



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

BY HAND DELIVERY

MAY 24 2011

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

Re: Complainant's Reply to Respondent's Memorandum in Opposition to  
Complainant's Motion for Accelerated Decision on Liability  
Docket No. TSCA-HQ-2010-5022

Dear Ms. Anderson:

Enclosed please find an original and two (2) copies of Complainant's Reply to Respondent's Memorandum in Opposition to Complainant's Motion for Accelerated Decision on Liability.

Please file the original Reply and return one date-stamped copy to Complainant.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in cursive script that reads "Mark A.R. Chalfant".

Mark A.R. Chalfant  
Counsel for Complainant

Enclosures

cc: John J. McAleese, III, Morgan, Lewis & Bockius LLP (via U.S. first-class mail & email)  
Ronald J. Tenpas, Morgan, Lewis & Bockius LLP (via email)  
William S. Pufko, Morgan, Lewis & Bockius LLP (via email)  
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., )  
f/k/a Elementis Chromium, LP )  
 )  
Respondent. )  
 )  
 )  
 )  
 )

Docket No. TSCA-HQ-2010-5022

COMPLAINANT'S REPLY TO RESPONDENT'S MEMORANDUM IN OPPOSITION  
TO COMPLAINANT'S MOTION FOR ACCELERATED DECISION ON LIABILITY

Complainant, the United States Environmental Protection Agency (Complainant, EPA or the Agency) respectfully submits this reply to Respondent Elementis Chromium, Inc.'s<sup>1</sup> (Respondent's or Elementis's) Memorandum in Opposition to Complainant's Motion for Accelerated Decision on Liability. Pursuant to 40 C.F.R. §§ 22.16 and 22.20(a), Complainant renews its request that the Presiding Officer issue an order finding that Respondent is liable for a violation of sections 8(e) and 15(3)(B) of the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2607(e) and 2614(3)(B), as described in the administrative complaint filed on September 2, 2010 (Complaint).

<sup>1</sup> The Complaint identifies Respondent as "Elementis Chromium, LP." However, in its Answer, Respondent represents that Elementis Chromium, LP was merged into Elementis Chromium GP Inc. on September 10, 2010, and then changed its name to "Elementis Chromium Inc." By Order dated March 28, 2011, the caption of the instant case was amended to be consistent with Respondent's current corporate name. (Order on Resp't Mot. for J. on the Pleadings at 1).

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## I. Introduction

There are no genuine issues of material fact in this case. Respondent Elementis obtained a 2002 study of lung cancer mortality risk to workers from occupational exposure to hexavalent chromium, a known carcinogen, in modern chromium production plants.<sup>2</sup> 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. (Cooper Aff. C's Ex. 11, ¶¶ 9, 30; Hernandez Aff. C's Ex. 13, ¶ 20). The Modern Report reasonably supports the conclusion that hexavalent chromium exposure presents a substantial risk of injury to health. In the Modern Report's authors' own words, the study helped to fill a "critical gap" in the scientific understanding of the extent of lung cancer mortality risk under modern plant conditions. (C's Ex. 1 at 18, 41). Yet, in spite of obtaining this study,

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<sup>2</sup> In Complainant's filings, chromium production facilities that are described as "modern" or "post-process change" refer to those facilities that used the low- or no-lime processes for manufacturing chromium chemicals to replace the traditional high-lime process. (C's Ex. 1 at 25-26; see also Compl. ¶¶ 28-30; Complainant's Mot. for Accelerated Decision on Liability at 7). Respondent asserts that the newer facilities at the Baltimore plant, which were the subject of the 2000 Gibb et al. study, "could also be considered 'modern.'" (Gibb Aff. Resp't. Ex. C, ¶ 12). Complainant does not dispute that the Baltimore plant's newer facilities had improved engineering controls. (C's Ex. 1 at 29-30; 93-94 and Arnold Aff. C's Ex.10, ¶27). However, these newer facilities did not utilize the low or no-lime manufacturing processes. (C's Ex. 1 at 93) ("In a recently released study of a high-lime chromate production facility, Gibb et al. reported a two-fold excess of lung cancer mortality . . . among employees of two Baltimore, MD facilities.") (emphasis added). Therefore, the Baltimore plant's newer facilities do not fit Complainant's definition of modern or post-process change facilities.

Elementis failed to inform the Administrator of the Modern Report or its findings until it responded in 2008 to a TSCA subpoena issued by EPA. Respondent's failure to immediately submit the Modern Report to the Agency constitutes a violation of TSCA section 8(e).

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

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

15 U.S.C. § 2607(e). Complainant has proven the four elements of TSCA section 8(e) liability. Respondent admits that: (1) it is a person who manufactures, processes, and distributes in commerce chromium chemical products; (2) it obtained the Modern Report; (3) the Modern Report contains "substantial risk information"; and (4) it failed to immediately inform the Administrator of the Modern Report. (Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 11-12). Thus, Respondent has admitted all four elements of section 8(e) liability. Therefore, there is no genuine issue of material fact as to Respondent's liability under section 8(e) for failing to immediately submit the Modern Report to the

Administrator and EPA is entitled to judgment as a matter of law.

The disposition of Complainant's Motion for Accelerated Decision on Liability turns on Respondent's statutory affirmative defense. To prevail on this defense the statute requires Elementis to show that it "has actual knowledge that the Administrator has been adequately informed" of the information in the Modern Report at the time it obtained the report. 15 U.S.C. § 2607(e). Having admitted that the Modern Report contains information about substantial risk, Elementis argues that it was not required to submit the Modern Report to the Agency given EPA already knew that occupational exposure to hexavalent chromium causes an increased risk of lung cancer under pre-process change conditions. This argument is wrong because the Modern Report contains substantial risk information that was not previously known by the Administrator.

At the time of the Modern Report study, the extent of risk under modern plant conditions had yet to be adequately quantified. (C's Ex. 1 at 15, 32). The limited studies that had examined the extent of risk under modern plant conditions could not establish an association between hexavalent chromium exposure and lung cancer mortality risk. Id. at 29, 32. Unlike these studies, the Modern Report study found such a relationship between exposure and elevated risk under modern plant

conditions. Id. at 86-99. In light of the fact that the Modern Report contains information that was not previously known, the Administrator had not been adequately informed of the information in the report. (Hernandez Aff. C's Ex. 13 ¶¶ 17-20, 23; Krasnic Aff. C's Ex. 14 ¶¶ 18-20; Cooper Aff. C's Ex. 11 ¶¶ 27-32). Consequently, Respondent's statutory affirmative defense fails and the Presiding Officer should grant Complainant's Motion for Accelerated Decision on Liability.

## II. Argument

### A. Complainant Is Entitled to Accelerated Decision on Liability Because There Are No Genuine Issues of Material Fact.

EPA has proven a prima facie case of TSCA section 8(e) liability against Respondent: (1) Elementis is a person who manufactures or distributes in commerce a chemical substance or mixture; (2) Elementis obtained the Modern Report; (3) the Modern Report reasonably supports a conclusion that hexavalent chromium exposure presents a substantial risk of injury to health; and (4) Elementis failed to immediately inform the Administrator of the Modern Report. (Complainant's Mot. for Accelerated Decision on Liability at 12-21). In its response, Respondent admits all four elements of TSCA section 8(e) liability.<sup>3</sup> (Resp't Mem. in Opposition to Complainant's Mot. for

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<sup>3</sup> In its response, Respondent lists three elements that must be proven to establish a violation of TSCA section 8(e) because it combined Complainant's elements 3 and 4 into a single element. (Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 10).

Accelerated Decision on Liability at 2, 11, 12). Consequently, Complainant is entitled to an accelerated decision on liability because there are no genuine issues of material fact.

Furthermore, as we explain below, Respondent's statutory affirmative defense does not a bar an accelerated decision on liability.

1. Respondent admits that it is a person who manufactures, processes, and distributes in commerce chromium chemical products.

In the Motion for Accelerated Decision on Liability, EPA states that Elementis is a manufacturer or distributor in commerce of chromium chemicals. (Mem. in Support of Complainant's Mot. for Accelerated Decision on Liability at 13-14). In its response, 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. EPA need only prove that Elementis 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). Respondent has admitted all three and,

therefore, the Presiding Officer should grant the Motion for Accelerated Decision on Liability as to the first element of liability.

2. Respondent admits that it obtained the Modern Report.

In the Motion for Accelerated Decision on Liability, Complainant states that Elementis obtained the Modern Report on or about October 8, 2002. (Mem. in Support of Complainant's Mot. for Accelerated Decision on Liability at 14). Respondent states, "Nor is there any dispute that Elementis received the [Modern] Report in October 2002...." Id. at 11. Respondent has admitted that it obtained the Modern Report and, therefore, the Presiding Officer should grant the Motion for Accelerated Decision on Liability as to the second element of liability.

3. Respondent admits that the Modern Report contains "substantial risk information."

In the Motion for Accelerated Decision on Liability, EPA states that the Modern Report contains information which reasonably supports the conclusion that hexavalent chromium exposure presents a substantial risk of injury to health. (Mem. in Support of Complainant's Mot. for Accelerated Decision on

Liability at 14-20). Respondent admits,

The [Modern] Report ... concluded that workers in the cohort who had been subjected to high levels of cumulative exposure to hexavalent chromium showed an increased incidence of lung cancer when compared to the general population where the plants were located.... The [Modern] Report concludes that exposure to high levels of hexavalent chromium leads to an increased risk of lung cancer.

(Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 11-12). Tellingly, Respondent characterizes the Modern Report's conclusion as "substantial risk information" in its response. Id. at 12-13. Thus, as admitted by Respondent, the Modern Report contains information which reasonably supports the conclusion that hexavalent chromium exposure presents a substantial risk of injury to health.<sup>4</sup> Id.; see also C's Ex. 1 at 98.

As previously noted by Complainant, the Modern Report is replete with statements and data that document the report's finding of elevated lung cancer mortality risk. (Mem. in Support of Complainant's Mot. for Accelerated Decision on Liability at 18-19). We will not repeat those statements and

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<sup>4</sup>In its response, Respondent contends that there is a factual dispute regarding what information in the Modern Report reasonably supports a conclusion that hexavalent chromium presents a substantial risk to health. (Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 11). However, as we note above, Respondent has admitted that the Modern Report's conclusion constitutes "substantial risk information." Consequently, where Respondent has admitted that the Modern Report contains at least some substantial risk information, the Presiding Officer need not resolve the extent to which the Modern Report contains information which reasonably supports a conclusion of substantial risk of injury to health to conclude that Complainant has proven the third element of TSCA section 8(e) liability.

data here, but note that the Modern Report, on its face, contains information which reasonably supports the conclusion of substantial risk of injury to health without reliance upon expert interpretation. See e.g., C's Ex. 1 at 98. Moreover, EPA's TSCA section 8(e) guidance explains that information showing "[a]ny instance of cancer" or "[a]ny pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce cancer" constitutes substantial risk information and should be reported. (Mem. in Support of Complainant's Mot. for Accelerated Decision on Liability at 15). The Modern Report documents multiple instances of lung cancer. See e.g., C's Ex. 1 at 16-18, 77-81 (Mortality Analysis), 81-85 (Logistic Regression Analysis), 88-95, 98. As such, the Modern Report meets the mandatory reporting threshold under TSCA section 8(e). Consequently, there is no genuine issue of material fact as to whether the Modern Report reasonably supports a conclusion of substantial risk of injury to health.<sup>5</sup> Therefore, the Presiding Officer

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<sup>5</sup> Respondent devotes considerable discussion in its response to the Modern Report's alleged deficiencies implying that it was an invalid and scientifically unreliable study. (Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 3, 5, 7-8). Whether or not the Modern Report has deficiencies is irrelevant to determining if substantial risk information is subject to reporting under TSCA section 8(e). A manufacturer's belief that a study is low quality is not a valid basis for withholding information under TSCA section 8(e). "Under the plain language of the statute, a manufacturer's 'belief' about the quality of a study plays no role in determining whether it should have been reported. The only question is whether the study 'reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment.'" In re Methyl Tertiary Butyl Ether (MTBE) Products Liability

should grant the Motion for Accelerated Decision on Liability as to the third element of liability.

4. Respondent admits that it failed to immediately inform the Administrator of the Modern Report.

In the Motion for Accelerated Decision on Liability, Complainant states that Elementis failed to immediately inform the Administrator of the Modern Report. (Mem. in Support of Complainant's Mot. for Accelerated Decision on Liability at 20-21). In its response, Respondent admits, "Nor is there any dispute that Elementis ... did not provide it [Modern Report] to the Administrator until November 18, 2008, when it responded to a subpoena from EPA." (Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 11). Respondent has admitted that it failed to immediately inform the Administrator of the Modern Report and, therefore, the Presiding Officer should grant the Motion for Accelerated Decision on Liability as to the fourth element of liability.

In summary, Respondent admits to the four elements of EPA's prima facie case of TSCA section 8(e) liability, and EPA has proven all four elements of its prima facie case. Therefore, the Presiding Officer should grant Complainant's Motion for Accelerated Decision on Liability.

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Litigation, 559 F. Supp.2d 424, 437 (S.D.N.Y. 2008). The purpose of the statutory provision would be frustrated if a company were free to substitute its judgment for EPA's regarding whether a particular study is of sufficient quality to trigger TSCA section 8(e)'s reporting requirement.

B. Respondent's Statutory Affirmative Defense Fails Because EPA Had Not Been Adequately Informed of the Information Contained in the Modern Report.

The disposition of Complainant's Motion for Accelerated Decision on Liability turns on Respondent's statutory affirmative defense under TSCA section 8(e). This defense requires Respondent to demonstrate it "has actual knowledge that the Administrator has been adequately informed" of the information in the Modern Report at the time Respondent obtained the Modern Report in 2002. 15 U.S.C. § 2607(e). When relying on an affirmative defense to oppose EPA's Motion for Accelerated Decision, Respondent must "provide more than a scintilla of evidence on a disputed factual issue to show their entitlement to a trial or evidentiary hearing: the evidence must be substantial and probative in light of the appropriate evidentiary standard of the case." In Re BWX Technologies, Inc., 9 E.A.D. 61, 76, (EAB 2000), 2000 EPA App. LEXIS 9 at \*40 (emphasis added). Respondent has failed to produce substantial and probative evidence on a disputed factual issue entitling Elementis to an evidentiary hearing on its statutory affirmative defense.

In its response, Respondent alleges that it had actual knowledge that the Administrator had been adequately informed of

the information contained in the Modern Report.<sup>6</sup> (Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 10). Elementis cannot produce evidence to demonstrate "actual knowledge" for two key reasons. First, as Respondent has admitted, Elementis did not provide the Agency with the Modern Report or the information it contains until 2008. Id. at 11. Second, the Modern Report itself contains information about the extent of lung cancer mortality risk under modern plant conditions that was not previously known to the Agency.

The Modern Report study sought to answer the open question of whether, and to what extent, lung cancer mortality risk remained under modern plant conditions. (C's Ex. 1 at 40-41). As of the late 1990s, the limited scientific literature suggested that modern chromium production processes (low- or no-lime) had reduced lung cancer mortality risk compared to the traditional production process (high-lime). (C's Ex. 1 at 15; 18-19; 29; 32; 40-44). However, as noted by the authors of the Modern Report, these modern studies were inconclusive and, thus,

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<sup>6</sup> Respondent contends that the Modern Report "does not add to the knowledge base on the lung cancer risk from occupational exposure to hexavalent chromium." (Gibb Aff. Resp't Ex. C ¶ 9). The fact that the Modern Report analyzes lower exposure levels than had previously been studied refutes this statement. Risk is a function of assessing a particular hazard at a certain exposure; because the exposure levels studied in the Modern Report were significantly lower than exposures studied in other reports, the risk assessment in the Modern Report is different from the others. Furthermore, in the Modern Report's authors' own words, the Modern Report, together with other recent epidemiologic studies, constitutes the "best available scientific evidence of the relationship between chromium exposure and human lung cancer risk." (C's Ex. 1 at 19).

this question remained unanswered. Id. The Modern Report provides information that helps answer the question of the the extent of lung cancer mortality risks in the modern, post-change plants. (C's Ex. 1 at 74-99).

Respondent erroneously contends that the Modern Report's conclusion about substantial risk is limited as follows:

The only information in the [Modern] Report reasonably supporting the conclusion that hexavalent chromium presents a substantial risk of injury to human health was the finding by Applied Epidemiology that there was a statistically increased incidence of lung cancer in the employees exposed to high levels of hexavalent chromium in Germany.

(Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 2; see also id. at 13, 16). Elementis has misconstrued the scope of the substantial risk information in the Modern Report as restricted to information about workers exposed to "high cumulative levels of hexavalent chromium." Id. at 11. For purposes of accelerated decision, it is important to note that Respondent's narrow characterization of the substantial risk information in the Modern Report is not supported by the report itself.<sup>7</sup> (C's Ex. 1 at 93-95). Notably, as shown in Table 18 of the Modern Report, the logistic regression analysis suggested an elevated risk in both the intermediate and high exposure categories, controlling for age

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<sup>7</sup> As noted earlier by Complainant, even the "lowest" exposure levels in the Gibb study are significantly higher than the low exposure levels that exist in the post-process change plants that were studied in the Modern Report. (Cooper Aff., C's Ex. 11, ¶¶ 9, 28 and 32).

and smoking status. (C's Ex. 1 at 122; see also Cooper Aff. C's Ex. 11, ¶ 26). As such, the Modern Report's finding regarding the intermediate exposure group also constitutes information which reasonably supports the conclusion that hexavalent chromium presents a substantial risk of injury to health. (Cooper Aff. C's Ex. 11, ¶¶ 26-32).

Moreover, Respondent wrongly asserts that the information contained in the Modern Report is the same as the information previously known to EPA through the EPA-funded 2000 Gibb et al. study (Gibb study). (Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 13). Although the Gibb study is widely regarded as one of the most methodologically strong and comprehensive epidemiologic studies of hexavalent chromium exposure conducted to date, the Modern Report and Gibb study have important differences.<sup>8</sup> These two studies evaluated different populations at different plants with different exposure levels under varying manufacturing process conditions, and each of these studies contains distinct information about risk.

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<sup>8</sup> In its response, Respondent argues that the Modern Report corroborates the Gibb study and, therefore, was not required to be submitted under EPA's TSCA section 8(e) guidance. (Resp't Mem. in Opposition to Complainant's Mot. for Accelerated Decision on Liability at 15). For the reasons discussed in Complainant's Motion for Accelerated Decision and herein, the Modern Report does not substantially duplicate or confirm "well-recognized/well-established" information. (Mem. in Support of Complainant's Mot. for Accelerated Decision on Liability at 29-30).

A few examples of the differences between the Modern Report and Gibb studies are illustrative. First, the Modern Report demonstrated increased lung cancer mortality risk among workers who had worked exclusively in plants utilizing modern low- or no-lime manufacturing processes. (Cooper Aff. C's Ex. 11, ¶¶ 9, 30; Hernandez Aff. C's Ex. 13, ¶ 20). The Gibb study "did not evaluate ... [the] risk for those who worked exclusively in the new facilities...." (C's Ex. 1 at 30). Second, the Modern Report studied workers exposed to lower average hexavalent chromium concentrations than workers in the Gibb study. (Cooper Aff. C's Ex. 11, ¶¶ 14, 28, 32). Third, the Modern Report study excluded workers employed for less than one year, whereas the Gibb study "included many short term employees; over half worked less than six months, and 42% worked less than 90 days." (C's Ex. 1 at 30). As a result, the Modern Report study assessed the risks associated with longer exposure periods than the Gibb study. Finally, the Modern Report study evaluated lung cancer mortality risk in relation to both cumulative and peak exposures while the Gibb study evaluated risk only from cumulative exposure. (Cooper Aff. C's Ex. 11, ¶¶ 19, 24; see Resp't. Ex. D). Consequently, as these examples illustrate, Respondent's contention that the substantial risk information contained in the Modern Report is the same as the substantial risk information in the Gibb study has no basis in the record.

In short, Respondent has failed to provide evidence that it "has actual knowledge that the Administrator ha[d] been adequately informed" of the information contained in the Modern Report. Respondent's statutory affirmative defense is predicated upon the mistaken position that the Modern Report did no more than confirm the already-known fact that exposure to high levels of hexavalent chromium causes an increased risk of lung cancer. Importantly, the Modern Report 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. (Cooper Aff. C's Ex. 11 at ¶ 9, 30; Hernandez Aff. C's Ex. 13, ¶ 20). This information was not previously available; therefore, the record belies Respondent's assertion that the Administrator had been adequately informed of the information in the Modern Report.

Respondent has failed to provide any evidence that at any time prior to 2008, it had actual knowledge that the Administrator had been adequately informed of the information contained in the Modern Report. Consequently, Respondent's statutory affirmative defense does not bar an accelerated decision on liability in light of Respondent's in light of Respondent's failure to provide evidence that

Respondent had actual knowledge that the Administrator had been adequately informed of the substantial risk information.

III. Conclusion

Complainant has proven the four elements of TSCA section 8(e) liability. Therefore, there is no genuine issue of material fact as to Respondent's liability under section 8(e). Moreover, Respondent has failed to provide evidence supporting its statutory affirmative defense; thus, the affirmative defense does not bar an accelerated decision on liability.

Respectfully submitted,

5/29/2011  
Date

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Counsel for Complainant

CERTIFICATE OF SERVICE

I certify that the foregoing *Complainant's Reply to Respondent's Memorandum in Opposition to Complainant's Motion for Accelerated Decision on Liability* in Docket No. TSCA-HQ-2010-5022, dated May 24, 2011, was sent this day in the following manner to the addresses listed below:

Original by hand and email to:

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U.S. Environmental Protection Agency  
Office of Administrative Law Judges  
Franklin Court, Suite 350  
1099 14th Street, N.W.  
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Copy by hand to:

Presiding Officer:

The Honorable Susan L. Biro  
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Copy by U.S. first-class mail and email to:

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Date: 5/24/2011