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, L.P.,	)	
	)	
Respondent.	)	

ORDER ON COMPLAINANT'S MOTION FOR ACCELERATED DECISION AND RESPONDENT'S REQUEST FOR ORAL ARGUMENT

I. Background

On September 2, 2010, the United States Environmental Protection Agency ("EPA" or "Agency"), Waste and Chemical Enforcement Division, Office of Civil Enforcement ("Complainant"), filed a Complaint pursuant to Section 16(a) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2615(a), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits ("Rules of Practice"), 40 C.F.R. Part 22, against Respondent, Elementis Chromium, Inc. The Complaint alleges that Respondent violated TSCA § 8(e), 15 U.S.C. § 2607(e), by failing to immediately inform the EPA Administrator of substantial risk information it obtained on October 8, 2002, via receipt of a report entitled "Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998 - FINAL REPORT" ("Final Report").

On October 4, 2010, Respondent's Answer and Affirmative Defenses to Complaint and Notice of Opportunity for Hearing ("Answer" and "Ans.") was filed. In its Answer, Respondent admitted that it received the Final Report on October 8, 2002 (Ans. ¶ 42), but denied that it did not immediately inform the Administrator of substantial risk information allegedly contained in the Final Report (Ans. ¶ 49). The Answer included affirmative defenses, including the assertions that EPA had adequate knowledge of the information contained in the Final Report at the time of Respondent's receipt thereof, and that Complainant's claim is barred by the applicable statute of limitations. Ans. at 6-7.

On December 15, 2010, Respondent filed a Motion for Judgment on the Pleadings. Complainant filed a Motion in Response to Respondent's Motion for Judgment on the Pleadings

on January 7, 2011, and Respondent filed a Reply Memorandum of Law in Support of Respondent's Motion for Judgment on the Pleadings on January 24, 2011. By Order dated March 25, 2011, Respondent's Motion for Judgment on the Pleadings was denied on the basis that the requirement set forth in Section 8(e) of TSCA is "continuing in nature," and therefore, Complainant's claim is not barred by the applicable statute of limitations.

On April 7, 2011, Respondent filed a Motion Requesting the Presiding Officer to Recommend Interlocutory Review of the March 25, 2011 Order by the Environmental Appeals Board. Complainant filed a Response in opposition on April 14, 2011, and the undersigned denied the Motion on April 27, 2011. A Prehearing Order was issued on April 28, 2011.

Complainant's Motion for Accelerated Decision on Liability and Memorandum in Support were filed on April 28, 2011 ("Motion" and "Mot."), to which fourteen exhibits and affidavits were attached.[1] On May 18, 2011, Respondent filed a Memorandum in Opposition to Complainant's Motion for Accelerated Decision on Liability ("Opposition" and "Opp.").[2] Complainant filed a Reply on May 24, 2011.

On June 1, 2011, Respondent filed a Request for Oral Argument on Complainant's Motion for Accelerated Decision on Liability ("Request"). Complainant filed a Response on June 10, 2011, and Respondent filed a Reply on June 16, 2011.

II. Arguments For and Against Accelerated Decision on Liability

A. Complainant's Motion

Complainant argues that there are no genuine issues of material fact as to Respondent's liability for violating TSCA Section 8(e), and that it is entitled to judgment as a matter of law. Listing the prima facie elements of liability, the Motion states that Respondent's admissions and documentary evidence submitted shows by a preponderance of the evidence that (1) Respondent is a person who manufactures or distributes in commerce a chemical substance or mixture; (2) Respondent obtained the Final Report; (3) the Final Report reasonably supports the conclusion that hexavalent chromium exposure presents a substantial risk of injury to health; and (4) Respondent failed to immediately inform the Administrator of the Final Report. Mot. at 12.

As to the first element, Complainant claims that Respondent is a corporation, and therefore a "person,"[3] and that it has admitted owning a manufacturing facility in the United

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[1] The exhibits to Complainant's Motion will be referenced herein as "CX __."

[2] The exhibits to Respondent's Opposition will be references herein as "Opp. Ex. __."

[3] Complainant cites TSCA Section 8(e); Notification of Substantial Risk; Policy

(continued...)

States at the time of the Final Report. Ans. ¶¶ 6, 8; Mot. at 13. Also, Complainant points out, Respondent has admitted that it manufactures and distributes in commerce chromium chemicals including chromic acid, chromic oxide and sodium dichromate. Ans. ¶¶ 9-12; Mot. at 13.

To the second element, Complainant states that Respondent has admitted that Dr. Joel Barnhart, its then-Vice President, obtained the Final Report on or about October 8, 2002. Ans. ¶ 42; Mot. at 14. Complainant submits a record of an email dated October 8, 2002 (CX 4) as evidence of Dr. Barnhart's receipt of the Final Report on that date. Mot. at 14.

To the third element, Complainant argues that the Final Report contains "information that reasonably supports the conclusion of substantial risk of injury to health or environment," specifically, an elevated lung cancer risk. Mot. at 15. Respondent admits that exposure to hexavalent chromium may result in adverse human health effects under certain circumstances, Complainant states. *Id.*; Ans. ¶¶ 19-21. The Final Report, Complainant argues, "found *elevated* risk of lung cancer mortality in the combined study cohort from four modern chromium production plants in Germany and the United States." Mot. at 17-18. Also, the Final Report is "replete with statements and data" supporting the elevated risk finding, Complainant states. Mot. at 18. Noting that TSCA itself doesn't define "substantial risk information," Complainant argues that Section 8(e) guidance includes information showing "[a]ny pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce cancer" or information showing "[a]ny instance of cancer" in the definition of "substantial risk information." Mot. at 15; 1978 Guidance, 43 Fed. Reg. at 11,1112; 2003 Guidance, 68 Fed. Reg. at 33,138. Complainant cites other parts of the 1978 and 2003 Guidance in support of its argument that "even a single instance of cancer would be reportable if a chemical is strongly implicated" in epidemiological studies such as those documented in the Final Report. Mot. at 16. Therefore, the Final Report contains information that Respondent should have reported to the Administrator, Complainant concludes.

To the fourth element, that Respondent failed to immediately inform the Administrator about the Final Report, Complainant argues that because Respondent received the Final Report on October 8, 2002, and did not submit it to EPA until November 17, 2008 (in response to two concurrent TSCA Section 11 subpoenas), accelerated decision is appropriate on this issue. Mot. at 20-21; 15 U.S.C. § 2610. Acknowledging that "EPA independently obtained a copy of the [Final] Report on or about March 14, 2006, shortly after the publication of an article regarding the report in The Washington Post dated February 24, 2006," Complainant argues this receipt does not extinguish Respondent's continuing reporting obligation under Section 8(e). Mot. at 21, n.15. Furthermore, EPA could not confirm whether the Final Report it obtained was the same version that Respondent failed to submit until 2008, Complainant argues. *Id.*

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[3](...continued)
Clarification and Reporting Guidance, 68 Fed. Reg. 33,129, 33,137 (June 3, 2003) ("2003 Guidance"), which includes "corporation" in the definition of "person" under TSCA. The 2003 Guidance modifies, in small part, Statement of Interpretation and Enforcement of Policy; Notification of Substantial Risk, 43 Fed. Reg. 11,110 (Mar. 16, 1978) ("1978 Guidance").

Complainant then challenges Respondent's remaining affirmative defenses as alleged in the Answer. Per Order dated March 25, 2011, Respondent's limitations period defense was rejected, leaving the first, second, third and fifth affirmative defenses.

First, Respondent's allegation that Complainant was adequately informed of the information in the Final Report at the time Respondent received it is unsupported by specific facts, Complainant argues. Mot. at 23. "To the best of EPA's knowledge, the Agency did not have a copy of the [Final] Report on or about October 8, 2002, nor did the Agency know about the [Final] Report at that time," Complainant states. Mot. at 24-25. Complainant claims that the Agency did not even know the information described in the Final Report was available at that time. Mot. at 25. It was aware, however, of a 2000 study "conducted by Gibb, et al." regarding hexavalent chromium exposure at a Baltimore, Maryland facility ("Gibb Study"). Mot. at 25, n.18. Funded in part by EPA, the Gibb Study "made important contributions to the scientific understanding of lung cancer mortality risk for hexavalent chromium exposure," however, it involved a facility operating under conditions that "pre-dated" those used by the "modern plants" analyzed in the Final Report. *Id.* Therefore, Complainant argues, the Gibb Study could not have provided the same kind of information that the Final Report contained. *Id.* The Final Report contained new information, not known to the Agency, Complainant states, and therefore, Respondent's first defense is not a bar to granting accelerated decision on liability.

Second, Respondent's allegation that it had actual knowledge that EPA was adequately informed of the information in the Final Report at the time Respondent received it is also unsupported by specific facts, Complainant argues. Mot. at 26-27. Complainant points to Dr. Barnhart's responses to one of EPA's subpoenas, where he states that he "does not know exactly how or when EPA first obtained the Study." *Id.*; CX 6 at 19. Because Respondent has not provided any supporting facts as to this defense, Complainant argues, it does not bar accelerated decision on liability.

Third, Respondent's allegation that EPA was generally aware of the increased risk of cancer from chromium exposure "rests on the mistaken assumption that the nature and magnitude of health risks . . . in modern chromium production plants was a settled matter" at the time of the Final Report study. Mot. at 27. On the contrary, Complainant claims, the Final Report contained the unexpected finding that changes in the chromium production process that have reduced exposure do not lessen the lung cancer risk, and that the lung cancer mortality risk persists in modern plant processes. Mot. at 28. The Final Report filled a "critical gap" in the scientific understanding of occupational chromium exposure and cancer risk, Complainant argues, and therefore, the Agency was not aware of this new information at the time Respondent received the Final Report. *Id.*; *see* CX 1 (Final Report) at 4 ("this study is intended to help fill the critical gap in the published literature on which . . . a risk assessment . . . may be based").

Respondent's fifth affirmative defense, that Complainant's own published guidance and

interpretation of the law exempts the Final Report from information that must be disclosed, "is derived from a flawed understanding of EPA's Section 8(e) guidance," Complainant states. Mot. at 28. Complainant argues that EPA's guidance documents are not binding, first of all. Mot. at 29. Complainant also refutes the assertion that the guidance exempts the risk information in the Final Report from the reporting requirement. *Id.* While the guidance does exempt information that substantially duplicates or confirms a well-recognized, well-established serious adverse effect, the Final Report does not fall within this category, Complainant argues. *Id.* The Final Report contained new information on the potential health risks of occupational exposure to chromium in modern plants that "had yet to be established" before the Final Report was issued, Complainant asserts, and therefore, the Final Report neither confirmed existing findings nor duplicated existing studies. *Id.* Complainant argues further that the study of the Final Report was designed to address deficiencies in earlier studies, studies which were "few" and "on the whole . . . inconclusive." Mot. at 29-30. Therefore, Respondent's fifth defense is not sufficiently supported to bar the imposition of adverse accelerated judgment on liability. Mot. at 30.

B. Respondent's Opposition

Respondent does not dispute that it is a manufacturer, processor and distributor in commerce of hexavalent chromium-containing chemicals. Opp. at 2, 4, 11. Nor does it dispute receiving the Final Report in October 2002 and first providing it to the Administrator on November 18, 2008, in response to an Agency subpoena. *Id.* Respondent asserts, however, that the parties still dispute "three critical factual issues": (1) exactly *what* the substantial risk information is in the Final Report; (2) whether that substantial risk information was already known to EPA; and (3) whether Respondent had actual knowledge that the substantial risk information was already known to EPA. Opp. at 11. Respondent maintains its statutory affirmative defense that the evidence will establish that EPA already knew the information contained in the Final Report that supported the conclusion that hexavalent chromium presents a substantial risk of injury to health, and that Respondent had actual knowledge of the Agency's awareness. Opp. at 2; 15 U.S.C. § 2607(e). Therefore, Respondent concludes, it had no duty to submit the Final Report to the Administrator.

First, Respondent states that the only "substantial risk information" in the Final Report is its conclusion that "exposure to high levels of hexavalent chromium leads to an increased risk of lung cancer." Opp. at 12. Complainant's assertion that the Final Report's findings about modern plant conditions comprise new substantial risk information is, Respondent counters, "inapposite to this case." *Id.* TSCA Section 8(e) addresses information associated with "a chemical substance or mixture," Respondent states, and does not impose a duty to report information regarding "processes or exposures" that involve those chemical substances or mixtures. *Id.*

Second, Respondent argues that "it is clear that the Substantial Risk Information in the [Final] Report was also found in the Gibb Study," which, as Complainant acknowledges, was funded in part by EPA. Opp. at 13; Mot. at 25, n.18. Quoting the affidavit of Dr. Herman J.

Gibb, one author of the Gibb Study, Respondent argues that the Final Report "does not add to the knowledge base on the lung cancer risk from occupational exposure to hexavalent chromium." *Id.*; Opp. Ex. C (Affidavit of Herman J. Gibb, Ph.D., M.P.H.) ¶ 9. Therefore, Respondent argues, the substantial risk information in the Final Report was well known to EPA.

Third, Respondent argues that it knew EPA was aware of the substantial risk information in the Final Report because Dr. Barnhart compared it with the findings in the Gibb Study when he received the Final Report and concluded that the risk information in the latter was included in the former. Opp. at 3, 13. Also, Dr. Barnhart knew that Dr. Gibb was employed by EPA at the time the Gibb Study was prepared, and he also knew that EPA funded it, asserts Respondent. Opp. at 14. Because the Gibb Study contained the same information, and because "Dr. Barnhart also had serious concerns about the combined data sets used in the [Final] Report, as did its principal author, Dr. Kenneth Mundt, and thus believed that the study, as a whole, was flawed," Respondent explains, "Elementis chose not to submit the Report to EPA pursuant to TSCA Section 8(e)." Opp. at 3; *see also* Opp. at 5 ("This required Applied Epidemiology [which prepared the Final Report] to make some very substantial assumptions."); *see also* Opp. at 7 ("epidemiologists . . . questioned the propriety of combining the German plant cohort with the [U.S.] cohort . . . because of the different methods used to measure exposure in the two cohorts"); *see also* Opp. at 8 ("complications and problems associated with correlating urinary chromium measurements with air sampling data").

As to its fifth affirmative defense, Respondent explains that the 2003 EPA Guidance exempts information that "[c]orroborates . . . a well-recognized/well-established serious adverse effect for the chemical(s) under consideration" from Section 8(e) disclosure. Opp. at 15; 2003 Guidance, 68 Fed. Reg. at 33,139. The risk in the Final Report had been identified in "many epidemiology studies before," and both Dr. Barnhart and Dr. Gibb can support this assertion, Respondent argues. Opp. at 15. Also, the Occupational Safety and Health Administration ("OSHA") set the first exposure limit for hexavalent chromium in 1971, acknowledging the associated risk forty years ago, Respondent states. *Id.* Furthermore, in its own online guidance, EPA's response was, "Typically no," to a question on the website for Section 8(e) that read, "Would industrial hygiene assessments need to be considered for TSCA § 8(e) reporting?" Opp. at 15, n.7; Frequent Questions, Q.38. and A.38., Reporting of Modeling and Risk Assessment Studies (September 2006) ("Such assessments are often conducted in situations where potential exposure to the chemical has already been identified.").[4] As a collateral matter, Respondent notes that Complainant cites the 1978 and 2003 Guidance documents as support in its Motion, but then, in response to Respondent's reliance on the same, argues the same Guidance is not binding. Opp. at 14, n.6. Complainant cannot rely on those materials and simultaneously deny the regulated community the same ability to rely, Respondent argues, especially given that there are no promulgated regulations to aid in implementing Section 8(e). *Id.* Respondent concludes that the Final Report "simply re-identifies" a substantial risk already known to EPA and generally well-recognized, and in accordance with EPA's Section 8(e) guidance materials, did

[4] *See* http://www.epa.gov/opptintr/tsca8e/pubs/frequentlyaskedquestionsfaqs.html.

not need to be disclosed to the Administrator for that reason. Opp. at 16.

Finally, Respondent argues that information about *exposure* to hexavalent chromium does not constitute substantial risk information that must be disclosed because every chemical manufacturing process is different, every individual's exposure is unique, TSCA is "chemical-specific, not process-specific," and the health effect was the same in the studies underlying the Gibb Study as well as the Final Report. Opp. at 16. The fact that the facilities at issue were different, and whether they involved a "low-lime" process or "high-lime" process, is irrelevant, Respondent argues, in light of the same finding in each report: "respiratory exposure to hexavalent chromium at certain levels leads to an increased risk of lung cancer." *Id.*

Respondent concludes that because there is a genuine issue on the material facts establishing Respondent's defense to Complainant's allegations, the Motion must be denied. Opp. at 17.

Additionally, in a footnote, Respondent implies that EPA is selectively enforcing Section 8(e) against Elementis Chromium, by not bringing enforcement actions against two other corporations that were chromium chemical manufacturers, processors and distributors, that received the Final Report at the same time as Respondent, and did not provide the Final Report to the Administrator. Opp. at 4, n.2. These two other corporations, Respondent explains, were members, along with Elementis Chromium, of the organization that initiated the Final Report study (Industrial Health Foundation). Opp. at 4.

C. Complainant's Reply

Complainant restates that Respondent has admitted and is liable for each of the four elements of a Section 8(e) violation. Reply at 4. Therefore, Complainant argues, it is entitled to judgment as a matter of law. Reply at 5.

Regarding whether the Final Report contains information that "reasonably supports the conclusion that hexavalent chromium exposure presents a substantial risk," the third element of liability according to Complainant, Complainant addresses some of Respondent's contentions. First, Complainant argues that any dispute about "what" substantial risk information is in the Final Report is irrelevant to a finding of liability and the undersigned need not resolve "the extent to which the Modern Report contains [such] information," because Respondent admits that there is at least some substantial risk information in the Final Report, which is sufficient. Reply at 8-9, n.4; Opp. at 12-13. Second, Complainant states that despite the implication by Respondent and its witnesses that the Final Report was viewed as scientifically unreliable, "[w]hether or not the Modern Report has deficiencies is irrelevant to determining if substantial risk information is subject to reporting under TSCA section 8(e)." Reply at 10-11, n.5; Opp. at 3, 5, 7-8. In support, Complainant cites to *In re Methyl Tertiary Butyl Ether ("MTBE") Products Liability Litigation*, 559 F. Supp. 2d 424, 437 (S.D.N.Y. 2008), for the proposition that a manufacturer's belief that a

study is low quality is not an excuse to withhold the risk information therein in violation of TSCA Section 8(e). Reply at 10-11, n.5. The purpose of Section 8(e) would be frustrated, Complainant argues, "if a company were free to substitute its judgment for EPA's" regarding the quality of a particular study. *Id.*

Complainant asserts that the disposition of its Motion turns on Respondent's affirmative defense that Respondent had actual knowledge that the Administrator had been adequately informed of the substantial risk information in the Final Report at the time of receipt. Reply at 5, 12. Complainant responds to Respondent's assertion that the Agency already knew about the risk information from the Gibb Study by describing the "important differences" between the Gibb Study and the Final Report. Reply at 15. They evaluated different populations, plants, exposure levels, and manufacturing processes, resulting in "distinct information about risk," Complainant argues. *Id.* The Final Report, Complainant states, "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," as opposed to the traditional high-lime process, which was utilized at the Baltimore, Maryland, plant in the Gibb Study. Reply at 3, 3 n.2, 15-16. Thus, "[a]t the time of the Modern Report study, the extent of risk under modern plant conditions had yet to be adequately quantified." Reply at 5; *see* Reply at 13-14. The limited modern plant studies at the time "could not establish" the risk that the Final Report did establish, Complainant argues. Reply at 5-6. Also, the Final Report included exposure to lower average concentrations than the Gibb Study, and excluded workers employed for less than one year, whereas the Gibb Study included "many short term employees," Complainant states. Reply at 16; CX 1 at 30. Therefore, the Final Report assessed the risk of longer exposure periods than the Gibb Study, Complainant contends. Reply at 16. Furthermore, while the Gibb Study evaluated risk from cumulative exposure only, the Final Report evaluated risk of both cumulative and peak exposure. *Id.* Also, because exposure levels studied in the Final Report were significantly lower than those studied in previous reports, the risk assessment in the Final Report is different. Reply at 13, n.6. Even the lowest exposure levels analyzed in the Gibb Study are "significantly higher" than the lower levels analyzed in the Final Report, Complainant argues. *Id.*; Reply at 14, n.7. Finally, Complainant cites the Final Report itself, which describes its findings as the "best available scientific evidence of the relationship between chromium exposure and human lung cancer risk," as proof that it contained new information at the time. *Id.*; CX 1 at 19. The Final Report, Complainant argues, did not confirm risks already known to EPA, but "demonstrated increased lung cancer mortality among workers who had worked exclusively in modern plants and thus were exposed to significantly lower chromium levels than had previously been studied." Reply at 17. For these reasons, Complainant challenges Respondent's claim that the only substantial risk information is the data concerning workers subject to "high levels of cumulative exposure." Reply at 14; Opp. at 11-12. Therefore, because Respondent's characterization of the substantial risk information in the Final Report is unsupported by the documents presented, accelerated decision on liability is appropriate where the prima facie elements of a Section 8(e) violation have been shown. Reply at 14.

III. Request for Oral Argument

In its Response to Respondent's Request for Oral Argument, Complainant argues that Respondent failed to contact counsel for Complainant in contravention of the Prehearing Order, which requires a moving party to determine whether the non-moving party objects to the relief sought in the motion. Response ¶ 2. Complainant argues further that Respondent's Request did not state any grounds with particularity, as Rule 22.16(a) requires of all motion. Response ¶¶ 4-5. Also, Complainant asserts, the Motion for Accelerated Decision on Liability, the Opposition and the Reply provide "ample explanation of the arguments along with factual evidence, affidavits and analysis . . . to rule on the motion without a hearing." Response ¶ 6. Oral argument would be inconsistent with judicial economy, Complainant argues, as "sufficient elaboration of the arguments" has already been submitted. Response ¶ 8.

In its Reply, Respondent distinguishes motions, in which a party states the relief it seeks, from its request for oral argument on the Motion for Accelerated Decision on Liability, stating that the granting of oral argument would not be relief, by itself, to either party, and therefore, its Request is not a motion. Reply ¶¶ 3-4. On the substance of its Request, Respondent asserts that "given the technical issues raised by both parties, [they] would benefit from oral argument." Reply ¶ 5.

The Rules of Practice provide that the presiding officer "may permit oral argument on motions in its discretion." 40 C.F.R. § 22.16(d). Looking to Federal Court practice for guidance, it is noted that "a district court should have 'wide latitude' in determining whether oral argument is necessary before rendering summary judgment." *Bratt v. Int'l Bus. Machs. Corp.*, 785 F.2d 352, 363 (1st Cir. 1986) (quoting *Cia. Petrolera Caribe, Inc. v. Arco Caribbean, Inc.*, 754 F.2d 404, 411 (1st Cir. 1985)). "Where affidavits . . . and other documentary material indicate that the only issue is a question of law, and where the briefs have adequately developed the relevant legal arguments, it is not error to deny oral argument," whereas oral argument is appropriate where the motion for summary judgment depends on "difficult questions of law and alleged questions of fact." *Cia. Petrolera Caribe*, 754 F.2d at 411. It is appropriate to deny oral argument on a motion for accelerated decision where the motion, responses and supporting material clearly show that there is a genuine dispute of a material fact concerning liability.

Because, as explained below, some issues as to Respondent's liability can be disposed of through accelerated decision at this time without oral argument, and the issues that remain are better resolved after an evidentiary hearing, Respondent's Request for Oral Argument is **DENIED**.

IV. Accelerated Decision Standard

Section 22.20(a) of the Rules of Practice provides, in pertinent part:

> The Presiding Officer may at any time render an accelerated decision in favor of a party as to any or all parts of the proceeding, without further hearing or upon such limited additional evidence, such as affidavits, as he may require, if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law.

40 C.F.R. § 22.20(a). If accelerated decision is rendered on less than all the issues in the proceeding, the decision "shall specify the facts which appear substantially controverted, and the issues and claims upon which the hearing shall proceed." 40 C.F.R. § 22.20(b)(2).

Similar to Rule 22.20(a), Rule 56 of the Federal Rules of Civil Procedure ("FRCP") states that courts "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Motions for accelerated decision under 40 C.F.R. § 22.20(a) are therefore akin to motions for summary judgment under FRCP 56. *See, e.g., Rogers Corp. v. EPA*, 275 F.3d 1096, 1103 (D.C. Cir. 2002); *BWX Techs., Inc.*, 9 E.A.D. 61, 74-75 (EAB 2000). The standard for summary judgment in FRCP 56 and federal court decisions interpreting such standard provide guidance in evaluating whether to hold an evidentiary hearing in the administrative context. *Mayaguez Reg'l Sewage Treatment Plant*, 4 E.A.D. 772, 781 (EAB 1993), *aff'd sub nom. P.R. Aqueduct & Sewer Auth. v. U.S. EPA*, 35 F.3d 600, 607 (1st Cir. 1994) ("Rule 56 is the prototype for administrative summary judgment procedures, and the jurisprudence that has grown up around Rule 56 is, therefore, the most fertile source of information about administrative summary judgment").

The party moving for summary judgment carries the burden of showing that no genuine issue of material fact exists and that it is entitled to judgment as a matter of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). A factual dispute is material where it "might affect the outcome of the suit under the governing law" and is genuine "if the evidence is such that a reasonable [fact finder] could return a verdict for the nonmoving party." *Anderson* at 248. When the non-moving party has asserted an affirmative defense, the moving party must show that there is an absence of facts present in the record to support the defense in order to dispose of that defense. *Rogers Corp.* at 1103 (quoting *BWX Techs.* at 78). If the moving party does show an absence of facts supporting the defense, the non-moving party must identify "specific facts" from which a reasonable fact finder could find in its favor by a preponderance of the evidence in order to preserve its defense. *Id.*

Overall, the tribunal must construe the evidentiary material and reasonable inferences drawn therefrom in a light most favorable to the non-moving party. *Anderson* at 255. When conflicting inferences may be drawn from the evidence and a choice among them would amount to fact finding, summary judgment is inappropriate. *Rogers Corp.* at 1105. Ultimately, "at the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson* at 249. Even where summary judgment appears technically proper, sound judicial policy and the exercise of judicial discretion may support denial of the motion in order for the case to be more fully developed at hearing. *Roberts v. Browning*, 610 F.2d 528, 536 (8th Cir. 1979); *Anderson* at

255.

V. Discussion

TSCA Section 8(e) provides:

(e) Notice to Administrator of substantial risks

Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

15 U.S.C. § 2607(e).

To obtain judgment on liability through accelerated decision, Complainant has the burden of proving by a preponderance of the evidence that there are no genuine disputes of material fact as to the following prima facie elements of a Section 8(e) violation: (1) Respondent manufactured, processed or distributed in commerce, a chemical substance or mixture; (2) Respondent obtained information "which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment;" and (3) Respondent failed to immediately inform the EPA Administrator of such information. 15 U.S.C. § 2607(e); *MTBE*, 559 F. Supp. 2d 424, 434-435 (S.D.N.Y. 2008)

Once Complainant has established its prima facie case, Respondent bears the burden of proving by a preponderance of the evidence that it had "actual knowledge that the Administrator ha[d] been adequately informed of such information." *MTBE* at 435.

A. Respondent Manufactured and Distributed a Chemical Substance or Mixture

TSCA defines the term "chemical substance" to mean "any organic or inorganic substance of a particular molecular identity, including (i) any combination of such substances occurring in whole or in party as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical." 15 U.S.C. § 2602(2)(A). TSCA defines "mixture" in part as "any combination of two of more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction." 15 U.S.C. § 2602(8).

Respondent admits that it is a manufacturer, processor and distributor in commerce of hexavalent chromium-containing chemicals, including chromic acid, chromic oxide and sodium dichromate. Ans. ¶¶ 9, 11-12; Opp. at 2, 4, 11; *see also* Opp. Ex. A (Sworn Statement of Dr.

Joel Barnhart, ¶ 3). Respondent also admits that it has two main manufacturing facilities that produce chromium chemicals in the U.S., one in Texas ("Corpus Christi Facility"), and one in North Carolina ("Castle Hayne Facility"). Ans. ¶¶ 6-8. Respondent acquired the Castle Hayne Facility in December 2002. Ans. ¶ 7.

As such, there is no dispute that, at all times relevant hereto, Respondent is and was a "person who manufactures, processes, or distributes in commerce a chemical substance or mixture," and as such, was and is subject to the requirements of Section 8(e). 15 U.S.C. § 2607(e).

B. Respondent Obtained Substantial Risk Information

Respondent admits to receiving the Final Report on or about October 8, 2002, specifically that Dr. Joel Barnhart, the "then Vice President of Elementis Chromium LP," received the Final Report on October 8, 2002. Ans. ¶¶ 24, 41-42; Opp. at 2; *see* CX 4 (Email to Dr. Barnhart, et al., Dated: 10/08/2002, Subject Line: "AEI's Final Report," Attachment: "IHF Chrome Epidemiology Study Final Report"); *see* CX 7 at 5 (Index of Documents Produced to EPA by Elementis Chromium, LP, including 10/8/2002 email sending Final Report to Dr. Barnhart). Therefore, there is no dispute that Respondent "obtained" the Final Report on October 8, 2002. 15 U.S.C. § 2607(e).

Respondent also does not dispute Complainant's allegation that the Final Report contains substantial risk information, or information "which reasonably supports the conclusion that [chromium] presents a substantial risk of injury to health or the environment." 15 U.S.C. § 2607(e); Opp. at 12. Therefore, the second element of a Section 8(e) violation is shown.

However, *which* statements or data in the Final Report constitute substantial risk information for Section 8(e) reporting purposes remains a matter of dispute between the parties. Opp. at 11-12, 16. Because this dispute is relevant to Respondent's affirmative defense that the Administrator knew of the substantial risk information at the time of the Final Report's publication, it will be discussed in that section below. Likewise, Respondent's contention that the risk information in the Final Report is exempt from Section 8(e)'s reporting requirement pursuant to exceptions in the 2003 Guidance is asserted as Respondent's Fifth Affirmative Defense, and will also be addressed below. Opp. at 14-16.

C. Respondent Failed to Immediately Inform the EPA Administrator

Respondent has admitted that it did not provide the Final Report to EPA until November 17, 2008, in response to a subpoena from the Agency. Opp. at 2; *see also* CX 12, ¶¶ 6-7 (Affidavit of Tony Ellis, Enforcement Case Development Officer, U.S. EPA). Indeed, Respondent admitted that "Elementis chose not to submit the Report to EPA." Opp. at 3.

The question of whether the applicable five-year statute of limitations, 28 U.S.C. § 2462, barred Complainant's claim that Respondent failed to "immediately" provide the Final Report to the Agency was answered by the undersigned's Order on Respondent's Motion for Judgment on the Pleadings:

> Thus, the term "immediately" reflects not a date certain but a [sic] imprecise *relation in time*, variable according to facts and circumstances. . . . [A]s Complainant suggests, the illegal act due to failing to inform as required by TSCA § 8(e) can be seen to occur "immediately" and continue thereafter, as long as the information remains withheld from the Administrator. . . . In enacting 15 U.S.C. § 2607(e), Congress intended to ensure that the regulators received "timely access to information regarding health and safety studies concerning chemicals covered by the Act" . . . . Under Respondent's interpretation, this goal would be frustrated because "a manufacturer could violate the reporting requirement without fear of punishment if it could successfully hide the evidence . . . for five years." [citation omitted]. . . . [T]he harm from a chemical presenting a substantial risk of injury to health or the environment does not dissipate over time. Rather, its continued use . . . by the [sic] others without such information . . . may spread or increase the risk and/or resultant damage. . . . [T]here is no subsequent event which necessarily overtakes such disclosure . . . . Therefore, it is concluded that the TSCA 8(e) disclosure requirement is continuing in nature.

Order on Respondent's Motion for Judgment on the Pleadings at 7, 9, 11-12. Because the violation is continuing in nature and Respondent has acknowledged that it failed to "immediately" inform the Administrator of the information in the Final Report, this third and final element of Complainant's prima facie case is also established.

D. Respondent's Affirmative Defenses

Respondent has raised in this case the affirmative defense made available to it in Section 8(e), specifically that it had "actual knowledge that the Administrator ha[d] been adequately informed of such information." Ans. at 6-7[5]; *MTBE* at 434 ("once plaintiffs prove that defendants have withheld information from the EPA, defendants bear the burden of persuasion in showing that they had 'actual knowledge' that the EPA was already 'adequately informed'"). Therefore, for Complainant to obtain an accelerated decision on liability in its favor, Complainant must demonstrate that there is an absence of facts in the record to support the defense. *Rogers Corp.* at 1103 (citing *BWX Techs.* at 78). Because Complainant has not shown an absence of facts to support the defense, and because Respondent has presented specific matters of dispute that cannot be resolved on accelerated decision, the hearing will proceed on

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[5] Respondent alleged this defense as its first, second and third affirmative defenses in the Answer, but together they comprise the affirmative defense available in TSCA Section 8(e), and will be regarded as a single affirmative defense.

the issues as presented below. *MTBE* at 442 (denying summary judgment as to whether the Administrator had been adequately informed based upon the prior studies not making conclusions regarding chemical concentrations as low as that in the undisclosed study).

Whether the Administrator was informed about the substantial risk information in the Final Report is highly contested mostly because the parties dispute whether it contained any *new* substantial risk information that the Administrator did not already know about in October 2002.[6]

i. *Information in the Final Report*

The most logical starting point for determining which information is substantial risk information in the Section 8(e) context, is the Final Report itself, which was submitted by both Complainant (CX 1) and Respondent (RX 9). The Final Report is over 150 pages long and details the results of a highly technical epidemiological study of over 1,000 workers, conducted in two different countries at four different facilities, utilizing personalized vital statistics, complex mathematical and scientific formulas, industrial hygiene data and various exposure indicators, over a period beginning in 1958 through 1998. CX 1. The findings of the Final Report, which are highly material to the outcome in this case given Respondent's asserted defense, are not easily or, at this point in the proceeding, fully understood given the Report's complexity and without the aid of live testimony. The parties' submissions contain contradictory views about the significance of the Final Report's risk information, and those views are supported sufficiently enough in the materials submitted to warrant a hearing on the credibility of those testifying in support of each view.

For example, Complainant submits an affidavit supporting the Motion (CX 13), wherein the Director of the Risk Assessment Division of EPA's Office of Pollution Prevention and Toxics, Mr. Oscar Hernandez, declares that the Final Report contains substantial risk information not only because it finds serious adverse health effects involving an incidence or pattern of cancer, but also because of its "firsts": (1) the results showed that increased risk persists even under lower exposure levels than had been studied before, contrary to expectations; (2) the researchers studied workers who were exposed to hexavalent chromium exclusively under modern plant conditions; and (3) the findings enhanced the Agency's and scientific community's understanding of chromium exposure and was therefore of value to the industry, its workers, regulators, and the public. CX 13, ¶¶ 18-22. A Senior Epidemiologist at EPA, Glinda Cooper, states in an affidavit, that the Final Report is the "first large, comprehensive evaluation of respiratory (lung) cancer mortality among chromium production workers . . . in modern chromate production plants." CX 11 ¶ 9.

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

Respondent submits materials contradicting this interpretation of the Final Report, arguing that and any data concerning the "processes or exposures" utilized at the plant does not qualify as substantial risk information under Section 8(e). Opp. at 12, 16. For example, in Dr. Barnhart's affidavit (Opp. Ex. A), he states that the "only information" that can be qualified as substantial risk information for Section 8(e) purposes, "is that persons subject to higher exposure levels have an increased incidence of lung cancer." Opp. Ex. A, ¶ 16. Also, Dr. Gibb declares in his affidavit (Opp. Ex. C) that "regardless how 'modern' a facility is, EPA, as well as others in the scientific community . . . considers any hexavalent chromium exposure to present some lung cancer risk." Opp. Ex. C ¶ 11. Also, Dr. Gibb states, the Baltimore plant that was the focus of the 2000 Gibb Study "could also be considered 'modern'," noting that it was rebuilt in 1950 and major modifications were made to it in 1960. *Id.* ¶ 12.

There are still genuine disputes of fact as to whether the following differences between the Final Report and the Gibb Study (or any other study or source of substantial risk information Respondent intends to use in its arguments) qualify the Final Report as new substantial risk information of which the Administrator was not aware in October 2002: different populations, plants, exposure levels and exposure period, and varying plant conditions; subjects working in exclusively low- or no-lime plants as opposed to high-lime environments; varying average concentrations of hexavalent chromium; modern processes versus non-modern processes, length of exposure period; cumulative exposure data only versus cumulative and peak exposure data; the inclusion or exclusion of short term employees; facilities with more or less stringent environmental controls; combined cohort significance; assumptions made to combine air and urine sampling data.

ii. *Exemptions in the Guidance*

The Guidance reads, in pertinent part:

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

2003 Guidance, 68 Fed. Reg. at 33,139.

The risk information in the Final Report confirms what was already well-known, Dr. Barnhart declares in an affidavit attached to Respondent's Opposition. Opp. Ex. A, ¶ 18 ("the Gibb study had already identified this potential risk"). Dr. Kenneth A. Mundt, in another affidavit in support of Respondent's Opposition, said similarly: "Numerous prior studies . . . had identified the same substantial risks of exposure . . . ." Opp. Ex. B, ¶ 13. Complainant submits the affidavit of Toni Krasnic, TSCA Section 8(e) Coordinator, U.S. EPA, to rebut Respondent's assertion: The Final Report "does not meet any of the situations described in the 2003 Guidance

where TSCA section 8(e)-reportable information need not be reported." CX 14, ¶ 20. Respondent also puts forth the assertion that the Agency's own Frequent Questions website implies that hygiene assessments are exempt from Section 8(e) reporting. Opp. at 15, n.7; Frequent Questions, Q.38. and A.38., Reporting of Modeling and Risk Assessment Studies (September 2006).[7]

The guidance documents are not binding, but may be persuasive: "The EPA's Q. & A. simply falls within a wide range of documents that are published by agencies that may be considered for their 'power to persuade' when a court interprets a statute." *MTBE*, 559 F.Supp. 2d at 440 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). Nonetheless, these competing assertions raise doubt as to whether Complainant is entitled to judgment as a matter of law on accelerated decision.

iii. *The Washington Post Article*

Complainant is correct in its assertion that even though "EPA independently obtained a copy of the [Final] Report on or about March 14, 2006," after the publication of an article in The Washington Post, that fact alone would not extinguish Respondent's continuing reporting obligation under Section 8(e) at that time. *See* Order on Respondent's Motion for Judgment on the Pleadings. However, if Respondent can prove that it had actual knowledge that the Administrator knew of the substantial risk information in the Final Report at that point in 2006, it may argue that the violation, if found, did not continue beyond that date.

iv. *"Flawed" Study*

Complainant's argument that "[w]hether or not the Modern Report has deficiencies is irrelevant to determining if substantial risk information is subject to reporting under TSCA section 8(e)" is persuasive. Reply at 10-11, n.5; *MTBE*, 559 F. Supp. 2d at 437 ("Defendants may argue to the jury that a particular study does not 'reasonably support' the conclusion that MTBE harms groundwater because it was a poorly designed or executed study . . . . [A]nd the jury may well agree - but defendants may not contend that their subjective belief absolves them of liability for failing to report[]"). If Respondent is found liable, it may argue that its view that the Final Report study was flawed or unreliable is a justified reason why it decided not to submit the Final Report to the Administrator for purposes of making a penalty determination. Opp. at 3 ("Elementis chose not to submit the Report"); 15 U.S.C. § 2615(a)(2)(B) (penalty factors).

v. *Selective Enforcement*

If Respondent intends to assert the defense of selective enforcement, as implied in its

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[7] *See* http://www.epa.gov/opptintr/tsca8e/pubs/frequentlyaskedquestionsfaqs.html.

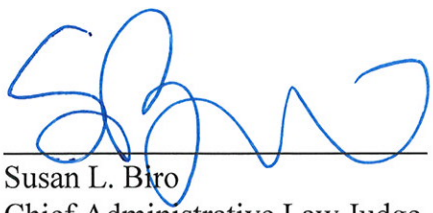
Opposition (Opp. at 4, n.2), Respondent "faces a daunting burden in establishing that the Agency engaged in illegal selective enforcement, for courts have traditionally accorded governments a wide berth of prosecutorial discretion in deciding whether, and against whom, to undertake enforcement actions." *In re B&R Oil Co.*, 8 E.A.D. 39, 51 (EAB 1998). To successfully raise a "selective enforcement" defense requires establishing "(1) that, while others similarly situated have not generally been proceeded against . . . [Respondent] has been singled out for prosecution, and (2) that the government's discriminatory selection of [Respondent] for prosecution has been invidious or in bad faith, i.e., based upon such impermissible consideration as race, religion, or the desire to prevent [its] exercise of constitutional rights." *United States v. Berrios*, 501 F.2d 1207, 1211 (2d Cir. 1974); *see also Newell Recycling Co.*, 8 E.A.D. 598, 635 (EAB 1999). Thus far, Respondent has not produced any materials to support an allegation of selective enforcement.

VI. Conclusion

Though Complainant has proven the prima facie elements of a TSCA Section 8(e) violation, ultimately, when viewed in a light most favorable to Respondent, the evidence submitted thus far creates genuine issues of material facts regarding whether in October 2002 or at some later point, Respondent had actual knowledge that the Administrator had been adequately informed of the Final Report's substantial risk information. Apart from the affidavits submitted in support of and in opposition to Complainant's Motion, the parties intend to introduce evidence at the hearing additionally that may resolve the factual and legal disputes present in the materials submitted thus far. It is prudent to wait for exploration of the evidence at an evidentiary hearing to determine whether Respondent may prove its affirmative defense by a preponderance of the evidence.

ORDER

Complainant's Motion for Accelerated Decision on Liability is **DENIED**.



Susan L. Biro
Chief Administrative Law Judge

Date: August 8, 2011
Washington, D.C.

In The Matter of Elementis Chromium, Inc. f/k/a Elementis Chromium, L.P. TSCA-HQ-2010-5022

CERTIFICATE OF SERVICE

I certify that the foregoing **Order on Complainant's Motion for Accelerated Decision and Respondent's Request for Oral Arguement**, dated August 8, 2011 following manner to the addresses listed below.

Sybil Anderson
Headquarters Hearing Clerk

Dated: **August 8, 2011**

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