

Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103-2921
Tel: 215.963.5000
Fax: 215.963.5001
www.morganlewis.com

Morgan Lewis
C O U N S E L O R S A T L A W

John J. McAleese, III
215.963.5094
jmcaleese@morganlewis.com

November 18, 2011

VIA HAND DELIVERY

Headquarters Hearing Clerk (1900L)
United States Environmental Protection Agency
Office of Administrative Law Judges
1200 Pennsylvania Avenue NW
Washington, DC 20450

RECEIVED BY OALJ
2011 NOV 18 PM 2:33

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

Dear Madam:

This firm represents Elementis Chromium Inc. (formerly Elementis Chromium, LP) in the above matter. Enclosed please find an original and two (2) copies of Respondent's Prehearing Brief. Please file the original Prehearing Brief and return one time-stamped copy in the enclosed self-addressed stamped envelope.

Please call me if you have any questions. Thank you for your attention to this matter.

Very truly yours,


John J. McAleese, III

JJMjta

Enclosure

cc: Hon. Susan L. Biro, Chief Administrative Law Judge, USEPA (via FedEx)
Mark A.R. Chalfant, Esq., USEPA (via email and FedEx)
Karin Koslow, Esq., USEPA (via email and FedEx)

**UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY**

IN THE MATTER OF:)
)
)
Elementis Chromium, L.P.,)
)
)
Respondent.)
_____)

Docket No. TSCA-HQ-2010-5022

RECEIVED BY DALJ
2011 NOV 18 PM 2:33

RESPONDENT'S PREHEARING BRIEF

Pursuant to the Presiding Officer's August 22, 2011 Notice of Hearing and Scheduling Order, Respondent Elementis Chromium Inc.¹ ("Elementis") respectfully submits its Prehearing Brief in defense of this action.

I. INTRODUCTION

This enforcement action has been brought by the United States Environmental Protection Agency ("Complainant" or "EPA") against Elementis for alleged violation of Section 15(c) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2614(c). EPA alleges that Elementis was required by Section 8(e) of TSCA to submit the "Collaborative-Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998, Final Report" prepared by Applied Epidemiology, Inc. ("Applied Epidemiology") dated September 27, 2002 (the "Report") to EPA. To the contrary, pursuant to TSCA Section 8(e) and EPA's guidance interpreting the reporting obligations of Section 8(e), Elementis was not required to submit the Report to EPA. Any

¹ Elementis Chromium LP was merged into Elementis Chromium GP Inc. on September 10, 2010. Elementis Chromium GP Inc. then changed its name to Elementis Chromium Inc.

substantial risk information in the Report regarding hexavalent chromium was merely corroborative of the well-known and well-established health effects associated with hexavalent chromium, and Elementis knew that EPA was fully aware of such information.

II. FACTUAL BACKGROUND

The evidence to be presented at the hearing in this matter will demonstrate that it has been well known for more than half a century that workers in chromium manufacturing facilities who have respiratory exposure to hexavalent chromium have an increased risk of lung cancer over the risk faced by the general population. Scores of epidemiologic studies have identified this risk. In fact, the evidence will show that, in 1984, more than a quarter of a century ago, EPA itself determined that there was a linear relationship between airborne exposure to hexavalent chromium and the risk of lung cancer.

In 1998, the Chromium Chemicals Health and Environmental Committee (the “Chromium Committee”) of the Industrial Health Foundation (“IHF”) retained Applied Epidemiology to conduct an epidemiologic study of chromium workers at five chromium manufacturing facilities. Elementis, along with Occidental Chemical Corporation (“Occidental”) and Bayer AG (“Bayer”) were the industry members of the Chromium Committee. The five plants proposed for the study were owned and operated by the three member companies, with one being owned by Occidental, two being owned by Bayer and two being owned by Elementis.²

In commissioning the epidemiologic study, the Chromium Committee was interested in determining whether the significant process changes incorporated in each of the plants had resulted in any difference to the risk of lung cancer previously seen in the chromium

² In 1999, it became apparent that the data from Elementis’ Eaglescliffe, England plant would not be compiled in time to be included in the study. This plant was thus eliminated from the study, resulting in just four plants in the study.

manufacturing industry. It was the supposition of the companies that the process changes had resulted in less lung cancer risk to the workers in these plants, primarily due to the reduction in respiratory exposure to hexavalent chromium as a result of those changes. The method chosen by the Chromium Committee to investigate the impact of the changes was an epidemiologic study that would analyze the health of workers who had been employed at the facilities after the process changes had taken place.

From 1998 to 2002, Applied Epidemiology conducted the study requested by the Chromium Committee and produced the Report summarizing its findings in October 2002. As detailed in the Report, Applied Epidemiology's study found that only those workers who fell into the highest group of cumulative exposure among the four plants in the study showed an increased risk of lung cancer when compared to the general population. In the three other, lower exposure groups, the study did not find any statistically significant increase in the risk of lung cancer among the workers when compared to the general population. The study did not identify *any* increased risk of lung cancer in the workers at the Elementis plant located in Corpus Christi, Texas³.

Applied Epidemiology's finding of elevated risk among the highest exposed workers in the two German plants, while noteworthy in that the process changes in the German plants apparently had not completely eliminated risk to workers there, was entirely consistent with findings of many prior epidemiologic studies, and simply corroborated the well-known and well-established adverse health effect associated with hexavalent chromium recognized by many experts for decades and by EPA more than 25 years ago.

³ The study also did not identify any increased risk of lung cancer at the other United States plant, the Occidental plant in Castle Hayne, North Carolina, which was purchased by Elementis in December 2002.

Since the three companies who made up the Chromium Committee were well aware of the known lung cancer risks associated with workers in chromium plants who experience high respiratory exposure to hexavalent chromium, the report provided absolutely no new information on the risk associated with hexavalent chromium. More importantly, because the companies also knew that EPA had full awareness of hexavalent chromium's risk profile, which was only confirmed by the Applied Epidemiology study, none of the companies, including Elementis, believed that the Report from Applied Epidemiology should be provided to EPA pursuant to Section 8(e) of TSCA. Both the statute on its face, plus the only other guidance available to industry, namely EPA's TSCA reporting guidance document, absolutely informed against providing the Report to EPA. Thus, none of the companies felt compelled to provide the Report to EPA.

Although the companies were not required to provide the Report to EPA pursuant to TSCA, the findings of the Report were widely shared by Applied Epidemiology with independent reviewers, as well as with the epidemiology expert community. In fact, prior to providing the final Report to the Chromium Committee in October 2002, Applied Epidemiology presented the study's finding to an international conference of epidemiologists in Barcelona in September 2002.

However, more than five years after the study was made public by Applied Epidemiology and more than a year after the Occupational Safety and Health Administration ("OSHA") publicly acknowledged that "the Agency does not believe that quantitative analysis [in the Report] would provide additional information on risk from low exposure to Cr(VI),⁴" EPA inexplicably threatened to bring an enforcement action against Elementis (but not the two other

⁴ Hexavalent chromium is also referred to as Cr(VI).

member companies of the Chromium Committee, both of which received the Applied Epidemiology study on the same day as Elementis, and neither of which provided it to EPA). Despite Elementis' clear and convincing explanation as to why the Report was not provided to EPA under section 8(e) of TSCA, EPA launched this enforcement action on September 2, 2010.

The evidence presented at hearing in this matter by both Elementis *and* EPA will unequivocally establish that Elementis was not required to submit the Report to EPA under Section 8(e) of TSCA. The evidence will show that the findings of the study, as detailed in the Report, corroborated the well-known and well-established adverse health effects associated with hexavalent chromium. On its face, and as further explained by EPA's own guidance, such information is not reportable under TSCA § 8(e).

III. ARGUMENT

The body of legal authority applicable to this matter is paltry. It is essentially limited to the statutory provision. There are no implementing regulations. There is no relevant legislative history, and there are no relevant decisions interpreting the statute. The regulated community, which includes Respondent, is guided solely by the one-sentence statutory provision, and unpromulgated guidance provided by EPA. Applying the statute, as informed by EPA's guidance, to the facts of this case leads to the clear and undeniable conclusion that Elementis did not violate TSCA Section 8(e) by failing to provide the Report to EPA.

A. Neither The Statute Nor EPA's Own Published Guidance And Interpretation Of Law Require Information Contained In The Report To Be Provided To EPA.

Section 8(e) of TSCA, the operative statutory provision under which EPA has brought this enforcement action, provides as follows:

Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which

reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information *unless such person has actual knowledge that the Administrator has been adequately informed of such information.*

15 U.S.C. § 2607(c) (emphasis added). EPA has never promulgated any regulations elaborating on Section 8(e) of TSCA. Instead, it has issued a “guidance” document, first on March 16, 1978, entitled “Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk,” 43 FR 11110-11116 (March 16, 1978), followed by an amendment thereto on June 3, 2003, entitled “TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance,” 68 FR 33129-33314 (June 3, 2003). One of the stated purposes of the revision was to “address . . . which certain information need not be reported to EPA under section 8(e) of TSCA.” 68 FR 33129, 33139 (June 3, 2003). Further, in the 2003 revision, EPA stated that “[s]ince the policy statement was published in 1978, this republication is intended to ensure that a single reference source for the TSCA section 8(e) policy and guidance is easily available to the regulated community and other interested parties.” *Id.*

In the preamble to the 2003 guidance, EPA acknowledges that “[t]he statutory language of section 8(e) requires the exercise of a certain degree of judgment in determining what information must be reported.” *Id.* at 33131. To assist the regulated community in exercising that judgment, EPA published the guidance.

With regard to epidemiologic studies, such as the Applied Epidemiology study commissioned by the Chromium Committee at issue in this matter, EPA’s guidance provides that “designed studies,” such as “[e]pidemiological studies,” should be reported if any such study contains “reliable evidence ascribing the effect to the chemical” and the study shows “[a]ny pattern of effects or evidence which reasonably supports the conclusion that the chemical

substance or mixture can produce cancer mutation, birth defects or toxic effects resulting in death, serious or prolonged incapacitation.” Id. at 33138-33139.

However, even if an epidemiologic study meets these two criteria, EPA’s guidance directs that the study should not be provided to EPA if “the respondent has actual knowledge that the Administrator is already informed” of the conclusion that the chemical substance can produce the adverse effect or the study “[c]orroborates (i.e., substantially duplicates or confirms) ... a well-recognized/well-established serious adverse effect for the chemical(s) under consideration...” Id. at 33139.

1. EPA Was Adequately Informed of the Adverse Health Effect Identified in the Report at the Time of Elementis’ Receipt Thereof.

The Applied Epidemiology study for the Chromium Committee identified a significant adverse effect from exposure to hexavalent chromium, namely that there was an observed higher incidence of lung cancer for those employees who had the highest cumulative exposure level. But the evidence in this matter will show, however, that at the time of EPA’s receipt of the Report, EPA was in possession of numerous studies that had identified the exact same risk information.

The cohort for the Applied Epidemiology study consisted of workers at the four plants who had only worked after significant process changes had been made to the plants, such that the processes were “low-lime” or “no-lime.” The Applied Epidemiology Report analyzed the study cohort in four different groups based on relative cumulative exposure levels: low (0 - 39.9 µg/L-years), intermediate-low (40.0 - 99.9 µg/L-years), intermediate – high (100.0 – 199.9 µg/L-years) and high (\leq 200.0 µg/L-years). For each exposure group, Applied Epidemiology then compared the number of persons within each group who had contracted lung cancer with the number of

people that would be expected to contract lung cancer in the group based on statistics from the general population in the localities where the plants were situated.

The highest exposure group, the persons with exposures of ≥ 200 $\mu\text{g/L}$ -years, contained a total of 117 workers. Of this number of workers, there were 12 reported cases of lung cancer. When compared with the number of cases of lung cancer that would be expected in the general population based on historical reporting, 5.72 expected cases, Applied Epidemiology concluded that the number of actual cases of lung cancer in this group indicated that there was a statistically significant elevated risk of contracting lung cancer exhibited by this group. Importantly, none of the other groups showed a statistically significant increase in the rate of cancer cases among the workers when compared to the general population.

Many studies have identified an increased risk of lung cancer in workers who have experienced high cumulative respiratory exposure levels of hexavalent chromium, and this relationship between high cumulative respiratory exposure and increased lung cancer risk has been known to EPA for many years. Elementis will present testimony and documentary evidence of these studies and their findings, as well as EPA's knowledge of them.

In this action, though, EPA will attempt to focus the Presiding Officer on the different manufacturing processes between the plants involved in these prior studies and those plants involved in Applied Epidemiology's study. These differences in processes, however, are irrelevant to the analysis of TSCA section 8(e)'s reporting requirement, because TSCA section 8(e) is focused solely on risk associated with any "chemical substance or mixture," not processes resulting in exposures to chemical substances or mixtures for which known risk exists. Every single chromium chemical manufacturing process is different in some way, and every individual's exposure is unique.

Moreover, EPA has for years taken the position that any respiratory exposure to hexavalent chromium presents some risk of lung cancer, no matter how that exposure occurs. For EPA to now take the position that the Report contains new information on substantial risk of injury from hexavalent chromium is disingenuous. As Dr. Herman Gibb, an epidemiologist for EPA for 30 years – and an expert witness for Elementis – will testify, the Report does not add to the knowledge base on the lung cancer risk from occupational exposure to hexavalent chromium.

The Gibb Study, which was performed by Dr. Gibb when he worked for the National Center for Environmental Assessment at EPA, was a comprehensive and substantial epidemiologic study of workers at a chromium chemicals manufacturing plant located in Baltimore, Maryland. EPA funded this study pursuant to a grant, and the study was completed in 2000. The Gibb 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. When the exposure groups in the Gibb Study are compared with those in the Report, it is clear that the substantial risk information in the Report was also found at least two years prior in the Gibb Study.

Given that the Gibb Study, a study done for EPA, was completed in 2000 and that Elementis received the Report in 2002, there can be no argument that EPA was adequately informed of the findings of increased incidence of lung cancer in persons exposed to high levels of chromium at the time Elementis received the Report.

2. Elementis had Actual Knowledge that EPA was Adequately Informed of the Information Described in the Report at the Time of Elementis' Receipt Thereof.

Dr. Joel Barnhart, an Elementis employee and Elementis' resident chromium expert, will testify that, when he received the Report from Applied Epidemiology in October 2002, he

compared the substantial risk information in the Report with the findings of the Gibb Study and concluded that the substantial risk information in the Report was already contained in the Gibb Study. Furthermore, Dr. Barnhart will testify that he knew that EPA had the Gibb Study in its possession at the time he received the Report because he knew: (1) the Gibb Study was completed in 2000, two years before Dr. Barnhart received the Report; (2) at the time the Gibb Study was prepared, Dr. Gibb was employed by EPA; and (3) EPA funded the Gibb Study.

3. The Findings in the Report Corroborate a Well-Known and Well-Established Adverse Health Effect Associated with Hexavalent Chromium

At the hearing in this matter, the evidence will clearly show that it has been well-known by the scientific community, EPA and other federal agencies such as OSHA, that significant respiratory exposure to hexavalent chromium increases the risk of lung cancer. As exhaustively detailed by OSHA in its 2006 rulemaking setting a new Permissible Exposure Limit for hexavalent chromium, there have been many epidemiologic studies in the past 60 years that have concluded that respiratory exposure to hexavalent chromium causes lung cancer. In fact, EPA's Toxicological Profile for hexavalent chromium, published in 1984, clearly recognized this already well-known risk. As discussed above, the only substantial risk identified by the Applied Epidemiology study was a statistically significant increased incidence of lung cancer in the highest exposure group in the study cohort. This finding simply corroborated what had been well-known and well-established for decades, namely that significant cumulative exposure to hexavalent chromium causes an increased risk of lung cancer.⁵

⁵ Dr. Mundt from Applied Epidemiology and Dr. Barnhart will both testify that there were serious concerns raised about the methodology employed by Applied Epidemiology in combining the exposure data from the two United States plants with the biological data from the two German plants. This concern called into question the reliability of the findings in the Report, especially on the combined cohort basis. As EPA has provided in its guidance that the reliability of the information is a factor to be applied in determining whether the information should be provided to EPA under TSCA 8(e) (*see* 68 FR 33139), had Elementis believed that the Report was

Although, by their very nature, every epidemiologic study is different from any other, EPA's guidance acknowledges that such studies can be corroborative despite their differences. EPA's guidance expressly provides that studies identifying a "well-recognized/well-established serious adverse effect for the chemical(s) under consideration" need not be reported. Thus, it is clear that the regulated community is to focus on the "effect" finding of the study, not on the cohort differences or distinctions between the studied facilities, when determining whether to provide a study to EPA.

EPA will try to obfuscate the appropriate inquiry in this action by focusing on the distinctions between the processes in the plants studied by Applied Epidemiology and other plants in other studies. However, this analysis flies in the face of EPA's own guidance as to the appropriate analysis. Applying the appropriate analysis leads to the singular conclusion that Elementis (and Occidental and Bayer) correctly concluded that the Report did not need to be provided to EPA pursuant to TSCA section 8(e) because it only corroborated the well-known and well-established adverse health effect associated with high cumulative exposure to hexavalent chromium.

Thus, based on the plain language of TSCA section 8(e), and, more importantly, its mandate that substantial risk information does not need to be provided to EPA if the person has actual knowledge that such substantial risk information is already known to EPA, Dr. Barnhart correctly concluded that Elementis had no obligation to provide the Report to EPA.

B. Even If Elementis' Failure To Provide The Report Is Determined To Be A Violation Of Section 8(e) Of TSCA, No Penalty Is Appropriate.

As discussed above, Elementis firmly believes that the Report was not reportable under TSCA 8(e) because Elementis had actual knowledge that the substantial risk information

reportable under TSCA section 8(e) based on all of the other criteria, the reliability of the methodology utilized in the study may have dictated against providing the Report to EPA.

contained in the Report was well-known to EPA, and the substantial risk information in the Report only corroborated the well-known and well-established adverse health effect associated with hexavalent chromium. Elementis' good faith reliance on EPA's guidance cannot be validly challenged. If a violation is determined, it would be on a hyper-technical interpretation, as Elementis' position as to why it (and two other much larger, multi-national and experienced companies) did not provide the Report to EPA is well-grounded in fact and the law.

Furthermore, there is no competent evidence that Elementis or anyone else attempted to obscure the Report or its findings. In fact, the evidence is 100% to the contrary- -Applied Epidemiology presented the findings to an international epidemiologic conference *in advance* of giving the Report to the Chromium Committee. Had the Chromium Committee had any concerns about disclosure of the results of the study, it certainly would not have allowed Applied Epidemiology the unconditioned right to present the results at an international epidemiology conference.

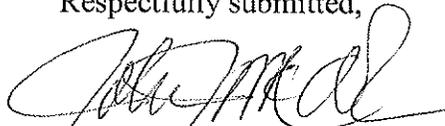
Most importantly, EPA cannot point to any actual detriment to the Agency's knowledge about hexavalent chromium resulting from EPA's not getting the Report at the time Elementis received it. Dr. Gibb, a renowned epidemiologist, and former high-level EPA epidemiologist, will unequivocally testify that the Report added nothing to the already vast body of science on the health effects of hexavalent chromium. Moreover, OSHA even agreed the Report provided no useful new information to it in preparing the revised occupational permissible exposure level.

For these reasons, even if a violation of TSCA section 8(e) is found, a penalty is not appropriate.

IV. CONCLUSION

The evidence at the hearing on this matter, as summarized in the discussion of Elementis's defense above, will show that Elementis did not violate Section 8(e) of TSCA.

Respectfully submitted,



John J. McAleese, III
Ronald J. Tenpas
William S. Pufko
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103
(215) 963-5000

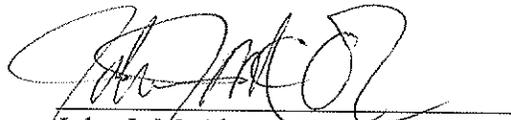
*Attorneys for Respondent Elementis
Chromium Inc.*

CERTIFICATE OF SERVICE

I, John J. McAleese, III, hereby certify that on November 18, 2011, I served a copy of **Respondent's Prehearing Brief**, via e-mail and Federal Express on the following:

Mark A.R. Chalfant, Esquire
Waste and Chemical Enforcement Division
Office of Civil Enforcement
U.S. Environmental Protection Agency
1595 Wynkoop Street (Mailstop: 8ENF-L)
Denver, CO 80202-1129

Karin Koslow, Esquire
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Mail Stop 2224A
Washington, DC 20460-2001



John J. McAleese, III