



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

BY HAND DELIVERY

JUN 10 2011

Sybil Anderson
Headquarters Hearing Clerk (1900L)
Office of Administrative Law Judges
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington D.C. 20460

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ENFORCEMENT AND
COMPLIANCE ASSURANCE
2011 JUN 10 PM 1:27

Re: Complainant's Initial Prehearing Exchange
Docket No. TSCA-HQ-2010-5022

Dear Ms. Anderson:

Enclosed please find an original and two (2) copies of Complainant's Initial Prehearing Exchange. Attached to Complainant's Initial Prehearing Exchange are Complainant's Exhibits Numbered 1 - 90.

Consistent with instructions from the Office of Administrative Law Judges, attached exhibits are provided in the following format: one (1) paper copy of Complainant's Exhibits 1-90; and two (2) Compact Disks (CD). Each CD contains electronic copies of Complainant's Exhibits Numbered 1 - 90.

Please file the original Initial Prehearing Exchange and return one date-stamped copy to Complainant.

Thank you for your attention to this matter.

Sincerely,


Mark A.R. Chalfant
Counsel for Complainant

Enclosures

Cc: John J. McAlesse, III, MORGAN LEWIS & BOCKIUS LLP (via overnight delivery)
The Honorable Susan L. Biro, U.S. EPA Office of Administrative Law Judges (hand delivery only)

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.)	COMPLAINANT'S PREHEARING
)	EXCHANGE
)	
)	
_____)	

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Pursuant to Rule 22.19(a) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation/Termination or Suspension of Permits ("Consolidated Rules of Practice"), 40 C.F.R. § 22.19(a), and the Order of Presiding Officer Susan L. Biro, dated April 28, 2011, Complainant, the United States Environmental Protection Agency (EPA or the Agency), respectfully submits Complainant's Initial Prehearing Exchange.

I. FACT AND EXPERT WITNESSES AND BRIEF NARRATIVE SUMMARY OF EXPECTED TESTIMONY

Complainant may call any and/or all of the following witnesses at a hearing of the above-captioned matter. In

addition, should Respondent's Initial Prehearing Exchange or other discovery reveal the need for further witnesses to rebut Respondent's case, Complainant respectfully reserves the right to supplement this list of witnesses upon adequate notice to the Presiding Officer and Respondent, and to call such witnesses at the hearing of this matter. Complainant reserves the right to cross-examine any witnesses offered by Respondent.

Complainant notes that some of the testimony described below may be rendered unnecessary by stipulations or by rulings on dispositive motions. It is Complainant's intent to promote judicial efficiency by resolving factual issues through stipulations or dispositive motions where possible.

Fact Witnesses

Fredric C. Arnold, Ph.D., EPA, Office of Chemical Safety and Pollution Prevention. Dr. Arnold is a Chemical Engineer in EPA's Economics, Exposure and Technology Division within the Office of Pollution Prevention and Toxics. Dr. Arnold holds a Doctorate in Chemical Engineering from the University of Minnesota, Minneapolis, Minnesota. Dr. Arnold is expected to testify regarding the matters discussed in his affidavit (CX 10) filed in connection with Complainant's Motion for Accelerated Decision on Liability. Dr. Arnold's testimony will

include, but not be limited to, technical information concerning chromium and the manufacture of chromium chemicals by the chromium production plants that participated in the "Collaborative-Cohort Mortality Study of Four Chromate Production Facilities, 1958 - 1998 (FINAL REPORT)," (referred to herein as the Modern Four Plant Report or Modern Report) (CX 1) and other chromium production plants. Dr. Arnold will testify about changes to the manufacturing process that the chromium industry has implemented to convert from a high-lime to a low- or no-lime manufacturing process.

Dr. Arnold will testify regarding Elementis' 2006 Inventory Update Reporting submissions to the Agency which document that Elementis is a manufacturer of: 1) trivalent chromium oxide (also known as chromic oxide); 2) hexavalent chromium oxide (also known as chromic acid); and 3) chromic acid ($H_2Cr_2O_7$), sodium salt (1:2) (also known as sodium dichromate). Dr. Arnold will testify that these three substances are "chemical substances," as defined by TSCA section 3.

Amanda Edens, Department of Labor, Occupational Safety and Health Administration. Ms. Edens is the Deputy Director for the Directorate of Guidance and Standards for the Occupational Safety and Health Administration (OSHA).

From 2002 until 2007, Ms. Edens was the Director of the Office of Chemical Hazards - Metals (OCH-M) for OSHA. The OCH-M was the lead OSHA office for overseeing the OSHA rulemaking to establish the revised Permissible Exposure Limit (PEL) for occupational exposure to hexavalent chromium (PEL rulemaking). See CX 70, 76. As the Director of the OCH-M, Ms. Edens was responsible for overseeing the PEL rulemaking from 2002 to 2006.

Ms. Edens will testify about her role in overseeing the PEL rulemaking. Ms. Edens will testify regarding the rulemaking process, including the legal standards of "material impairment of health" and "significance of risk." Ms. Edens will testify about OSHA's efforts to gather the best available information to resolve complex technical issues and fill data gaps as well as to develop and enhance the analyses necessary to support the PEL rulemaking. Ms. Edens will testify as to OSHA's "Request for information," which was published on August 22, 2002 in the Federal Register and was part of the PEL rulemaking. (CX 66). Ms. Edens will testify that OSHA's information request sought data, information, and comments on issues relevant to occupational exposure to hexavalent chromium including, among other things: significant epidemiological studies; the relationship between occupational exposures to

hexavalent chromium and the development of adverse health effects; and current exposures. Ms. Edens will testify that OSHA's information request specifically noted that this type of information was being sought to help OSHA address the "data gaps on current usage of and exposure to CrVI" and "differences in opinion on the interpretation of health effects data." Occupational Exposure to Hexavalent Chromium, Request for information, 67 Fed. Reg. 54,389, 54,390 (Aug. 22, 2002). Ms. Edens will testify that OSHA was seeking "information associated with, and analysis of, the most recent and important studies that the agency [OSHA] can use to evaluate health effects." Id. Ms. Edens will testify that OSHA was especially interested in receiving "studies of occupational exposure that quantify exposure data and control for important confounding variables, have good statistical power, and are well conducted." Id. at 54,391.

Ms. Edens will testify that the Modern Four Plant Report contains information responsive to OSHA's August 22, 2002 information request. Ms. Edens will testify that Elementis did not submit a copy of the Modern Four Plant Report to OSHA in response to the information request. Ms. Edens will testify that OSHA received a copy of the Modern Four Plant Report from a third party on June 29, 2005,

after the public comment period on the proposed PEL rule had closed.

Ms. Edens will testify regarding information OSHA received from Elementis (on behalf of the Chrome Coalition) and other parties in response to OSHA's August 22, 2002 information request. Ms. Edens will testify concerning testimony and comments received from Elementis, the Chrome Coalition, and others in response to OSHA's October 4, 2004 "Proposed rule; request for comments and scheduling of informal public hearings," which was published in the Federal Register. (CX 70). Ms. Edens will testify as to the testimony and comments received concerning the level of scientific uncertainty as to the extent of lung cancer mortality risk to workers from exposure to hexavalent chromium in modern (post-process change) chromium production plants.

Ms. Edens will testify regarding OSHA's process and rationale for concluding that all hexavalent chromium compounds should be considered carcinogenic and that a linear model should be used to estimate the lung cancer risk from low dose exposure.

Tony Ellis, EPA, Office of Enforcement and Compliance Assurance. Mr. Ellis is a Case Development Officer in the Waste and Chemical Enforcement Division within the Office

of Civil Enforcement, and serves as the Case Development Officer for EPA's enforcement action against Elementis Chromium, Inc. Mr. Ellis is expected to testify as to the calculation of EPA's proposed civil penalty in this matter, based on the facts of this case and the application of the Guidelines for Assessment of Civil Penalties Under Section 16 of the Toxic Substances Control Act; PCB Penalty Policy, 45 Fed. Reg. 59,770 (Sept. 10, 1980) (Guidelines) and the Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12 and 13, (March 31, 1999) (TSCA ERP), effective June 1, 1999. Mr. Ellis is expected to testify regarding the matters discussed in his affidavit (CX 12) filed in connection with Complainant's Motion for Accelerated Decision on Liability, including but not limited to, providing testimony to authenticate documents that Elementis Chromium, Inc. submitted to EPA in response to two TSCA subpoenas issued on August 22, 2008. Mr. Ellis will testify that the first time Elementis Chromium, Inc. submitted the Modern Four Plant Report to the Agency was on or about November 17, 2008, in response to EPA's August 22, 2008 TSCA subpoenas.

Oscar Hernandez, Ph.D., EPA, Office of Chemical Safety and Pollution Prevention. Dr. Hernandez is the Director of the Risk Assessment Division within the Office of Pollution

Prevention and Toxics (OPPT). Dr. Hernandez holds a Doctorate degree in Chemistry from the University of Virginia, Charlottesville, Virginia, and oversees a multi-disciplinary group of environmental professionals who provide expert scientific support in the areas of chemical hazard identification and risk assessment to OPPT's programs, including the TSCA section 8(e) substantial risk notification program.

Dr. Hernandez is expected to testify regarding the matters discussed in his affidavit (CX 13) filed in connection with Complainant's Motion for Accelerated Decision on Liability, including, but not limited to, testimony that TSCA section 8(e) sets the statutory reporting threshold at whether information "reasonably supports the conclusion of substantial risk of injury to health or environment." Dr. Hernandez will testify as to the EPA's TSCA section 8(e) substantial risk notification program's determination that the Modern Four Plant Report meets the TSCA section 8(e) statutory reporting threshold of reasonably supports the conclusion of substantial risk of injury to health.

Dr. Hernandez will testify about the TSCA section 8(e) substantial risk notification program generally, including an explanation of why the program is important to EPA, to

other agencies, and to the public. Dr. Hernandez will testify about how the Agency receives, uses, and shares information submitted under the TSCA section 8(e) substantial risk notification program. Dr. Hernandez will testify about the types of information the TSCA section 8(e) substantial risk notification program typically receives from persons subject to the reporting requirement.

Dr. Hernandez will testify that the first time OPPT learned about the existence of the Modern Four Plant Report was the week of February 24, 2006, through an inquiry from EPA's national enforcement office. Dr. Hernandez will testify that OPPT obtained a copy of the Modern Four Plant Report within weeks of learning of its existence. Dr. Hernandez will testify why the Modern Four Plant Report meets the statutory reporting threshold. Dr. Hernandez will testify that OPPT determined that the Modern Four Plant Report should have been submitted to the Agency immediately because it reasonably supports the conclusion of substantial risk of injury to health.

Dr. Hernandez will testify about why the Agency does not consider the Modern Four Plant Report to be "information which need not be reported," including testimony as to why the Modern Four Plant Report is not "corroborative" of other well-known, well-established

information about hexavalent chromium. Dr. Hernandez will testify that the Administrator was not informed of the information in the Modern Four Plant Report until the Agency actually obtained a copy of it and was then able to review the Modern Report.

Toni Krasnic, EPA, Office of Chemical Safety and Pollution Prevention. Mr. Krasnic is a Chemist in EPA's Chemical Control Division within the Office of Pollution Prevention and Toxics. Mr. Krasnic is the TSCA section 8(e) Coordinator for the Agency. Mr. Krasnic is expected to testify regarding the matters discussed in his affidavit (CX 14) filed in connection with Complainant's Motion for Accelerated Decision on Liability, including, but not limited to, EPA's TSCA section 8(e) guidance. Mr. Krasnic will testify why Elementis Chromium, Inc. was required to submit the Modern Four Plant Report to EPA's Document Processing Center for TSCA section 8(e) as a TSCA section 8(e) "substantial risk notice" under EPA's guidance.

Mr. Krasnic's testimony will include, as necessary, explanations of the TSCA Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk (1978 Policy Statement) (CX 17); the TSCA Section 8(e) Reporting Guide (1991 Reporting Guide) (CX 21); the TSCA Section 8(e); Notification of Substantial Risk; Policy

Clarification and Reporting Guidance (2003 Guidance) (CX 67); and the Agency's Frequently Asked Questions (2006 Qs & As). (CX 78). Mr. Krasnic's testimony will include an explanation of these TSCA section 8(e) guidance documents, and the Agency's experience in applying the guidance.

Mr. Krasnic will testify that the Modern Four Plant Report should have been submitted to the Agency as 8(e)-reportable information. Mr. Krasnic will testify as to why the Modern Four Plant Report cannot be considered "information which need not be reported."

Anjali Lamba, EPA, Office of Chemical Safety and Pollution Prevention. Ms. Lamba is a Certified Industrial Hygienist in the Economics, Exposure and Technology Division within the Office of Pollution Prevention and Toxics, and holds a Master of Public Health with specialization in Environmental-Occupational Health from The George Washington University in Washington D.C. Ms. Lamba is expected to testify regarding industrial hygiene and the role of a Certified Industrial Hygienist in industrial hygiene assessments and epidemiologic studies. Ms. Lamba will testify about the purpose, nature, and scope of a typical "industrial hygiene assessment." Ms. Lamba will testify as to the protocols typically used in conducting an industrial hygiene assessment, and how the

results of an industrial hygiene assessment are often used to determine if workers are exposed or overexposed to hazards, the adequacy of existing controls and personal protective equipment (PPE), and/or to recommend appropriate controls and PPE to protect workers. Ms. Lamba will testify as to how an industrial hygiene assessment compares to an epidemiologic study, and how industrial hygiene data is typically used in epidemiological studies. Ms. Lamba will testify about why the Modern Four Plant Report is not an industrial hygiene assessment, including providing testimony that an industrial hygiene assessment does not follow a study cohort retrospectively over several years to calculate mortality ratios. Ms. Lamba will testify about how the industrial hygiene data appears to have been used in the Modern Four Plant Report.

Chandler Sirmons, EPA, Office of Chemical Safety and Pollution Prevention. Mr. Sirmons is the Chief of the Records Docket Management Branch in the Information Management Division within the Office of Pollution Prevention and Toxics. Mr. Sirmons manages the staff responsible for the Confidential Business Information Center (CBIC) for TSCA section 8(e). The CBIC is the first unit within EPA to receive information reported to the Agency pursuant to TSCA section 8(e). Mr. Sirmons is

expected to testify that EPA did not receive the Modern Four Plant Report as a TSCA section 8(e) submission from Elementis Chromium, Inc.

Expert Witnesses

Richard W. Clapp, D.Sc., MPH. Dr. Clapp is a Senior Environmental Health Scientist with the Environmental Health Initiative in the Lowell Center for Sustainable Production at the School of Health and Environment, University of Massachusetts, Lowell, Massachusetts. Dr. Clapp is also a Professor Emeritus at the Boston University School of Public Health, Boston, Massachusetts. Dr. Clapp holds a Doctor of Science in Epidemiology from the Boston University School of Public Health, Boston, Massachusetts; a Master of Public Health in Health Services from the Harvard School of Public Health in Boston, Massachusetts; and a Bachelor of Arts from Dartmouth College in Hanover, New Hampshire. Dr. Clapp's Curriculum Vitae is included in Complainant's Initial Prehearing Exchange as CX 89. Dr. Clapp may testify about his educational background, research and professional experience.

Dr. Clapp is expected to testify as an expert witness in this case based on his extensive experience as an Epidemiologist. Dr. Clapp's epidemiologic work has included studies of Vietnam veterans exposed to Agent

Orange, studies of occupational exposure to electromagnetic fields, and studies of workers at various IBM computer manufacturing plants in the United States. Dr. Clapp has also testified about his work before three committees of Congress, and has both presented to and participated in committees of the National Academies of Science. Dr. Clapp will testify about the purpose of epidemiologic studies and the type of information such studies typically convey. Dr. Clapp will provide testimony regarding how epidemiologic studies are used by the scientific community, and specifically by the public health community. Dr. Clapp will testify about the benefit of relying on multiple epidemiologic studies when assessing health risks from exposure to a particular chemical.

Dr. Clapp will testify about the state of the scientific understanding of the risk of lung cancer mortality from occupational exposure to hexavalent chromium, including under both pre- and post-process change conditions (i.e., high-lime versus low- or no-lime). Dr. Clapp will testify that, as of the time of the Modern Four Plant Report, there was scientific uncertainty about the extent of risk that remained to workers in the modern, post-process change (i.e., low- or no-lime) chromium production plants.

Dr. Clapp will testify that the Modern Four Plant Report is a standard epidemiological mortality study, and that the Modern Four Plant Report follows established methodologies and protocols in the field of epidemiology. Dr. Clapp will testify that the Modern Four Plant Report is not an industrial hygiene study or assessment. Dr. Clapp will testify that the Modern Four Plant Report study analyzes hexavalent chromium exposure using two standard methods used in epidemiologic studies: 1) standardized mortality ratio (SMR) analysis using an external comparison group representing the general population in the study area; and 2) statistical modeling (logistic regression analysis) using an internal comparison group representing workers in the study with no or low exposure. Dr. Clapp will testify about the strengths and weaknesses of each method and that it is advantageous to evaluate risk using both methods in epidemiologic studies.

Dr. Clapp will testify that the Modern Four Plant Report concludes there is an elevated risk of lung cancer mortality for workers in the modern, or post-process change, plants. Dr. Clapp will testify that the workers studied in the Modern Four Plant Report experienced lower exposure levels to hexavalent chromium over a longer period of time than had been studied previously. Dr. Clapp will

testify that the Modern Four Plant Report provides information about risk to human health that was not previously known or available.

Dr. Clapp will testify about the Modern Four Plant Report and the Gibb et al. (2000a) studies and how each of these two studies contributes to the scientific understanding of the increased risk of lung cancer to workers in chromium processing plants.

Dr. Clapp is expected to testify, if necessary, that the Modern Four Plant Report study's employed methodology for converting the air monitoring exposure valuations to urine chromium levels followed an established protocol. Dr. Clapp will testify about how the protocol for the Modern Four Plant Report study (CX 2, 3) addressed the need for the conversion, and how the conversion appeared to be implemented. Dr. Clapp will provide testimony about the impact of the conversion on the Modern Four Plant Report's data and the conclusions presented in the Modern Four Plant Report.

Glinda Cooper, Ph.D., EPA, Office of Research and Development. Dr. Cooper is a Senior Epidemiologist for the National Center for Environmental Assessment in EPA's Office of Research and Development. Dr. Cooper holds a Bachelor of Science in Public Health from the University of

North Carolina, Chapel Hill, North Carolina; a Master of Science in Health Policy and Management from the Harvard School of Public Health, Boston, Massachusetts; and a Doctorate degree in Epidemiology from the University of North Carolina, Chapel Hill, North Carolina. Dr. Cooper's Curriculum Vitae is included in Complainant's Initial Prehearing Exchange as CX 88. Dr. Cooper may testify about her educational background, research, and professional experience in epidemiology and public health.

Dr. Cooper is expected to testify as an expert witness based on her professional training and experience as an Epidemiologist studying the effects on human health from exposure to chemical substances. Dr. Cooper is the lead EPA epidemiologist for updating the Agency's 1998 Toxicological Review of hexavalent chromium. The Toxicological Review provides scientific support and rationale for the hazard identification and dose-response assessment in EPA's Integrated Risk Information System (IRIS) pertaining to exposure to hexavalent chromium. EPA's National Center for Environmental Assessment (NCEA) within the Office of Research and Development (ORD) administers the IRIS program.

Dr. Cooper will testify regarding the identification of hazards and the exposure of workers to those hazards in

chromium production facilities, including the potential health effects of occupational exposure to hexavalent chromium. Her testimony will focus on lung cancer mortality risk from inhalation exposure to hexavalent chromium. Dr. Cooper will testify about EPA's classification of hexavalent chromium as a carcinogen and the significance of that classification. Dr. Cooper will testify about the potential significance of data from relatively low-exposure levels when EPA conducts a health assessment for a known carcinogen.

Dr. Cooper is expected to testify regarding the matters discussed in her affidavit (CX 11) filed in connection with Complainant's Motion for Accelerated Decision on Liability, including, but not limited to, testimony described herein. Dr. Cooper will testify about the state of scientific understanding of the extent of lung cancer mortality risk from occupational exposure to hexavalent chromium at the time the Modern Four Plant Report study was conducted. Dr. Cooper will testify as to the purpose, methodology, and conclusions of the Modern Four Plant Report study, and differences between the Modern Four Plant Report study, the Gibb et al. (2000a) study, and other previous occupational studies of chromate production workers.

Dr. Cooper will testify that the study described in the Modern Four Plant Report is the first large, comprehensive evaluation of lung cancer mortality among chromium production workers who had been employed exclusively in modern chromium production plants. Dr. Cooper will testify that the Modern Four Plant Report provides information about whether hexavalent chromium poses a risk of lung cancer to workers employed at chromate production facilities that used low- or no-lime manufacturing processes and instituted more stringent environmental controls to substantially reduce exposure levels. Dr. Cooper will testify that the Modern Four Plant Report study found elevated lung cancer mortality risk among workers who had been employed exclusively in modern chromium production plants. Dr. Cooper will testify that these workers were exposed to significantly lower estimated air concentrations of hexavalent chromium than had been experienced by workers in previous studies. Dr. Cooper will testify as to why exposure levels are a critical component for EPA in understanding and assessing risks from chemicals. Dr. Cooper will testify that the Modern Four Plant Report provides information about risk to human health that was not previously known or available.

If necessary, Dr. Cooper is prepared to testify as to EPA's considerations with respect to threshold and linear models for estimating risk of lung cancer from exposure to hexavalent chromium.

Frank E. Speizer, M.D. Dr. Speizer is the Edward H. Kass Distinguished Professor of Medicine at the Harvard Medical School in Boston, Massachusetts, and Professor of Environmental Science, Harvard School of Public Health. Dr. Speizer's research effort is divided between his role as a senior investigator in the Exposure, Epidemiology, and Risk Assessment Program in the Department of Environmental Health, at the Harvard School of Public Health and his responsibilities in the Channing Laboratory in the Department of Medicine at Harvard Medical School. The two programs are integrated specifically in the area of studies of the natural history of respiratory diseases and in the studies of environmental risks for chronic diseases including risks for cancer and cardiorespiratory diseases. The projects in cardiac and respiratory diseases involve population based studies of large groups of subjects who are identified because of acute and chronic exposure to indoor and outdoor air pollutants and are monitored for symptoms and physiologic changes as well as morbidity and mortality. In addition, Dr. Speizer has conducted

occupational cohort studies for cancer risks. Dr. Speizer holds a Bachelor of Arts degree in Biology from Stanford University in Palo Alto, California; and a Doctor of Medicine from Stanford University Medical School.

Dr. Speizer is expected to testify as an expert witness based on his extensive experience in public health, epidemiology, and medicine. Dr. Speizer is a pioneer in the field of chronic disease epidemiology, and established the landmark Nurses' Health Study in 1976 with funding from the National Institutes of Health. Dr. Speizer, through the Brigham and Women's Hospital and Harvard Medical School, was the founding Principal Investigator of the Nurses' Health Study, which involves 121,000 middle-aged women who have now been followed prospectively for over 35 years. The Nurses' Health Studies are among the largest and longest running investigations of factors that influence women's health. Dr. Speizer has also conducted landmark studies assessing the impact of air pollution on human health. He is a member of the National Academies of Science Institute of Medicine and has served on several review committees for the Academy. Dr. Speizer's Curriculum Vitae is included in Complainant's Initial Prehearing Exchange as CX 90. Dr. Speizer may testify

about his educational background, research and other professional experiences.

Dr. Speizer is expected to testify about the purpose of epidemiologic studies that assess the risks from occupational exposure to chemical substances generally, and the type of information such studies typically convey. Dr. Speizer will provide testimony regarding how epidemiologic studies are used to assess risk and understand disease. Dr. Speizer is expected to testify about the benefit of relying on multiple epidemiologic studies when assessing health risks from exposure to a particular chemical. Dr. Speizer will testify about the importance of continuing to study the human health impacts from known carcinogens, including hexavalent chromium.

Dr. Speizer will testify about the state of the scientific understanding of the risk of lung cancer mortality from occupational exposure to hexavalent chromium, including under both pre- and post-process change conditions (i.e., high-lime versus low- or no-lime). Dr. Speizer will testify that, as of the time of the Modern Four Plant Report study, there was scientific uncertainty about the extent of risk that remained to workers in the modern, post-process change (i.e., low- or no-lime) chromium production plants.

Dr. Speizer will testify that the Modern Four Plant Report is a standard retrospective cohort epidemiological mortality study, and that the Modern Four Plant Report follows established methodologies and protocols in the field of epidemiology. Dr. Speizer will testify that the Modern Four Plant Report, although it uses industrial hygiene techniques to define and estimate exposure, is not an industrial hygiene study or assessment. Dr. Speizer will testify that the Modern Four Plant Report study analyzes hexavalent chromium exposure using two standard methods used in epidemiologic studies: 1) standardized mortality ratio (SMR) analysis using an external comparison group representing the general population in the study areas; and 2) statistical modeling (logistic regression analysis) using an internal comparison group representing workers in the study with no or low exposure. Dr. Speizer will testify about the strengths and weaknesses of each method and that it is advantageous to evaluate risk using both methods in epidemiologic studies.

Dr. Speizer will testify that the Modern Four Plant Report concludes there is an elevated risk of lung cancer mortality for workers in the modern, or post-process change, plants. Dr. Speizer will testify that the workers studied in the Modern Four Plant Report experienced lower

exposure levels to hexavalent chromium over a longer period of time than had been studied previously. Dr. Speizer will testify the Modern Four Plant Report provides information about risk to human health that was not previously known or available. Dr. Speizer will testify that the Modern Four Plant Report provides considerable additional insight into the degree and nature of the occupational exposure and response in chromium processing workers. Dr. Speizer is expected to testify that the study summarized in the Modern Four Plant Report provides scientifically credible insight into the exposure-response relationship for workers exposed to CrVI, that the low- or no-lime change in processing appears to alter the risk of lung cancer, and that the study concludes an increased risk of lung cancer mortality remains for workers in the post-process change plants. Dr. Speizer will testify about the Modern Four Plant Report and the Gibb et al. (2000a) studies and how each of these two studies contributes to the scientific understanding of the increased risk of lung cancer to workers in chromium processing plants.

II. EXHIBITS COMPLAINANT INTENDS TO INTRODUCE INTO EVIDENCE AT HEARING

Complainant intends to introduce at hearing the exhibits numbered and listed below:

COMPLAINANT'S PROPOSED EXHIBIT LIST		
Complainant's Exhibit No.	Document	Number of Pages
	EXHIBITS PREVIOUSLY SUBMITTED WITH COMPLAINANT'S MOTION FOR ACCELERATED DECISION ON LIABILITY	
1.	Applied Epidemiology, Inc., <i>Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958 – 1998: Final Report</i> (Modern Four Plant Report), dated September 27, 2002	153
2.	Applied Epidemiology, Inc., <i>Draft Protocol – Collaborative Cohort Mortality Study of Five Chromate Production Facilities, 1958 – 1998</i> (Draft Protocol for Modern Four Plant Report), dated April 23, 1999	30
3.	Applied Epidemiology, Inc., <i>Revised Protocol – Collaborative Cohort Mortality Study of Five Chromate Production Facilities, 1958 – 1998</i> (Revised Protocol for Modern Four Plant Report), dated July 9, 1999	70
4.	Email from Marianne C. Kashak, Industrial Health Foundation, Inc., to Joel Barnhart, Vice President, Elementis Chromium – U.S. et al., entitled, "AEI's [Applied Epidemiology, Inc.'s] Final Report," dated October 8, 2002	1
5.	U.S. Environmental Protection Agency TSCA Subpoena in the Matter of Hexavalent Chromium Investigation Served on Dr. Joel Barnhart, Elementis, dated August 22, 2008	10
6.	Elementis response to U.S. Environmental Protection Agency TSCA Subpoena served on Dr. Joel Barnhart, Elementis, dated November 17, 2008, with index of responsive documents	34
7.	Elementis supplemental response to U.S. Environmental Protection Agency TSCA Subpoenas, dated December 12, 2008, with index of responsive documents	16
8.	Elementis 2006 TSCA section 8(e) Inventory Update Report (Chromic acid)	2
9.	Elementis 2006 TSCA section 8(e) Inventory Update Report (Chromium oxide)	3

COMPLAINANT'S PROPOSED EXHIBIT LIST		
Complainant's Exhibit No.	Document	Number of Pages
10.	Affidavit of Fredric Arnold, Ph.D., Engineer, Economics, Exposure and Technology Division, Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency	7
11.	Affidavit of Glinda Cooper, Ph.D., Senior Epidemiologist, National Center for Environmental Assessment, U.S. Environmental Protection Agency	10
12.	Affidavit of Tony Ellis, Case Development Officer, Waste and Chemical Enforcement Division, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency	2
13.	Affidavit of Oscar Hernandez, Ph.D., Director, Risk Assessment Division, Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency	4
14.	Affidavit of Toni Krasnic, TSCA 8(e) Coordinator, Chemical Control Division, Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency	5
	1951	
15.	T.F. Mancuso et al., <i>Occupational Cancer and Other Health Hazards in a Chromate Plant: A Medical Appraisal. I. Lung Cancers in Chromate Workers</i> , 20 IND. MED. SURG. 358 (1951)	6
	1975	
16.	T.F. Mancuso, <i>Consideration of Chromium as an Industrial Carcinogen</i> , Int'l Conf. on Heavy Metals in the Env't, Toronto, Ontario 343 (1975)	14
	1978	
17.	U.S. Environmental Protection Agency, Notification of Substantial Risk Under Section 8(e) (TSCA section 8(e) Guidance), 43 Fed. Reg. 11,110 (March 16, 1978)	7
	1979	
18.	R.B. Hayes et al., <i>Mortality in Chromium Chemical Production Workers: A Prospective Study</i> , 8 INT'L J. EPIDEMIOL. 365 (1979)	10
	1981	
19.	M.R. Alderson et al., <i>Health of workmen in the chromate-producing industry in Britain</i> , 38 BR. J. IND. MED. 117 (1981)	8
	1985	
20.	E.R. Braver et al., <i>An Analysis of Lung Cancer Risk From</i>	14

COMPLAINANT'S PROPOSED EXHIBIT LIST		
Complainant's Exhibit No.	Document	Number of Pages
	<i>Exposure to Hexavalent Chromium</i> , 5 TERATO., CARCINOGEN., and MUTAGEN. 365 (1985)	
	1991	
21.	U.S. Environmental Protection Agency, <i>TSCA Section 8(e) Reporting Guide</i> (June 1991)	122
22.	J.M. Davies et al., <i>Mortality from respiratory cancer and other causes in United Kingdom chromate production workers</i> , 48 BR. J. IND. MED. 299 (1991)	15
23.	The Chemical Manufacturers Association's Epidemiology Task Group, <i>Guidelines for Good Epidemiology Practices for Occupational and Environmental Epidemiologic Research</i> , 33 J. OCCUP. MED. 1221 (1991)	9
	1993	
24.	U.S. Environmental Protection Agency, TSCA Section 8(e); Notification of Clarification and Solicitation of Public Comment, 58 Fed. Reg. 37,735 (July 13, 1993)	8
25.	U. Korallus et al., <i>Bronchial carcinoma mortality in the German chromate-producing industry: The effects of process modification</i> , 65 INT'L ARCH. OCCUP. ENVIRON. HEALTH 171 (1993)	8
	1994	
26.	H. Pastides et al., <i>A Retrospective-Cohort Study of Occupational Exposure to Hexavalent Chromium</i> , 25 AM. J. IND. MED. 663 (1994)	13
	1996	
27.	Minutes of Chrome Coalition Ad Hoc PEL [Permissible Exposure Limit] Committee – Special Meeting with ChemRisk, dated February 13, 1996	3
28.	Chrome Coalition Ad Hoc PEL Committee – Special Meeting/Interview with ChemRisk Committee – Discussions and Recommendations, dated February 13, 1996	3
29.	Memorandum entitled, "Recent Activities of the Chrome Coalition OSHA/PEL [Permissible Exposure Limit] Ad Hoc Committee," from M.A. Buczynski, Occidental Chemical Corporation, to Dave B. Stephenson, Occidental Chemical Corporation, dated April 4, 1996	1
30.	Minutes of the Environmental Subcommittee – IHF Chromium Chemicals Health and Environmental Committee, dated October 16, 1996	4
31.	Minutes of the Management Committee Meeting – IHF Chromium Chemicals Health and Environmental Committee, dated October 17, 1996	7

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	1997	
32.	Facsimile Transmittal from Bruce Norman, Elementis Chromium – UK, to Members IHF Health, Safety, and Environment Committee, dated March 17, 1997	3
33.	Applied Epidemiology, Inc., <i>Epidemiological Study of Six Modern Chromate Production Facilities: A Unified Strategy for Updating Mortality Experience Through 1998 (A Draft Proposal)</i> , dated March 17, 1997 (Draft Protocol for Modern Four Plant Report)	21
34.	Minutes of the Special Session of the Epidemiology/ Human Effects Subcommittee Meeting – IHF Chromium Chemicals Health and Environmental Committee, dated April 16, 1997	8
35.	Letter from Leo Miksche, Bayer, AG, and Kenneth A. Mundt, Applied Epidemiology, Inc., to Kamal Singh, Occidental Chemical Corporation, entitled, “Exposure Questionnaire,” dated September 18, 1997	1
36.	Applied Epidemiology, Inc., <i>Epidemiological Study of Six Modern Chromate Production Facilities: A Unified Strategy for Updating Mortality Experience Through 1998 – Part I: Exposure Assessment – A Draft Proposal</i> , dated October 21, 1997 (Draft Protocol for Modern Four Plant Report)	14
37.	Minutes of the Special Session of the Epidemiology/ Human Effects Subcommittee Meeting – IHF Chromium Chemicals Health and Environmental Committee, dated October 22, 1997	3
38.	Minutes of the Environmental Subcommittee Meeting – IHF Chromium Chemicals Health and Environmental Committee, dated October 23, 1997	3
39.	Minutes of the Epidemiology/Human Effects Subcommittee Meeting – IHF Chromium Chemicals Health and Environmental Committee, dated October 23, 1997	4
40.	Letter from Kenneth A. Mundt, Ph.D., Applied Epidemiology, Inc., to Marianne Kaschak, Industrial Health Foundation, Inc., dated November 19, 1997, transmitting revised proposal and attachment entitled, <i>Collaborative Cohort Mortality Study of Six Chromate Production Facilities, 1958-1998 (A Proposal)</i> , dated November 18, 1997	36
41.	Memorandum from Joel Barnhart to IHF Chromium Chemicals Health and Environmental Committee entitled,	2

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	"OSHA Consideration of a Workplace Standard for Cr+6," dated November 19, 1997	
42.	T.F. Mancuso, <i>Chromium as an Industrial Carcinogen: Part I</i> , 31 AM. J. IND. MED. 129 (1997)	11
	1998	
43.	Email from Mark R. Stenzel to Gene Renzaglia, Plant Manager, Castle Hayne, North Carolina, Occidental Chemical Corporation (OxyChem) et al., entitled, "Re: AEI Epidemiology Proposal," dated January 26, 1998	2
44.	Applied Epidemiology, Inc., <i>Collaborative Cohort Mortality Study of Five Chromate Production Facilities, 1958 – 1998, Revised Proposal</i> , dated February 24, 1998	39
45.	"Agreement for Consulting Services," between the Industrial Health Foundation, Inc. and Applied Epidemiology, Inc., dated March 1, 1998, regarding consulting services for proposed epidemiology study entitled, <i>Collaborative Cohort Mortality Study of Five Chromate Production Facilities, 1958 – 1998: Revised Proposal</i> , Applied Epidemiology, Inc., dated February 24, 1998	46
46.	Letter from Kenneth A. Mundt, Applied Epidemiology, Inc., to Marianne C. Kaschak, Industrial Health Foundation, Inc., entitled, "Signed contract," dated April 4, 1998	1
47.	Minutes of the Special Session of the Epidemiology/ Human Effects Subcommittee Meeting – IHF Chromium Chemicals Health and Environmental Committee, dated April 21, 1998	3
48.	Minutes of the Management Committee Meeting – IHF Chromium Chemicals Health and Environmental Committee, dated April 23, 1998	7
49.	Letter from R.J. Barnhart, Ph.D., Vice President – Technical, Elementis Chromium, to Kenneth A. Mundt, Applied Epidemiology, Inc., dated June 1, 1998, and signed copy of new contract, "AGREEMENT FOR CONSULTING SERVICES," between Elementis Chromium, LP and Applied Epidemiology, Inc., dated May 22, 1998	11
50.	Invoice #EC98-0616 for \$15,000 from Kenneth A. Mundt, Ph.D., to R. Joel Barnhart, Ph.D., Vice-President-Technical, Elementis Chromium, LP, dated June 16, 1998	1
51.	Elementis Chromium – Check Preparation Request for \$15,000 to Applied Epidemiology Inc., dated June 19,	1

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	1998	
52.	Letter from Bruce Norman, Chairman, Chromium Chemicals Health and Environmental Committee, Industrial Health Foundation, Inc., to Dr. Adam Finkle, Occupational Safety and Health Administration, U.S. Department of Labor, dated July 24, 1998	1
53.	U.S. Environmental Protection Agency, <i>Toxicological Review of Hexavalent Chromium (CAS No. 18540-29-9): In Support of Summary Information on the Integrated Risk Information System (IRIS)</i> (August 1998)	77
54.	Minutes of the Management Committee Meeting – IHF Chromium Chemicals Health and Environmental Committee, dated October 8, 1998	6
	1999	
55.	Email from Bruce Norman, Elementis Chromium – UK, to Joel Barnhart, Elementis Chromium – U.S. et. al., entitled, “Re: Chrome Study,” dated February 15, 1999	1
56.	Email from Joel Barnhart, Elementis Chromium – U.S., to Bruce Norman, Elementis Chromium – UK, dated February 19, 1999	2
57.	Email from Ching Aw, Elementis Chromium – UK, to Joel Barnhart, Elementis Chromium – U.S., entitled “Study Protocol etc.,” dated March 1, 1999	5
58.	Letter from Joseph P. Tritschler II, Applied Epidemiology, Inc., to Marianne C. Kaschak, Industrial Health Foundation Inc., dated March 30, 1999, with enclosures: <i>Guidelines for Good Epidemiology Practices for Occupational and Environmental Epidemiologic Research</i> , 33 J. OCCUP. MED. 1221 (1991), and <i>A Proposal for a Code of Good Epidemiological Practice</i> (March 1997)	50
59.	Email from Kenneth A. Mundt, Applied Epidemiology, Inc., to Marianne C. Kaschak, Industrial Health Foundation, Inc., entitled, “RE: Athens Conference,” dated June 23, 1999	1
60.	Facsimile Transmittal from Grant Darrie, Elementis Chromium – UK (Eaglescliffe, England), to Marianne C. Kaschak, Industrial Health Foundation, Inc., dated June 28, 1999, with copy to Joel Barnhart, Elementis Chromium – US	1
61.	U.S. Environmental Protection Agency, <i>Guidelines for Carcinogen Risk Assessment</i> (Review Draft) (July 1999)	211
	2000	
62.	H.J. Gibb et al., <i>Lung Cancer Among Workers in</i>	12

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Complainant's Exhibit No.	Document	Number of Pages
	<i>Chromium Chemical Production</i> , 38 AM. J. IND. MED. 115 (2000)	
	2001	
63.	Final Invoice #EC01-0628 for \$11,480 from Kenneth A. Mundt, Ph.D., Applied Epidemiology Inc., to R. Joel Barnhart, Ph.D., Vice-President-Technical, Elementis Chromium, LP, dated June 28, 2001	1
64.	Elementis Chromium – Check Preparation Request for – \$11,480 to Applied Epidemiology Inc. (Final Payment for Project Work), dated July 11, 2001	1
	2002	
65.	“Critique of Two Studies by Gibb et al.: Lung Cancer Among Workers in Chromium Chemical Production; Clinical Findings of Irritation Among Chromium Chemical Production Workers,” prepared by Exponent for Chromium Coalition and submitted as Appendix E to a filing in OSHA Docket No. H054a, dated June 2002	51
66.	U.S. Department of Labor, Occupational Safety and Health Administration, Occupational Exposure to Hexavalent Chromium (CrVI), Request for information, 67 Fed. Reg. 54,389 (Aug. 22, 2002)	6
	2003	
67.	U.S. Environmental Protection Agency, TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance (TSCA section 8(e) Guidance), 68 Fed. Reg. 33,129 (June 3, 2003)	12
68.	C. Crump et al., <i>Dose-Response and Risk Assessment of Airborne Hexavalent Chromium and Lung Cancer Mortality</i> , 23(6) RISK ANAL. 1147 (2003)	17
69.	R.S. Luippold et al., <i>Lung cancer mortality among chromate production workers</i> , 60 OCCUP. ENVIRON. MED. 451 (2003)	7
	2004	
70.	U.S. Department of Labor, Occupational Safety and Health Administration, Occupational Exposure to Hexavalent Chromium, Proposed rule; request for comments and scheduling of informal public hearings, 69 Fed. Reg. 59,306 (Oct. 4, 2004)	169
71.	Affidavit of Dr. Joel Barnhart, Vice President, Elementis Chromium, U.S. Bankruptcy Court for the Western District of Pennsylvania, dated December 17, 2004	3
	2005	
72.	U.S. Environmental Protection Agency, <i>Guidelines for</i>	166

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	<i>Carcinogen Risk Assessment</i> (EPA/630/P-03/001B) (March 2005)	
73.	Letter from Peter Lurie, Deputy Director, and Scott L. Nelson, Senior Attorney, Public Citizen, to Amanda Edens, Occupational Safety and Health Administration, U.S. Department of Labor, dated June 29, 2005	2
74.	R. Luippold et al., <i>Low-Level Hexavalent Chromium Exposure and Rate of Mortality Among US Chromate Production Employees</i> , 47(4) J. OCCUP. ENVIRON. MED. 381 (2005)	5
	2006	
75.	Rick Weiss, <i>Chromium Evidence Buried, Report Says: Authors Fault Industry Researchers</i> , WASH. POST, Feb. 24, 2006	3
76.	U.S. Department of Labor, Occupational Safety and Health Administration, Occupational Exposure to Hexavalent Chromium; Final Rule, 71 Fed. Reg. 10,100 (Feb. 28, 2006) (amending 29 C.F.R. parts 1910, 1915, 1917, 1918 and 1926)	287
77.	U.S. Environmental Protection Agency, Memorandum entitled, <i>Determination of TSCA Section 8(e) Roles and Responsibilities</i> , with August 1, 2006 effective date	3
78.	U.S. Environmental Protection Agency, <i>EPA Toxic Substances Control Act 8(e) Frequent Questions</i> (September 2006)	14
79.	T Birk et al., <i>Lung Cancer Mortality in the German Chromate Industry, 1958 - 1998</i> , 48(4) J. OCCUP. ENVIRON. MED. 426 (2006)	8
80.	R. M. Park et al., <i>A Search for Thresholds and Other Nonlinearities in the Relationship Between Hexavalent Chromium and Lung Cancer</i> , 26(1) RISK ANAL. 79 (2006)	10
	2008	
81.	U.S. Environmental Protection Agency TSCA Subpoena in the Matter of Hexavalent Chromium Investigation served on Mr. Eugene Renzaglia, dated August 22, 2008	10
82.	Elementis response to U.S. Environmental Protection Agency TSCA Subpoena served on Mr. Eugene Renzaglia, Elementis, dated November 17, 2008, with index of responsive documents	20
	2009	
83.	Tolling Agreement between U.S. Environmental Protection Agency and Elementis Chromium, LP signed June 30, 2009	2

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Complainant's Exhibit No.	Document	Number of Pages
84.	U.S. Environmental Protection Agency, Notice of Violation and Opportunity to Show Cause for Elementis Chromium, LP, with enclosed Summary of Violation, dated September 3, 2009	3
85.	Tolling Agreement between U.S. Environmental Protection Agency and Elementis Chromium, LP signed September 28, 2009	2
86.	Tolling Agreement between U.S. Environmental Protection Agency and Elementis Chromium, LP signed October 30, 2009	2
87.	Tolling Agreement between U.S. Environmental Protection Agency and Elementis Chromium, LP signed December 4, 2009	2
	2010	
88.	Curriculum Vitae of Glinda S. Cooper, Ph.D.	20
	2011	
89.	Curriculum Vitae of Richard W. Clapp, D.Sc., MPH	10
90.	Curriculum Vitae of Frank E. Speizer, M.D.	47

III. PLACE FOR HEARING AND ESTIMATED TIME FOR DIRECT CASE

Complainant's preferred place of hearing is Washington, D.C. Complainant estimates that presenting the direct case will take five (5) days. Complainant is not requesting translation services.

IV. DOCUMENTS IN SUPPORT OF THE ALLEGATIONS IN PARAGRAPHS 4, 7 AND 13 OF THE COMPLAINT

The following is responsive to the Presiding Officer's request for a copy of any documents in support of the allegations in Paragraphs 4, 7, and 13 of the Complaint.

Paragraph 4: Paragraph 4 of the Complaint alleges, "Respondent manufactures, processes, or distributes in commerce a chemical substance or mixture as those terms are

defined in TSCA § 3, 15 U.S.C. § 2602, and TSCA § 8(f), 15 U.S.C. § 2607(f).” As Respondent’s 2006 Inventory Update Rule submissions to the Agency show, Elementis is a manufacturer of: 1) trivalent chromium oxide (also known as chromic oxide); 2) hexavalent chromium oxide (also known as chromic acid); and 3) chromic acid (H₂Cr₂O₇), sodium salt (1:2) (also known as sodium dichromate). (CX 8, 9). These substances are “chemical substances,” as that term is defined under TSCA. Respondent admits that it is a “manufacturer, processor and distributor of chromium chemical products, including chromic oxide, chromic acid and sodium dichromate.” (Resp’t Mem. in Opposition to Complainant’s Mot. for Accelerated Decision on Liability at 4).

Paragraph 7: Paragraph 7 of the Complaint alleges, “Respondent has a domestic chromium manufacturing facility known as Castle Hayne (Castle Hayne Facility), located at 5408 Holly Shelter Road in North Carolina. Respondent was the owner and operator of the Castle Hayne Facility at all times relevant to this Complaint.” TSCA section 8(e) liability attaches to “[a]ny person who manufactures, processes, or distributes in commerce a chemical substance or mixture...” 15 U.S.C. § 2607(e). Although Respondent has denied being the owner and operator of the Castle Hayne

Facility at all times relevant to the Complaint, Respondent has admitted that it acquired the Castle Hayne Facility in December, 2002, approximately two months after it received the Modern Four Plant Report and nearly six years before it submitted the Modern Four Plant Report to the Agency during the period of continuing violation. See Answer ¶¶ 7, 41; Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 2.

For purposes of EPA's prima facie case, Complainant need only prove that Respondent is one of the following: a manufacturer, a processor, or a distributor in commerce of a chemical substance or mixture. 15 U.S.C. § 2607(e). In its response to Complainant's Motion for Accelerated Decision on Liability, Respondent admits, "Elementis is a manufacturer, processor and distributor of chromium chemical products, including chromic oxide, chromic acid and sodium dichromate." (Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 4) (emphasis added). Elsewhere in its response, Respondent states that "there is no dispute that Elementis is a manufacturer, processor and distributor in commerce of hexavalent chromium-containing chemicals." Id. at 11. Consequently, Respondent's status as a manufacturer, processor, and distributor in commerce is undisputed.

Paragraph 13: Paragraph 13 of the Complaint alleges, "Respondent manufactures chromium chemicals using the metallic element chromium." At the time EPA filed the Complaint, it was the Agency's understanding that Elementis manufactured chromium chemicals using the metallic element chromium. Since filing the Complaint EPA has since ascertained that it is more accurate to state that chromium chemicals are manufactured using sodium dichromate or other chromate compounds derived from sodium dichromate. However, for purposes of EPA's prima facie case, Complainant need only establish and prove that Respondent is a manufacturer, processor, or distributor in commerce of a chemical substance or mixture. In its Answer, Respondent admits that it manufactures and distributes in commerce chromic acid, chromic oxide, and sodium dichromate. (Answer ¶ 12). Respondent further admits that chromic acid and sodium dichromate are hexavalent chromium compounds. (Answer ¶ 18). Moreover, in its Response to Complainant's Motion for Accelerated Decision on Liability, Respondent admits, "Elementis is a manufacturer, processor and distributor of chromium chemical products, including chromic oxide, chromic acid and sodium dichromate." (Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 4) (emphasis added).

Elsewhere in its response, Respondent states that "there is no dispute that Elementis is a manufacturer, processor and distributor in commerce of hexavalent chromium-containing chemicals." Id. at 11. Consequently, Respondent's status as a manufacturer, processor, and distributor in commerce of a chemical substance or mixture is undisputed.

V. FINAL FOUR PLANT REPORT

A copy of the final four plant report "Collaborative-Cohort Mortality Study of Four Chromate Production Facilities, 1958 - 1998 (FINAL REPORT)," prepared by Applied Epidemiology, Inc. for Industrial Health Foundation, Inc., also referred to as the Modern Four Plant Report or Modern Report, is included in Complainant's Initial Prehearing Exchange at CX 1.

VI. STATEMENT OF THE PROPOSED PENALTY

Pursuant to 40 C.F.R. § 22.14(a)(4)(ii), Complainant did not propose a specific penalty in the Complaint. Pursuant to 40 C.F.R. § 22.19(a)(4), where the Complaint does not propose a specific penalty, a penalty is to be proposed within fifteen (15) days after Respondent files its Prehearing Exchange. However, in accordance with the Presiding Officer's April 28, 2011 Prehearing Order, Complainant has included in its Initial Prehearing Exchange a statement of the proposed penalty, including an

explanation of how the proposed penalty was calculated. Complainant's proposed penalty in this matter is \$2,338,000 as explained below. Upon receipt of Respondent's Initial Prehearing Exchange if new information is made available to Complainant warranting an adjustment to this proposed penalty, Complainant will submit an adjusted proposed civil penalty and explain such adjustments to the Presiding Officer within fifteen days after Respondent's Initial Prehearing Exchange consistent with 40 C.F.R.

§ 22.19(a)(4).¹

TSCA section 16(a)(1) authorizes the assessment of a civil penalty for violations of TSCA section 15 (15 U.S.C. § 2614) in an amount not to exceed \$25,000 for each day of the violation. 15 U.S.C. § 2615(a)(1). The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, requires EPA to adjust penalties to account for inflation. EPA's Civil Monetary Penalty Inflation Adjustment Rule establishes \$27,500 for each day of violation as the maximum civil penalty that may be assessed under TSCA section 16(a), per

¹ With respect to Respondent's ability to pay the proposed penalty, it is Respondent's responsibility to assert such a claim and provide to Complainant financial information and documentation regarding its own finances to support and establish any such claim that Respondent is unable to pay the proposed penalty. This will allow Complainant to evaluate and consider Respondent's ability to pay when calculating a revised appropriate proposed penalty.

violation, occurring between January 30, 1997 and March 15, 2004; \$32,500 for violations occurring between March 16, 2004 and January 12, 2009; and \$37,500 for violations occurring after January 12, 2009. See 40 C.F.R. part 19.

Respondent Elementis obtained a 2002 epidemiologic study of lung cancer mortality risk to workers from occupational exposure to hexavalent chromium, a known carcinogen, in modern chromium production plants. This 2002 study, which we refer to as the Modern Four Plant Report or Modern Report, was the first to show increased lung cancer mortality risk among workers who had worked exclusively in plants utilizing modern low- or no-lime manufacturing processes. The Modern Four Plant Report reasonably supports the conclusion that hexavalent chromium exposure presents a substantial risk of injury to health. Yet, in spite of obtaining this study, Elementis failed to inform the Administrator of the Modern Four Plant Report or its findings until it responded in 2008 to TSCA subpoenas issued by EPA. Respondent's failure or refusal to immediately submit the Modern Four Plant Report to the Agency constitutes a violation of TSCA section 8(e), 15 U.S.C. § 2607(e), an unlawful act under TSCA section 15(3)(B), 15 U.S.C. § 2614(3)(B), and is subject to penalties under TSCA section 16, 15 U.S.C. § 2615.

Respondent's violation began on October 8, 2002 upon its receipt of the Modern Four Plant Report, and continued until such time as Respondent submitted the information to the Administrator, or Respondent had actual knowledge that the Administrator had been adequately informed of such information. Respondent has failed to provide any specific facts or circumstances to support its contention that Elementis had actual knowledge the Administrator was adequately informed of the information in the Modern Four Plant Report at any point prior to when Respondent submitted the Modern Four Plant Report to Complainant on November 17, 2008, in response to the TSCA subpoenas. Therefore, the violation start date for purposes of calculating the proposed civil penalty is October 8, 2002 and the violation end date is November 16, 2008.²

The Agency uses TSCA section 8(e) information to assess risk in a variety of circumstances; therefore, the timely submission of section 8(e)-reportable information is essential to the Agency's chemical hazard identification and risk assessment, regulatory priority setting, and

² Elementis Chromium, Inc. submitted the Modern Four Plant Report to EPA on November 17, 2008; EPA has determined that the last day of the violation for purposes of the penalty calculation is November 16, 2008. As explained below, EPA has subtracted fifteen working days from the violation period for purposes of calculating the proposed penalty. This was done in recognition of the Agency's policy at the time of the violation which provided that TSCA section 8(e) information should be submitted to the Administrator within fifteen working days from when it is obtained.

regulation development processes. EPA considers the reporting requirement in TSCA section 8(e) to be critically important as an information gathering tool that serves as an early warning mechanism for keeping EPA, other federal agencies, and the public apprised of chemical hazards. The statute requires that this type of information be reported "immediately" to the Administrator; in this instance, Respondent did not submit the information to EPA until it was specifically requested by the Agency through a subpoena, more than six years after Respondent had obtained the information.

The proposed penalty of \$2,338,000 in this matter has been determined in accordance with the penalty factors established in TSCA section 16(a)(2)(B), 15 U.S.C. § 2615(a)(2)(B), which requires EPA to take into account the nature, circumstances, extent, and gravity of the violations alleged, as well as Respondent's ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. In developing the proposed penalty, Complainant relied upon the following two Agency guidance documents: the Guidelines and the TSCA ERP. The TSCA ERP provides a rational, consistent, and

equitable calculation methodology for applying the statutory factors enumerated above to particular cases.

It is undisputed that Respondent obtained the Modern Four Plant Report on October 8, 2002 and did not submit it to the Agency until November 17, 2008. (Respondent's Memorandum in Opposition to Complainant's Motion for Accelerated Decision on Liability at 11). This violation spanned a total of 2,232 days (6 years, 1 month and 9 days). As explained above, the civil penalty assessed in this matter may be up to \$27,500 per day for the violation period running from the first day of violation on October 8, 2002, through March 15, 2004 (first phase of the calculation) and \$32,500 per day for the violation period running from March 16, 2004 through the last day of the violation, November 16, 2008 (second phase of the calculation).³ Thus, the maximum allowable statutory penalty for Elementis' continuous violation of TSCA section 8(e), spanning more than six years, would be over \$69 million. However, EPA is not proposing the statutory maximum penalty in this matter, and has applied the factors

³ The penalty calculation is divided into "phases" to reflect the increase in the daily penalty amount that occurred during the period of continuous violation in this matter. As stated earlier, federal law requires the Agency to routinely adjust statutory daily penalty amounts to account for inflation.

in the TSCA ERP to determine that a penalty of \$2,338,000 is appropriate and reasonable.

In calculating the appropriate proposed civil penalty for this TSCA section 8(e) violation, EPA determined the "base penalty" for the violation using the TSCA ERP and its Penalty Matrix. As explained below, the base penalty is used in a formula provided in the TSCA ERP to determine the appropriate "gravity based penalty." After the gravity based penalty is calculated, it may be adjusted upward or downward by taking into account the following factors: degree of culpability; history of prior such violations; ability to pay; ability to continue in business; and such other matters as justice may require.

Base Penalty

To establish the base penalty in this case, EPA has used the analytical framework in the TSCA ERP. As the TSCA ERP provides, a violation may be classified as chemical control, chemical-associated data gathering, or hazard/risk assessment in nature. TSCA ERP at 9. For all reporting violation penalty assessments, the nature of the violation is "hazard/risk assessment." TSCA ERP at 9, 18. This classification stems from the Agency's use of TSCA section 8(e) information to evaluate the potential risks associated with chemicals and to initiate immediate action necessary

to protect health and the environment. TSCA ERP at 20. As such, the nature of this TSCA section 8(e) violation is "hazard/risk assessment."

The circumstances component of the violation establishes the "level" of the base penalty, which is found on the vertical or y-axis of the Penalty Matrix in the TSCA ERP. TSCA ERP at 18. The circumstances axis reflects the probability of harm resulting from a particular violation. Id. For reporting violations, the potential harm is to the Agency's ability to assess hazard/risk to human health and the environment. Id. As the TSCA ERP states, "non reporting/failure to report ... are extremely serious violations...." Id. at 19. Similarly, the TSCA ERP states, "Failure to comply with the TSCA § 8(e) reporting requirements can be the most serious violation of TSCA § 8." Id. at 20. Non-reporting of TSCA section 8(e) information is treated as a "Level 1" violation, and the TSCA ERP further provides that penalties for this type of violation should be assessed on a per day basis. Id. at 9.

The extent of the violation reflects the extent of potential harm caused by a violation, and is found on the horizontal or x- axis of the Penalty Matrix. For reporting requirements such as TSCA section 8(e), "harm is defined as the inability of the Agency to carry out its risk

assessment responsibilities under TSCA.” Id. at 11.

Respondent’s failure to submit the Modern Four Plant Report to the Agency constitutes a violation of TSCA section 8(e) involving human data, and, therefore, is characterized as a “Major Extent” violation.

This is one of the most serious violation types for purposes of calculating the appropriate penalty and, consequently, is subject to the highest base penalty under the TSCA ERP’s Penalty Matrix. Pursuant to the Penalty Matrix, the base penalty for the first phase of the calculation is \$27,500 and the base penalty for the second phase of the calculation is \$32,500.

Gravity Based Penalty

After determining the base penalty for the violation, EPA applied the appropriate formula to determine the gravity based penalty. TSCA section 8(e) violations do not have a cap on the number of days for penalty assessment; therefore, EPA is entitled to propose an assessment of penalties for every day of the violation. The TSCA ERP notes that

[f]ailure to comply with the TSCA §8(e) reporting requirements can be the most serious violation of TSCA §8. These reports alert the Agency to new information which may have a bearing on the Agency’s chemical hazard/risk assessment and chemical control efforts. This ERP reflects the seriousness the Agency attaches

to violations of TSCA §8(e) by not placing caps on the penalties assessed for these violations.

TSCA ERP at 20. Assessment of a per day penalty for the full period of violation is consistent with both section 16(a)(1) of TSCA, which provides for penalties to be assessed for each day of the violation, and with the Presiding Officer's ruling that TSCA section 8(e) violations are continuing in nature. (Order on Respondent's Motion for Judgment on the Pleadings at 12 (March 25, 2011)). In this case, the TSCA section 8(e) violation did not disrupt the Agency's ability to address situations which involve potential imminent hazard, substantial endangerment situations or unreasonable risks. Therefore, the formula provides for a significant reduction in the per day penalty assessment for a TSCA section 8(e) violation, after the first day of violation. The applicable penalty formula for determining the gravity based penalty in this matter is as follows:

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

30

As explained in the TSCA ERP, the first "Base Penalty" in the formula represents the first day of the violation.

In applying the applicable formula above to calculate the gravity based penalty, EPA has determined it was reasonable to use October 29, 2002 as the first day of violation for purposes of calculating the gravity based penalty. This applies a fifteen working day "grace period" that was provided for in the Agency's guidance at the time of the violation, even though the statute requires that the information be reported "immediately" to the Administrator. See 1978 Policy Statement (CX 17). Therefore, the gravity based penalty is based on a period of violation beginning October 29, 2002 and ending November 16, 2008 and is calculated as follows:

$$\begin{aligned} \text{First phase: } & \text{October 29, 2002 - March 14, 2004} = 503 \text{ days} \\ & 27,500 + \frac{(503-1) \times 27,500}{30} = \underline{\$487,667} \end{aligned}$$

$$\begin{aligned} \text{Second phase: } & \text{March 15, 2004 - November 16, 2008} = 1,708 \text{ days} \\ & \frac{(1708) \times 32,500}{30} = \underline{\$1,850,333} \end{aligned}$$

The final gravity based penalty for this action is equal to the sum of the two phases and is \$2,338,000.

Adjustments to Gravity Based Penalty

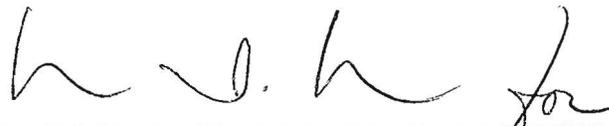
EPA has considered the adjustment factors and has determined at this time that no upward or downward adjustment to the gravity based penalty is appropriate in

this case and therefore the gravity based penalty is the proposed civil penalty amount to be assessed in this matter. However, as noted above, EPA will consider new information received after the filing of this Initial Prehearing Exchange and submit to the Presiding Officer any appropriate adjustments to the proposed penalty within fifteen days of Respondent's Initial Prehearing Exchange consistent with 40 C.F.R. § 22.19(a)(4).

VII. EPA PENALTY POLICY

In developing the proposed penalty, Complainant only relied upon the following two Agency guidance documents: the Guidelines and the TSCA ERP, effective June 1, 1999. Complainant previously provided a copy of these guidance documents to Respondent at the time Complainant filed the Complaint.

Respectfully submitted,



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303-312-6177

June 19, 2011
Date

CERTIFICATE OF SERVICE

I certify that the foregoing *Complainant's Initial Prehearing Exchange* in Docket No. TSCA-HQ-2010-5022, dated June 10, 2011, was sent this day in the following manner to the addresses listed below:

Original by hand;

and email (without Exhibits to):

Sybil Anderson
Headquarters Hearing Clerk
U.S. Environmental Protection Agency
Office of Administrative Law Judges
Franklin Court, Suite 350
1099 14th Street, N.W.
Washington, DC 20005

Overnight delivery to:

Attorneys for Respondent: John J. McAleese, III
Ronald J. Tenpas
William S. Pufko
Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103

Copy by hand to:

Presiding Judge: The Honorable Susan L. Biro
U.S. Environmental Protection Agency
Office of Administrative Law Judges
Franklin Court, Suite 350
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Washington, DC 20005



Tony R. Ellis, Case Officer
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