn't report. One is the Administrator already knows about it and the second is it can be inferred from epidemiologic studies. Correct?
>
> * * *
>
> A [Mr. Krasnic] Correct but –

Tr. 47-50 (emphasis added). These "Notes" do communicate different things, as Respondent's counsel pointed out. However, it appears the Agency recognized that it was a mistake to combine the two romanettes into one compound sentence with "or," because in 2005, the Agency changed it back to the 1978 language. 70 Fed. Reg. 2162 at 2163 (Jan. 12, 2005) ("In the 2003 guidance document . . . the second paragraph of Part V. entitled *What Constitutes Substantial Risk* is removed and the following language from the 1978 TSCA Section 8(e) Policy Statement (continued...)

states. CX 67 at 5. Therein, the Agency sets forth its position on corroborative risk information:

> "Substantial risk" information need not be reported under section 8(e) if it:
> * * *
> (b) Corroborates (i.e., **substantially** duplicates or confirms) in terms of, for example, route of exposure, dose, species, strain, sex, time to onset of effect, nature and severity of effect, a **well-recognized/well-established** serious adverse effect for the chemical(s) under consideration . . . .

CX 67 at 11 (emphasis added). Notably, the Agency added "substantially" to this description. *See* CX 24 at 5 ("essentially duplicates and/or confirms").

The "corroborative" question is also explored in the Agency's online 2005 Q&A:

> Q.2. If a company obtains **new human exposure-related information** on a chemical it manufactures, such as blood or **urine monitoring data** on a chemical **known** to have serious toxic effects, is it reportable under TSCA §8(e)?
>
> A.2. **Yes.** If the new information on a chemical known to have serious toxic effects **indicates a level of exposure previously unknown** to the Administrator, it should be reported. Information that corroborates **known exposure levels**, such as those within the range of chemical blood levels and other biological monitoring data recorded in the NHANES (National Health and Nutrition Examination Survey) data base, is not reportable.

CX 78 at 1 (emphasis added). To another question, EPA answered as follows:

> A.25. [ ] The discovery of previously unknown and significant human exposure to a chemical, when combined with knowledge that the subject chemical is recognized or suspected as being capable of causing serious adverse health effects (e.g., cancer, birth defects, neurotoxicity), provides a sufficient basis to require the reporting of the new-found exposure data to EPA under section 8(e).

CX 78 at 8.

Ultimately, the 2003 Guidance (which "should be applied prospectively" (CX 67 at 5)) and the 2005 Q&A, both having been issued after the alleged violation began and therefore not something on which Respondent could have relied at the time the Final Report was issued, do not inform the present liability determination as much as the guidance issued before October 2002. Respondent does not address the recent guidance in either of its post-hearing briefs; Complainant

---

[19](...continued)
is added in its place.").

makes only brief reference to the 2003 Guidance in its briefs. EPA Brief at 51 n.17. However, I have considered some of these recent comments on "corroboration" particularly because Respondent did not submit the Final Report even after these guidance documents became available to the public.

iii. Testimony on "Corroborative of Well-Established Adverse Effects"

The following testimony informs the meaning of what is considered "corroborative" information of a "well-established" adverse effect in the context of the guidance and in the particular field at issue in this case, occupational epidemiology.

a. Dr. Mundt

Dr. Mundt led the endeavor to produce the Final Report, beginning from the first meetings with Dr. Barnhart and the IHF Chromium Chemicals Committee, through the issuance of the 2002 and 2003 Final Reports, and the eventual publication of the Final Report results in two separate papers. Tr. 648-895; *see* CX 1 at 3; CX 3-4; CX 30; CX 33-40; CX 44-46; CX 49-50; CX 59; CX 63; CX 92; RX 12-14. The parties stipulated to his expertise in epidemiology and assessment of human health risk associated with hexavalent chromium exposure. JX 2 at 2; *see also* RX 7. His testimony at the hearing was thoughtful and credible, and his opinions were insightful.

When Respondent's counsel asked Dr. Mundt at hearing what the Final Report details, he answered: "[D]etail is the right word. It describes the whole process from data acquisition, gathering, processing, [ ] through analysis." Tr. 716. In the "Strengths of this Study" section of the Final Report, the authors cite its "multi-site design," i.e. the inclusion of four different chromate plants, and "large cohort of post-change chromium chemical workers, along with the corresponding increase in statistical power generally lacking in previous studies of post-change cohorts." CX 1 at 32, 95; *see also* Tr. 870 (Dr. Mundt: "technically by increasing the numbers, there is improved statistical power. That is, the ability to actually identify a true effect, if one exists."). Also touted is the fact that "[o]ver 40% of this post-change cohort was followed for at least 20 years . . . the typical latency period for lung cancer." CX 1 at 95; *see also* Tr. 846, 858-59 (Dr. Mundt testified that typically "you need 20 years from first exposure to expect to see cases;" the Final Report plausibly "had sufficient follow-up to detect lung cancers."); CX 1 at 86 (Dr. Mundt and his colleagues acknowledged that "the risk period may continue beyond the study period," but they also declared that the study "has adequate latency to detect work-related cancers."). Third, "[r]elatively large numbers of samples were taken at each facility in nearly all study years, and for most work areas." CX 1 at 95; *see also* Tr. 872 (Dr. Mundt: "Most of the studies, especially the earliest ones in the industry were not able to derive individual estimates of exposure."). Other strengths include certain "methodological attributes" such as the use of multiple referent groups in the SMR analyses, the time-dependent evaluation of exposure indicators ("rarely used even in recent occupational mortality studies"), and the incorporation of smoking information on a large majority of the cohort as a potential confounding variable. CX 1 at 96.

Dr. Mundt was asked by counsel to explain what was presented in the Final Report, table by table, figure by figure, and was also asked to address several paragraphs of the written portion. Tr. 716-886. His answers illuminate the wealth of information presented in the Final Report. For example, as to Table 14, which presents an SMR analysis for peak exposures, Dr. Mundt explained that it shows "the quartiles of exposure in urine equivalents, and we see that . . . for all of the first three quartiles there's no indication of increased risk," "[b]ut in the fourth . . . there's roughly a doubling of risk that is statistically significant." Tr. 737. This "suggests that those employed in work areas unlikely to experience peak exposures were not at any increased risk of lung cancer," the Report reads. CX 1 at 80. Table 19 shows that smoking is not playing a role in the risk levels, and also indicates that "there's probably a contribution of cumulative and peak." CX 1 at 123; Tr. 758-59; *see also* Tr. 861. There are charts presenting the geometric means (raw and running average) of exposure for particular jobs in particular plants, e.g., Figure 7 shows the mean exposure for the Uerdingen plant's ADC/KDC production workers, who worked this job in one distinct location in the plant, and Figure 9 shows the mean exposure for Electricians, who "moved throughout the facility and performed different tasks in different work areas." CX 1 at 130, 132; Tr. 823-24. For the former, there are "very high spikes" in the mean, showing "clear and profound variability from year to year" of hexavalent chromium exposure, and for Electricians, there is a very weak and flat trend, showing that "throughout their work histories, [they] were not exposed to hexavalent chromium." CX 1 at 130, 132; Tr. 823-25. In Figure 18, showing air data for Crystal Packing at the Castle Hayne plant, the data go "up and down" and do not show a continuous decline over time. Tr. 834. Dr. Mundt explains: "That is why we look at these individual areas. They have **very different profiles of exposure**. That is what we need to capture when we estimate individuals working in crystal packing versus say shipping or kiln areas." *Id*. (emphasis added). Speaking generally about what the tables and figures show, Dr. Mundt states, "all of these analyses are kind of exploratory. They're not standard. They were really efforts to creatively use information to try to elucidate what the data are saying . . . ." Tr. 747; 753 (Table 17 is "let's say exploratory"). In the e-mail transmitting the Final Report to IHF, Dr. Mundt explained that in reaction to comments he received in Barcelona from colleagues regarding a possible threshold effect, he said he "eased up" on the threshold language in the Final Report, thereby "leav[ing] the interpretation more to the reader." RX 12 at 1.

The main criticism of the Final Report study, Dr. Mundt discussed, was the attempted "harmonization" of air and urine exposure measurements using a .77 conversion factor. Tr. 705-12. Ultimately, however, Applied concluded that "despite the limitations, the exposure data incorporated into our analysis of lung cancer risk may be among the best available today for risk estimation and risk assessment purposes." CX 1 at 96 (emphasis added). Dr. Mundt testified to the value in the data collected for the Final Report study in terms of what is added to the scientific base for hexavalent chromium risk assessment:

> JUDGE BIRO: And there was really no better raw data that could have been acquired in terms of a snapshot in time as to the effect of hex-c [Cr(VI)] on lung cancer?

> THE WITNESS [Dr. Mundt]: I would mostly agree, but the exception is if the U.K. plant had joined, it was large. It may have tipped us over the critical numbers if they were able to participate at the time. But I think short of that, they were – there were no other remedies.

Tr. 939. *See also* CX 74 (U.S. Results Paper) at 5 ("[t]he data obtained . . . represent a valuable resource for documenting control of Cr(VI) exposures, and for future investigations of potential health effects."); Tr. 871 (Dr. Mundt: "So it was in relative terms an improvement over what was known before or what was looked at before."); 879 (Dr. Mundt: "[B]ased on Table 2, you can see that there is a rich data resource[] not fully exploited. And what we had to do to try to correlate air and urine was just scratching the surface."); 919-22 (Dr. Mundt: the studies that will show a threshold to the dose response relationship "all require substantial numbers;" in the Final Report, there is not enough statistical power to demonstrate a threshold, but through the Final Report's SMR analysis, there is at least the suggestion of one (CX 1 at 92)). Dr. Mundt's testimony overwhelmingly demonstrates that the wealth of SRI in the Final Report is not only new and interesting, but also suggests that in terms of the dose-response relationship between Cr(VI) exposure and cancer, is not corroborative of a well-established effect.

b. Dr. Cooper

Concomitantly, Dr. Cooper testified that the exception laid out in the 1991 Reporting Guide for information "corroborative . . . of a **well-established** adverse effect," does not apply to the SRI in the Final Report because of the guidance stated immediately thereafter:

> 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 (emphasis in exhibit); Tr. 203-205. In this case, the newly-identified serious toxic effect is "lung cancer at lower dose levels." Tr. 204. According to Dr. Cooper, although it is well-founded that chromium causes lung cancer, it was "assumed that it causes cancer at all exposures," which assumption can only be based on "the available information." *Id.* The Final Report adds evidence of lung cancer at lower exposure levels "than . . . levels for which we had data in hand" before the report. *Id.* A majority of Dr. Cooper's testimony was in support of Complainant's long-duration, low-intensity argument, and will be discussed at more length below.

c. Dr. Clapp

At the hearing, Dr. Clapp, qualified as an expert in the fields of environmental and occupational epidemiology (JX 2; CX 89), described what "well-established" in his field means: "Multiple studies done by multiple investigators showing the same cause and effect relationship and in peer reviewed published literature, open literature," i.e., a generally accepted or validated

causal relationship.[20] Tr. 477.

Dr. Clapp was asked whether the Final Report corroborated the Gibb Study in terms of route of exposure, dose, species, time to onset, severity and strain, as listed in the 1991 Reporting Guide. CX 21 at 19; Tr. 478-482; JX 2. As to route of exposure, he confirmed that it was the same in both studies – primarily inhalation; regarding dose, he said the cumulative exposure levels presented differ, but "the trend is the same;" the species studied is obviously the same; the time to onset, or the "wait and see" between the initial exposure and lung cancer death, is different in each study; the severity of lung cancer and lung cancer mortality was the same; and strain was irrelevant. Tr. 478-482. Dr. Clapp concluded that the Final Report "does not just replicate a previous finding, it's new;" the Final Report "does provide new information about the dose response relationship between long-term low dose exposure to hexavalent chromium, and the subsequent development of lung cancer, and controlling for cigarettes or tobacco smoking experience." Tr. 296, 340; *see also* Tr. 335. When put to the question of whether it was possible for "one study to replicate another if those studies involve different data sets," Dr. Clapp answered, "No." Tr. 466.

d. Dr. Speizer

Dr. Speizer has contributed a great deal of work to the field of epidemiology. Tr. 493-500 (describing his retrospective study involving railroad yard workers' exposure to diesel and their risk of developing lung cancer; his prospective Nurses Study and the Harvard Six Cities Study); Tr. 501, 506-07 (describing his published work and review credentials); *see* CX 90 (Dr. Speizer's curriculum vitae). Asked about "association" in epidemiology, Dr. Speizer analogized to the history of the association of cigarette smoking and cancer risk:

> [I]n 1948, the first studies on smoking and lung cancer came out. And it was an association. And people challenged it up and down the line. And it wasn't until 1964 that the first publication of the Surgeon General's report that that association was accepted as being causal. **What made it causal was the repeated evidence obtained in many studies and by many of the investigators with a significant dose response relationship and dealing with a wide variety of potential confounders** that were seen in many of the studies.
> * * *
> It's the **accumulation of information on the associations**, the biological relevance of what those associations mean, and often but not necessarily all the

[20] Dr. Clapp's definition pithily expresses the essence of the scientific method by which knowledge is gathered, corroborated, and integrated through documenting and openly sharing methodology and data so that experimental studies may undergo scrutiny and repetition until the reliability of the cause and effect is definitively established. Under such method, duplication by others of the same or a similar study reaching the same result multiple times, is the means for verifying the reliability of the result and the absence of bias, error and chance. Such duplication is not pointless, but rather *the* point of the method. Tr. 1064-68.

> time, one essentially hopes for those response relationships. And if one sees one, that's added information.
>
> Because there's always the potential, particularly at low levels of risk of bias and confounding and just random noise, a random chance, **it is important in looking at those associations that there be some reproducibility of them in different settings.**

Tr. 511-13 (emphasis added). As to what constitutes "corroboration" in his field, Dr. Speizer explains:

> There are different outcomes that relate to the same exposure. And we have different exposures that relate to the outcome. . . . **It really is important that you actually have different investigators working on different populations. And that's not corroboration. That's *adding information* to the scientific base.**

Tr. 552 (emphasis added). Studies that show an association interpreted as causal, is not the same as corroborating the conclusion, Dr. Speizer testified. Tr. 553. Instead of accepting counsel's statement that studies can "build up to give you greater confidence," Dr. Speizer answered that they instead "[r]educe uncertainty." Tr. 556. Reducing uncertainty, or eliminating doubts, is a different concept than building up the same information, or corroboration. For cigarette smoking, "it took dozens, if not hundreds of studies in '49, '48 and in 1964 before the Surgeon General concluded that smoking causes lung cancer." Tr. 556.

The association between lung cancer mortality risk and exposure to hexavalent chromium "goes back at least 30 years," Dr. Speizer explained. Tr. 519-20. It was "pretty well settled" that hexavalent chromium "was a potent chemical," "[h]owever, 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 lower levels." Tr. 521-22. As you moved down the exposure level, Dr. Speizer continues, "the certainty about both the potency and the magnitude of risk are really equivalent in that sense – was essentially unknown I think." Tr. 522. "[I]t was hypothesized . . . but we didn't know . . . ." *Id*. The four plant study was designed to address weaknesses in the studies that preceded it, and ultimately it did confirm their "low risk at low levels" finding. Tr. 568-69.

Dr. Speizer described Applied's efforts to gather the immense longitudinal data on the workers in four plants, owned by three companies, in two countries, underlying the Final Report as "almost a herculean task," and that Dr. Mundt "performed very well." Tr. 1084-85. He disagrees that there's a problem with the .77 air to urine conversion factor - "it's the best we've got." Tr. 1085-86. To the strengths of the Final Report study, he stated:

> They knew the defects in previous studies. They constructed a population group which had adequate power overall to answer the question of whether there was an excess risk and whether there was a trend. And they went about finding the

> appropriate measures of exposure and using them to construct a cumulative exposure matrix and did appropriate analyses, giving due consideration to the population basis that they were working with.

Tr. 536-37. Dr. Speizer testified that the division of the results into two publications did not change his interpretation of the Final Report, but did find that with splitting the data, "the power to detect is just reduced." Tr. 1082-84.

Dr. Speizer did not find the quartile information to be particularly reliable; focusing on the quartile points is "throw[ing] away three quarters of the data." Tr. 565-66; *see also* Tr. 568 ("I'm focused on trend because that is the use of all of the data rather than individual points."). He testified:

> The Mundt study, I believe, adds to that information considerably because it is I still believe a significant dose response within the whole population. It adds another point in this area, where you put the point doesn't make any difference, but it gives us another degree of information in this region which I think reduces the uncertainty. And it probably only from a policy side helps OSHA to be able to move the standard from 50 to 5 [$\mu g/m^{3}$], a ten-fold increase in the standard and not suffer from continued involvement from industry saying you don't have enough data. It helps in that way, as well.

Tr. 1091. Further: "I think it's very important that one keep in mind that those are useful data." Tr. 1086. What Applied pulled together comprise "a very valuable resource of data which has the potential, if not already having accomplished a great deal, of adding important information to our understanding of the dose response - exposure response relationship between exposure to these chemicals and the outcome of lung cancer." Tr. 1085. As to whether the Final Report contains SRI, Dr. Speizer stated:

> I think it contains certainly additional information. It helps reduce the uncertainty about what we hypothesize as the linear dose response curve. It probably also offers EPA additional information which they could use to construct their lower risk estimates.
> * * *
> I think that, in fact, the information that was in the final report certainly provided a number, a set of numbers that were well below what was known before, **and provides information that increases the certainty about the hypothesis that the linear dose response curve continues at lower levels**. . . . [**A]s compared to Gibb it provides a different dimension of that effect** in the sense that Gibb is not biased, but certainly is influenced by the presence of the short-term workers as a . . . significant fraction of the population.

Tr. 1093-94, 1097 (emphasis added). Thus, Dr. Speizer's testimony wholeheartedly rejects the assertion that the Final Report "corroborated" what was already "well-established."

e. Dr. Gibb

At hearing, Dr. Gibb simultaneously celebrated the "information advantage" he had for his Study of the Baltimore plant and downplayed the advantages in the data presented in the Final Report. CX 97 at 129. When asked why EPA would fund a study in 2000 when it had known for decades that hexavalent chromium was a carcinogen, Dr. Gibb responded: "Because it could provide much more detailed exposure information than we had before." Tr. 1061. When asked again about his motivation, Dr. Gibb responded:

> The intent really was it was done for EPA. It was done so that we had – we, the EPA, had a better dose response analysis for hexavalent chromium. I mean, and we just had this **incredibly rich database to mull on, to move risk assessment forward, and to move the risk assessment on hexavalent chromium forward**.

Tr. 1068 (emphasis added). When it comes to his Study, he clearly recognizes the importance that raw data can provide in risk assessment. At the OSHA hearing in February 2005, during which he provided expert testimony for the hexavalent chromium PEL rulemaking, Dr. Gibb opined:

> I think when you are doing studies like this, I wouldn't want to denigrate anybody's study, because I think you work with what you have. I think that we had an advantage. I mean, we had an information advantage, I think that's true. That doesn't mean to say that other authors didn't do what they did well, but I think, I mean, I know we had an **information advantage** because we had **considerable exposure information, we had a larger workgroup, we had smoking information.**

CX 97 at 129 (emphasis added); *see also* Tr. 1071 ("people in this field would agree that the best study is my study, because of the size of the study, the follow-up, the number of lung cancer cases and that sort of thing"). So according to Dr. Gibb, "considerable exposure information" of "a larger workgroup," a long follow-up, the "number of lung cancer cases," and "smoking information" constitutes an "information advantage." *Id*.

As to whether the four plant Final Report added any valuable exposure information about the risk of hexavalent chromium, Dr. Gibb answered in the negative. Tr. 1061-62; 1057 (the Final Report information about substantial risk is "corroborative of existing information" and "adds nothing new"). He asserted that the same type of risk information can be inferred from other studies, such as his own, and listed the reasons why his Study was better than the four plant study. Tr. 1057-1059 ("in any one of my quartiles, there were more person years of observation than there were in the whole Mundt study for the German plants"; ". . . the data in my study, the results of my study are much more robust than the Mundt study"; "Mundt's follow-up wasn't as long as mine;" "I had five times as many lung cancer cases almost."). Ultimately, Dr. Gibb testified, "there's an issue of how good the data is . . . I mean it just speaks to how certain you are about the data." Tr. 1059. He explained:

> I looked at it as it was another study in a long line of studies that showed excess risk from hexavalent chromium. But in terms of what it would offer, for example in terms of dose response assessment, which is what, I think one would want to look at [ ], is that it offered nothing . . . . I mean I would have regarded this as part of maybe a second tier study, in terms, you know, what it could do with dose response assessment. . . . [I]t offered nothing new. [A]s exposure increased, the risk increased. I mean that wasn't anything new, and it also had urinary data, which would be difficult. . . . [T]here [were] limited air measurements. So it didn't offer anything that I thought would be . . . helpful to the risk assessment for chromium.
> * * *
> [T]here were no risks reported for the U.S. plants, for Corpus Christi and Castle Hayne. . . . [T]here was an excess risk in the German plants. When you look at the SMR, at the highest dose, there was an increased risk.
> * * *
> [A]nd then there was just a regression done, to look at the smoking, to see if smoking could have confounded the results, and found that it did not, that hexavalent chromium was still – still was associated with an increased risk. Again, not surprising.

Tr. 1041-43.

Dr. Gibb's assessment of which SRI in the Final Report is "corroborative," like Respondent's assessment, is based on an incorrect interpretation of what TSCA Section 8(e) requires. As explained above, the test for exemption is not whether the findings or interpretations of data "corroborate" merely what another study has found or what a particular research team ultimately concludes, but is instead whether the SRI, which is much broader, "corroborates" what is already "well-established."

Moreover, given the other statements in the record made by Dr. Gibb on this topic in other circumstances, his interpretation of "corroborative" proffered at the hearing of this case is surprising. For example, at the 2005 OSHA hearing Dr. Gibb stated as follows:

> I think one thing that is noteworthy is that the quantitative assessment from our study is remarkably similar to the quantitative assessment using the Mancuso data. It is also remarkably similar to the quantitative assessment using the Luippold data. What is incredible and as a risk assessor I spent considerable time doing risk assessment, three different studies showing remarkably similar quantitative estimates. **I mean, it is just very unusual. Especially with human data where there is a lot of concerns about follow up and so forth.** So that's rather remarkable.
> * * *
> **I think what is particularly strong about this database is that we have two other studies showing risks that are almost exactly the same, which is**

uncanny really in risk assessment.
* * *
Well, we had exposure information with Mancuso, but we didn't have airborne hexavalent chromium measurements, we had to estimate it. In the Luippold study, there wasn't smoking information. There was smoking information for maybe 1/3 of the cohort. My understanding is there were no data on the race of the workers. . . . So there are a variety of factors, little things that you wish you had the details but you don't. **Those things can make a fair amount of difference.** But still . . . I think if you talk to people in the risk assessment community and take three different epidemiology studies done by three **different people** of three **different cohorts** and then have **different people do the quantitative assessments** and they come out so close, it is pretty remarkable.

CX 97 at 106, 111-113 (emphasis added). In this testimony from 2005, Dr. Gibb touts the fact that the quantitative risk assessments in the Mancuso study, the Luippold study, and his study are so similar; in fact, he calls it "remarkable," and suggests it would be significant to those in the "risk assessment community" despite the differences in the data sets, regarding airborne measurements, dissimilar amounts of smoking information, unknown race factor, "little things" which "can make a fair amount of difference." *Id*. Yet at the hearing in this case in 2011, he characterized the same "uncanny" similarity between the Final Report and studies that preceded it, particularly his, as offering "nothing." Tr. 1046.

Dr. Gibb's viewpoint on risk assessment, as exhibited in the following exchange from the OSHA hearing, is also informative as to the meaning of "corroborative" in risk assessment, and adds doubt as to whether Dr. Gibb's present conclusion regarding the Final Report is consistent and reliable:

DR. GIBB: I think determining whether there is a risk depends on – you have to look over the range of studies, the range of information that you have. **You can't focus on one or two studies** and say well, this study says there is not a risk. You have to look over the range of information you've got and take it given the information that you know on other exposures. You have to make that determination.

DR. MARR: That is sort of a weight of evidence thing?

DR. GIBB: I think the weight of evidence is a risk assessor. The weight of evidence doesn't just pertain to – you are looking at hexavalent chromium. Is hexavalent chromium carcinogenic? That's the question here, okay? For that, you use the weight of the evidence. **You look at *all* of the studies**, and then you have to make a determination.

CX 97 at 148 (emphasis added). And as further exhibited in this proceeding:

JUDGE BIRO: I mean isn't the whole purpose of putting out your methodology in your research papers . . . so that someone can come along and not only evaluate your methods, but potentially reproduce your study . . . in order to see whether it changes the outcome?

THE WITNESS [Dr. Gibb]: As a way to reproduce the study?

JUDGE BIRO: Or test the credibility of your results?

THE WITNESS [Dr. Gibb]: Well I guess you look at consistency among studies, and so that's kind of a tenet of the evaluation. Is there a consistency among different studies, and of course 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. . . . [W]hat OSHA used in its rulemaking were [ ] my study, and then there was a second study, Luippold. . . . similar to the follow-up I had, but much smaller. . . . But it's interesting that the risks from the three studies were pretty similar, and so I mean that to me is kind of remarkable. But I don't know if that was serendipity or if we're just that consistent.

But they were three different groups essentially. Luippold and Mancuso were done at Painesville, Ohio. . . . But the Luippold plant used different exposure, and I think there was a different group . . . than what Mancuso had used.

So they were somewhat independent, and then there was my study, which is the largest study done to date.

JUDGE BIRO: Did your study, was it accepted by the industry as being [ ] conclusive, establishing the connection between hex-c [hexavalent chromium] and lung cancer?

THE WITNESS [Dr. Gibb]: Well, there were a lot of criticisms in the industry, and in the OSHA rulemaking there were [a] number of – because the industry had the data . . . I had given it to OSHA and . . . NIOSH. But there were, you know, maybe you could have done this differently, you could have done that differently or that sort of thing. But I think in the end –

JUDGE BIRO: So did they challenge your results, the accuracy of your results?

THE WITNESS [Dr. Gibb]: I'm not sure the accuracy. The interpretation perhaps, but generally I think that they challenged things like we should have used Baltimore City as the background. We used the state of Maryland, which was, I think, reasonable . . . .

* * *

They argued that maybe there was a threshold, [ ] but I don't know if they ever accepted it. But that is the – I mean it did become the basis of the OSHA.

Tr. 1064-68. The foregoing suggests that in fact Dr. Gibb's study did not definitely establish the linear or nonlinear dose response relationship between hexavalent chromium and cancer, and thus did not make all subsequent studies, including the Final Report, merely "corroborative" of a "well-established" effect.

Moreover, in an interesting comment given his criticism of the Final Report, Dr. Gibb describes the impetus for so much of the epidemiological inquiry that has been documented in this record:

JUDGE BIRO: . . . [I]f you establish hex-c [Cr(VI)] causes lung cancer, and you assume it's linear, the fight is going to be not whether we expose them to zero, because that's not going to happen, or your high threshold. The fight is in the middle ground, isn't it?

THE WITNESS [Dr. Gibb]: . . . I would agree. [ ]

JUDGE BIRO: So the whole issue is really what can we say about the data in the middle; isn't that correct?

* * *

THE WITNESS [Dr. Gibb]: Yes. I think it's between zero and where you first observed a significant risk, or maybe even a little bit below that.

Tr. 1072-73. Dr. Gibb was later asked which study showed lower risk within the "middle ground," and he answered that his own did: "It was like my lowest dose that was statistically significant was 20 times lower than the risk that was statistically significant in Mundt, et al., in the four plant study." Tr. 1075. This final critique would be meaningful if statistically significant information was the only SRI being compared between studies, but as has been established above, it is not.

f. Ms. Edens and OSHA

In the Final Rule establishing the new PEL for hexavalent chromium, OSHA concluded that the Final Report, the U.S. Results Paper and the German Results Paper provided at least more meaningful information, albeit not immediately useful information given the procedural posture of the Final Rule: "OSHA believes the elevated lung cancer mortality in these post-change workers are **further evidence** that occupational exposure to the less carcinogenic water-soluble Cr(VI) present a lung cancer risk." CX 76 at 101 (emphasis added). Ms. Edens explained at hearing that the Final Report "was giving us **additional information** that even in these **post change environments** one of the forms of hexavalent chromium which had been alleged to be less carcinogenic was actually showing a level of carcinogenicity that was of

concern." Tr. 1129-30 (emphasis added).

iv. Specifically Non-Exempt SRI in the Final Report

Specific examples of SRI in the Final Report that disqualify it from the exceptions listed in the guidance documents, and prove the Final Report is not "corroborative" of the Gibb Study SRI[21] in terms of dose, time to onset of effect, etc., include the following:

a. Modern Conditions

First, the Final Report presents a more accurate assessment of risk to workers in a modern chromate plant environment where low-lime and no-lime processes are utilized. At the start of their investigation, the team at Applied consulted previous studies of worker cohorts at plants in Castle Hayne, Corpus Christi, Leverkusen and Uerdingen.[22] CX 1 at 43. From these historical cohorts already assembled by previous researchers, the Final Report authors identified and extracted post-change employees, and added employees of those plants that had been hired since previous studied concluded. *Id*. Technicians at the plants worked with Applied to determine the dates that each plant's processes changed to reflect modern conditions, however, Dr. Mundt admitted that "there was always some doubt" about when the conversions were complete. Tr. 655-56; CX 1 at 43-44. Nevertheless, the Final Report claims that all 1,518 employees included in its combined cohort worked in plants using low- or no-lime chromium production processes. CX 1 at 15.

In comparison, evidence in the record shows that a substantial number of workers in the

[21] Respondent's affirmative defense is based on Dr. Barnhart's decision not to submit the Final Report because at the time he deemed it corroborative of the Gibb Study in particular. The inquiry in this decision therefore focuses on comparing the Final Report with the Gibb Study. Whether the Final Report "corroborates" the SRI of every other study is not detailed here.

[22] "All four plants had been studied previously, but each of these studies included employees exposed to high-lime processes," the Final Report explains. CX 1 at 86. The Castle Hayne workers previously studied include those who had worked at least one year between the time the plant opened as a low-lime process in September 1971 and December 1989. CX 1 at 38-39, 105. The Corpus Christi workers previously studied had worked at least one year after the date the plant came under new ownership in October 1979, even though the new owner of the plant did not finish converting the plant to a no-lime process until some point in 1980. CX 1 at 37-38, 105. The conversion of the German Leverkusen plant process to no-lime was probably completed sometime after the official completion date of January 1, 1958, though that was the date after which workers who worked for at least a year were studied in earlier reports. CX 1 at 33-34, 105. While the German Uerdingen plant's official date of conversion to a no-lime process was January 1, 1964, the Final Report authors assert that it was probably later; regardless, the cohort previously studied at that plant included workers who had worked for at least one year beginning on January 1, 1964. CX 1 at 35-36, 105.

Gibb Study cohort, who had initial hire dates at the Baltimore plant between 1950 and 1974 (CX 62 at 1), did not work under modern processing conditions. The Gibb Study investigated the Baltimore plant cohort that Hayes had used as the basis of his report published in 1979 (CX RX 24). CX 62 at 2. The Gibb Study authors removed from the Hayes cohort those workers who began work at the Baltimore plant before August 1, 1950, "because on that date, the construction of a new mill and roast and bichromate plant was completed and extensive exposure information began to be collected." *Id*. According to the Hayes study, the new "Mill and Roast and Bichromate Plant" was constructed during 1950-1951, but also, a new "Chromic Acid and Special Products Plant" was opened in 1960. RX 24 at 2. These new plants were "designed to improve process technique and environmental control of exposure to chromium bearing dusts." CX 1 at 30. Braver affirmed in 1985 that the new production facilities were built in 1950 and 1960 at the Baltimore site, but added, "the old facility continued to operate until 1960." CX 20 at 2. In the Hayes cohort used by Gibb and his team, 930 workers were hired between 1950-1959, and 157 of them worked in "Special products" *before* the new Chromic Acid and Special Products Plant was opened in 1960, and therefore cannot be said to have worked under exclusively modern conditions. RX 24 at 3. Elementis Chromium itself stated in its 2004 comments (prepared by Dr. Barnhart) to the OSHA rulemaking that "the general understanding in the industry was that except for a period in the early 1970's, the Baltimore plant operated with a feed mix to the roasting kilns having a ratio of lime to ore of about 0.5," which most people in the chromium chemicals production industry would refer to as "high-lime," and certainly not low-lime or no-lime. CX 95 at 8. In addition to the amount of lime used historically at the Baltimore plant, Dr. Barnhart stated that:

> There are other aspects of the exposures in the older chromate chemicals production facilities such as the Baltimore and Painesville plants that are specific to this type of facility. For example the high alkalinity of the dust produced from some of the processes. . . . In the older plants it was typical for this roast [containing residual lime] to be handled in several pieces of equipment . . . coolers, conveyors, and sometimes mills . . . to make it more suitable for leaching. Each of these was a potential source for very alkaline dust containing Cr(VI) and perhaps other oxidation states of chromium intermediate between Cr(III) and Cr(VI). In modern plants the roast is usually discharged from the kiln directly into a "quench" tank where it is immediately slurried with water greatly reducing the amount of dust formation.

Id. Because of the inclusion of the workers in the 1950s who must have been working in older facilities, the Gibb Study cannot be said to accurately reflect the post-change occupational experience of the chromate worker, at least not as accurately as the Final Report. For that reason, the two studies present distinct SRI, which cannot be claimed "corroborative" of "well-established" effects.

b. <u>Dose – Impact of Short-Term Workers</u>

Second, the Final Report excluded short-term workers, while the Gibb Study deliberately

included those workers. The Final Report explains:

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

CX 1 at 43 (Applied excluded workers who had less than one year total employment in the modern plants). The Gibb Study states: "It was also decided to include workers in the current study who worked less than 90 days . . . to expand the size of the low exposure group." CX 62 at 2; Tr. 1030-31 (Dr. Gibb: "I wanted to look at . . . the risk to people who are exposed less than 90 days") CX 1 at 30 ("the Gibb cohort included many very short-term employees; *over half worked less than six months, and 42% worked less than 90 days.*") (emphasis added). This choice was broadly criticized by most sources cited in this record, save OSHA. Tr. 142-43 (Dr. Cooper: "if somebody worked a day, they would be included . . . or a week or a month;" citing CX 62 at 6 (Table II), "50 percent of this cohort had worked for less than five months, a relatively short period of time"); 150-51 (Dr. Cooper: "So I wonder about the generalizability of the results from that situation to a situation of lower exposures at longer periods of time . . . that's the scenario that is of greater interest from the EPA's perspective . . . ."); CX 76 at 20 (OSHA's Final Rule) (despite its limitations, "[t]he Gibb study is one of the better cohort mortality studies of workers in the chromium production industry").

Dr. Speizer questions the biological relevance of an exposure assessment of short-term workers in the Gibb Study: "[I]t 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." Tr. 530-31; EPA Brief at 36. "I have some concern that what we're looking at is the effect of chance when we see those effects at very low levels." Tr. 531. Dr. Speizer credited the Gibb Study for adding "a degree of certainty about what's going" at relatively low levels of exposure, "[h]owever, the Gibbs data suffers in my mind from having to do deal with . . . a substantial number of people with very short-term exposure." Tr. 1090; 1096-97 ("*[A]s compared to Gibb, [the Final Report] provides a different dimension of that effect* [that the linear dose response curve continues at lower levels] in the sense that Gibb is not biased, but certainly is influenced by the presence of short-term workers as a . . . significant fraction of the population.") (emphasis added). Dr. Speizer explained further the difference this can make in the information produced in these two studies: "[I]f you look at the first exposure group of the Gibb study, which is probably made up of people who worked for less than five months, since 50 percent of the population worked for less than five months, 25 percent of them probably at least would fall in that first exposure category." Tr. 547. That group's SMR is close to 1, he stated, in other words, close to the risk of the residents of Baltimore. *Id*. Compare that to "the first category of the four plant study, where there's a little more flexibility in what the baseline population is[,] is substantially below one. They are different from the general population and they worked at least one year. So there are distinct reasons why one might see these kinds of differences and I would not have anticipated if you showed me." Tr. 547-48.

In the Critique performed by Exponent for the Chrome Coalition, it was concluded "[f]or several reasons," one being the "substantial" impact of short-term workers on the cohort, that the Gibb Study "likely underestimated Cr(VI) exposures." CX 65 at 4; CX 65 at 5 ("The analysis should be reevaluated without the data from short-term workers to determine their effect on the conclusions."). The Critique specifically found that "the appropriateness of extrapolating lifetime cumulative exposures . . . from relatively short duration exposures (e.g., 2 years), is highly questionable and *not generally considered an acceptable risk assessment practice*." CX 65 at 6 (emphasis added). Further, Exponent wrote:

> It would be far more appropriate to assess the risks of lung cancer based on a subset of these data, focused on the longer-term workers (e.g., those with at least 1 year of tenure) [like those in the Final Report], than to extrapolate the Gibb et al. findings to occupational standards designed to protect against exposures for an occupational lifetime. The findings at the lower dose levels are highly questionable and extrapolation of the risks due to short-term exposures to long-term cumulative exposures is not scientifically defensible.

CX 65 at 41. In sum, because of the influence of short-term workers on the results presented in the Gibb Study, and the lack of such influence on the Final Report data, the two studies ultimately present different risk information on dose and time to onset of effect, and they cannot be deemed "corroborative" of a "well-established" effect.

In what is necessarily a related issue, Complainant states that the main difference between the two papers is that the Final Report cohort worked under "long-term, low-intensity exposure conditions," and the Gibb Study cohort worked under "short-term, high-intensity exposure conditions." EPA Brief at 4. The testimony in support of this argument did not successfully quantify the difference in "intensity" or concentration, or otherwise factually support the "sense" that this was true. Tr. 235. Mr. Krasnic, in his capacity as the Agency's TSCA Section 8(e) Coordinator, determined that the Final Report "showed effects at the lower dose and therefore would not be considered to be corroborative." Tr. 37-38. When asked, "[a] lower dose than what?," Mr. Krasnic could not answer and explained that the program's technical experts had determined that figure. Tr. 40. When asked to explain the "low-intensity" argument, Dr. Cooper stated, "I gave my sense of the difference in exposure, and that was a sense that I took into consideration my perception of the pattern of exposures over time in both . . . the Gibb study and in the four plants." Tr. 235. When pressed, Dr. Cooper added, "I have a sense from my analysis that the exposure levels were higher. I'm going to say two to five times higher, or approximately three times higher, in the Gibb cohort compared to the four plant study." *Id*. Dr. Clapp relied on Complainant's Exhibit 98 to show "quite a difference in the magnitude of the concentration" between the two cohorts.[23] Tr. 314-15. However, it has already been established that

[23] Dr. Clapp also stated that the Final Report and the Gibb Study were "both post process change reports . . . of workers who were exposed to chromium-6 after a process change that was presumed to have reduced exposure." Tr. 315-16. He continued, "But the conditions under

(continued...)

Complainant's Exhibit 98 is not a credible source of information in this proceeding.

The Agency bases its argument mainly on the cumulative exposure calculation discussed at length at hearing: (Exposure Intensity or Concentration) x (Duration of Work Exposure) = Cumulative Exposure. EPA Brief at 4, 32; Tr. 143-45. While the cumulative exposure levels in both studies were comparable, according to Dr. Cooper (Tr. 177), the average duration of work for the Gibb Study cohort was 3.1 years (brought down by the presence of short-term workers), and for the Final Report cohort was 8-12 years (workers who worked less than one year were excluded). EPA Brief at 4, 11, 33; CX 1 at 113; CX 62 at 6. Complainant blithely concludes: "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." EPA Brief at 33. Respondent aggressively challenges this conclusion. Respondent's Brief at 15, 18, 30-46.

Since Complainant has decided not to explicate what the intensity levels are in the two studies, this Tribunal shall not undertake such inquiry either, and instead rejects Complainant's argument. It could still be true that the Final Report cohort was exposed to lower concentrations of hexavalent chromium over a longer period of time than the Gibb cohort, however it was not proven here. Nor does it need to be, given that Respondent carries the burden of proving that the Final Report SRI was corroborative of that in the Gibb Study, and the reasons why it did not succeed have been described. There are additional examples of SRI in the Final Report that further distinguish it from the Gibb Study besides the difference in plant conditions and the inclusion or exclusion of short-term workers.

c. Dose – Urinary Data

As a third example of the Final Report's distinct SRI, the raw data used in the study were comprised of urine and air samples; the Gibb Study had only air samples. CX 1 at 16; CX 62 at 3; CX 1 at 106 (showing over 12,000 urine samples in Final Report). The Final Report authors converted the air measures taken at the U.S. plants to urine equivalents. CX 1 at 16. There is significant evidence in the record indicating that urinalysis data provide a better measure of how much hexavalent chromium actually gets inside the body (dose). Dr. Mundt explains:

As was described by previous experts, the dose is the amount of material that's

---

[23](...continued)
which they were exposed must have been different, because the duration and the cumulative exposure were different." Tr. 315. And later, he stated, "[t]he average concentration in the Four Plant study must have been lower for the cumulative exposure to have been what it was, with longer duration of work." Tr. 468. His premise, that both studies were "post-change," has been discounted. Therefore, his finding that the conditions "must have been different" may be attributable to the inclusion of "pre-change" workers or short-term workers, but cannot alone support a finding that the Final Report reported "low-intensity" exposures.

> internalized and specifically reaches the target organ. And what's in the air is potential exposure. Once you breathe it in, what's measured by a device out here doesn't mean that's what's entered your body. Urine has to reflect what's been internalized. Now, there could be some from ingestion, there could be some from dermal absorption, but there's a strong general correlation with high exposure to or uptake of hexavalent chromium and urinary output of chromium in – chrome content in urine. So, it's telling you what amount has actually been in somebody's body rather than what's floating around in their work space. That's the difference between exposures, what's out here, and dose is what goes inside.

Tr. 710-11; *see also* Tr. 517-18 (Dr. Speizer: "We call them exposures because they are what is in the air in contrast to dose, which actually gets into the lung. And that's why we use those two different terms."); RX 13 at 7 (Barcelona presentation: "Urine concentrations better estimate of dose"). The Final Report was therefore able to more accurately present a picture of dose at least for the German plants, and did present this information in Figures 1, 2, and 6-13. CX 1 at 124, 125, 129-36. It is for this reason, Dr. Mundt states, that the studies cannot be compared "directly" (as evidenced by Dr. Barnhart's testimony as to the calculations he had to do upon receipt of the draft Final Report even to begin comparing the results with the Gibb Study). Tr. 869, 980-81. Ideally the same measurements would have been available in all plants, he said, "[b]ut because we had so many urines and they were done on such a regular basis for all employees since the beginning of the time period we're interested [in], it was quite good for estimating exposures." Tr. 675.

d. JEM Details

Fourth, the Final Report is distinguishable from the Gibb Study because it goes into great detail about how the JEM was constructed and why the authors made the choices they did. CX 1 at 59-64. For example, the authors describe how they built two types of JEMs for each plant, one for average exposure concentration and another for peak exposure index. CX 1 at 59. And they explain why:

> For example, two areas with identical average exposure concentrations may differ drastically . . . one area may have consistently moderate levels whereas the other may have generally low levels with occasional high-level periods (or peaks). To determine whether this occurs, and if so whether it is associated with risk, both measures can be applied and results compared.

Id. The Final Report describes that next, the authors determined which outliers were to be removed and which were "considered plausible," why they chose the geometric mean to rank exposure levels, how certain cells for exposure groups were collapsed, and in over 2 1/2 pages, how sparse and empty cells were stabilized for both JEMs for each plant. CX 1 at 59-64. No study in the record conducted prior to the Final Report provides such detailed information on what has been shown to be a critical part in occupational risk assessment studies. In the Gibb Study, approximately two paragraphs outline the construction of the JEM used. CX 62 at 4.

The JEM details constitute "information" about the substantial risk of lung cancer from exposure to hexavalent chromium. Dr. Speizer explained: "It's just the nature of the beast that we don't have data for all the years in terms of exposure." Tr. 517. "I would put more strength on how well the job exposure matrix is created and how people are in their years in those jobs," he asserted; "not having complete data on exposure that was occurring year to year is not so critical as not having the complete data on the duration of employment in a given job category." *Id*.

The Final Report itself speaks to the assumptions necessarily made when constructing JEMs across studies:

> Although our study did not find any excess of lung cancer among those with less than 200 μg/L-years - urinary chromium in the SMR analyses, substantial differences in risk by quantitative exposure level can be expected across studies, or within studies under different exposure assessment approaches. Because none of the recent studies presenting risk estimates by quantitative exposure categories had actual individual exposure measures, exposure was estimated based on job exposure matrices (JEMs). In the Luippold study, the JEM assimilated industrial hygiene data from 20 plant wide surveys describing over 800 airborne concentrations of speciated Cr(VI); for most years of the study period no industrial hygiene measurements were available. In the Gibb study, the JEM was based on approximately 70,000 area and personal air samples of chromium over the entire study period, however a large proportion of the employees had very short duration of employment. **Given the numerous assumptions necessary to construct individual exposure estimates, all of which are ultimately ecological averages (i.e., based on aggregate data from groups of individuals), differences in risk would be expected even if the underlying relationship between exposure and lung cancer risk were identical in each study.**

CX 1 at 94-95 (internal citations omitted) (emphasis added). The route or story of the workers' exposure, depending on where an employee worked in the plant and for how long, and the corresponding dose for that particular experience, is accounted for in the JEM. As the Final Report states, this is unique to the cohort studied. For that reason, the Final Report's lengthy discussion of its JEM details could potentially be very important to the field, particularly in modern plants. At the very least, it contributes additional information that the Gibb Study does not.

e. Adverse Effects - Smoking

Fifth, the Final Report presented risk information on effects on workers that more accurately accounted for their smoking history as a potential confounder. The Gibb Study did not have robust smoking information, as it admits:

> The availability of extensive smoking data is unusual for any occupational study.

> The measure of smoking in the current study was yes/no at the time of beginning employment. Such a measure does not provide information on the amount smoked or the number of individuals who smoked at time of employment and who subsequently quit or the number of nonsmokers who became smokers.

CX 62 at 11. About the Gibb Study, the Exponent Critique determined:

> The authors present smoking-adjusted risk estimates from the Cox regression models; however, the authors did not control for smoking in the standardized mortality ratio (SMR) analysis, and the results could be substantially biased.
> * * *
> The SMRs, which are typically used for cancer risk assessment, were not adjusted for smoking. The utility of these data for cancer risk assessment would be substantially improved if the SMRs were adjusted for smoking.

CX 65 at 5-6. The Final Report, on the other hand, was able to factor in substantially more smoking data:

> Smoking status information was available for approximately 90% of employees hired after 1957 at Leverkusen and nearly all employees hired after 1963 at Uerdingen. . . . [I]nformation collected included smoking status, age began smoking, number of cigarettes or cigars smoked per day, grams of pipe tobacco smoked per week and the year the employee quit smoking. . . . Each study subject's medical record was checked to verify this information as well as obtain smoking information for study subjects who were hired since the end of the previous study.
>
> For the Corpus Christi plant, data on smoking habits were obtained from a questionnaire sent in 1993 to current and former employees, of whom 202 (of 351 total) responded . . . . Additional smoking information was provided from plant personnel who conducted pulmonary function and audiometry screenings.
> * * *
> For the Castle Hayne plant, data on smoking habits were obtained in 1989 . . . from a self-administered questionnaire for active and most former employees, or a telephone interview . . . . Of 381 total cohort members, 289 responded. . . . [C]ompany medical records provided smoking information for employees hired since conclusion of the first study.

CX 2 at 51-52. The relatively substantial amount of smoking data was incorporated into several analyses and presented in the Final Report, e.g, in Tables 18 and 19. CX 1 at 122-23; Tr. 863-864.

f. Conclusion

In conclusion, Respondent's view of TSCA Section 8(e) and the issued guidance is at odds with the plain language of the statute, the intent of Congress, and the nature of occupational epidemiology and risk assessment, as the testimony, record and analysis thereof makes clear. The SRI in the Final Report includes much more than the statistically significant risk finding at the highest exposures. And when the Final Report is compared to the Gibb Study, there are multiple and significant distinctions in the SRI presented. Respondent's argument that these differences are "irrelevant" because only "cumulative total exposure . . . is relevant in assessing risk," has not been supported by a preponderance of evidence in the record. While Respondent is correct that the evidence shows that cumulative exposure is the preferable way to assess risk associated with occupational exposure to chromium, TSCA Section 8(e) was not written so narrowly as to exclude SRI from the reporting mandate if it did not analyze data in terms of cumulative exposure. *See*, *e.g.*, Tr. 431 (Dr. Clapp); 524 (Dr. Speizer).

Next, while the carcinogenicity of hexavalent chromium had been well-established in high-lime production environments by 2002, the record shows that the effect under the conditions at the four plants studied by Applied, which have been established as different than the Baltimore plant conditions (as even Elementis argued in 2004 (CX 95 at 7-8)), had not. Instead, the association of risk at that time (and perhaps still) lay somewhere "between zero and where you first observed a significant risk" in prior studies. Tr. 1072-73 (Dr. Gibb). Of the many studies of the association of hexavalent chromium and lung cancer conducted over the years, many are endeavors to follow-up and re-analyze the same cohort and the same exposures that had been studied before, sometimes many times before. The Gibb Study is no exception, yet it was the basis for OSHA's 2006 PEL. As Dr. Gibb pointed out in 2005 at the OSHA hearing, studies with meaningful differences can have remarkably similar risk findings. CX 97 at 106, 111-113. If "well-established" means having "[m]ultiple studies done by multiple investigators showing the same cause and effect relationship" (Dr. Clapp, Tr. 477), and that something can be deemed "causal" when "the repeated evidence obtained in many studies and by many of the investigators with a significant dose response relationship and dealing with a wide variety of potential confounders" and is "[an] accumulation of information on the associations" (Dr. Speizer, Tr. 511-13), then the effect documented so painstakingly in the Final Report was not well-established. Plainly, the fact that in 2002 OSHA was still seeking from the interested public relevant studies and evaluating whether a nonlinear (threshold) or a linear dose response relationship existed in order to establish an new PEL for hexavalent chromium shows that the full range of the dose-response relationship between hexavalent chromium and cancer in post-change plants was clearly not "well-established." The record here shows that the Final Report was not exempt from the TSCA Section 8(e) reporting requirement by way of any of the Agency's guidance documents.

Respondent has not sustained its burden of proving by a preponderance of the evidence that it had "actual knowledge that the Administrator has been adequately informed of [the] information" in the Final Report, at the time it was required to "immediately inform the Administrator of such information" under TSCA Section 8(e), 15 U.S.C. § 2607(e). Respondent's violation of Section 8(e) constitutes a violation of Section 15(3)(B) of TSCA, which states that it is unlawful to fail to submit reports or information as required under the Act,

15 U.S.C. § 2614(3)(B). Respondent is therefore liable for a civil penalty under TSCA Section 16(a), 15 U.S.C. § 2615(a).

VI. PENALTY

Complainant seeks the imposition of a civil penalty in the amount of $2,338,000. EPA Brief at 45. Respondent maintains that if a penalty is assessed, it should be nominal.[24] Respondent's Brief at 50. The Rules of Practice provide that Complainant "has the burdens of presentation and persuasion . . . that the relief sought is appropriate." 40 C.F.R. § 22.24; *New Waterbury, Ltd.*, TSCA Appeal No. 93-2, 5 E.A.D. 529, 536-38 (EAB 1994) (Remand Order). The factors to be considered in determining an appropriate civil penalty are: "the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, 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). The Rules of Practice require the undersigned to "consider any civil penalty guidelines issued under the Act" and to "explain in detail in the initial decision how the penalty to be assessed corresponds to any penalty criteria set forth in the Act." 40 C.F.R. § 22.27(b). Further, if a penalty is imposed that is greater or lesser than Complainant proposed, the specific reasons for doing so shall be set forth by the undersigned. *Id*.

In 1980, the Agency issued "Guidelines for the Assessment of Civil Penalties Under Section 16 of the Toxic Substances Control Act; PCB Penalty Policy" ("1980 Guidelines"). CX 102. The 1980 Guidelines set forth "a general penalty assessment policy which will be supplemented by regulation-specific penalty assessment guidance." CX 102 at 2. Penalty guidance is issued by the Agency "to assure that TSCA civil penalties be 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." *Id*.; Tr. 596. Penalties are calculated in two stages according to the 1980 Guidelines. CX 102 at 2. First, a "gravity based penalty" ("GBP") is determined using a matrix based on the "nature" of the violation, the "extent" of environmental harm that could result from a given violation, and the "circumstances" of the violation. *Id*. Second, upward or downward adjustments are made to the GBP based on culpability, history of such violations, ability to pay, ability to continue in business, and such other matters as justice may require. *Id*.

In 1999, EPA issued a revised "Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12, and 13" ("ERP"). CX 103. The ERP provides specific guidance on calculating penalties for reporting violations, including Section 8(e) violations. CX 103 at 4.

---

[24] In its Initial Pre-Hearing Exchange (page 14), Respondent states that no penalty is appropriate, but that if a penalty is imposed "it should be nominal and in no case should exceed $50,000."

A. Gravity-Based Penalty

i. Nature

The ERP governing Section 8 violations flatly states that "[t]he 'nature' of all record keeping and reporting violations discussed in this policy is 'hazard assessment'" or "'hazard/risk assessment.'" CX 103 at 8, 21; Tr. 597. "Hazard assessment" requirements under TSCA "are 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." CX 102 at 3; Tr. 593-94. Specific to TSCA Section 8, the ERP states, "data gathering often occurs at the early stages of regulatory decision making," therefore, "complete and accurate information is essential." CX 103 at 21. Further, the ERP provides:

> Incomplete and inaccurate information will have far-reaching effects on the Agency's risk assessment, regulatory priority setting, and regulation development processes. Some information such as TSCA § 8(e) information may affect the Agency's ability to initiate immediate action necessary to protect health and the environment, e.g., seeking injunctive relief.

Id.

Complainant's proposal is in line with this guidance, as it argues that when information is not timely submitted to the Agency for risk evaluation, its "ability to initiate immediate action necessary to protect human health and the environment is affected." EPA Brief at 48 (citing CX 103 at 18). Dr. Cooper testified at length about the importance of epidemiological studies to the Agency's work. Tr. 84 ("What they want to see is an accumulation of evidence."); 96 ("it is a primary component in . . . the human health risk assessments that are conducted by the Agency"); 97 (the studies with "that kind of detailed exposure information that you need for . . . quantitative analysis" are few and far between). At the EPA's National Center for Environmental Assessment ("Center"), Dr. Cooper explained, hazard identification is one of the first steps in its comprehensive reviews of chemical risks. Tr. 104-105. Hazard identification is a "systematic evaluation of the available studies" during which the team at the Center "comprehensively evaluate[s] that weight of evidence pertaining to specific kinds of effects; for example, cancer." Tr. 105. The second major component of the Center's assessment work is reviewing dose response information. *Id*. The epidemiologists look for "the shape of the exposure response curve . . . the magnitude, the steepness of the relationship that is being observed." *Id*. Measures of the potency of a chemical are "essential to the work of EPA," and would be included in the Agency's Integrated Risk Information System comprehensive reviews. Tr. 114; *see* CX 53. EPA is particularly interested in "lifetime exposures to . . . relatively low levels of exposure" and the "chronic risks associated with that type of exposure." Tr. 153. The Agency's 1991 Reporting Guide describes the provision as "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.

The record substantially supports Complainant's determination that the "nature" of the present violation is "hazard assessment," and Respondent does not challenge Complainant's determination on this point. Therefore, Complainant's determination as to the nature of the violation is hereby found appropriate.

ii. Extent

"Extent" takes into consideration "the degree, range, or scope of the violation" and "reflects the extent of potential harm caused by a violation." CX 102 at 3; CX 103 at 14; Tr. 594. The 1980 Guidelines provide that for violations of requirements designed to facilitate hazard assessment, the "extent" determination "will focus on the goals of the given hazard assessment regulation, and the types of harm it is designed to prevent." CX 102 at 4. For reporting rules, "harm is defined as the inability of the Agency to carry out its risk assessment responsibilities under TSCA." CX 103 at 14. There are three extent levels: Major, Significant, and Minor. *Id*. at 14-15. A "Major" extent level is applied under the ERP to TSCA Section 8(e) violations that involve human data. *Id*. at 14. "Major" violations also include Section 8(e) violations "which directly interfere with the Agency's ability to address situations involving potential imminent hazard, unreasonable risks, or substantial endangerment to health or the environment," and those involving information on emergency incidents of environmental contamination. *Id*.

The "extent" of Respondent's violation, Complainant argues, is "Major," because human health effects data are involved. EPA Brief at 50-51; CX 103 at 14, 26. Animal or aquatic studies would be labeled Significant, Mr. Ellis compared, but not reporting human health data "is the highest level of serious harm." Tr. 599.

Respondent argues that the penalty determination must take into consideration the fact that the Agency has taken no action as a result of obtaining the risk information in the Final Report. Respondent's Brief at 48 ("even if reportable, the information is of so little consequence that not a single regulatory action has resulted or is contemplated based on information in the [Final Report]"); 49 ("Dr. Cooper . . . testified that EPA has not updated its risk information on hexavalent chromium since it received the [Final Report]" (citing Tr. 259). Nor did OSHA, Respondent argues. Respondent's Brief at 49.[25] Dr. Edens of OSHA admitted that the Final Report did not influence the agency's determination on the hexavalent chromium PEL.

> Q [Respondent's Counsel]: And, ultimately, they didn't change the decision the agency was making about where it was going to set the PEL. Correct?

[25] Respondent cites OSHA's Final Rule preamble which states that "quantitative analysis of the [Final Report] would not provide any additional information on risk from low level exposures to hexavalent chromium." Respondent's Brief at 49. However, the language Respondent is relying on in the preamble is not referring to the Final Report, but instead to the bifurcated papers that were published subsequently. CX 76 at 81.

> A [Dr. Edens]: We didn't evaluate them to make that determination. We looked at technologic and economic feasibility. That was the driver. We didn't do an analysis of the Four Plant Study in the detail the way that we did the Gibb Study. We simply didn't do it. I can't say we made that conclusion because we didn't do the analysis.

Tr. 1142-43; *see also* 1149.

Respondent's assertions do not persuade the undersigned to assign this violation a lesser "extent" level. The 1980 Guidelines clearly state 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." CX 102 at 4; EPA Brief at 49-50. Mr. Ellis explained that the "extent" is "not based on actual [harm]," but "potential harm." Tr. 622-23. Dr. Gibb pointed out that if the Final Report had been published in the Journal of Occupational and Environmental Medicine as the U.S. Results Paper and German Results Paper were, EPA would have likely been able to review SRI that way. Tr. 1063. Ms. Edens testified that early in the PEL rulemaking for hexavalent chromium, she and her colleagues at OSHA "were very aggressively trying to get Dr. Gibb's data unsuccessfully until it was actually published. . . . [W]e didn't have access to it until he actually published the study." Tr. 1159. Typically, Ms. Edens explained, when OSHA takes on a rulemaking such as the hexavalent chromium PEL determination, "we would sort of look at the IRIS database, whatever data they have in there to see if they'd done something." *Id*. Obviously, the Final Report was not in the IRIS database at the time OSHA conducted the PEL rulemaking, although arguably it should have been, maybe even in draft form, by early 2002.

Complainant asserts that its proposed penalty already "takes a conservative approach" by assuming the violation did not disrupt the Agency's ability to address an imminent hazard. EPA Brief at 50. As Mr. Ellis testified, the program office did make a determination that ultimately, there was no disruption. Tr. 624. If the Agency had determined that its ability to act on the data was impeded, it could have sought "a per day penalty or the $62 million approach."[26] Tr. 624;

---

[26] The two approaches are described in the ERP as follows:

> 1) TSCA 8(c), 8(d), 8(e) when there is OPPTS written determination that the violation disrupts the Agency's ability to address situations which involve Potential Imminent Hazard/Substantial Endangerment Situations/Unreasonable Risks
>
> Base Penalty x # of days in violation = Penalty
>
> 2) TSCA 8(e)
>
> Base Penalty + $\frac{(\text{\# of days in violation} - 1) \times \text{base penalty}}{30}$ = Penalty

(continued...)

EPA Reply at 14.

In sum, it is found that the evidence supports the Agency's classification of the extent level as "Major."

iii. Circumstances

The "circumstances" factor represents "the probability of the assigned level of 'extent' of harm actually occurring." CX 102 at 4. A "variety of facts surrounding the violation as it occurred" should be examined to determine whether there is a high, medium, or low probability that damage will occur. *Id*. "High" means that the violation is likely to cause damage; "medium" means there is a significant chance that damage will result from the violation; "low" means that there is a small likelihood that damage will result. *Id*. For reporting requirements, the ERP provides, "the potential harm is to the Agency's ability to assess hazard/risk to human health and the environment." CX 103 at 21. High range violations can be Level 1 or 2; medium or mid-range violations can be Level 3 or 4; and low range violations can be Level 5 or 6. CX 103 at 22-25; CX 102 at 4. Per the ERP, the Agency has determined that all Section 8(e) violations are "Level 1" violations.

> Failure 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.

Complainant supports the assignment of the present violation as a Level 1 in "circumstances" because "[w]hen 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." EPA Brief at 49; CX 103 at 22; *see also* Tr. 597-98. As Dr. Cooper explains, "[r]elatively few" occupational studies "provide that kind of detailed exposure information that you need for [the] quantitative analysis" that is important for evaluating risk. Tr. 96-97. "What they want to see is an accumulation of evidence," Dr. Cooper explains. Tr. 84. Further, "[t]he second, the third and the fourth paper on a particular topic are just as important as the first because it allows the science, the field, to develop and either solidify around the initial findings or those initial findings might be modified by subsequent research." *Id*. Complainant stresses the 1980 Guidelines' provision that the probability of harm at issue in a "circumstances" assessment "will

---

[26](...continued)
CX 103 at 15-16.

always be based on the risk inherent in the violation *as it was committed*." CX 102 at 4; *see* EPA Brief at 48. Further, Respondent does not directly challenge Complainant's assignment of Level 1 in "circumstances." I find that the record supports Complainant's characterization of Respondent's violation as such.

iv. Dates of Violation

Although arguably Respondent was obliged under Section 8(e) to submit to EPA the draft of the Final Report, which it received in the early months of 2002, the parties have stipulated that for the purposes of this action Respondent is deemed to have obtained the reportable information in the Final Report on October 8, 2002, some 7-10 months later. JX 1 ¶¶ 17-18; CX 21 at 18; CX 17 at 3. Complainant extended the start date of the violation further, to October 29, 2002, providing Respondent with a grace period of fifteen working days after receipt of the (finalized) Final Report, pursuant to the 1978 Guidance. EPA Brief at 51; CX 17 at 2; Tr. 602. Because the parties also stipulate that Respondent responded to the Agency subpoena on November 17, 2008 (JX 1 ¶ 20), the last day of the violation was November 16, 2008. EPA Brief at 53. Thus, Complainant has calculated the period of violation as totaling just over six years at 2,211 days. Tr. 601; EPA Brief at 53. Respondent does not challenge this calculation.

v. Gravity-Based Penalty (GBP)

Using the ERP's Penalty Matrix for Violations Occurring After January 30, 1997, for violations qualifying as Major in "extent" and Level I in "circumstances," Complainant calculated the GBP as follows:

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

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

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

$$\frac{(1708) \times 32{,}500}{30} = \mathbf{\$1{,}850{,}333}$$

EPA Brief at 53; CX 103 at 11, 15-16. Added together, the GBP totals $2,338,000. *Id*.

B. Adjustments to the GBP

i. Culpability

The GBP may be increased, decreased, or stay the same based on a violator's culpability, or "blameworthiness." CX 102 at 5. The criteria for measuring culpability are: "(a) the violator's *knowledge* of the particular TSCA requirement, and (b) the degree of the violator's

control over the violative condition." *Id*. (emphasis in original). The test for the first prong, knowledge, "will be whether the violator knew or should have known of the relevant TSCA requirements *or* of the general hazardousness of his actions." *Id*. (emphasis in original). Under the second criterion, a lack of control, e.g., if an employee disobeyed the employer-respondent in order to commit the violative conduct, may warrant a reduction in the penalty. *Id*. Level I in culpability is assigned to "willful" violations, i.e., when "the violator intentionally committed an act which he knew would be a violation or would be hazardous to human health or the environment;" this level warrants a 25% penalty increase. *Id*. Level II means the violator "either had sufficient knowledge to recognize the hazard created by his conduct, or significant control over the situation to avoid committing the violation;" this level warrants no adjustment. *Id*. Level III would be assigned if violator "lacked sufficient knowledge of the potential hazard created by his conduct, and also lacked control over the situation to prevent occurrence of the violation;" this level warrants a 25% penalty reduction. *Id*.

The 1980 Guidelines include "attitude" as a sub-factor of culpability. CX 102 at 5. For attitude, the Agency should consider any good faith efforts of the violator to comply, the promptness of the violator's corrective actions, and any assistance given to EPA to minimize harm caused by the violation. *Id*.; CX 103 at 19. "Attitude" is already reflected in Level I culpability, the Guidelines state, and it is irrelevant to Level III culpability. CX 102 at 5. While Level II culpability "normally yields no reduction or increase in penalty, the attitude of the violator may justify a penalty adjustment of up to 15% of the GBP in either direction." *Id*.; CX 103 at 19. The ERP provides: "An upward adjustment of a maximum of 15% may be justified where company officials continue the violative activity after being notified to stop, do not act in good faith, hinder EPA's progress, cause increased government expenditures, or are otherwise uncooperative." CX 103 at 19.

Complainant finds that Respondent was fully responsible for the violation's occurrence. EPA Brief at 54-55. Although Dr. Barnhart testified that he wasn't sure if he had "ever read 8(e) or the guidance," he admitted 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. 991; EPA Brief at 54. Dr. Barnhart's interpretation of TSCA Section 8(e) is wrong, Complainant states, and does not justify a reduction in the penalty. EPA Brief at 54 n.18. Complainant argues that Respondent and Dr. Barnhart, in his capacity as a "long-time senior manager" at Elementis Chromium, knew the chromium compounds at issue were highly carcinogenic. EPA Brief at 54. The fact that Respondent complied with a subpoena to submit the Final Report to EPA does not exhibit "good faith" warranting a reduction. EPA Brief at 55. Respondent argues that "the failure to report was clearly made in a good-faith belief that the information was only corroborative and not new." Respondent's Brief at 48. Respondent further argues that "there was no evidence presented indicating Elementis intended to hide the Final Four Plant Report from EPA or anyone else;" in fact Dr. Barnhart was aware that Dr. Mundt would be presenting the results at the Barcelona conference to a wide audience of professionals in the epidemiology field. Respondent's Brief at 49 (citing Dr. Mundt's testimony at Tr. 703-06; and Dr. Barnhart's testimony at Tr. 986-87). In its Reply Brief, Complainant argues that since Dr. Barnhart testified he's not sure he ever read

TSCA Section 8(e) or its guidance, he cannot claim that he made a good faith judgment about what was required under the law. EPA Reply at 15-16; Tr. 990-91.

Complainant states that it *did* consider whether it had any evidence of Respondent hiding the Final Report from the regulators, and if there had been any such evidence, the penalty could have been increased by 25% for culpability as a Level 1 violation; however, Complainant allegedly found no evidence upon which to make such an adjustment. EPA Reply at 16; CX 102 at 5. Despite Complainant's finding on this point, multiple documents in the record and the lengthy factual background set forth above demonstrate exactly the opposite: that Respondent, and Dr. Barnhart as an agent of Respondent, acted in bad faith by not timely submitting the Final Report to OSHA and EPA, particularly when they knew the government was looking for more data, and when they were actively, roundly criticizing the database upon which the government was promulgating a new PEL in an effort to alter, delay or derail the regulatory process.

Even though Complainant has not sought an upward adjustment to the GBP for Respondent's "attitude," the undersigned may increase the penalty as long as the "specific reasons" for doing so are set forth. 40 C.F.R. § 22.27(b). The evidence supporting the determination must be "objective," "such as statements or actions in support of any alleged 'bad attitude' on the part of Respondent." *Cotter Corp., Schwartzwalder Uranium Mine*, EPA Docket No. PCB-81-004, slip op. at 44 (ALJ, Mar. 21, 1984), *aff'd, Cotter Corp. (Schwartzwalder Uranium Mine)*, 2 E.A.D. 10 (EAB 1985); CX 102 at 5.

Evidence as to the motives and activities of the IHF Committees and the Chrome Coalition leading up to the completion of the Final Report has been cited at length above (*see* Factual Background). Examples of Respondent, and Dr. Barnhart as Respondent's agent, acting in bad faith are found within that context, some of which will be set forth again as necessary below.

Since 1982, Dr. Barnhart worked for Elementis Chromium (formerly AC&C), and from 1986 through 2007, Dr. Barnhart served as Chairman of the Chrome Coalition. RX 8[27]; CX 71. Under his governance, the Coalition invited consultants to offer proposals on helping the Coalition "review and critique all the . . . relevant epidemiology studies, adding weight to the effort of convincing OSHA not to go forward with what they presently have" and "insure that there would be enough in the docket to mount a significant legal challenge." CX 27 at 2 (PEL Committee meeting minutes, February 13, 1996). A 1996 memorandum to the Coalition's PEL Committee, which appears to have been written by Dr. Barnhart (*see supra*, n.9), sets forth a candid summary of the Coalition's intent regarding OSHA's efforts at the time concerning

[27] Dr. Barnhart's curriculum vitae states that he has worked for "Elementis Chromium (American Chrome & Chemicals)" from 1982 – Present. RX 8; *see also* 945-46. Dr. Barnhart clarified at the hearing that the same parent company has changed names over the years (American Chrome & Chemicals, Harrison and Crossfield (Harcros Chemical Group) (Dr. Barnhart's employer is cited as AC&C and Harcros at different times during the mid- to late-90's; *see* CX 27, 30-32, 34, 37-39, 47)). Tr. 942-43.

hexavalent chromium:

> The driving force for current OSHA regulatory efforts concerning hexavalent chromium . . . is the Mancuso study of workers at the Painesville, Ohio, chromium chemicals plant. Although there are many deficiencies in this work, it has been widely accepted . . . . [I]t would take a major effort with better data to successfully challenge it.
>
> For the past several years we have expected that the study being conducted at Johns Hopkins University [the Gibb Study] . . . would significantly clarify the relationship between exposure to hexavalent chromium and lung cancer. It was hoped that it would provide a better database than Mancuso. This study was commissioned by EPA and we know that OSHA is planning to use the findings in this study as the basis for setting a new [PEL].
>
> We now know that the analysis of this study is much more complicated than originally anticipated since there was limited manipulation of the data. We are concerned about how OSHA will interpret this information. Unless a more complete review of the Johns Hopkins study is conducted we believe that OSHA will maintain their position, that the Chromium PEL should be lowered in the 0.5 to 1.0 ug/m^3 range. The main health concern is the impact of hexavalent chromium on lung cancer.
>
> The Chrome Coalition felt that it was necessary to contract with a well regarded consultant . . . to review all of the information that OSHA might use, determine the limitations and organize and develop a proper scientific basis (model) for predicting the impact of hexavalent chromium on lung cancer in the workplace. Although this route is expensive and success is not guaranteed, the longer we wait the more difficult the task becomes.

CX 28 at 1-2. The Coalition's motives were also summarized bluntly in an OxyChem internal memorandum dated April 4, 1996: "It is the intention of the Chrome Coalition to refute/influence OSHA's decision making. Should the final PEL be as low as OSHA would like, the Chrome industry, both producers and users, will suffer severely and similarly to what is happening with cadmium." CX 29.

Moreover, the Coalition remained well-informed about OSHA's explicit requests for comments and/or information for the PEL rulemaking. *See, e.g.,* CX 30 at 2. The IHF Management Committee and the Environmental Subcommittee discussed how one Coalition member is "conceptualizing and developing an 'industry friendly' standard for Cr^{+6}," "which will hopefully provide a starting point for rebuttal once the proposed standard is published." CX 30 at 2; CX 31 at 3. "Also supporting the Coalition's pro active [sic] stance is development of an advocacy mechanism which will focus on identifying and lobbying appropriate Administration principles when OSHA sends the proposed standard to the OMB." CX 30 at 3. On March 17,

1997, the Chairman of the Management Committee faxed members of the Chromium Chemicals Committee, including Dr. Barnhart, a list of key objectives for the Committee, which included:

> Epidimiology [sic]
>
> Provide convincing evidence to regulatory authorities that chrome chemicals plants operated to current standards do not give rise to excess cancer risk.
>
> A multi company co-ordinated [sic] epidemiological study update using the same protocol and cut off date would seem to be the best way to achieve this.
>
> Hexavalent Chrome Regulation
>
> Achieve a revised standard in US/EC that can be met by current modern facilities without major additional investment. A level of 0.025 mg/m^3 as chromium would be considered an acceptable outcome.

CX 32 at 3.

Dr. Barnhart was instrumental in initiating the four plant study, was Respondent's and IHF's point person on the study and the activities of the Coalition, monitored Applied's progress, and stayed in touch with Dr. Mundt throughout the process. *See, e.g.,* Tr. 965-66; CX 31 at 5 (Dr. Mundt invited to Management Committee meeting as guest/contractor of AC&C); CX 47 at 3 (Dr. Barnhart appointed to steering committee for Applied study); CX 49 (May 22, 1998 Agreement signed by Dr. Barnhart for Elementis Chromium LP and by Dr. Mundt for Applied); CX 50, 63 (Applied invoices sent to Dr. Barnhart); CX 56 (Dr. Barnhart refers to February 1999 conversation with Dr. Mundt).

Dr. Barnhart even communicated with OSHA representatives about their intentions. CX 38 at 2. From the minutes of an Environmental Committee meeting on October 23, 1997:

> The Chrome Coalition is continuing a dialogue with OSHA and is planning to meet with them in November. Dr. Barnhart and Ms. Jackson met with them approximately three weeks ago . . . . As events unfold, Dr. Barnhart will continue to apprise the subcommittee of the status.

Id. Dr. Barnhart also kept the Committee apprised of EPA's activities related to chromium:

> Dr. Barnhart said that the U.S. EPA is developing a revised reference dose (RfD) and reference concentration (RfC) for both Cr^{+3} and Cr^{+6}. . . . This past summer EPA contracted . . . to develop these for the IRIS database. . . . Dr. Barnhart further explained that, although these values are not regulations, certain states do base their hazardous waste clean-up regulations on these values.

Id. at 2-3.

Dr. Barnhart recognized the potential impact that OSHA's PEL could have on EPA's regulatory actions; at an Epidemiology Committee meeting in October 1997, "Dr. Barnhart presented an overhead which listed the EPA-recognized carcinogens by inhalation which was published in 1990. He showed how these were adjusted following OSHA's issuance of new PELs for certain compounds." CX 39 at 3-4.

In November 1997, Dr. Barnhart wrote a memorandum to the Chromium Chemicals Committee about a meeting between the Coalition and OSHA representatives on PEL developments. CX 41. He concluded that their discussions presented "several possibilities for us to influence the proposed rule." CX 41 at 2. First, if OSHA is going to do a "quick analysis" of the Gibb Study data "and call it the definitive study," Dr. Barnhart writes, "we certainly should make an effort to be involved and consider announcing that we are doing an even more extensive study." *Id*.

At a Management Committee meeting in April 1998, "Dr. Barnhart reported that the Cr Coalition is considering the development of its own webpage to put a positive spin on chromium." CX 48 at 3. Also at that meeting, it was decided that the Management Committee would inform OSHA, EPA "and other regulatory groups" that they would be initiating "a study of this magnitude" through a letter that Dr. Barnhart volunteered to draft. CX 48 at 4-5. Dr. Barnhart also offered to arrange a meeting with OSHA. *Id*. The letter to OSHA, dated July 24, 1998, from Elementis Chromium-UK employee and then-Chairman of the Chromium Chemicals Committee Bruce Norman, announced the initiation of the study, stating: "Whereas current risk assessment is based on limited information from plants operating 50 years ago this study will provide a **comprehensive database for risk assessment of plants operating to modern standards**." CX 52 at 1 (emphasis added); *see also* CX 54 at 2.

Dr. Barnhart even contributed to developing the study protocol with Dr. Mundt. CX 56 at 2; CX 58 at 1 ("Dr. Barnhart and I have been working to resolve" issues surrounding the study protocol). In doing so, Dr. Barnhart was alerted to or should have recognized at least the ethical obligation to disseminate the Final Report, regardless of Respondent's obligation under TSCA. Determining the ground rules for public access and dissemination appears to be an important step in developing a study protocol. *See* CX 45 at 4 (data disclosure provisions included in Applied's contract with IHF); CX 49 at 4 (confidentiality provision in Applied's contract with Respondent); CX 55 ("desired outcome" is for study to be published to establish credibility); CX 57 at 1 ("desired end-point" is "peer-reviewed paper in a leading . . . journal"). One of the two guides that he and Dr. Mundt used to develop the protocol, the Guidelines for Good Epidemiology Practices for Occupational and Environmental Epidemiologic Research, developed by the Chemical Manufacturers Association's Epidemiology Task Group (Journal of Occupational Medicine 1991), provides in part that:

> Government agencies shall be informed of study results in a manner that complies with applicable regulatory requirements. Scientific peers shall be informed of

> study results by publication in the scientific literature of presentations at scientific conferences, workshops, or symposia, to the extent possible.

CX 58 at 8. The second set of guidelines, A Proposal for a Code of Good Epidemiological Practice, was drafted by experts with the European Centre for Ecotoxicology and Toxicology of Chemicals (with the participation of Applied (CX 58 at 1)), and published in March 1997. CX 58 at 12-50. In commentary about third party access, the practice guide provides in part:

> Interpreting the results of epidemiological studies is a complex intellectual process requiring scientific judgment that is dependent upon relevant education and practical experience as refined by exposure to peer review. In many cases, an epidemiological study will yield results that are subject to multiple interpretations.
> * * *
> [I]t is entirely appropriate for the sponsor(s) to request the right to review and comment on study reports before the reports are disseminated. Under no circumstances, however, should the principal investigator permit the sponsor(s) to control the interpretation or impede the timely dissemination of reports on the study.
>
> There is a clear public interest in the widespread dissemination of reports concerning epidemiological studies, at least within the scientific and public health communities. A decision not to disseminate research results can be justified in only the most extraordinary circumstances – for example, when methodological problems are believed to have deprived the results of any meaning. It should be understood that failure to reject the null hypothesis can be as important as "affirmative" results. **Consequently, a decision not to disseminate research results seldom if ever can be justified by the mere failure to find statistically significant associations.**
>
> A decision not to disseminate research results, including "negative" or "no-association" findings, contributes to the widely acknowledged problem of publication bias and can distort the conclusions reached in any meta-analyses that may be conducted. **Indeed, it is extremely difficult to justify the collection of personal data and the resulting risk to personal privacy unless the study results are placed on the public record so that they can be taken into account by others, including by policy makers.**

CX 58 at 43-44 (emphasis added). Dr. Barnhart mentioned these two guides specifically as those he and Dr. Mundt were relying on to draft the study protocol. CX 56 at 2; *see also* CX 58 at 1 (Applied "followed the ideas set forth in two general guides for good epidemiological practice.").

Under Dr. Barnhart's leadership, the Chrome Coalition hired Exponent to critique the Gibb Study, an affirmative step taken to breed uncertainty in OSHA's decision-making process. CX 65. Exponent's Critique was submitted to OSHA as part of a larger package from the

Coalition in June 2002 (before the publication of the proposed rule). CX 65. The Critique listed several findings, including the following:

> For several reasons, it has been concluded that the methods used to measure airborne Cr(VI) in the Baltimore plant likely underestimated Cr(VI) exposures.
> * * *
> The value of these data for quantitative cancer risk assessment seems to be overstated. . . . CIs for relative risks . . . with smoking included . . . were not presented. Thus, it is difficult to assess the precision of those risk estimates. The SMRs, which are typically used for cancer risk assessment, were not adjusted for smoking. The utility of these data for cancer risk assessment would be substantially improved if the SMRs were adjusted for smoking. Finally, the appropriateness of extrapolating lifetime cumulative exposures . . . from relatively short duration exposures (e.g., 2 years), is highly questionable and not generally considered an acceptable risk assessment practice.
> * * *
> In summary, the findings of this study should be judged cautiously because of the many uncertainties in the information presented. In particular, risk estimates for lung cancer at the lower levels of cumulative Cr(VI) exposure may be inaccurate for several reasons and should not be relied upon for health risk assessment.

CX 65 at 4, 6-7. Because it was submitted to the rulemaking record, OSHA specifically addressed Exponent's critique, but ultimately was not persuaded to discount the Gibb Study based on its limitations. CX 76 at 19-20.

On August 22, 2002, OSHA published a request for information in the Federal Register seeking any criticism of the Gibb Study, "data, comments, and information on issues relevant to occupational exposure to hexavalent chromium (CrVI), including: Significant epidemiological . . . studies; the relationship between occupational exposures to CrVI and the development of adverse health effects . . . ." CX 66 at 1, 3. The publication also sets forth as follows: "OSHA is especially interested in studies of occupational exposure that quantify exposure data and control for important confounding variables, have good statistical power, and are well conducted." CX 66 at 3. It has been established that Dr. Barnhart decided not to submit the Final Report to OSHA or EPA when he obtained a draft in early 2002, or then the final report later in October 2002. JX 1 ¶ 20. In making this decision, Dr. Barnhart undertook somewhat substantial calculations involving conversions and judgments. Respondent's Brief at 23-25; Tr. 980-81. The fact that Dr. Barnhart had to manipulate the data presented in the Final Report in this way in order to determine if they "fit in with what had been known," the Gibb Study, by itself shows that he should have recognized the inherent differences in what each study presented. Tr. 972. The deadline for comments to OSHA, November 20, 2002, passed without Respondent's submission of the Final Report. CX 66 at 1; Tr. 1151-52, 1161.

Two years later, on October 4, 2004, OSHA proposed its new PEL for hexavalent chromium and set a deadline of January 3, 2005 for comments. CX 70 at 1. The Agency sought

"comment on all relevant issues, including health effects, risk assessment, significance of risk determination, technological and economic feasibility, and the provisions of the proposed regulatory text." *Id*. at 2. Further, it explicitly sought studies besides Gibb and Luippold: "Are there any other studies that you believe are better suited to estimating the risk to exposed workers; if so, please provide the studies and explain why you believe they are better." *Id*. at 2. And: "Does the OSHA exposure-response assessment based on the higher [levels] and/or shorter durations experienced by the Gibb and Luippold cohorts lead to a serious underprediction or overprediction in estimated risks for the occupational exposure scenarios of interest to OSHA? Please provide any data to support your rationale." *Id*. at 3. The notice also requested "additional data that will enable the Agency to refine its profile of the worker population exposed to Cr(VI)," for example, information on the job categories of workers at plants, a description of their activities in that job, how many employees work each job, and what the "frequency, duration and levels" of exposures at each of the jobs. *Id*.

In comments prepared by Dr. Barnhart that Respondent submitted to OSHA for the proposed PEL docket (dated December 31, 2004), and in Dr. Barnhart's written testimony for the proposed PEL public hearing in February 2005 (submitted January 2005), they heavily criticized the Gibb Study and the database overall on which OSHA relied to develop the proposed PEL. CX 95; CX 96. First, Respondent criticizes OSHA for basing the PEL "in large part on studies of elevated risk of lung cancer for workers exposed to hexavalent chromium, especially those exposed during the period of 1930-1970, in the chromate chemicals production industry." CX 95 at 5. These studies are not adequate to form the basis for a PEL that will impact more than just the "one small industry," Respondent argues, which employs less than 200 workers in the U.S. *Id*. Respondent continues:

> It is very unlikely that the high exposure levels and the types of compounds to which workers were exposed in the chromate production industry in the 1930s through the 1970s are representative of the current exposures to hexavalent chromium in either this or other industries.

Id.; *see also* CX 96 at 2. Second, their comments specifically criticize the Gibb Study. Because "most of the samples in the Baltimore study were area samples," and it is "reasonable to expect that the workers would have been closer to the materials being processed than the area samples," the workers were likely exposed to higher concentrations than those measured. CX 96 at 3. Then, because the Gibb Study was designed to look at typical exposures, it is likely that spikes in exposure, "such as when equipment malfunctioned," were not factored in. *Id*. Also, the Braver study reported higher exposures for a similar time period. *Id*. And, it's "very likely" that the hexavalent chromium sampled in the Baltimore plant was "chemically reduced" on the sampler mechanism, and consequently, the exposures were actually higher than reported. *Id*. Additionally, as cited earlier in this decision, Respondent questions whether the Gibb Study actually reported on the modern chromium production experience. CX 95 at 7-8 (Baltimore plant's roasting kilns feed mix had ratio of lime to ore of "about 0.5," which is commonly known as high-lime or medium-lime, "certainly . . . not a 'low-lime' or 'no-lime' mix," which would be 0.1 or less). In sum, Respondent asserts, "we think that it is very likely that the exposures

assigned to workers in the studies of these older plants underestimated the actual exposures." CX 95 at 8.

It was not until later that year, by letter dated June 29, 2005, from Public Citizen, that Ms. Edens of OSHA, received a copy of the Final Report; this was about two months after OSHA's revised deadline for post-hearing comments on its proposed PEL. Tr. 1116-18, 1161; CX 73. Ms. Edens testified that Respondent had not referenced the Final Report, (which Dr. Mundt estimated cost approximately $500,000 (Tr. 926)), in either its comments to the proposed PEL or its testimony at hearings on the proposed PEL. Tr. 1151-52, 1161-62. When asked why at the hearing, Dr. Barnhart answered, "because I believed that OSHA would consider publications in a peer reviewed journal more strongly than an industry-sponsored non-peer reviewed study, so I was hoping that – and anxious for the publications to be available in time to be useful for the rulemaking." Tr. 1166-67. Despite Dr. Barnhart's purported contemporaneous hope and anxiety, it appears that neither he nor Respondent, nor the Coalition (led by Dr. Barnhart) helped fund their publications, although there is no evidence that they lacked the resources to do so. Tr. 927-28 (Dr. Mundt said that after the report was completed, the contractual agreement ended, however "what we had hoped to be the next step would be that they would support us in funding in publishing those papers." "[T]hat turned out not to be the case. [IHF] disbanded before those papers were done and I actually did all of the work and our staff did all of the work . . . at our own expense."); 1006-07 (Dr. Barnhart characterized Dr. Mundt's interest in publishing the results as something akin to pride or vanity: "maybe it was based on the fact that people doing studies like this want to publish the results in order to get credit for them. And so it's kind of expected that they will be published. And I didn't really appreciate that he expected there would need to be some more financial – and maybe it has to do with this last minute change that has to be made in the study that would need more support." To get it published, he asserts, "was pushed from a company point of view," however there was "probably a misunderstanding between Dr. Mundt and me or between [Dr.] Mundt and other people in the company.").

It is not unusual for an industry group to very aggressively try to protect itself in the face of what it views as unfavorable government action; indeed, protecting interests against regulation is an industry in itself. However, it must be done consistent with the law. Here Respondent violated federal law, and therefore its corollary efforts to subterfuge regulatory action warrant scrutiny under the statutory penalty factors that I am required to consider. Respondent itself and Dr. Barnhart on Respondent's behalf submitted objections to OSHA's proposed PEL on the official record that decried a lack of available information on hexavalent chromium risks under modern plant conditions, which is exactly what the Final Report study was designed to examine and did examine, blasted the Gibb Study's usefulness and reliability on numerous grounds, and argued that the proposed PEL is "not justified by the available health information." CX 95 at 2, 5, 9. All the while, Respondent had in its back pocket an expensive and extensive study that Dr. Barnhart played a major role arranging, specifically with the hope of using it to influence the OSHA rulemaking, that Respondent supported financially and with its own workers' health data, and which was explicitly designed and undertaken to fill the same "data gap" Respondent so often lamented in its comments to OSHA. As such, after significant consideration of the record as a whole, I find it appropriate to increase the GBP in this case by 10% for Respondent's

"attitude."

ii. History of Such Violations, Ability to Pay, Ability to Continue in Business

In its proposed penalty calculations, Complainant identified no aggravating or mitigating circumstances based on the factors of history of prior violations, ability to pay, or effect of penalty on violator's ability to continue in business. EPA Brief at 53. Specifically, in terms of a history of violations, the Agency identified none.

As to ability to pay and/or effect of the penalty on the violator's ability to continue in business, Complainant states that it investigated Respondent's financial standing by consulting the company's Dun & Bradstreet report and financial information on the company's website. EPA Brief at 56. These sources revealed "no concerns" about Respondent's ability to pay the proposed penalty, Complainant asserts. *Id*. There is very little otherwise in the record concerning the size, volume or success of Respondent's business. As indicated above, in 2004, Elementis has described itself as "the only U.S. manufacturer of basic hexavalent chromium chemicals, sodium dichromate and chromic acid" and the manufacturer of "the largest volume of these chemicals worldwide." CX 95 at 2. Inventory Update Reporting records for 2006 indicate that at that time, Elementis Worldwide, Inc., at its Elementis Chromium, L.P. site in Castle Hayne, N.C., was the only manufacturer in the United States of chromium oxide (total national production volume 50-100 million pounds), and was one of two national manufacturers of chromic acid (total national production volume 100-500 million pounds). CX 9 at 1; CX 8 at 1. The transcript shows that Respondent's sales market is primarily in the United States, however, because there are no European producers of chromium chemicals left, Respondent supplies at least part of that market, too. Tr. 1005. Due to chromium products' main role in manufacturing, a large part of Respondent's market has moved to China. *Id*. Dr. Barnhart testified that to his knowledge, alternative products to chromium are not less expensive, but there may be some that in some applications create less risk to people working with them. Tr. 1004-5. Significantly, Respondent has not claimed an inability to pay the penalty in this action. As such, no adjustment upwards or downwards to the GBP is deemed appropriate on these limited facts under these factors.

iii. Such Other Matters as Justice May Require

Respondent argues that there are many factors weighing against "the excessive and unreasonable penalty being sought by EPA," and that "justice plainly does not support" the Agency's assessment. Respondent's Brief at 48, 50. First, Dr. Gibb, the witness with the broadest and deepest experience with hexavalent chromium risk assessment, does not believe the Final Report presents significant new risk information, Respondent states. Respondent's Brief at 49. Even if mistaken, Dr. Barnhart's conclusion that the [Final Report] was exempt was ultimately a reasonable one, "i.e. this presents, at best for the Agency, an exceedingly close case by which it has barely established a violation and it would be unfair to treat this case on equal-footing with more significant and obvious violations." Respondent's Brief at 48-49. Second, the Agency's guidance documents "lend comfort to the conclusion that reporting would not have

been required here." Respondent's Brief at 50. Third, the two other companies who received the Final Report did not submit it to EPA, and according to Mr. Ellis, the Agency has not pursued an enforcement action against either of them. *Id*. (citing Tr. 618-19). Respondent summarized, "if a violation occurred at all, it must have been by the barest of margins and in a circumstance where, at best for EPA, reasonable scientific and regulatory minds might disagree." *Id*. The penalty should be nominal if there is one imposed at all, Respondent argues. *Id*. Further:

> There is no need to punish Elementis, as the uncontroverted evidence is that its actions were based on a good faith interpretation of a one-sentence provision with little guidance and precedence on which it could have relied, and there was no loss to the useful knowledge base of the risks associated with hexavalent chromium.

Id.

Dr. Cooper did admit that there has been no change to the Agency's IRIS database on hexavalent chromium since 1998. Tr. 259-60. Ms. Edens admitted that no action was taken at OSHA because of the Final Report. Tr. 1142-44. Mr. Ellis admitted that the Agency did not pursue claims against other companies that had knowledge of the Final Report. Tr. 618-19. Nevertheless, given the other facts of this matter, no mitigation based upon the arguments raised by Respondent warrant mitigation of the penalty.

The notion that Respondent made a considered and "good-faith" evaluation as to whether it was required under the "one-sentence provision" of Section 8(e) to submit the report to EPA is controverted by the record. Respondent's Brief at 50. Dr. Barnhart testified that he was not sure if he had "ever read 8(e) or the guidance," but had the idea "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. 990-91; EPA Brief at 54. Concluding that the Final Report did not meet this criteria, Respondent did not promptly produce it to EPA. In my opinion this is not evidence of a good faith effort to determine whether production of the Final Report was legally required. Seeking EPA's guidance on the issue would have evidenced good faith. Hiring outside counsel or at least tasking in-house counsel to provide an opinion regarding the necessity of production would have evidenced good faith, and was certainly a course available to a company of Respondent's financial resources and appropriate in light of the significant cost of the study (approximately $500,000). Tr. 926. Failing that, had Dr. Barnhart himself contemporaneously, thoughtfully reviewed the statute and guidance, and concluded based thereon that production was unnecessary, that might be sufficient evidence of good faith. However, purporting to rely solely on vague general recollections of perhaps third party information on the relevant legal requirements to decide whether to submit the Final Report is not only not good faith, but it is not even credible in light of the precise nature of Dr. Barnhart's work, his leadership positions on environmental matters in the industry organizations, his intimate involvement in initiating the study and dictating its protocol, and his general demeanor and testimony at hearing. Tr. 949-53, 956-59; CX 30 at 1. The record as a whole suggests that it is far more likely that the decision not to submit the Final Report was influenced by a preference to withhold from the government another study, particularly an industry-

sponsored study, that lacked the shortcomings of the Gibb Study (as identified by IHF), and which may have lent further support to OSHA setting a lower PEL for Cr(VI) than industry desired.

The fact that EPA has not pursued an enforcement action against the other entities that received the Final Report is of no significance. It is clear from the record before me that Dr. Barnhart was the point person on the Final Report for the industry through his positions with IHF and the Coalition. There is no evidence that any improper factor played into the Agency's enforcement decision, such as invidiousness or bad faith, and it certainly falls within the government's discretion to determine which actions to pursue. *United States v. Berrios*, 501 F.2d 1207, 1211 (2d Cir. 1974); *B&R Oil Co.*, 8 E.A.D. 39, 51 (EAB 1998).

Further, it should be noted that at no time did Respondent argue that submitting the Final Report to EPA would have been unduly burdensome, or that submitting future SRI would be either. Respondent did argue, however, that recognizing differences between cohorts of studies that show the same risk as grounds for reportability will make it "impossible for any occupational epidemiological exposure study not to demonstrate new risk, as every time that risk will have, by assumption, emerged in a different context that the Agency regards as significant under TSCA 8(e)." Respondent's Brief at 33. It is not appropriate for the undersigned, as fact finder, to imagine or predict what kinds of studies would be exempt from reporting under TSCA Section 8(e); it is sufficient that this determination is limited to whether Respondent carried its burden of proving by a preponderance of the evidence its defense, which it did not.

C. Conclusion

In his dissent to the majority opinion in *Industrial Union Dep't. v. American Petroleum Institute*, 448 U.S. 607 (1980), which held that OSHA's PEL for benzene was unenforceable for lack of adequate support in the record, Justice Thurgood Marshall (joined by Justices Brennan, White, and Blackmun), wrote:

> In recent years there has been increasing recognition that the products of technological development may have harmful effects whose incidence and severity cannot be predicted with certainty. The responsibility to regulate such products has fallen to administrative agencies. Their task is not an enviable one. Frequently no clear causal link can be established between the regulated substance and the harm to be averted. Risks of harm are often uncertain, but inaction has considerable costs of its own. The agency must decide whether to take regulatory action against possibly substantial risks or to wait until more definitive information becomes available – a judgment which by its very nature cannot be based solely on determinations of fact.

448 U.S. at 722-23. Under TSCA Section 8(e), manufacturers, processors and distributors have to make judgments about what risk information to submit to the Administrator. *See* 3 William H. Rodgers Jr., Environmental Law: Pesticides and Toxic Substances § 6.4 (1988) (TSCA Section

8(e) "represents a legal statement to do what's right when serious hazards are unearthed."). This is exactly what Congress intended; indeed, it was the first policy penned in the Act: "It is the policy of the United States that – (1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that **the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures**." Toxic Substances Control Act, Pub. L. No. 94-469, § 2(b)(1), 90 Stat. 2003 (1976) (emphasis added). While Congress wrote that the Agency should avoid unfair or unduly burdensome submission requirements, it also passed TSCA acknowledging the "ever-accelerating growth of the chemical industry," with a stated goal to continually study and understand chemical risks in an ever-changing industrial and commercial environment. S. Rep. No. 94-698, at 3-6 (1976); 15 U.S.C. § 2601(a), (b). Over time, as workplace conditions are improved and industrial processes are made less hazardous, the frontier in risk assessment is always going to be studying lower and lower exposures, or in Dr. Gibb's words, "between zero and where you first observed a significant risk, or maybe even a little bit below that." Tr. 1072-73. This decision takes into account that Congress intended to place the onus for understanding that frontier on the industries whose workers may be at risk.

After consideration of the record in this matter and the penalty factors set forth in TSCA Section 16, 15 U.S.C. § 2615, Respondent is hereby assessed an appropriate penalty as set forth below.

ORDER

1. Respondent Elementis Chromium Inc., f/k/a Elementis Chromium, L.P., is assessed a civil penalty of $2,571,800 for violating Section 8(e) and Section 15(3)(B) of the Toxic Substances Control Act, 15 U.S.C. §§ 2607(e), 2614(3)(B).

2. Payment of the full amount of this civil penalty shall be made within 30 days of the date on which this Initial Decision becomes a final order pursuant to Section 22.27(c) of the Rules of Practice, 40 C.F.R. § 22.27(c) by one of the following means:

   a. by submitting a cashier's check or a certified check in the amount of $2,571,800, payable to "Treasurer, United States of America," and mailed via U.S. Postal Service to:

      U.S. Environmental Protection Agency
      Fines and Penalties
      Cincinnati Finance Center
      P.O. Box 979077
      St. Louis, MO 63197-9000

      Primary Contact: Craig Steffen (513) 487-2091
      Secondary Contact: Molly Williams (513) 487-2076

   b. by submitting a cashier's check or a certified check in the amount of $2,571,800, payable to "Treasurer, United States of America," and mailed via expedited delivery service (UPS, FedEx, DHL, etc.) to:

      U.S. Environmental Protection Agency
      Government Lockbox 979077
      1005 Convention Plaza
      SL-MO-C2-GL
      St. Louis, MO 63101

      Primary Contact: Craig Steffen (513) 487-2091
      Secondary Contact: Molly Williams (513) 487-2076

   c. by one of the electronic methods described at the following Agency website: http://www.epa.gov/cfo/finservices/payment_instructions.htm[28]

---

[28] Those methods include:

Vendor Express: Payers authorize their financial institutions to initiate an automated clearing house (ACH) credit transaction to a unique routing number at the Federal Reserve Bank of

(continued...)

3. A transmittal letter identifying the subject case and EPA docket number, TSCA-HQ-2010-5022, as well as Respondent's name and address(es), must accompany the check.

4. If Respondent fails to pay the penalty within the prescribed statutory period after the entry of the final order, interest on the civil penalty may be assessed. 31 U.S.C. § 3717; 40 C.F.R. § 13.11.

5. Pursuant to 40 C.F.R. § 22.27(c), this Initial Decision shall become a final order 45 days after its service upon the parties, unless (1) a party moves to reopen the hearing within 20 days after service of this Initial Decision under 40 C.F.R. § 22.28; (2) an appeal is taken to the Environmental Appeals Board within 30 days after service of this Initial Decision pursuant to 40 C.F.R. § 22.30(a); or (3) the Environmental Appeals Board elects to review this Initial Decision upon its own initiative pursuant to 40 C.F.R. § 22.30(b).

SO ORDERED.

Susan L. Biro
Chief Administrative Law Judge

---

[28](...continued)
Richmond.

Fedwire: Payers authorize a Financial Institution to initiate an electronic (Fedwire) payment to the Federal Reserve Bank of New York (FRBNY). Generally, this is used for foreign payments.

Pay.gov: Payers can use their credit or debit cards to make payments. This option is only available for the following payment types – Superfund, fines and penalties, FOIA, travel, and miscellaneous fees.

In The Matter of **Elementis Chromium Inc., f/k/a Elmentis Chromium, LP, Respondent**
TSCA-HQ-2010-5022

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Initial Decision**, dated November 12, 2013, was sent this day in following manner to the addresses listed below:

Sybil Anderson
Office of Administrative Law Judges
U.S. Environmental Protection Agency
(202)564-6261

Dated: **November 12, 2013**

By Regular Mail and E-mail To:

Mark A.R. Chalfant, Esq.
Environmental Protection Agency
1595 Wynkoop Street (8ENF-L)
Denver, CO 80202

Email: chalfant.mark@epa.gov

Erin K. Saylor, Esq
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
WJC Building: MC 2249A
Washington, DC 20460

Email: saylor.erin@epa.gov

Eurika Durr
Environmental Appeals Board
1200 Pennsylvania Avenue, N.W.
WJC Building: MC 1102M
Washington, Dc 20460

Email: durr.eurika@epa.gov

Cynthia Giles
Assistant Administrator
Office of Enforcement and Compliance Assurance
U.S. EPA
William Jefferson Clinton Building Mail Code 2201A
1200 Pennsylvania Ave NW
Washington DC 20460

Email: giles.cynthia@epa.gov

John J. McAleese, III Esq.
(Formerly Morgan, Lewis & Bockius, LLP)
McCarter & English, LLP
1735 Market Street, Suite 700
Philadelphia, PA 19103

Email: jmcaleese@mccarter.com

Ronald J. Tenpas, Esq.
Morgan, Lewis & Bockius, LLP
1111 Pennsylvania Avenue, N.W.
Washington, DC 20004

Email: retenpas@morganlewis.com