(Slip Opinion)

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BEFORE THE ENVIRONMENTAL APPEALS BOARD
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

In re:	)	
	)	TSCA Appeal No. 13-03
Elementis Chromium, Inc.	)	
	)	
Docket No. TSCA-HQ-2010-5022	)	

[Decided March 13, 2015]

FINAL DECISION AND ORDER

Before Environmental Appeals Judges Leslye M. Fraser and Kathie A. Stein.

IN RE ELEMENTIS CHROMIUM, INC.

TSCA Appeal No. 13-03

FINAL DECISION AND ORDER

Decided March 13, 2015

Syllabus

Elementis Chromium, Inc. ("Elementis") appeals an Initial Decision the Chief Administrative Law Judge ("ALJ") issued assessing a $2,571,800 administrative civil penalty against it for violating section 8(e) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2607(e). The ALJ concluded that Elementis failed to report to the Environmental Protection Agency information contained in an occupational epidemiology study on hexavalent chromium. On appeal, Elementis challenges the ALJ's decision arguing that: the complaint filed by EPA's Office of Enforcement ("EPA-OCE") was time-barred by the statute of limitations; and the ALJ erred on the merits because Elementis was exempt from the section 8(e)'s reporting obligation.

Held: While the ALJ correctly concluded that under the continuing violations doctrine EPA-OCE timely filed its complaint, the ALJ erred in finding Elementis liable for failing to submit the epidemiology study to EPA. The Board reverses the ALJ's judgment and penalty against Elementis. The Board's most significant findings are as follows:

1. EPA-OCE's enforcement action is not time barred:

Under the continuing violations doctrine, EPA-OCE's complaint was timely. The continuing violations doctrine is a special rule of accrual. Under this doctrine certain violations that begin and continue accrue anew each day. TSCA section 8(e) imposes a continuing duty on "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" to inform EPA of such information "unless such person has actual knowledge that the Administrator has been adequately informed of such information." This duty continues for as long as reportable information is required and not provided. Therefore, a section 8(e) violation constitutes a "continuing violation" for statute of limitations purposes. The period of limitations for a section 8(e) violation runs anew each day the obligation to provide reportable information remains unfulfilled. In this case, Elementis' last act of non-compliance took place on November 17, 2008, and EPA-OCE filed the Complaint within the 5-year period of limitations running from that date. Therefore, the complaint against Elementis was timely and EPA-OCE could seek

penalties for any non-compliance preceding the five years from the date it filed the complaint.

2. Elementis was not required to submit the occupational epidemiology study to EPA under TSCA section 8(e) guidance documents:

Elementis obtained an epidemiology study that showed that occupational exposure to hexavalent chromium is associated with an elevated incidence of lung cancer. Neither Elementis nor any other party immediately submitted the study to EPA. Over six years after obtaining the study, Elementis submitted it to EPA in response to a subpoena.

But for EPA's section 8(e) guidance documents, Elementis' failure to immediately submit the study would violate the plain language of the statute because the epidemiology study reasonably supports a conclusion of a substantial risk to health (lung cancer). However, as stated in EPA's section 8(e) guidance documents, EPA considers itself to be "adequately informed already" of information that is "corroborative of well-established adverse effects." The guidance states that information is deemed corroborative if it does not show the adverse effect is "of a more serious degree or a different kind" than previously known. Further, the guidance clarifies that information showing adverse effects at lower dose levels is treated as non-corroborative, whereas information showing such effects at similar or higher dose levels is considered corroborative.

It has been well-established for decades that hexavalent chromium causes the adverse effect of lung cancer. Moreover, the epidemiology study Elementis received identified a lung cancer effect only at a substantially *higher* cumulative dose level than the cumulative dose level showing lung cancer in a pre-existing EPA epidemiology study on hexavalent chromium. Thus, the study Elementis received is corroborative of a well-established adverse effect. Elementis did not have to submit the study to EPA because EPA guidance documents had notified the regulated community that EPA is adequately informed of such corroborative information.

In an attempt to show that the epidemiology study was non-corroborative despite only finding lung cancer at a higher cumulative dose, EPA-OCE witnesses testified at the evidentiary hearing in this matter that the study involved a lower *intensity* of exposure than the earlier EPA study (lower exposure level over a longer period of time). The ALJ, however, rejected EPA-OCE's evidence on this point. Nonetheless, the ALJ concluded that the epidemiology study was non-corroborative because it contained different exposure information than the earlier EPA study that was "valuable" in assessing lung cancer risk. The ALJ also held, and EPA-OCE argues on appeal, that Elementis should have reported the epidemiology study because the "adverse effects" of hexavalent chromium in terms of its dose-response relationship and the cancer risk it poses in modern chromium plants are not well-established.

The Board concludes that the ALJ's reasoning is inconsistent with the plain language of EPA's guidance documents. Merely asserting that the new exposure

information is "important" or "valuable" does not demonstrate that the information is *non-corroborative* as that term is used in EPA guidance documents – i.e., information showing adverse effects "of a more serious degree or different kind" than previously known. Neither are the dose-response relationship between hexavalent chromium and lung cancer or the cancer risk posed by hexavalent chromium in modern chromium plants an *adverse effect*. Equating these terms – adverse effect, dose-response relationship, and risk – disregards decades of EPA risk assessment practice and the National Academy of Sciences' framework for risk assessment in the Federal Government.

The Board's decision is controlled by the instruction EPA's guidance documents provided to the regulated community on the information as to which the Agency considers itself to be "adequately informed" for section 8(e) purposes. Although the guidance documents narrow the scope of the reporting obligation in section 8(e), nothing in the Board's opinion suggests that the statute compels the interpretation of the term "adequately informed" that EPA has chosen to include in these guidance documents. Nonetheless, while guidance documents' exemption for corroborative information remains extant, regulated parties cannot be held to violate section 8(e) for acting in a manner consistent with such guidance.

Before Environmental Appeals Judges Leslye M. Fraser and Kathie A. Stein.

Opinion of the Board by Judge Stein:

I. *STATEMENT OF THE CASE*

Respondent Elementis Chromium, Inc. ("Elementis"), which manufactures and distributes chromium chemicals, appeals an Initial Decision the Chief Administrative Law Judge ("ALJ") issued assessing a $2,571,800 administrative civil penalty against it for violating section 8(e) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2607(e). The ALJ concluded that Elementis failed to report to the Environmental Protection Agency information contained in an occupational epidemiology study on hexavalent chromium. On appeal, Elementis challenges the ALJ's decision on two separate grounds. First, it argues that the complainant, EPA's Office of Civil Enforcement ("EPA-OCE"), filed the complaint too late – eight years after Elementis obtained the information. Second, it argues that the ALJ erred on the merits because Elementis was exempt from the section 8(e)'s reporting obligation under both a plain reading of the statute and EPA's guidance documents on section 8(e).

For the reasons explained below, the Environmental Appeals Board ("Board") vacates the ALJ's decision. The Board finds that under the continuing violations doctrine, EPA-OCE timely filed its complaint. However, the Board concludes that the ALJ erred in finding Elementis liable for failing to submit the epidemiology study to EPA, as the information in the study falls within an exemption provided in EPA's TSCA section 8(e) guidance documents. Accordingly, the Board reverses the judgment and penalty against Elementis.

II. *STATUTORY AND REGULATORY HISTORY*

The case before the Board implicates both the general statute of limitations set forth in 28 U.S.C. § 2462, which provides that an action for the enforcement of any civil fine or penalty must be commenced within five years from the date when the claim first accrued, and section 8(e) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2607(e), which imposes an obligation on chemical manufacturers to immediately report to EPA certain information bearing on risk.

"Statutes of limitations are intended to 'promote justice by preventing surprises through the revival of claims that have been allowed to slumber until evidence has been lost, memories have faded, and witnesses have disappeared.'" *Gabelli v. Sec. & Exch. Comm'n*, 586 U.S. __, 133 S. Ct. 1216, 1221 (2013) (quoting *R.R. Telegraphers v. Ry. Express Agency, Inc*., 321 U.S. 342, 348-49 (1944)). The "standard rule" of accrual provides that a claim "accrues" or begins to run "when the plaintiff has a complete and present cause of action." *Id*. at 1220 (quoting *Wallace v. Kato*, 549 U.S. 384, 388 (2007) (internal quotations omitted)). Exceptions to this rule "in which 'a statute of limitation may be suspended by causes not mentioned in the statute itself * * * are very limited in character, and are to be admitted with great caution.'" *Id*. at 1224 (quoting *Amy v. Watertown (No. 2)*, 130 U.S. 320, 324 (1889)). The continuing violations doctrine, however, is a special rule of accrual that, depending on the type of violation, allows for the cause of action to accrue anew each day or toll the limitations period. *See infra* Part V.A. Therefore, when the continuing violations doctrine applies, actions may be brought more than five years after a claim first accrued. *See id*.

In this appeal, the underlying violations arise under TSCA, which Congress enacted as "a comprehensive measure to protect the public and the environment from exposure to hazardous chemicals." S. Rep. No. 94-698, at 3 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4493. To further this aim, the statute requires "scrutiny" of chemicals prior to their manufacture to prevent "the public or the environment [from] be[ing] used as a testing ground for the safety of these products." *Id*. In addition, TSCA includes requirements, such as those in section 8(e), to "provide regulators timely access to information regarding health and safety studies concerning chemicals covered by the Act." *Id*. at 6, *reprinted in* 1976 U.S.C.C.A.N at 4496.

Section 8(e) provides in full:

> 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.

TSCA § 8(e), 15 U.S.C. § 2607(e). Congress imposed this reporting requirement in response to testimony it received alleging that certain industry groups had withheld information from the government on the cancer effects of vinyl chloride and bis(chloromethyl)ether ("BCME"). S. Rep. No. 94-698, at 6, *reprinted in* 1976 U.S.C.C.A.N. at 4496; *see* Hearings on S.776 Before the Subcomm. on the Env't of the S. Comm. on Commerce, 94th Cong. 61 (1975) (statement of Andrea Hricko, staff associate, Health Research Group) ("[H]ad there been legislation requiring industry to submit data on adverse health effects, the Government would not have had to rely on the corporate good will * * * to voluntarily submit this information" about worker deaths from lung cancer caused by exposure to BCME.).

To assist regulated entities in complying with TSCA section 8(e), EPA has issued several guidance documents interpreting TSCA section 8(e)'s reporting obligations. Those documents discuss what information EPA believes reasonably supports a conclusion that a chemical or mixture poses a substantial risk of injury and what information persons can assume EPA to be adequately informed of, thereby excusing them from the duty to disclose such information to EPA. In particular, EPA's guidance documents state that EPA considers itself to be adequately informed already of information that is "corroborative of well-established adverse effects" of a chemical. Notification of Substantial Risk Under Section 8(e), 43 Fed. Reg. 11,110, 11,112 (Mar. 16, 1978) [hereinafter *1978 Policy Statement*]; U.S. EPA Office of Toxic Substances, *TSCA Section 8(e) Reporting Guide*, at 8 (June 1991)[1] [hereinafter *1991 Reporting Guide*]. The guidance documents further specify that information can be corroborative "in terms of, for example, route of exposure, dose, species, time to onset, severity, species strain, etc." *1991 Reporting Guide* at 8. Information is deemed non-corroborative if it shows an effect to be more serious than previously known, such as demonstrating an adverse effect at a lower level. *Id*., *see* Part V.B.3, *infra*.

III. *SUMMARY OF RELEVANT FACTUAL HISTORY*

To a large degree, the facts in this matter are not disputed. The parties stipulated to many critical facts, *see* Joint Set of Stipulated Facts, Exhibits and Testimony ("Joint Stipulation") (Nov. 10, 2011); other facts have never been seriously contested or were admitted by the parties in the course of the proceedings before the ALJ or the Board. Finally, the ALJ resolved those facts that were disputed, and the parties have not appealed those determinations. In brief, these facts show the following.[2]

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[1] This document is available at http://www.epa.gov/oppt/tsca8e/pubs/1991guidance.pdf.

[2] The ALJ's opinion contains a much more detailed statement of the facts. Init. Dec. at 6-32.

Elementis manufactures chromium chemicals, including hexavalent chromium, and has operated manufacturing plants in both the United States and England. Joint Stipulation ¶¶ 4-5; Hearing Transcript ("Hearing Tr.") at 942-43, 954 (testimony of Dr. Joel Barnhart). Multiple epidemiological studies on chromium workers conducted over the last half century have shown that inhalation exposure to hexavalent chromium is associated with an increased risk of lung cancer. Occupational Exposure to Hexavalent Chromium, 71 Fed. Reg. 10,100, 10,111-24 (Feb. 28, 2006). Because of concerns with the carcinogenic effects of hexavalent chromium, chromium manufacturers upgraded their facilities beginning in the 1950's to reduce workers' exposure to chromium dust. Applied Epidemiology, Inc., *Collaborative Cohort Mortality Study of Four Chromate Production Facilities* ("*Collaborative Cohort Mortality Study*"), *1958-1998*, at 12 (Sept. 27, 2002) (Complainant's Exhibit ("CX") 1 at 26).[3]

In 1998, an industry trade group of which Elementis is a member commissioned Dr. Kenneth Mundt to conduct an epidemiological study of worker risk from inhalation exposure to chromium under the conditions in modern chromium manufacturing facilities ("Mundt study").[4] Initial Decision ("Init. Dec.") at 11, 15. The trade group

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[3] The Board includes a reference to the hearing exhibit number for unpublished materials.

[4] Dr. Mundt conducted the study cited as Applied Epidemiology, Inc., *Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998* (Sept. 27, 2002) (CX 1), which has been referred to by several names in this proceeding. *See, e.g.*, Init. Dec. at 72 ("Final Report"); Complainant's Initial Post-Hearing Brief, at 1 ("Final Four Plant Report"). The Board will refer to this study as the Mundt study because identifying a study by its primary author is common practice for scientific studies generally and has been used to identify the other studies involved in this litigation. *See* Init. Dec. at 7-10, 19. The Board's citations to the Mundt study will use a shortened form ("*Collaborative Cohort Mortality Study*") of its full title. The full study report is included in the hearing record under the designation of CX 1. Dr. Mundt, in conjunction with other scientists, has published two articles detailing the results of the study. *See* Rose S. Luippold et al., *Low-Level Hexavalent Chromium Exposure and Rate of Mortality Among US Chromate Production Employees,* 47(4) J. Occup. Environ. Med. 381 (2005); Thomas Birk et al., *Lung Cancer Mortality in the German Chromate* (continued...)

funded this study in large part because of a concern that the Occupational Safety and Health Administration ("OSHA") of the U.S. Department of Labor was considering lowering the permissible exposure limit for hexavalent chromium in occupational settings. *Id*. at 11-13. At about the same time, Dr. Herman Gibb, an EPA employee, was conducting a similar epidemiological study for the Agency ("Gibb study"). Herman J. Gibb et al., *Lung Cancer Among Workers in Chromium Chemical Production* ("*Lung Cancer Among Workers*"), 38 Am. J. of Ind. Med. 115 (2000). Dr. Gibb based his study on data from a chromium facility in Baltimore, Maryland, whereas Dr. Mundt studied facilities in Corpus Christi, Texas; Castle Hayne, North Carolina; Leverkusen, Germany; and Uerdingen, Germany. *Collaborative Cohort Mortality Study* at 18 (CX 1 at 32); *Lung Cancer Among Workers*, 38 Am. J. of Ind. Med. at 116.

Dr. Gibb completed his study in 2000. Like earlier epidemiological studies of chromium workers, Dr. Gibb found a positive association between cumulative hexavalent chromium exposure and lung cancer. *Lung Cancer Among Workers*, 38 Am. J. of Ind. Med. at 124. Dr. Mundt completed his study in 2002. He also found a positive association between cumulative hexavalent chromium exposure and lung cancer. *Collaborative Cohort Mortality Study* at 75-76 (CX 1 at 89-90). However, the only exposure (dose) level in the Mundt study at which a statistically significant lung cancer effect was observed was substantially higher than the lowest dose level in the Gibb study that was associated with a statistically significant lung cancer effect.[5] Hearing Tr.

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[4](...continued)
Industry, 1958 – 1998, 26(1) Risk Anal. 79 (2006).

[5] The Mundt study showed a statistically significant cancer effect at a cumulative yearly dose of 325 micrograms/meters^3, which is approximately 20 times higher than the cumulative yearly dose level of 15.6 micrograms/meters^3 at which the Gibb study found a significant cancer effect. Hearing Tr. at 240:13 – 241:20 (testimony of Dr. Glinda Cooper), 458:13 – 459:20 (testimony of Dr. Herman Gibb); *Lung Cancer Mortality Risk in Relation to Cumulative Chromium Exposure Using External Referent Groups (Standardized Mortality Ratios (SMRs): Gibb and Modern Four Plant Report Studies*, CX 99.

at 1044:9–1045:21 (testimony of Dr. Herman Gibb); 908:3–909:16 (testimony of Dr. Kenneth Mundt).

Dr. Mundt submitted a final copy of his study to Dr. Joel Barnhart, a corporate official at Elementis, on October 8, 2002. Joint Stipulation ¶¶ 17, 18. After reviewing the study, Dr. Barnhart concluded that Elementis was not obligated to submit it to EPA under TSCA section 8(e) because it did not contain any information "showing an adverse effect that was especially unexpected or much greater than expected." Hearing Tr. at 991:3–5 (testimony of Dr. Joel Barnhart). Dr. Barnhart admitted that he did not specifically review TSCA or any EPA guidance documents in making this determination. *Id*. at 990:22–991:3. Nor did Dr. Barnhart consult with others in his organization on this decision. *Id*. at 991:17–22.

Elementis also did not submit the Mundt study to OSHA, even though OSHA had made a public request for data on hexavalent chromium that was pending when Elementis received the Mundt study. *Id.* at 1166:18-21 (testimony of Dr. Joel Barnhart); Occupational Exposure to Hexavalent Chromium (CrVI), 67 Fed. Reg. 54,389, 54,390 (Aug. 22, 2002) (requesting data, including epidemiology studies, relevant to the risks from occupational exposure to hexavalent chromium be submitted to OSHA by November 11, 2002). OSHA specifically asked for data on the "dose response behavior" of hexavalent chromium, data on exposure to hexavalent chromium based on job category, and studies that "quantify exposure data and control for important confounding variables." 67 Fed. Reg. at 54,390, 54,391, 54,392. Testimony at the hearing before the ALJ showed that the Mundt study provides data on all of these points. Hearing Tr. at 679:9–685:15, 717:15–718:18, 754:1–757:22, 919:4–922:19, 938:20–939:3 (testimony of Dr. Kenneth Mundt).

Elementis did participate in the OSHA rulemaking proceedings on hexavalent chromium permissible exposure limits that transpired between 2002 and 2006. On several occasions, Elementis submitted comments to OSHA criticizing OSHA's reliance on the Gibb study to choose the permissible exposure limits. Joel Barnhart, *Comments of*

Elementis Chromium LP (Dec. 31, 2004) (CX 95); Letter from Kathryn M. McMahon-Lohrer to OSHA (Jan. 3, 2004) (attaching hearing testimony of Dr. Joel Barnhart on the proposed hexavalent chromium rule) (CX 96). At no point did Elementis mention the Mundt study in these comments.

Toward the end of the rulemaking proceeding, a public interest group submitted a copy of the Mundt study to OSHA. Hearing Tr. at 1117:1-4. OSHA briefly considered the study but decided not to rely on it, noting that not only had the public interest group submitted the study after the close of the public comment period, but also that "[OSHA] does not believe that quantitative analysis of these studies would provide additional information of risk from low exposures to [hexavalent chromium]." 71 Fed. Reg. at 10,179. OSHA did note that the Mundt study provides "further evidence that occupational exposure to [hexavalent chromium] present[s] a lung cancer risk." *Id*. at 10,199.

From accounts published in the *Washington Post* in 2006, EPA became aware of the existence of the Mundt study. Hearing Tr. at 612:19-22 (testimony of Antony Ellis). On August 8, 2008, EPA-OCE issued a subpoena requesting that Elementis provide EPA with a copy of the study, which Elementis complied with on November 17, 2008. Joint Stipulation ¶ 20.

The parties engaged in settlement discussions and entered into several tolling agreements in which they agreed to toll the statute of limitations while settlement discussions continued. *See, e.g*., Tolling Agreement (June 30, 2009) (CX 83); Tolling Agreement (Sept. 24, 2009) (CX 85). Settlement discussions proved unsuccessful, and on September 2, 2010, EPA-OCE filed an administrative complaint against Elementis charging it with failure to immediately inform the Administrator of the Mundt study as required by TSCA section 8(e). Complaint and Notice of Opportunity for Hearing ("Complaint") (Sept. 2, 2010). Elementis filed an answer to the Complaint and a motion requesting that the ALJ rule on the pleadings, arguing that the statute of limitations barred the enforcement action. The ALJ denied the motion holding that under the continuing violations doctrine, EPA-OCE timely filed the Complaint.

Order on Respondent's Motion for Judgment on Pleadings (ALJ Mar. 25, 2011) ("ALJ's Mar. 2011 Order").

The ALJ held a three-day evidentiary hearing on the liability issue, after which the parties filed post-trial briefs. On November 12, 2013, the ALJ issued an Initial Decision concluding that Elementis had violated section 8(e). The ALJ's analysis proceeded in two steps. First, the ALJ assessed what information in the Mundt study constituted "'information which reasonably supports the conclusion that [a] substance or mixture presents a substantial risk of injury to health or the environment.'" Init. Dec. at 38 (quoting 15 U.S.C. § 2607(e)). The ALJ concluded that the term "information" should be broadly construed and there was "much" information in the Mundt study that reasonably supported a conclusion of substantial risk. *Id*. at 48, 72. Second, the ALJ examined whether Elementis was exempt from reporting that information because it had actual knowledge that EPA was "adequately informed of such information." *Id*. at 48. In resolving this latter issue, the ALJ considered how EPA's guidance had interpreted this affirmative defense to the reporting obligation. *Id.* The ALJ held that the Mundt study was not exempt "corroborative information" under EPA guidance, both because it did not concern "a well-established adverse effect" and because it included distinct and more accurate information on exposure than had been included in the Gibb study. *Id*. at 72.

Finding liability, the ALJ imposed a penalty of $2,571,800, reflecting 2,211 days of violation. *Id*. at 92. This included a base penalty of $2,338,000 that considered the gravity, extent, and circumstances of the violation. In addition, the ALJ raised the base penalty by ten percent based on Elementis' culpability or attitude. Specifically, the ALJ concluded that Elementis and its agent, Dr. Barnhart, "acted in bad faith by not timely submitting the [Mundt study] to OSHA and EPA, particularly when they knew the government was looking for more data, and when they were actively, roundly criticizing the database upon which the government was promulgating a new [permissible exposure limit] in an effort to alter, delay or derail the regulatory process." *Id*. at 80.

On January 15, 2014, Elementis filed an appeal challenging the ALJ's decision. On October 30, 2014, the Board held oral argument on this matter. Substantive briefing for this appeal was complete on November 17, 2014.

IV. *STANDARD OF REVIEW*

The Board generally reviews appeals from an ALJ's initial decision *de novo*. *See* 40 C.F.R. § 22.30(f) (providing that, in an enforcement proceeding, the Board "shall adopt, modify, or set aside the findings of fact and conclusions of law * * * contained in the decision or order being reviewed"); *see also* Administrative Procedure Act, 5 U.S.C. § 557(b) ("On appeal from or review of [an] initial decision, the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule."). All matters in controversy must be established by a preponderance of the evidence. 40 C.F.R. § 22.24(b). The complainant (i.e., EPA-OCE) has the burdens of presentation and persuasion to prove that "the violation occurred as set forth in the complaint and that the relief sought is appropriate." *Id.* § 22.24(a). Once the complainant meets this burden, the respondent (i.e., Elementis) has the burdens of presentation and persuasion to prove any affirmative defense(s) that excuse it from liability. *Id*.; *see also In re Gen. Motors Auto*., 14 E.A.D. 1, 54-55 (EAB 2008) (describing burden of proof for affirmative defenses).

V. *ANALYSIS*

As previously noted, this case involves both the general statute of limitations set forth in 28 U.S.C. § 2462, which provides that an action for the enforcement of any civil fine or penalty must be commenced within five years from the date when the claim first accrued, and section 8(e) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2607(e), which imposes an obligation on chemical manufacturers to immediately report to EPA certain information bearing on risk. Accordingly, in light of these two statutory provisions, the Board must answer four questions to resolve this appeal:

1. Given that EPA-OCE filed its complaint more than five years after Elementis obtained the Mundt study, is the Complaint timely under the continuing violations doctrine?

2. Did Elementis obtain information that reasonably supports the conclusion that hexavalent chromium presents a substantial risk of injury to human health or the environment?

3. If the answer to question 2 is yes, did Elementis immediately inform EPA of "such information"?

4. If the answer to question 3 is no, has Elementis established as an affirmative defense that it had actual knowledge that EPA had been adequately informed of "such information" and thus Elementis did not have to disclose "such information"?

To answer these questions, the Board examines below the statutory language and applicable caselaw, the underlying purposes of the general statute of limitations and TSCA, and EPA's guidance documents interpreting TSCA section 8(e)'s reporting obligations. In sum, the Board concludes that:

1. Under the continuing violations doctrine EPA-OCE filed a timely complaint;

2. The Mundt study that Elementis received qualifies as information that reasonably supports the conclusion that hexavalent chromium presents a substantial risk of injury to human health (lung cancer);

3. Elementis did not immediately inform EPA of the Mundt study; and

4. But for EPA's section 8(e) guidance documents, Elementis' failure to immediately submit the Mundt study would violate the plain language of the statute because the study reasonably supports a conclusion of a substantial risk to health and EPA was not adequately informed of the study until over six years after Elementis obtained it. EPA's guidance documents, however, state that EPA is "adequately informed *already*" of information that is corroborative of well-established adverse effects. Elementis demonstrated that the information in the Mundt study is corroborative of the well-established adverse effect (lung cancer) caused by exposure to hexavalent chromium, as the term "corroborative" is defined by EPA. Thus, Elementis established its affirmative defense that it had actual knowledge that EPA was adequately informed of the Mundt study.

Accordingly, the Board finds that the ALJ erred by finding Elementis liable for violating TSCA section 8(e) and vacates the assessed penalty of $2,571,800.

A. *Was the Complaint EPA-OCE Filed Timely?*

Elementis argues that EPA-OCE filed its complaint too late because the general statute of limitations already had expired. Therefore, we first resolve whether the general statute of limitations bars this enforcement action. The general statute of limitations provides in relevant part:

> Except as otherwise provided by Act of Congress, an action, suit or proceeding for the enforcement of any civil fine, penalty, or forfeiture, pecuniary or otherwise, shall not be entertained unless commenced within five years from the date when the claim first accrued * * *.

28 U.S.C. § 2462.

Elementis argues that the alleged violation "accrued" on or about November 7, 2002, when it obtained the Mundt study, and the five-year statute of limitations expired on or about November 7, 2007 – three years before EPA-OCE filed the Complaint. Accordingly, Elementis claims that under the "standard rule of accrual" the Complaint was untimely. *See* ALJ's Mar. 2011 Order at 2. EPA-OCE argued before the ALJ that the continuing violations doctrine applies to TSCA section 8(e) violations and that the Complaint was timely filed because it was filed within five years from the day Elementis provided the Mundt study to EPA. *Id*. at 3. The ALJ agreed with EPA-OCE and held that, under the continuing violations doctrine, EPA-OCE filed a timely complaint. *Id*. at 5-12.

For the reasons stated below, the Board finds that EPA-OCE's enforcement action against Elementis is not time barred.

1. *The "Continuing Violations Doctrine" and the Term "Continuing Violations"*

The "continuing violations doctrine" is a special rule of accrual that can mitigate the effect of the statute of limitations. In determining whether an action is subject to this doctrine, courts first examine whether the alleged violation is of a continuing nature or a "continuing violation."[6] The term "continuing violations," however, has been used and applied in the statute of limitations context in at least three distinct ways, which has led to considerable confusion and resulted in seemingly disparate treatment of similar claims. As Judge Easterbrook recently explained in his concurring opinion in *Turley v. Rednour*, the term "continuing violations" has been used to describe:

[6] Courts also use the term "continuing violations" in other contexts, including to determine proper venue, standing in citizen enforcement actions, and imposition of multi-day penalties.

> [1. Continuing Violations.] Violations [that] begin and continue, and the prevailing rule treats new acts, or ongoing inaction, as new violations * * *[;]
>
> [2. Cumulative Violations.] Deeds that are not themselves violations of law [but] become actionable if they add up [to a violation]* * * [; and]
>
> [3. Continuing-Injury Claims.] Discrete wrongful act[s that] cause continuing harm.

729 F.3d 645, 654 (7th Cir. 2013) (Easterbrook, J. , concurring); *accord United States v. Midwest Generation, LLC*, 720 F.3d 644, 646 (7th Cir. 2013) (noting that the phrase continuing violations "may mean any of at least three things: (1) ongoing discrete violations; (2) acts that add up to one violation only when repeated; and (3) lingering injury from a completed violation" and that "[a]nalysis will be easier if we call the first situation a continuing violation, the second a cumulative violation and the third a continuing-injury situation.") (citing *Turley*, 729 F.3d at 654).

Courts and litigants often refer interchangeably to all three situations as "continuing violations," but rely in their analysis on principles or definitions that apply to one, but not all three types of situations. *Turley*, 729 F.3d at 654. Each category, however, serves a distinct purpose, and of the three categories only the first two – continuing and cumulative violations – trigger the continuing violations doctrine. Moreover, even where the continuing violations doctrine is triggered, its effect on the statute of limitations will differ. Depending on the category, the continuing violations doctrine will either allow for the cause of action to accrue anew each day the violation persists or toll the limitations period.

Specifically, violations that fall under the "continuing violations" category Judge Easterbrook describes accrue anew each day.[7] This category considers misconduct that is perpetuated as actionable in its own right and divides what might be considered a single time-barred course of action into separate and fresh claims, each with its own limitations clock.[8] Thus, the limitations period for violations that fit into this category "runs from each independently unlawful act or failure to act." *Id*. Recovery for violations in this category is limited to those acts that occur within the limitations period of the last violative act. *See, e.g., Hoery v. United States*, 324 F.3d 1220, 1222 (10th Cir. 2003) ("For continuing torts, however, the claim continues to accrue as long as [the] tortious conduct continues, although the plaintiff's recovery is limited by the statute of limitations to the two-year period dating back from when the plaintiff's complaint was filed.").

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[7] The best example of this type of violation is a nuisance claim on which the failure to act gives rise to a new violation each day. *See, e.g.*, *Rapf v. Suffolk County*, 755 F.2d 282, 292 (2d. Cir. 1985) ("[T]he tortious conduct in question is [the] * * * failure to maintain the groins or to authorize funding for construction of additional groins. *Since this failure occurs each day that appellee does not act*, *the* * * * alleged tortious *inaction constitutes a continuous nuisance for which a cause of action accrues anew each day*. Therefore, even if the time from * * * 'the happening of the event upon which the claim is based[]' were to be considered equivalent to the accrual date of the cause of action, appellants' complaint would still not be time-barred.") (emphasis added).

[8] Kyle Graham, *The Continuing Violations Doctrine*, 43 Gonz. L. Rev. 271, 275, 281 (2008) (noting that this category of continuing violations "dissects misbehavior, instead of aggregating it" and "divides what might otherwise represent a single, time-barred course of action into several separate claims, at least one of which accrues within the limitations period prior to suit."). The author argues that these violations occupy "the conceptual grey area between misconduct recognized as giving rise to multiple related but independent claims even without application of the continuing violations doctrine * * * and activity that may comprise multiple acts or omissions but which is understood as producing a single claim." *Id*. at 281.

In contrast, events that have the cumulative effect of constituting a violation toll the statute of limitations.[9] Cumulative violations, are those whose "character as a violation did not become clear until [they] w[ere] repeated during the limitations period, typically because it is only [the] cumulative impact * * * that reveals [their] illegality." *AKM LLC v. Sec'y of Labor*, 675 F.3d 752, 757 (D.C. Cir. 2012) (quoting Taylor v. FDIC, 132 F.3d 753, 765 (D.C. Cir. 1997) (internal quotations omitted); *see Turley*, 729 F.3d at 654 (explaining that "one or two offensive remarks do not violate Title VII, but a cascade of remarks over the course of months may do so"). For violations that fall under this category, courts examine all of the events, including events that occurred outside the limitations period. The limitations period for "cumulative violations" runs from the last unlawful act, and plaintiffs can reach back to the first event even when it lies outside the statute of limitations. *See, e.g.*, *Nat'l R.R. Passenger Corp. v. Morgan*, 536 U.S. 101, 115-16 (2002) (noting that in hostile environment claims courts are authorized to consider the entire period of the hostile environment for the purpose of determining liability).

Finally, under the "continuing-injury" approach, recovery may be had only if the single event or act giving rise to injuries occurred within the statute of limitations period. As Judge Easterbrook explained: *Morgan* and "*Ledbetter* [*v. Goodyear Tire & Rubber Co., Inc.*, 550 U.S. 618 (2007)] hold that a continuation of injury does not extend the period of limitations," and "a new discrete violation does not extend the time to

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[9] Hostile environment claims are an example of cumulative violations. In a recent Civil Rights Act of 1964, Title VII case, the Supreme Court clarified the nature of hostile environment claims and other discriminatory acts. *Nat'l R.R. Passenger Corp.v. Morgan*, 536 U.S. 101, 115-21 (2002). The Court held that the statute of limitations at issue in that case allowed for hostile environment claims to be subject to the continuing violations doctrine. The Court explained that hostile environment claims are different in kind from discrete acts and that the very nature of hostile environment claims "involves repeated conduct" that "cannot be said to occur on any particular day." *Id*. at 115-16. In contrast, the Court added, discrete discriminatory acts, such as termination, failure to promote, denial of transfer, or refusal to hire, are not actionable if time barred. Each discrete discriminatory act starts its own clock for filing charges alleging that act. *Id*. at 114. *See also Turley*, 729 F.3d at 654 (explaining that the period of limitations for a hostile-environment claim runs from the last remark rather than the first).

sue about an old discrete violation, even if the new violation occurs while the injury from the old discrete violation continues." *Turley*, 729 F.3d at 654; *see Midwest Generation*, 720 F.3d at 648 ("enduring consequences of acts that precede the statute of limitations are not independently wrongful"); *Knight v. Columbus*, 19 F.3d 579, 580-81 (11th Cir. 1994) (noting that the present consequences of a one-time violation does not extend the limitations period).

Notably, the case before us does not involve cumulative violations or continuing injury. EPA-OCE conceded at oral argument that the violations in this case are not the type where their character becomes known or is fully understood only when the course of illegal conduct is complete. Oral Argument Transcript ("Oral Arg. Tr.") (Oct. 30, 2014) at 110. Nor does EPA-OCE or Elementis allege that this case involves a continuing-injury claim.

The violations in this case would appear to fit naturally within the "continuing violations" approach Judge Easterbrook and the Seventh Circuit describe, in which an ongoing inaction can give rise to new violations each day the violative conduct continues.[10] However, a TSCA section 8(e) violation can be characterized as continuing for statute of limitations purposes only if Congress intended that violations of this provision be treated as violations that continue each day rather than as one-time violations.

[10] EPA-OCE does not necessarily agree with this interpretation. EPA-OCE argues that the violations in this case fall under another category of violations that are subject to the continuing violations doctrine: a "single uninterrupted course of conduct" that entitles the plaintiff to seek penalties for the entire period of violation, which here would entitle EPA-OCE to seek penalties between 2002-2008. Complainant's Supplemental Brief ("EPA's Post-Oral Arg. Br.") at 18; *id.* at 15-17 (arguing that this case does not involve a series of discrete violations). Elementis strongly disagrees. Because we find that, at a minimum, the case before us fits into the first category described above (the "continuing violations" category), and because we find no liability in this case and therefore assess no penalty, the Board does not need to resolve this issue.

2. *Is a TSCA Section 8(e) Violation a Violation That Continues or a One-time Violation?*

In determining whether a violation is continuing for statute of limitations purposes or a one-time violation, the Board looks first to the statutory language and structure of the act that serves as the basis for the specific violation at issue, and when appropriate, consults the legislative history to determine Congress' intent. *See, e.g.*, *In re Newell Recycling Co., Inc.*, 8 E.A.D. 598, 615 (EAB 1999), *aff'd*, 231 F.3d 204 (5th Cir. 2000); *In re Lazarus, Inc.*7 EAD 318, 366 (EAB 1997).[11]

Elementis appears to disagree with this analytical framework, arguing that the lack of express language in a statute characterizing a violation as continuing for statute of limitations purposes demonstrates Congress unequivocal rejection of the doctrine. *See* Elementis' Post-Oral Arg. Br. at 8. Elementis is mistaken. Silence in the substantive statute does not end the analysis. American jurisprudence recognizes that the doctrine may apply even when the statutory obligation does not expressly state that it should be treated as continuing for statute of limitations purposes. Whether a violation is continuing for statute of limitations purposes does not depend solely on the express language of the statute; of equal importance is whether the nature of the violation is such that Congress must assuredly have intended that it be treated as a continuing one.

Thus, courts typically begin their analysis by examining the substantive obligation and the governing statute to identify the specific conduct the statute prohibits and the nature of the violation. *See, e.g., Toussie v. United States*, 397 U.S. 112, 115 (1970) (noting that a continuing offense should be construed when "the explicit language of the substantive criminal statute compels such a conclusion, *or the nature* of the crime involved is such that Congress must assuredly have intended that it be treated as a continuing one") (emphasis added); *accord*

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[11] Since the Board decided *Lazarus* and *Newell,* several federal courts have expanded and elaborated on the continuing violations doctrine. *See* cases cite *supra* Part V.A.

Morgan, 536 U.S. at 115-21 (examining prohibited conduct and relevant statute of limitations to determine nature of violative conduct); *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 380 (1982) ("[i]gnor[ing] the continuing nature of the alleged violation[] only undermines the remedial intent of Congress embodied in the [Fair Housing] Act.").[12] Courts also may consult the legislative history and the statutes' structure to ascertain Congress' intent. *See, e.g.*, *Toussie*, 397 U.S. at 116-19 (1970) (examining history of Universal Military Training Service Act to determine nature of violation); *AKM LLC*, 675 F.3d at 755 (considering substantive obligation as well as structure of the act to determine Congress' intent).

Accordingly, consistent with the analytical framework described above, we examine the specific substantive obligation imposed by TSCA to determine the nature of the violation - i.e., is the failure to provide information under section 8(e) a one-time violation or a continuing one?

a. *The Plain Language of TSCA Section 8(e) Supports the Conclusion That a Section 8(e) Violation Is of A Continuing Nature*

Section 15 of TSCA prohibits, or makes it "unlawful for, any person to * * * fail or refuse to * * * submit reports, notices or other information, * * * as required by [TSCA] or a rule thereunder." 15 U.S.C. § 2614(3)(B). Section 8(e) states that:

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[12] *See also Midwest Generation*, 720 F.3d at 646-47 (analyzing structure of act as well as substantive obligation to determine nature of violation); *Nat'l Parks Conservation Ass'n v. Tenn. Valley Auth.,* 480 F.3d 410, 418 (6th Cir. 2007) (noting that courts that have analyzed the continuing violations doctrine begin "with a careful examination of the specific conduct prohibited by the statute at issue"); *Wright v. Superior Court*, 936 P.2d 101, 104 (Cal. 1997) (noting that "[t]he answer [to whether a violation is continuing for statute of limitations purposes] does not depend solely on the express language of the statute[; of] [equal] importan[ce] is whether 'the nature of the [violation] involved is such that Congress must assuredly have intended that it be treated as a continuing one.'") (quoting *Toussie*, 397 U.S. at 115).

> 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 [EPA] Administrator of such information *unless* such person has actual knowledge that the Administrator has been adequately informed of such information.

Id. § 2607(e) (emphasis added). Accordingly, the prohibited conduct here is the failure to inform EPA of information that reasonably supports a conclusion that a chemical poses a substantial risk of injury to human health or the environment.

This prohibited conduct translates into a continuing obligation to inform. Words such as "shall" and "unless" denote an ongoing obligation and point to the continuing nature of a section 8(e) violation. *See, e.g., Newell*, 8 E.A.D. at 615-16 (citing *Lazarus*, 7 E.A.D. at 366 n.84) ("Words and phrases connoting continuity and descriptions of activities that are typically ongoing are indications of a continuing nature."). Specifically, the word "shall" in section 8(e) denotes an affirmative, mandatory duty to act, which continues "unless" the "person has actual knowledge that the Administrator has been adequately informed." *Cf. United States v. Advance Mach. Co.*, 547 F. Supp. 1085, 1091 (D. Minn 1982) (concluding that similarly written statutory obligation under the Consumer Protection Safety Act "explicitly sets forth the duty to report as continuing"); *Nat'l Parks Conservation Ass'n v. Tenn. Valley Auth.*, 480 F.3d 410, 418 (6th Cir. 2006) (noting that the words "shall apply" denote an ongoing obligation and concluding that cause of action for failure to install certain pollution control technology required under the Clean Air Act manifests itself anew each day the technology is required and not applied). Congress' use of the word "unless" further suggests that it envisioned that the violative conduct would last continuously until this proviso is satisfied. By its terms, therefore, TSCA section 8(e) creates an ongoing duty to inform for as long as reportable information is required and not provided.

Significantly, even Elementis acknowledges that a failure to provide required information can recur every day the information is not provided.[13]

Most courts that have examined similar obligations in enforcement cases, in both the statute of limitations and other contexts, also consider a party's failure to provide notice or report information to an administrative agency as a violation or obligation that continues for as long as the obligation remains unfulfilled. *See, e.g.*, *Ctr. for Biological Diversity v. BP Am. Prd. Co.*, 704 F.3d 413 (5th Cir. 2013) (holding that failure to submit required written emergency notice is a continuing violation); *Interamericas Invs. v. Bd. of Governors of the Fed. Reserve Sys.*, 1997 U.S. App. LEXIS 12695 (5th Cir. 1997) (noting that "[f]or reporting statutes such as the B[ank] H[olding] C[ompany] A[ct], so long as the reporting need not occur within a certain time span, a failure to report certain conditions will generally constitute a continuing violation for so long as the failure to report persists"); *Mayes v. EPA*, No. 3:5-cv-00478, slip op. at 13-18 (E.D. Tenn. Jan. 4, 2008) (finding a regulatory obligation to notify EPA and State agency of underground storage tanks created a continuing obligation of compliance and characterizing failure to notify as a "series of discrete violations," allowing recovery of penalties for violations that took place within 5 years from the filing of the complaint, even though EPA filed complaint 13 to 14 years after notice should have been provided); *Woodcrest Mfg., Inc. v. United States*, 114 F. Supp. 2d 775, 779 (N.D. Ind. 1999) (interpreting similarly written Emergency Planning and Community Right-to-Know Act provision as "each day the company fails to file the required reports is an additional violation" giving rise to per day penalties.); *Advance Mach.*, 547 F. Supp. at 1090-92; *In re Mobil Oil Corp.*, 5 E.A.D. 490, 517-18 (EAB 1994); *cf. United States v. DICO,*

[13] In its post oral argument brief, Elementis concedes that where a complaint is filed within five years from when reportable information must be provided, the Agency may be able to recover penalties for each day the violation continues. Elementis' Post-Oral Arg. Br. at 17. Elementis, however, claims that once the five year period has elapsed, the Agency can no longer recover. *Id.* Elementis' attempt to limit the scope of this concession is unavailing.

Inc., 4 F. Supp. 3d 1047, 1057-58 (S.D. Iowa 2014) (disagreeing with defendant's position that failure to provide notice only amounts to a one-day violation).[14]

Courts have long recognized continuity of the obligation as one of the characteristics of violations subject to the continuing violations doctrine. *See, e.g.*, *Advance Mach. Co.*, 547 F. Supp. at 1090 ("[A] cause of action for violation of section 2064(b) [of the Consumer Product Safety ("CPS") Act] first accrues upon the manufacturer's failure to file a timely report after learning of a defect. *As this is a continuing duty, however, the statute of limitations does not start running until a report is filed or the manufacturer acquires actual knowledge that the [CSP] Commission is adequately informed*.") (emphasis added).[15] Elementis ignores this and asserts that for statute of

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[14] Cases that have treated the failure to report or to provide notice as a single violation appear to be the exception and are readily distinguishable from the line of cases that have found the failure to provide notice or information continuing. These cases appear to fall into three main categories: (1) cases in which the obligation specifies a time span for compliance, *e.g.*, *United States v. Ill. Power Co.*, 245 F. Supp. 2d 951 (S.D. Ill. 2003), and *In re Lazarus, Inc.*, 7 EAD 318, 377 (EAB 1997), which the Board discusses more fully in the text below; (2) cases in which the penalty provision of the substantive statute contemplates multi-day penalties but does not include the specific obligation at stake, *e.g.*, *City of Toledo v. Beazer*, 833 F.Supp. 646 (N.D. Ohio 1993); and (3) cases in which the substantive obligation provides no indication that failure to comply could give rise to penalties based on the length of time that the breach exists. *See, e.g.*, *United States v. Trident Seafoods Corp*., 60 F.3d 556 (9th Cir. 1995). Unlike *City of Toledo* and *Trident*, the statutory provisions that apply in this case specifically include failure to provide reports, notice, or information in the list of violations subject to multi-day penalties. *See* TSCA §§ 15(3)(B), 16(a)(1), 15 U.S.C. §§ 2614(3)(B), 2615(a)(1).

[15] *See also Wright*, 936 P.2d at 103 ("'Ordinarily, a continuing offense is marked by a *continuing duty* in the defendant to do an act which he fails to do. The offense continues as long as the duty persists, and there is a failure to perform that duty.' * * * Thus, when the law imposes an affirmative obligation to act, the violation is *complete* at the first instance the elements are met. *It is nevertheless not completed as long as the obligation remains unfulfilled*.") (quoting *Duncan v. State*, 384 A.2d 456, 459 (Md. 1978)) (first and third emphases added). In a recent case, the Sixth Circuit found the obligation to install Best Available Control Technology ("BACT") – a Clean Air Act requirement – to be a continuing obligation, but declined to opine on the applicability of (continued...)

limitations purposes, the failure to provide the required information under section 8(e) operates as a one-time violation.[16] According to Elementis, the prohibited conduct here is not the "failure to provide notice" or "reportable information" but rather the failure to provide "immediate notice" or "immediately inform" EPA of the study's conclusion. Appeal Br. at 18 (stating that "it is not a 'fresh violation' of a duty to 'immediately inform' if the alleged violation fails to do so on Day 300, for example."). Elementis argues that the word "'immediately' precedes and qualifies the word 'inform,'" and that moving or omitting the word "immediately" changes the meaning of the statute and the obligation.[17] *Id*. at 18-19. In its view, the word "immediately" is a temporal limitation Congress included in section 8(e) to foreclose the possibility that a section 8(e) violation be considered continuing. *Id*. at 17-27; Elementis' Reply Br. at 2-9.

b. *The Term "Immediately" Does Not Signal Congress' Intent to Treat Section 8(e) Violations as One-Time Violations*

The term "immediately" in section 8(e) does not narrow the reporting obligation as Elementis propounds, which would effectively

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[15](...continued)
the "continuing violations doctrine" because it concluded that the obligation to install BACT is a discrete obligation, the violation of which gives rise to a new cause of action each day BACT is required and not installed. *Nat'l Parks,* 480 F.3d at 417, 419. Significantly, although characterized as a discrete obligation and not as a "continuing violation," this approach by the Sixth Circuit is in effect similar to Judge Easterbrook's " continuing violations" approach, in which a new cause of action emerges each day the obligation is unfulfilled.

[16] Elementis argues that the failure to provide reportable information to EPA under section 8(e) could be subject to daily penalties, but also asserts that the violation only accrues on day one. Elementis' Post-Oral Arg. Br. at 17; Appeal Br. at 18. In doing so, Elementis essentially argues that the failure to provide required information should be treated as a single violation.

[17] Yet, on page 27 of its appeal brief Elementis concedes that "[t]he duty [section 8(e)] imposes is that a chemical manufacturer 'inform the Administrator of such information.'"

eviscerate the scope of the duty to inform. The most natural reading of section 8(e) is to interpret the obligation to inform as continuing in nature and the term "immediately" as a strong indication of the importance of timely disclosure, not as a term of limitation.

A number of federal courts interpreting similar requirements likewise have concluded that the failure to provide "immediate" notice or to provide notice or reports "as soon as practicable" constitute continuing violations, rejecting contentions that these terms signal Congress' intent to treat failure to comply with these requirements as one-time violations. *See, e.g.*, *Ctr. for Biological Diversity*, 704 F.3d at 430 (concluding that failure to comply with provision requiring written notice "as soon as practicable after a release" is a "continuing violation"); *Advance Mach.*, 547 F. Supp. at 1090 (noting that the term, "immediately," in a similarly written Consumer Safety Act provision does not extinguish the continuing statutory duty to provide information).

Section 8(e) ensures that the EPA Administrator is adequately informed of "information that reasonably supports the conclusion that chemical substances or mixtures present a substantial risk of injury to health or the environment." Immediate notification serves the statutory purpose of alerting EPA in a timely manner. Timely notice is crucial for EPA to be able to take necessary measures to prevent potential risks or avoid harm.[18] *See generally* S. Rep. No 94-698, at 6, *reprinted in* 1976 U.S.C.C.A.N. 4491, 4496 (noting importance of provision that "would provide regulators timely access to information regarding health and safety studies concerning chemicals covered" by TSCA). Therefore, it stands to reason that Congress required this type of information to be provided immediately to underscore the importance of the information reportable under section 8(e), as well as the importance of acting promptly and without delay. To suggest that the duty to provide

[18] EPA considers section 8(e) a critically important information gathering tool that serves as an early warning mechanism for keeping the Administrator and others appraised of new-found serious chemical hazards and/or exposure. *1991 Reporting Guide* at 1.

information is not ongoing simply because Congress emphasized the importance of timely disclosure, not only is illogical, but also is not supported by either the plain reading of section 8(e), or by a reading of this provision in conjunction with other relevant TSCA provisions.

As noted above, the prohibited conduct as well as words like *shall* and *unless* in section 8(e) signal a continuing obligation. It seems incongruous that to override that clear mandate, Congress would use an imprecise term, "immediately," to signal it intended this obligation to be a "one-time" occurrence. *Accord Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979) ("In construing a statute we are obliged to give effect, if possible, to every word Congress used." (citing *United States v. Menasche*, 348 U.S. 528, 538-39 (1955)). As the ALJ stated, the term immediately "reflects not a date certain but a[n] imprecise *relation in time*, variable according to facts and circumstances." *See* ALJ's Mar. 2011 Order at 7 (citing Webster's Third New Int'l Dictionary ("Webster's Dictionary") 1129 (2002)). Courts that have had the opportunity to interpret this term, in the context of other statutes, also agree that the term is imprecise. *Id*. at 8 (citing at least ten federal cases with different interpretations of the term "immediately"); *cf. Envt'l Def. Fund, Inc. v. Costle*, 631 F.2d 922, 928 (D.C. Cir. 1980) ("[I]t is instructive to examine the meaning of similar terms in other statutes.").

Moreover, nothing in section 8(e) suggests that mere passage of time extinguishes the obligation to disclose reportable information.[19] If reportable information is not provided immediately, the violation is not

[19] That passage of time extinguishes an obligation is one consideration courts take into account in determining whether a statutory provision is continuing in nature. *See, e.g.*, *Wright*, 936 P.2d at 104; *Newell*, 8 E.A.D. at 617. Apparently recognizing as much, Elementis refined its position in its reply brief, denying it has taken the position that the obligation to report is discharged 30 days after receipt of the reportable information and clarifying that its position is that a section 8(e) violation has *occurred* and is *complete* once *immediate* reporting has failed to occur. Elementis' Reply Br. at 3. Presumably, Elementis urges us to conclude that an enforcement action for failure comply with section 8(e) therefore accrues for statute of limitations purposes after immediately. In the context of this case, where section 8(e) violations accrue anew each day reportable information is not provided, Elementis' clarification is of no consequence.

cured and the obligation remains. The violation continues to accrue each day that reportable information must be provided but instead remains undisclosed.

We therefore reject Elementis' argument that the term "immediately" signals Congress' intent to treat section 8(e) violations as one-time violations.

c. *The Nature of the Obligation Is Such That Congress Must Assuredly Have Intended That It Be Treated as a Continuing One*

Congress enacted TSCA in 1976 as a mechanism to prevent injury to human health and the environment from the many chemical substances and mixtures that are constantly being developed. *See generally* TSCA § 2, 15 U.S.C. § 2601. To characterize the failure to provide reportable information under section 8(e) as a continuing violation is not only the most natural reading of the statute, but it is the interpretation that furthers Congress' purpose in enacting TSCA. It would frustrate the purpose of TSCA if the duty to inform EPA of a study that reasonably supports a conclusion that a chemical presents a substantial risk of injury is treated as a single violation. Congress placed the onus of informing the Administrator on the regulated community. If failure to comply with this important obligation were to have trivial consequences, industry may have little incentive to comply. Under the reading Elementis propounds, the deterrent effect of the penalty provision would be severely limited, and the evil Congress sought to prevent by requiring reporting of information on substantial risks – *i.e.*, the potential risk of exposure to chemical substances that present a substantial risk of injury – will continue each day the Administrator is deprived of the information. *Accord United States v. ITT Cont'l Baking Co.*, 420 U.S. 223, 231 (1975) (noting that by characterizing "continuing failure or neglect to obey" as "a separate offense" Congress intended to avoid a situation in which the statutory penalty would be regarded by potential violators as nothing more than an acceptable cost of violation); *Toussie*, 397 U.S. at 122 (for a continuing offense, "each day's acts bring a renewed threat of the substantive evil Congress sought to prevent.").

We therefore conclude that the nature of the obligation set forth in section 8(e) is such that Congress must assuredly have intended that it be treated as a continuing one.

d. *Other TSCA Provisions Provide Support to the Conclusion That TSCA Section 8(e) Violations That Continue Accrue Each Day*

Not only does the plain language of section 8(e) support the conclusion that a section 8(e) violation is of a continuing nature, but also other TSCA provisions lend further support to the conclusion that violations of this provision accrue anew each day. Section 16(a) provides that:

> Any person who violates a provision of section 2614 or 2689 of this title shall be liable to the United States for a civil penalty in an amount not to exceed $25,000 for each such violation. *Each day such a violation continues* shall, for purpose of this subsection, *constitute a separate violation* of section 2614 or 2689 of this title.

TSCA § 16 (a)(1), 15 U.S.C. § 2615(a)(1) (emphases added).[20] The Board concludes that this language clearly conveys Congress's intent to treat any section 2614 violations that are determined to be continuing in nature as separate violations, thereby authorizing EPA to seek daily penalties for each day of violation.

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[20] In *Lazarus,* the Board stated that "section 16(a)(1) is evidence that Congress contemplated the *possibility* of continuing violations of TSCA." 7 E.A.D. at 368; *see also Newell*, 8 E.A.D. at 615. Mindful that applying the continuing violations doctrine should be the exception, the Board noted that TSCA section 16(a) does not transform every TSCA violation into a continuing one. 7 E.A.D. at 368. To make such a determination, the Board added, the substantive obligation alleged to have been violated must be examined. *See id.*; *Newell*, 8 E.A.D. at 615. Significantly, none of these cases required that the Board express an opinion regarding the phrase "each day such a violation continues * * * constitutes a separate violation."

Section 2614 includes TSCA section 8(e)'s requirement to submit information that supports a conclusion of substantial risk of injury. *See* TSCA § 15(3), 15 U.S.C. § 2614(3). Because nothing in section 8(e) suggests that its violation should be characterized as a one-time violation, the Board concludes that each day a manufacturer or distributor of chemical substances fails to provide the required section 8(e) information, a fresh violation springs anew, giving rise to a new cause of action each day information is required and not provided.[21]

We therefore reject Elementis' argument that section 16(a) is irrelevant in determining whether section 8(e) is a continuing violation for statute of limitations purposes. Elementis' Post-Oral Arg. Br. at 2, 9-11. According to Elementis, because section 16(a) "deals with determining the civil penalty for violations of Section[s] 15 and 409 of TSCA, the modifier 'for purpose of this subsection' [in section 16(a)(1)] can only be interpreted" to mean that this provision is only relevant to penalty calculations, and can not be read "as signaling a Congressional intention that a Section 8(e) violation is, for statute of limitations purposes, to be treated as a series of separate and recurring daily violations until the report is submitted." *Id*. at 10. Contrary to Elementis' suggestion, consideration of a penalty provision to determine Congress' perception of the nature of a provision is not an uncommon practice. *See, e.g.*, *Interamericas Invs. v. Bd. of Governors of the Fed. Reserve*, 1997 US App. Lexis 12695, at *17 (5th Cir. 1997) (noting that "[w]here the civil penalty provision at hand contemplates per diem penalties for violations, then continuing violations are cognizable under the general statute of limitations"); *CSC Holdings, Inc. v. Redisi*, 309 F.3d 988, 992 (7th Cir. 2002) (examining similarly written penalty provision (i.e., "[f]or purposes of all penalties and remedies established for violations of * * * this section, the prohibited activity * * * shall be deemed a separate violation") to determine nature of violation). In any event, we conclude that section 8(e) by its own terms establishes a

[21] The words "a separate violation" in section 16(a) could also be interpreted as authorizing recovery under the theory of "repeated violations of identical nature." *See Knight*, 19 F.3d at 582 (noting that when a "case involves a series of repeated violations of an identical nature * * * each violation gives rise to a new cause of action).

continuing duty to provide reportable information to EPA, the violation of which is subject to the continuing violations doctrine. Section 16(a)(1) simply provides additional support to the conclusion that a section 8(e) violation accrues anew each day.

e. *The Cases Elementis Relies Upon Are Neither Controlling Nor Compelling*

We reject Elementis' argument that case law interpreting requirements similar to those in section 8(e) support the conclusion that the continuing violations doctrine does not apply to section 8(e) violations. *See* Appeal Br. at 21-27 (relying on *In re Lazarus, Inc.*, 7 E.A.D. 318 (EAB 1997), *AKM LLC v. Sec'y of Labor*, 675 F.3d 752 (D.C. Cir. 2012), and *United States v. Ill. Power Co.*, 245 F. Supp. 2d 951 (S.D. Ill. 2003)); Elementis' Reply Br. at 5 (relying on *Toussie v. United States*, 397 U.S. 112 (1970)). None of these cases are either controlling or compelling.

Elementis relies on these cases to assert that when compliance depends on acting within a particular time frame (in this case "immediately"), the continuing violations doctrine does not apply. *See* Appeal Br. at 21-27. Elementis tries to draw a parallel between the obligation to inform the Administrator under TSCA section 8(e) and the obligation to prepare annual documents regarding the disposition of polychlorinated biphenyls under 40 C.F.R. § 761.108(a), examined in *Lazarus*. *Id*. at 21-22. There, the Board noted that nothing in section 761.108(a) suggests that the obligation to prepare annual documents was ongoing, that rather the obligation suggests that a new obligation begins each year. *Lazarus*, 7 E.A.D. at 377-79. Accordingly, the Board concluded that the obligation to prepare annual reports was not continuing in nature. *Id*. at 379. Section 8(e) does not involve creation of annual, monthly or daily reports, but as noted earlier, the provision denotes an ongoing obligation to disclose to EPA certain information. Accordingly, the Board finds Elementis' reliance on *Lazarus* unpersuasive.

Relying on *AKM LLC*, Elementis attempts to compare a recordmaking obligation under the regulations implementing the Occupational Safety and Health Act ("OSH Act") with the TSCA section 8(e) obligation to provide information to EPA. *AKM LLC* dealt with a regulatory obligation that requires employers to prepare work-related injury logs within 7 calendar days of the injury and a year-end summary. *AKM LLC*, 675 F.3d at 753. These OSH Act requirements are therefore similar to the recordmaking obligation the Board examined in *Lazarus*. Unlike the OSH Act provision in *AKM LLC*, the section 8(e) requirement is not subject to hard compliance deadlines. Moreover, *AKM LLC* involved a different statute of limitations, one that specifically applies to OSH Act recordmaking and recordkeeping requirements and imposes a very stringent limitations period. *See* OSH Act § 9 (c), 29 U.S.C. § 658 (c) ("No citation may be issued after the expiration of *6 months* following the *occurrence* of any violation.") (emphasis added). The D.C. Circuit focused its analysis on the language of the applicable statute of limitations, specifically the word "occurrence," noting that "every single violation for which [*AKM LLC*] was cited * * * and every workplace injury which gave rise to those unmet recording obligations were 'incidents' and 'events' which *'occurred*' more than six months before the issuance of the citations." *AKM LLC*, 675 F.3d at 755 (emphasis added). The court took issue with the Secretary of Labor's attempt to use a regulatory provision to circumvent a statute-specific statute of limitations. *Id*. at 754-57 (describing issue as "whether the Act's recordkeeping requirement, in conjunction with the five-year regulatory retention period, permits OSHA to subvert the Act's six-month statute of limitations"). Unlike the Secretary of Labor in *AKM LLC*, EPA-OCE here is not relying on a regulatory obligation to define the contours of a statute-specific statute of limitations. We find this case inapposite.

Elementis also cites *Illinois Power*, a case addressing Clean Air Act requirements, specifically requirements under the New Source Performance Standards and the Prevention of Significant Deterioration programs. 245 F. Supp. 2d at 954-59. There, the regulations required that the regulated entity provide notice to EPA before project construction (40 C.F.R. § 60.7(a)(4)) and within 60 to 180 days of

conducting required performance tests (40 C.F.R. § 60.8), and to obtain a Prevention of Significant Deterioration permit prior to construction. *Id*. None of these requirements are similar to section 8(e). Unlike section 8(e), the notice requirements in *Illinois Power* specify hard deadlines for compliance (i.e., within 60 to 180 days, before construction). In addition, section 8(e) is not a prerequisite for engaging in subsequent regulated activities. Some courts have concluded that, unless provided otherwise, obligations that must be satisfied prior to engaging in subsequent regulated activities, such as obtaining a pre-construction permit or providing notice before construction, are discrete obligations not subject to the continuing violations doctrine. *See, e.g.*, *United States v. EME Homer City Generation, L.P.*, 727 F.3d 274, 284 (3rd Cir. 2013); *United States v. Midwest Generation, LLC*, 720 F.3d 644, 647 (7th Cir. 2013). *But see United States v. Cemex, Inc*., 864 F. Supp. 2d 1040, 1048 (D. Colo. 2012); *Sierra Club v. Portland Gen. Elec. Co.*, 663 F. Supp. 2d 983, 993 (D. Or. 2009); *United States v. Duke Energy Corp.*, 278 F. Supp. 2d 619 (M.D.N.C. 2003), *aff'd on other grounds*, 411 F.3d 539 (4th Cir. 2005), *vacated on other grounds*, *Envtl. Def. v. Duke Energy Corp.*, 549 U.S. 561, 127 S. Ct. 1423, 167 L. Ed. 2d 295 (2007); *Sierra Club v. Dayton Power & Light, Inc.*, No. 2:04 CV 905 (S.D. Ohio Aug. 12, 2005); *cf. Nat'l Parks*, 480 F.3d at 419. Section 8(e) does not fall under this category of obligations. We therefore find *Illinois Power* unpersuasive.

Finally, we are not persuaded that *Gabelli* is controlling here as Elementis asserts. Elementis relies on this recent Supreme Court decision for the proposition that the continuing violations doctrine does not apply to TSCA section 8(e). Appeal Br. at 13-17. *Gabelli* was a civil penalty action for fraud initiated by the Securities Exchange Commission for violations of the Investment Advisers Act. The sole issue in that case was whether "the five-year [statute of limitations begins to run] when the fraud is complete or when the fraud is *discovered*." *Gabelli,* 133 S. Ct. at 1219 (emphasis added). At the heart of *Gabelli* was whether the discovery rule applied in government enforcement cases. Under the discovery rule, "accrual" is delayed until the plaintiff has discovered his cause of action. *Id.* at 1221. While the discovery rule and continuing violations doctrine are similar in that both

are special rules of accrual, these are two distinct doctrines serving different purposes. The discovery rule is aimed at protecting the blameless plaintiff, while the continuing violations doctrine is aimed at punishing illegal conduct.[22] Significantly, *Gabelli* did not rule on the applicability of the continuing violations doctrine in general, in TSCA enforcement cases, or in connection with section 8(e) violations. While *Gabelli* instructs us not to read statutes to abolish effective time constraints on litigation, analysis of the relevant TSCA provisions in this case demonstrates that a section 8(e) violation is of a continuing nature.

f. *EPA's Guidance Does Not Support Elementis' Argument That EPA Treats Section 8(e) Violations as One-Time Violations*

Elementis also argues that EPA guidance on TSCA section 8(e) shows that EPA interprets the provision as establishing an obligation that must be fulfilled within a certain time frame. Appeal Br. at 12, 18. EPA's guidance documents specify when section 8(e) information must be reported. The 2003 clarification to the TSCA section 8(e) Reporting Guidance states that the substantial risk information under TSCA section 8(e) must be submitted within 30 calendar days of obtaining reportable information.[23] TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33,129, 33,130 (June 3, 2003) [hereinafter *2003 Policy Guidance*]. According to Elementis, the five-year limitations period set forth in 28 U.S.C. § 2462 begins to run on the 31st day after receipt of the reportable

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[22] *Cf. O'Loghlin v. County of Orange*, 229 F.3d 871, 875 (9th Cir. 2000) (noting that the continuing violation doctrine is an equitable doctrine designed "to prevent a defendant from using its earlier illegal conduct to avoid liability for later illegal conduct of the same sort"); *In re Harmon Elecs., Inc.*, 7 E.A.D. 1, 21 (EAB 1997) (citing *Miami Nation of Indians of Ind. v. Lujan*, 832 F. Supp. 253, 256 (N.D. Ind. 1993)("The continuing claim doctrine prevents the statute of limitations from protecting an offender in an ongoing wrong.")), *rev'd on other grounds*, 19 F. Supp. 2d 988 (W.D. Mo 1998), *aff'd*, 191 F.3d 894 (8th Cir. 1999).

[23] The applicable guidance at the time Elementis obtained the Mundt study required that section 8(e) information be reported within 15 days after obtaining the information. *1991 Reporting Guide* at 11.

information, and any enforcement action must be brought within five years from that date. Elementis' Reply Br. at 3.

Noting that EPA's guidance is discretionary and cannot add a definitive time limit to a statute where none exits, the ALJ rejected Elementis' argument that EPA's interpretative enforcement guidance supports the proposition that the section 8(e) reporting obligation is not continuing in nature. ALJ's Mar. 2011 Order at 8. The Board agrees with the ALJ. *Cf. Toussie*, 397 U.S. at 121 (declining to construe continuing violation based on regulatory language and noting that "questions of limitations are fundamentally matters of legislative not administrative decision"). In addition, it is clear to the Board that EPA was exercising its enforcement discretion in establishing a grace period to allow time for persons to provide the Administrator with the required information without fear of being subject to prosecution if they fail to provide the information instantly. Nothing in EPA's guidance documents suggest that EPA intended, or has construed, this grace period as a limit on the applicability of the continuing violations doctrine. To the contrary, it is clear from the applicable EPA penalty policy guidance that the Agency considers section 8(e) violations as "continuing." Toxics & Pesticide Enforcement Div., Office of Regulatory Enforcement, U.S. EPA, *Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12, and 13*, at 9 (rev. Mar. 31, 1999) (explaining that "[w]hether a penalty is to be assessed as a one day assessment or as a continuing violation on a per day basis is specified in the Circumstances section," and classifying TSCA section 8(e) non-reporting as level one violations for which penalties are assessed as continuing (on a per day basis)).

3. *The Complaint EPA-OCE Filed Was Timely*

In sum, the Board finds that TSCA section 8(e) imposes a continuing duty on "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" to inform EPA of such information "unless such person

has actual knowledge that the Administrator has been adequately informed of such information." Thus, a section 8(e) violation constitutes a "continuing violation" for statute of limitations purposes. Because TSCA's penalty provision treats certain TSCA violations that continue as separate violations, including TSCA section 8(e), we conclude that section 8(e) violations fall under the category of violations that repeat themselves each day the duty remains unfulfilled.[24] The period of limitations for a section 8(e) violation therefore runs anew each day a defendant fails to act.

In this case, Elementis' last act of non-compliance took place on November 17, 2008. EPA-OCE filed the Complaint within the 5-year period of limitations from the last day of non-compliance. Accordingly, the Complaint was timely, and EPA-OCE could seek penalties for any non-compliance preceding the five years from the date it filed the complaint.[25] Having found that EPA-OCE timely filed its Complaint, we now turn to the merits of this case to determine whether Elementis is liable for failing to provide the Mundt study to EPA before it was subpoenaed to do so.

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[24] Elementis argues that using a "separate violation approach" would be arbitrary and capricious and would "penalize Elementis for violations that have never been charged." Elementis' Post-Oral Arg. Br. at 13. The Board finds this objection meritless. The Complaint charged Elementis with a violation that continued between 2002 and 2008, putting Elementis on notice of the duration of violation. Complaint at 9 ¶52, 11. The very nature of continuing violations allows for pleading a case in this fashion and does not require, as Elementis suggests, that 1317 separate counts be filed. *See, e.g.*, *CSC Holdings, Inc. v. Redisi*, 309 F.3d 988, 992 (7th Cir. 2002) ("A continuing violation exists 'where it would be unreasonable to require or even permit [a plaintiff] to sue separately over every incident of the defendant's unlawful conduct.'" (quoting *Heard v. Sheahan*, 253 F.3d 316, 319 (7th Cir. 2001)(alteration in original)). In addition, the Board can conform pleadings to the evidence with respect to issues actually tried at the hearing, which we do not need to do here given our liability finding. *In re Richner*, 10 E.A.D. 617, 628 (EAB 2002); *In re H.E.L.P.E.R., Inc.*, 8 E.A.D. 437, 449-50 (EAB 1999).

[25] As noted earlier in this decision, because we are finding no liability and therefore are not assessing a penalty, we need not address EPA-OCE's argument that it is entitled to recover penalties for the entire period of violations.

B. *Did Elementis Violate TSCA Section 8(e)?*

1. *Introduction - Overview of Issues and the Board's Decision*

The ALJ held that Elementis violated TSCA section 8(e) when it failed to submit to EPA an epidemiology study conducted by Dr. Kenneth Mundt that showed an association between exposure to hexavalent chromium and lung cancer. Init. Dec. at 72. TSCA section 8(e) presumptively requires that chemical manufacturers, processors, and distributors report information to EPA that reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. TSCA § 8(e), 15 U.S.C. § 2607(e). That section also provides an affirmative defense to this presumptive reporting obligation. A manufacturer, processor, or distributor need not submit otherwise reportable information to EPA if it can show that it has actual knowledge that EPA is adequately informed of such information.[26] *Id.*; *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 559 F. Supp. 2d 424, 434-35 (S.D.N.Y. 2008).

Given the factual stipulations of the parties, as well as the admissions in their briefs, the pivotal issue before the Board centers on whether Elementis established its affirmative defense to TSCA section 8(e)'s reporting obligation by showing that it had actual knowledge that EPA was adequately informed of the presumptively reportable information in the Mundt study. In these proceedings, Elementis makes two principal arguments as to why it met its burden of proving this affirmative defense:

1. Elementis first argues that the plain language of TSCA section 8(e) establishes a clear and relatively narrow

[26] For ease of reading, henceforth this decision will use "chemical" to mean the full statutory phrase, "chemical substance or mixture," and "substantial risk of injury" to mean the full statutory phrase, "a substantial risk of injury to health or the environment." Additionally, because this decision involves a chemical manufacturer, we refer to the obligation TSCA section 8(e) imposes on manufacturers while recognizing that section 8(e) applies to "[a]ny person who manufacturers, processes, or distributes in commerce a chemical substance or mixture."

definition of presumptively reportable information, and this definition compels the conclusion that EPA was adequately informed of the reportable information in the Mundt study. Appeal Br. at 27-31.

2. Elementis argues, in the alternative, that even if the Board does not accept its narrow interpretation of what constitutes reportable information, Elementis still was not required to submit the Mundt study to EPA because the Mundt study qualifies as information of which EPA was "adequately informed," as EPA has interpreted that language in its guidance documents. Specifically, Elementis claims that it meets the exemption in the guidance for information that corroborates a well-established adverse effect. Elementis' Post-Oral Arg. Br. at 21; Elementis' Init. Post-Hrg Br. at 26-30; *see* Appeal Br. at 31-32.

For the reasons discussed in Part V.B.2. and V.B.3. below, we do not find either of these arguments to be particularly difficult to resolve. We flatly reject Elementis' statutory argument concerning the limited scope of the presumptively reportable information requirement. Elementis' cramped reading of the statute is contradicted by the plain language of TSCA section 8(e), the statutory structure reflected in section 8 generally, and TSCA's legislative purpose. Additionally, Elementis' interpretation of section 8(e) flies in the face of EPA's contemporaneous and consistently-held construction of the statute as set forth in multiple guidance documents. We conclude that, under the statute, the Mundt study in its entirety is information that reasonably supports a conclusion of substantial risk of injury. And, because Elementis does not contend that it had actual knowledge that EPA had been informed of the full study, *see* Joint Stipulation ¶¶ 17-18 (stipulating that Elementist did not submit the Mundt study to EPA until 2008), if we were to rule on Elementis' affirmative defense considering solely the statutory language, we would affirm the ALJ's liability determination.

But we are not writing on a clean statutory slate. EPA's long-standing TSCA section 8(e) guidance documents effectively broaden the affirmative defense provided in section 8(e) in a way that presents a formidable hurdle to EPA-OCE's prosecution of this case. Since 1991, EPA guidance documents have stated that EPA considers itself "adequately informed already" of information that is corroborative of a well-established adverse effect (i.e., there is no duty to disclose such information), including information that is corroborative as to "dose." *1991 Reporting Guide* at 8; TSCA Section 8(e); Notice of Clarification and Solicitation of Public Comment, 58 Fed. Reg. 37,735, 37,739 (July 13, 1993) [hereinafter *1993 Proposed Policy Clarification*]; *2003 Policy Guidance*, 68 Fed. Reg. at 33,139. Further, these documents repeatedly emphasize that EPA considers information to be non-corroborative as to dose (and thus reportable) if the information shows that a chemical causes an adverse effect at a *lower* level than previously known. *1991 Reporting Guide* at 8; *1993 Proposed Policy Clarification*, 58 Fed. Reg. at 37,739; *2003 Policy Guidance*, 68 Fed. Reg. at 33,139. The parties agree that the Mundt study's conclusion that hexavalent chromium causes an adverse effect (i.e., death from lung cancer) is well-established. And the Board finds, as did the ALJ, Init. Dec. at 38, that Elementis demonstrated that the Mundt study established a link between hexavalent chromium and lung cancer only at a significantly *higher* dose than the dose associated with lung cancer in the Gibb study, an EPA study published prior to Elementis' receipt of the Mundt study. Accordingly, the Board holds that pursuant to EPA's guidance documents, Elementis demonstrated that the Mundt study was exempt from reporting as information corroborative of a well-established adverse effect.

2. *Under the Language of the Statute, Elementis Had a Duty to Disclose the Mundt Study to EPA*

TSCA section 8(e) requires manufacturers who obtain information that reasonably supports a conclusion of substantial risk of injury to report "such information" to EPA unless the manufacturer has actual knowledge that EPA is adequately informed of "such information." Here, Elementis admits that the Mundt study contains

information reasonably supporting a conclusion of substantial risk of injury, admits that it did not submit the Mundt study to EPA, and does not claim that some other entity reported the study to EPA. Nonetheless, Elementis contends that it did not violate the plain terms of TSCA section 8(e).

Elementis claims that the actual information in the Mundt study that must be reported is so limited and so generic that it adds nothing to the knowledge EPA gained from the study conducted by its employee, Dr. Gibb. Specifically, Elementis asserts that the only reportable information in the Mundt study is a single, generic nugget of information of which EPA is well aware as a result of the EPA-produced Gibb study: that workers in chromium plants experience "an increase in lung cancer mortality among those with the highest cumulative exposure."[27] Oral Arg. Tr. at 48:13–15 (quoting *Collaborative Cohort Mortality Study* at 75–76 (CX 1 at 89–90)); *see* Appeal Br. at 29. If this is correct, then Elementis was justified in not submitting the Mundt study reportable information to EPA because EPA was adequately informed of "such information."

The linchpin of this argument is that the only presumptively reportable information in the Mundt study under TSCA section 8(e) is the single sentence conclusion regarding an elevated risk of cancer. Accordingly, we turn our focus to the meaning of the phrase "information which reasonably supports the conclusion that such substance * * * presents a substantial risk of injury to health," and what information in the Mundt study comes within that phrase. In the end, for the reasons discussed below, we reject Elementis' narrow interpretation of TSCA section 8(e) and conclude that the Mundt study in its entirety constituted presumptively reportable information.

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[27] This argument fully emerged only at oral argument before the Board. Oral Arg. Tr. at 47:20 – 49:7. In its Appeal Brief, Elementis principally argued that the ALJ's decision should be reversed because "at no point did [the ALJ] identify what specific information in that Report 'substantially supports the conclusion that the risk is present,' beyond that which Elementis acknowledged – the information that showed a statistically significant cancer risk for the most highly exposed workers." Appeal Br. at 30.

a. Information Which Reasonably Supports a Conclusion of Substantial Risk of Injury

The key to interpreting what constitutes reportable information under TSCA section 8(e) is determining the meaning of the term "information" and the phrase "reasonably supports" a conclusion of substantial risk of injury. In common usage, the word "information" covers a wide swath of things, being defined as "*something* received or obtained through informing." Webster's Third New Int'l Dictionary ("Webster's Dictionary") 1160 (1996) (emphasis added). TSCA section 8 confirms that Congress intended that the term have a broad scope. That section is titled "Reporting and retention of *information*," 15 U.S.C. § 2607 (emphasis added), and TSCA section 8(a)(2) lists seven categories of information that EPA can require to be reported. Those categories include everything from the "common or trade name, the chemical identity, and molecular substance of each chemical substance" to "[a]ll existing data concerning the environmental and health effects of such substance" to "the manner or method of [the substance's] disposal." *Id.* § 2607(a)(2). Elementis conceded at oral argument that "there is a lot in the [Mundt] report that is information." Oral Arg. Tr. 44:10–14.

Not all information about a chemical, however, is reportable under TSCA section 8(e), only that information that "reasonably supports" a conclusion of substantial risk of injury. The verb "support" as used here has a dictionary definition of "to serve as verification, corroboration, or substantiation of (historic evidence [support]s such guesses * * *)." Webster's Dictionary at 2297. Thus, TSCA section 8(e) requires a manufacturer to report "information" it obtains about a chemical if the information verifies, corroborates, or substantiates a conclusion that the chemical poses a substantial risk of injury. The information in a study that verifies, corroborates, or substantiates a conclusion of substantial risk of injury may be *summarized* in a concluding section of the report, but it is the underlying data, assumptions, methodology, and analyses that actually provide the verification, corroboration, and substantiation.

For example, a trial lawyer, when defending a damage award on appeal, would not cite solely to his or her closing argument to show there was sufficient evidence to uphold the award. Rather, the lawyer would cite to the evidence admitted at trial – the testimony, exhibits, and other physical and demonstrative evidence – as reasonable support for the trial court's judgment. In other words, the conclusory statements in the closing argument are not what provides support for the judgment; it is the underlying evidence. *Cf. Morales v. Am. Honda Motor Co.*, 151 F.3d 500, 508 (6th Cir. 1998) (holding that "generalized and conclusory statement" by an expert witness is not "evidence" supporting the plaintiffs' theory of liability); *In re Swan Wood*, 582 F.2d 638, 642 (C.C.P.A. 1978) (holding, in a patent case, that "[m]ere lawyer's arguments and conclusory statements * * * unsupported by objective evidence" are insufficient to carry a party's burden of proof). Similarly, in the administrative context, a government agency, in defending a challenge to an agency rulemaking, cannot demonstrate a reasoned basis supporting its rule by merely pointing to conclusory statements in the final rule's preamble. Rather, the agency must document that reasoned basis by pointing to the underlying data in the administrative record. *See Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 643 (1986) (concluding that where, in a rulemaking, the agency relies on only "perceived discrimination against handicapped infants," the rule cannot be upheld because the agency "pointed to no evidence that such discrimination occurs").

EPA's guidance follows this plain language approach to interpreting the term "support." In EPA's initial policy statement on TSCA section 8(e), EPA repeatedly refers to the information that must be reported as "evidence." *1978 Policy Statement*, 43 Fed. Reg. at 11,112. For example, in describing the level of certainty that information supporting a conclusion of substantial risk of injury must have, EPA states:

> A person is not to delay reporting until he obtains conclusive information that a substantial risk exists, but is to immediately report any *evidence* which "reasonably supports" that conclusion. Such *evidence*

> will generally not be conclusive as to the substantiality of the risk; it should, however, reliably ascribe the effect to the chemical.

Id. (emphasis added); *see also id.* (defining a human health effect as "[a]ny instance of cancer, * * * [and] [a]ny pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce cancer"). Importantly, EPA's guidance prominently defines studies, including epidemiological studies, as the "type" of "information" that must be reported when the study reasonably supports a risk conclusion. In EPA guidance documents released in 1978 and 2003, the sections addressing the nature and sources of reportable information state:

> Information attributing any of the effects described in Part V above to a chemical substance or mixture is to be reported if it is one of the types listed below and if it is not exempt from the reporting requirement by reason of Part VII of this policy statement. * * *
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> * * * *
>
> (1) *Designed, controlled studies*. * * * Designed, controlled studies include:
>
> * * * *
>
> (ii) epidemiological studies.

Id. at 11,112 (emphasis in original). Thus, through its guidance documents, EPA has interpreted "information" that "supports" a conclusion of substantial risk of injury as studies and the evidence within them.

Information must not just "support" a conclusion of substantial risk of injury, it must "reasonably" support the conclusion. The modifier "reasonably" mandates a degree of certainty for identifying the

supporting information that must be reported. Information regarding substantial risk of injury may not be speculative in nature; rather, as EPA's guidance notes, it should "reliably ascribe the effect to the chemical." *Id.* Other than demanding a degree of reliability, however, the requirement that the information "reasonably" support a conclusion of substantial risk of injury does not provide a criterion for what *type* of information in a study – information on study design, information on data relied upon, data analysis, or study conclusions – qualifies as reportable information.

With this understanding of the individual terms in the phrase "information" that "reasonably supports" a conclusion of substantial risk of injury, we conclude that the Mundt study in its entirety was reportable information. A study, such as the Mundt study, can only reasonably support (i.e., verify, corroborate, or substantiate) a conclusion that a chemical poses a substantial risk of injury to the extent it is consistent with the scientific principles for conducting such studies, is based on reliable data, and uses appropriate analytical and statistical tools for analyzing those data. Thus, the information that supports a conclusion of substantial risk of injury is the information on the study's methodology, data, and analytics – in other words, all information in the study critical to establishing the linkage between the chemical and conclusion of substantial risk of injury. For the Mundt study, this supporting information, at a minimum, includes: (1) the methodology used to conduct the study (e.g., an explanation of how the study cohort was chosen and how exposure was measured); (2) information on the level of worker exposure to chromium in the plants studied; (3) mortality information on these workers; (4) data analyses comparing the mortality of workers and the general population that showed an elevated mortality risk from lung cancer in workers receiving the highest cumulative hexavalent chromium exposure; and (5) information on the smoking habits of the workers.[28]

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[28] The portion of the ALJ's decision that addressed the scope of the reporting obligation, Init. Dec. at 38–48, appears to have made this question more complicated than necessary, or worse, raised the bar as to what is "information which reasonably supports

(continued...)

Moreover, in its appeal brief, Elementis essentially concedes that the Mundt study contains information in addition to its conclusion that reasonably supports the conclusion that chromium exposure in modern chromium plants poses a cancer risk. Elementis writes that "the [Mundt] study both presented a conclusion, *and reasonably supported the conclusion*, that the highest cumulative exposure group experienced an increased risk of lung cancer." Appeal Br. at 29 (emphasis added). Elementis thus admits that "the Mundt study * * * reasonably supported the conclusion" that the highest exposed workers in modern chromium plants (which were the type of plants the Mundt study examined) have an elevated cancer risk.[29] Elementis repeats this concession when it argues that "at no point did [the ALJ] identify what specific information in [the Mundt study] * * * 'substantially supports the conclusion that the risk is present,' beyond that which Elementis acknowledged – the

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[28](...continued)
[a] conclusion [of] substantial risk." In addressing Elementis' argument that the only reportable information in the Mundt study was its conclusion of a statistically significant cancer finding, the ALJ examined whether section 8(e) only applied to statistically significant findings. She held that it did not. *Id.* at 48. Later, the ALJ also seemed to imply that information was reportable because it was different than the information in the Gibb study. *Id.* at 72. None of this was necessary. As we hold today, the data underlying the cancer finding in the Mundt study was information reasonably supporting a conclusion of substantial risk of injury. There was no reason to explore questions regarding data underlying non-statistically significant findings because there was a statistically significant finding in the Mundt study. Further, there was no need to show a distinction between the Mundt study information and the information in the Gibb study in this aspect of the inquiry. The statute merely requires that information reasonably support a conclusion of substantial risk of injury, not that it support such a conclusion in a new or different manner. Confirmatory studies that reasonably support a conclusion of substantial risk of injury are information reasonably supporting a conclusion of substantial risk of injury. Such studies may not need to be reported based on the exemption in the EPA guidance documents for corroborative information, but that is a separate issue. *See* Part V.B.3.a., *infra*.

[29] Elementis appears to be drawing a distinction between the Mundt study's conclusion that chromium is associated with an elevated risk of lung cancer in the four specific modern chromium plants Dr. Mundt studied and the substantial risk of injury that triggers the reporting obligation for the Mundt study (i.e., that chromium poses a lung cancer risk to workers in modern chromium plants). We consider this to be a distinction without a difference.

information that *showed* a statistically significant cancer risk for the most highly exposed workers." Appeal Br. at 30 (emphasis added). Notably, Elementis refers to "information" showing a cancer risk not a "conclusion" supporting that finding.

Only at oral argument did Elementis clarify that its position is that the "reasonably supports" criterion functions to differentiate between a study's conclusion and all of the other information included therein. Oral Arg. Tr. 47:20–49:8. Thus, Elementis' counsel at oral argument pointed to a single conclusory sentence in the 153-page report – "we identified an increase in lung cancer mortality among those with the highest cumulative exposure"[30] – and asserted that was the only reportable information in the study. It was only this sentence that was reportable, according to Elementis, because "[t]hat is the only place where this report says exposure to hexavalent chromium * * * was closely associated with any higher risk of cancer." *Id*. at 48:16–19. Elementis asserts that all other information in the Mundt study only provides "descriptions of what reasonably supports the [substantial risk] conclusion." *Id.* at 45:14–19. Alternatively, Elementis offers that "[t]he fact that X number of workers were studied somewhere does not support any conclusion. So those portions of the report that simply describe 'that's what we did,' are not information that reasonably supports." *Id.* at 45:29–46:2.

We are unpersuaded by Elementis' effort to dissect the Mundt study into small components and reduce the reportable information to the study's most summary conclusion. First, Elementis' argument wreaks an injustice on the plain language of the TSCA section 8(e). That provision speaks of "information" that reasonably supports a "conclusion." This choice of language indicates that Congress knew the difference between the broad term "information," and the term "conclusion," which is just one of many forms of information. If Congress only wanted to require submission of conclusions, it would have said so. Instead, Congress specified that if a person obtains

[30] Oral Arg.Tr. at 48:13–15 (quoting *Collaborative Cohort Mortality Study* at 75–76 (CX 1 at 89–90)).

"information" reasonably supporting a "conclusion" that a chemical presents a substantial risk of injury, the person shall submit "such information" to EPA. Moreover, as the legislative history demonstrates, Congress rejected a formulation of TSCA section 8(e) that would have required a person who obtains "information" reasonably supporting a conclusion of substantial risk of injury only to report "such risk." *See* House Conf. Rpt. No. 94-1679, at pp. 79–81 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4563-66 (House-Senate conference committee accepting language of the House bill); Toxic Substances Control Act, S. 3149, 94th Cong. § 8(e), 122 Cong. Rec. 8304, 8311 (1976) (as passed by Senate, Mar. 26, 1976); Toxic Substances Control Act, S. 3149, 94th Cong. § 8(e), 122 Cong. Rec. 27,205, 27,213 (1976) (as passed by House, Aug. 23, 1976).

Second, Elementis' reading of TSCA section 8(e) cannot be squared with the statutory context provided by section 8 generally. Subsections (a) and (d) of section 8 give EPA broad authority to require submission of a wide category of information without first requiring a determination of substantial risk of injury. 15 U.S.C. § 2607(a) (authorizing EPA to require reporting of, among other things, "[a]ll existing data concerning the environmental and health effects of [a] substance or mixture"), (d) (requiring a submission of lists of health and safety studies). It would be ironic to construe the scope of the reporting obligation in TSCA section 8(e) for information supporting a conclusion of substantial risk of injury more narrowly than the obligations in subsections (a) and (d), which are not triggered by a finding of substantial risk of injury.

Third, Elementis' interpretation of TSCA section 8(e) conflicts with EPA's contemporaneous and consistently-held position on the provision. As noted, EPA guidance published in 1978, shortly after TSCA's passage, provided an exemption for presumptively reportable information if that information was corroborative of a well-established adverse effect. *1978 Policy Statement*, 43 Fed. Reg. at 11,112. EPA reaffirmed this exemption in 1991, 1993, and 2003. *1991 Reporting Guide* at 8; *1993 Proposed Policy Clarification*, 58 Fed. Reg. at 37,739; *2003 Policy Guidance*, 68 Fed. Reg. at 33,139. But Elementis' counsel

claimed at oral argument that this exemption is superfluous because it is "actually a narrower protection than what the statute itself provides." Oral Arg. Tr. at 62:13–15. Thus, Elementis' interpretation is necessarily premised on the view that EPA has consistently misconstrued the meaning of TSCA section 8(e) over the 37-year period from EPA's initial contemporaneous interpretation until today.

Fourth, Elementis offers no plausible explanation of why the information in the Mundt study other than its one line conclusion does not support the study's conclusion and ultimately a conclusion of substantial risk of injury. Elementis' disparagement of all of the information in the Mundt study except its one sentence conclusion as merely "descriptions" of reasonably supportive information is unconvincing. Information, after all, is almost necessarily descriptive of something. For example, the Mundt study contains information describing exposure conditions in the four plants studied and information describing the cause of death for the workers in those plants. The fact that such information is a "description" does not disqualify it from being reasonably supportive of a conclusion of substantial risk of injury. Elementis' argument that the individual descriptive pieces of information in the Mundt study (e.g., X number of workers were studied) support no conclusion on risk is equally unavailing. The one line conclusion from the study is not what makes the study reasonably supportive of a conclusion of substantial risk of injury. Nor generally would the individual pieces of information independently support such a conclusion. It is the totality of the data and the data analysis that provide reasonable support for a conclusion of substantial risk of injury.

Finally, Elementis offers little to no support for construing TSCA section 8(e) in a manner so contradictory to TSCA's core focus of ensuring that information on chemical risks is timely provided to EPA. Elementis admitted that its interpretation would deprive EPA scientists of valuable information. Oral Arg. Tr. at 47:6–11. But Elementis provides no persuasive reason for such a counter-intuitive result. At oral argument, Elementis disingenuously suggested that requiring only conclusions be reported was not problematic because a conclusion would alert EPA to the potential risk and EPA has adequate authority to require

more data if it so desired. *Id.* at 46:3–18. But here, Elementis did not submit the Mundt study's conclusion to EPA. In fact, Elementis' argument that TSCA section 8(e) only requires the reporting of conclusions appears to have been constructed solely for the purpose of creating a loophole justifying its failure to submit the Mundt study conclusion or anything else about the Mundt study to EPA.

Elementis also argues that requiring the reporting of confirmatory studies such as the Mundt study would "dissuade" manufacturers, such as itself, from conducting such a study. Appeal Br. at 41. But TSCA section 8(e) is written broadly to require submission of studies that *reasonably support a conclusion* of substantial risk of injury – and thus, on its face, requires the submission of studies confirmatory of a conclusion of substantial risk of injury. The statute does not allow a manufacturer to withhold key supporting studies simply because it does not like the study's outcome, or the study did not support the proposition the manufacturer thought it would when it commissioned the study. To the extent there is a disincentive to manufacturers to conduct studies, it is one that Congress created in enacting TSCA section 8(e).[31] As noted earlier, Congress determined to strike the balance of requiring disclosure of such information to prevent "the public or the environment [from] being used as a testing ground for the safety of [chemicals]," and thus included a statutory requirement that would "provide regulators timely access to information regarding health and safety studies concerning chemicals covered by the Act." S. Rep. No. 94-698, at 3, 6 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4493, 4496.

b. *Conclusion on Elementis' Statutory Argument*

Because the Board rejects Elementis' claim that the only reportable information in the Mundt study is its most summary conclusion and instead finds the Mundt study to be reportable in its

[31] We suspect any disincentive to undertake studies attached to a requirement to submit confirmatory studies pales in comparison to the disincentive associated with the requirement to submit studies that show new or previously unknown risks.

entirety, Elementis' statutory argument against liability collapses. It is undisputed that the other elements of TSCA section 8(e) liability have been met: Elementis did not immediately submit the Mundt study to EPA and Elementis did not have actual knowledge that EPA had been informed of the Mundt study by some other means. Thus, if our decision was governed solely by the plain terms of the statute, we would find that Elementis' failure to submit the Mundt study to EPA violated TSCA section 8(e). However, through its guidance, EPA has exercised its discretion to broaden the scope of the information of which the Agency considers itself adequately informed, and Elementis additionally argues that this guidance excuses its failure to submit the Mundt study. In the following section we turn to this argument.

3. EPA's TSCA 8(e) Reporting Guidance Exempted Elementis From the Obligation to Submit the Mundt Study to EPA

EPA guidance documents explain that EPA considers itself to be "adequately informed" of information that is "corroborative of a well-established adverse effect." *1991 Reporting Guide* at 8. Thus, otherwise reportable information is exempted from TSCA section 8(e)'s reporting obligation if it addresses a well-established adverse effect in a manner that corroborates that effect. Accordingly, determining whether Elementis met its burden of showing it qualifies for this reporting exemption for corroborative information requires the Board to answer two questions: (1) Did the Mundt study address a well-established adverse effect of hexavalent chromium? and, if so, (2) Is the Mundt study corroborative of that effect? We preface our discussion of these two questions with a summary of the relevant EPA guidance documents on TSCA section 8(e).

a. EPA's Guidance Documents

EPA has released several guidance documents on TSCA section 8(e). It first issued a "Statement of Interpretation and Enforcement Policy" concerning TSCA section 8(e) in 1978, shortly after the enactment of TSCA. 43 Fed. Reg. 11,110 (Mar. 16, 1978). On June 3, 2003, EPA issued an update of this policy titled "Policy Clarification and

Reporting Guidance." 68 Fed. Reg. 33,129 (June 3, 2003). In between those two dates, EPA issued two other related documents: first, in 1991, a guide to its policy document titled "TSCA Section 8(e) Reporting Guide;" and second, in 1993, a proposed refinement to the *1978 Policy Statement* seeking comment on the proposed changes. 58 Fed. Reg. 37,735 (July 13, 1993). Finally, in 2006 EPA expanded an internet-based question and answer document to provide further guidance on its revised 2003 Policy Statement. U.S. EPA, Frequent Questions: September 2006, http://www.epa.gov/oppt/tsca8e/pubs/frequentlyaskedquestionsfaqs.html#2006 (last visited Feb. 4, 2015) ("Frequent Questions: Sept. 2006"). We focus primary attention on the pre-2002 documents because they were extant at the time Elementis received the Mundt study. We have considered the post-2003 documents as well, however, because they help enlighten the meaning of the earlier documents, and EPA issued them before Elementis submitted the Mundt study to EPA.

i. *1978 Statement of Interpretation and Enforcement Policy*

EPA's *1978 Policy Statement* lists a number of instances in which otherwise reportable information is exempt from the reporting obligation. 43 Fed. Reg. at 11,112. These exemptions provide a pathway for regulated parties to demonstrate that they do not need to submit to EPA otherwise reportable information under TSCA section 8(e). The exemption relevant to this case is an exemption for information that "[i]s corroborative of well-established adverse effects already documented in the scientific literature," hereinafter referred to as the Corroborative Information Reporting Exemption. *Id.* The 1978 guidance does not define further what information the Corroborative Information Reporting Exemption covers.

ii. *1991 TSCA Section 8(e) Reporting Guide*

EPA issued the 1991 TSCA Section 8(e) Reporting Guide to assist the regulated community in complying with TSCA section 8(e), and EPA intended it "to be used as a tool in conjunction with EPA's

March 16, 1978, Section 8(e) policy statement." *1991 Reporting Guide* at i. For the first time, EPA explained in the Reporting Guide the basis for its exemptions from TSCA section 8(e). EPA stated that these exemptions were appropriate because "[t]here are several kinds of information about which the Agency considers itself to be adequately informed *already* for the purposes of Section 8(e) of TSCA." *Id.* at 8 (emphasis added). Or to put this in terms of the relevant statutory language, the Agency's guidance provides "actual knowledge" to the regulated community of information of which the Agency considers itself to be "adequately informed."

Of particular relevance to this case, the *1991 Reporting Guide* expands on what information can be considered corroborative and, thus, not required to be reported to EPA. The Corroborative Information Reporting Exemption, as described in the *1991 Reporting Guide*, extends to information that "is corroborative (in terms of, for example, route of exposure, dose, species, time to onset, severity, species [sic], strain, etc.) of a *well-established* adverse effect." *Id.* (emphasis in original). The *1991 Reporting Guide* further states:

> [I]nformation that newly identifies a serious toxic effect *at a lower dose level* for example, or *confirms a serious effect that was previously only suspected*, is *not* considered by EPA to be corroborative and should be reported under Section 8(e) of TSCA.

Id. (emphasis in original).[32]

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[32] We are confused by the suggestion that information confirming a "suspected" serious effect is not considered "corroborative" information and would not be covered by the Corroborative Information Reporting Exemption. This exemption only applies to information corroborating "well-established" adverse affects. If the adverse effect is only "suspected," the Corroborative Information Reporting Exemption would not apply to information on such an effect for that reason alone. There is no reason to discuss whether the information is corroborative or not. Perhaps EPA only intended to emphasize the importance of the well-established criterion. If EPA intended something else by this language, we suggest it consider updating its guidance.

This revised explanation of the Corroborative Information Reporting Exemption makes clear that information on a well-established adverse effect is corroborative if it is based on a study that: (1) is conducted in the same species and strain of animal as used previously; (2) is administered by the same route of exposure (oral, dermal, or inhalation) as used in a prior study; (3) does not disclose more serious effects than were observed earlier (i.e., more severe effects; effects at a shorter time to onset); and (4) does not show effects at lower doses than previously documented.

iii. *1993 Proposed Revision to Statement of Interpretation and Enforcement Policy*

In 1993, EPA proposed to make several amendments to its *1978 Policy Statement*. Included in those changes were minor adjustments to the Corroborative Information Reporting Exemption that largely followed the *1991 Reporting Guide*. EPA also included in the proposal its most extensive discussion to date of the exemption. EPA explained that the Corroborative Information Reporting Exemption applies to information that "corroborates well-established, serious adverse effects that are already documented." 58 Fed. Reg. at 33,739. For the first time, EPA defined the term "corroborate." EPA wrote:

> The term "corroborates" in the context of this particular reporting exclusion, means that the information essentially duplicates and/or confirms an existing and well-documented understanding of a serious adverse effect of a particular chemical substance or mixture.

Id. EPA repeatedly emphasized that a study was not "corroborative" if it "show[s] adverse effects of a more serious degree or of a different kind than are already established." *Id.* Expanding on the language that first appeared in the *1991 Reporting Guide*, EPA provided a fuller explanation of study findings that were not corroborative of well-documented effects. EPA stated that studies that found serious toxic effects should not be considered corroborative if:

> such effects are substantially more serious in terms of the severity of the effects or the number of animals affected; occur within a significantly shorter time frame following exposure; occur via a different route of exposure; occur at a significantly lower dose or concentration; or occur in a different species, strain, or sex.

Id.

EPA also included four case study examples illustrating these type of non-corroborative findings. *Id.* at 37,740. The case studies emphasized that reporting was required where the new study "differ[ed] in a major way from the already available information." *Id*. The following "major" differences can be gleaned from the case studies: (1) a new chronic feeding study in mice showed benign and malignant pancreatic tumors whereas it was previously well-established only that the chemical caused malignant skin tumors in mice following dermal application; (2) a new study in rats showed the same effect by the same route of exposure that was previously established only in mice; (3) a dermal study showed the same effect in the same animal species as previously established only by the oral route of exposure; and (4) a new rat study showed the onset of an effect after 12 to 18 months of exposure whereas a previous rat study found the same effect found only after two years of exposure. *Id.* Further, the case studies provided the following examples of "adverse effects:" cancer (benign and malignant); birth defects; and neurotoxicity. *Id*.

iv. *2003 Amended Statement of Interpretation and Enforcement Policy*

Ten years after proposing to amend the *1978 Policy Statement*, EPA issued the 2003 Policy Clarification and Reporting Guidance. 68 Fed. Reg. 33,129 (June 3, 2003). The Corroborative Information Reporting Exemption contained in this version was nearly identical to what EPA proposed in 1993 and largely followed the *1991 Reporting Guide*. It specified that otherwise reportable information was exempt

from reporting if it "[c]orroborates (i.e., substantially duplicates or confirms) in terms of, for example, route of exposure, dose, species, strain, sex, time to onset of effect, nature and severity of effect, a well-recognized/well-established serious adverse effect for the chemical(s)." *Id.* at 33,139.

v. *Summary of Guidance Documents*

The guidance documents present a fairly detailed picture of what is considered an "adverse effect" (e.g., cancer, birth defects, neurotoxicity), what "terms" or factors bear on a study's potential corroboration (e.g., information on severity, dose, test species, etc.), and what type of findings on these terms or factors should be considered non-corroborative (findings showing "adverse effects of a more serious degree or of a different kind than are already established"). However, the explanatory information in the guidance documents appears to have been developed with a focus on toxicity testing in animals rather than human epidemiology testing. *See 1993 Proposed Policy Clarification*, 58 Fed. Reg. 37,740 (presenting Corroborative Information Reporting Exemption case examples only involving animal testing); Oral Arg. Tr. at 90:19–20 (EPA-OCE counsel admitting at oral argument that the guidance documents were drafted with a "primary focus" on "animal studies."). For example, two of the potential corroborating factors, species and strain of the test animal, can be dismissed out of hand as irrelevant to human epidemiology studies. Additionally, because the case studies used to explicate the corroborating factors are all based on animal studies, the guidance documents do not provide any specific insight as to how the corroborating factors should be applied to the complexities involved in human epidemiology studies.

The inquiry on corroboration is further narrowed as to the Mundt study because the corroborating factors bearing on the route of exposure and the severity of the effect have no relevance in this case. The route of exposure factor is not pertinent here because both the Mundt and Gibb studies, as well as the other leading epidemiology studies in chromium plants, involved the same route of exposure – inhalation. The severity of effects factor does not come into play because the leading

epidemiological studies on hexavalent chromium all focus on the same effect, death from lung cancer. *See* Hearing Tr. at 481–82 (testimony of Dr. Richard Clapp) ("I think lung cancer is equally severe and death due to lung cancer is ultimately severe in both studies."). Thus, the only relevant remaining named factors are time to onset of effects and dose.

b. *Lung Cancer Is a "Well-Established Adverse Effect" of Hexavalent Chromium Exposure*

The term "well-established adverse effect" serves as a gatekeeper for the Corroborative Information Reporting Exemption. In other words, unless the reportable information concerns a well-established adverse effect of a chemical, the information cannot qualify for the exemption no matter how corroborative the information is as to prior knowledge about the chemical. We thus must examine what is meant by the term "well-established adverse effect" and whether the Mundt study addressed such an effect. In the Initial Decision, the ALJ held that the Mundt study could not qualify for the Corroborative Information Reporting Exemption because "the full range of the dose-response relationship between hexavalent chromium and cancer in [modern] plants" was not a well-established adverse effect. Init. Dec. at 72. On appeal, EPA-OCE argues that the "adverse effect of lung cancer from hexavalent chromium exposure at the four modernized plants in the [Mundt] study had not been well-established." EPA's Resp. Br. at 32. For this case, we concentrate on the term "adverse effect" because, given our analysis of that term, the meaning of the modifier "well-established" is not put into question.

"Adverse effect" is a very commonly-used term in risk assessment parlance. EPA's Integrated Risk Information System ("IRIS")[33] defines an "adverse effect" as "a biochemical change,

[33] EPA describes IRIS as "a human health assessment program that evaluates risk information on effects that may result from exposure to environmental contaminants." U.S. EPA, Integrated Risk Information System (IRIS), http://www.epa.gov/iris/index.html (last visited on Feb. 4, 2015). Although EPA runs the IRIS program "to support the Agency's regulatory activities," *id.*, as the National (continued...)

functional impairment, or pathological lesion that affects the function of the whole organism, or reduces an organism's ability to respond to an additional environmental challenge."[34] Office of Research & Dev., U.S. EPA, *Vocabulary Catalog List Detail - Integrated Risk Information System (IRIS) Glossary* ("IRIS Glossary"), http://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS%20Glossary (last updated Aug. 31, 2011). The National Research Council of The National Academy of Sciences, which Congress chartered to advise the federal government on scientific matters, concurs. *See* 36 U.S.C. § 150303 (1998); Exec. Order No. 2859, as amended by Exec. Order No. 10,668, 3 C.F.R. § 323 (1954–1958) (establishing the National Research Council under the National Academies of Sciences charter). In its foundational work on risk assessment, *Risk Assessment in the Federal Government: Managing the Process*, the National Research Council equates "adverse health effects" with "an increase in the incidence of a health condition (cancer, birth defects, etc.)." Nat'l Research Council, *Risk Assessment in the Federal Government: Managing the Process* 19 (1983) (*"Risk Assmt in the Fed. Gov't*"). Similarly, the Agency for Toxic Substances and Disease Registry ("ATSDR"),[35] working in conjunction with EPA, has defined an

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[33](...continued)
Research Council has noted, "other federal agencies, various state and international agencies, and other organizations have come to rely on IRIS assessments for setting regulatory standards." Nat'l Research Council, *Review of EPA's Integrated Risk Information System (IRIS) Process* 3 (2014).

[34] This definition is ubiquitous in EPA risk assessment policy documents. *See, e.g.*, U.S. EPA, *Framework for Cumulative Risk Assessment* 72 (May 2003) *available at* http://www.epa.gov/raf/publications/pdfs/frmwrk_cum_risk_assmnt.pdf; U.S. EPA, *A Review of the Reference Dose and Reference Concentration Processes* G-1 (Dec. 2002), *available at* http://www.epa.gov/raf/publications/pdfs/rfd-final.pdf; U.S. EPA, EPA/630/R-94/007, *The Use of the Benchmark Dose Approach in Health Risk Assessment* G-1 (Feb. 1995) *available at* http://www.epa.gov/raf/publications/pdfs/BENCHMARK.pdf.

[35] ATSDR was created by Congress as a branch of the U.S. Public Health Service. 42 U.S.C. § 9604(i)(1).

"adverse health effect" as "a harmful or potentially harmful change in the physiologic function, psychologic state, or organ structure that may result in an observed deleterious health outcome." Minimal Risk Levels for Priority Substances and Guidance for Derivation, 61 Fed. Reg. 25,873, 25,875 (May 23, 1996) (listing adverse health effects ranging from reversible cell alterations at the ultrastructural level to cancer to death).

Although EPA did not explicitly define the term "adverse effect" in TSCA section 8(e) guidance documents, EPA's general usage of the term and the examples EPA provides of "adverse effects" in the guidance documents fit comfortably with the definitions quoted above. For example, the *1991 Reporting Guide* specifies that, in evaluating the "seriousness of the adverse effect" in the *1978 Policy Statement's* two-part balancing test for reportability, birth defects and cancer should be considered as examples of such "serious effects."[36] *1991 Reporting Guide* at 2; *see 1978 Policy Statement*, 43 Fed. Reg. at 11,111–12 (defining "serious" "human health effects" as including cancer and birth defects). The Reporting Guide also lists cancer, birth defects, and neurotoxicity as examples of "serious adverse health effects." *1991 Reporting Guide* at 2. Similarly, the 1993 Proposal provides examples

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[36] The *1991 Reporting Guide* treats the terms "serious effect," "serious toxicological effect," "serious adverse effect," and other variations on that theme as interchangeable. For example, in addition to the references cited in the text, the Guide also mentions "serious toxicologic effects (e.g., cancer, neurotoxicity, birth defects)," *1991 Reporting Guide* at 21, "serious embryotoxic or fetotoxic effects (e.g., significant embryo or fetal lethality, spontaneous abortion)," *id.*, and "serious adverse developmental effects (e.g., significant embryo or fetal lethality, significantly reduced fetal/birth weights, significantly retarded/incomplete skeletal ossification)," *id.* at 22. In the following question and answer sequence, the guidance uses the three terms to refer to the same concept:

> Q. When evaluating subchronic animal studies, what criteria should be used to determine reportability of *adverse effects*? * * *
>
> A. *Serious toxic effects* (e.g, neurotoxic effects, serious reproductive system effects) observed during the conduct of subchronic studies should be reported. This includes readily observable *serious effects* or *serious effects* seen only as the result of gross and/or histopathological examination.

Id. (emphasis added).

of adverse effects that are consistent with the IRIS definition.[37] For example, the 1993 Proposal specifies that the reportability of exposure information on a chemical depends on whether the chemical "is known or suspected to be capable of causing serious adverse health effects (e.g., cancer, birth defects, neurotoxicity) or serious adverse environmental effects (e.g., significant nontrivial toxicity in aquatic species)."[38] *1993 Proposed Policy Clarification*, 58 Fed. Reg. at 37,737.

Determining whether a chemical causes an adverse effect is just one step in estimating the risk posed by a chemical. The National Research Council has assigned the question of whether a chemical

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[37] TSCA regulations use the term "adverse effect" in an equivalent manner. *See, e.g.*, 40 C.F.R. §§ 798.6050(b) ("Neurotoxicity is any adverse effect on the structure or function of the central and/or peripheral nervous system related to exposure to a chemical substance."), 799.9135 ("Respiratory effects are any adverse effects on the structure or functions of the respiratory system related to exposure to a chemical substance.").

[38] Although the TSCA section 8(e) guidance documents use the term "adverse effect" consistently internally and with regard to general EPA risk assessment guidance, the same cannot be said for the use of the term "effect." The guidance documents frame the basic standard on reportability of information as involving a weighing of the seriousness of a chemical's "effect" with the likelihood of exposure. *1978 Policy Statement*, 43 Fed. Reg. at 11,111; *1991 Reporting Guide* at 2. Information on cancer and birth defects are given as examples of "effects" that are so serious that little or no consideration of exposure is necessary to conclude that such information must be reported. *Id.* But, in a definitional section, the guidance includes as an environmental "effect" a discovery of "widespread and previously unsuspected distribution in environmental media." *1978 Policy Statement*, 43 Fed. Reg. at 11,112. By defining such an exposure event as an "effect," the guidance's instruction to weigh the seriousness of effects with the likelihood of exposure becomes doctrinally incoherent: essentially, for some "effects," exposure is to be considered in light of exposure. Later guidance documents attempted to paper over this confusion by directing that exposure information on a chemical should not be judged reportable without considering the adverse health or environmental effects ascribed to the chemical. *1993 Proposed Policy Clarification*, 58 Fed. Reg. at 37,737. While this may have addressed a concern that exposure "effects" could be over-reported, *id*., it did nothing to remedy the definitional incoherence of the guidance. Like other parts of the guidance, *see infra* note 44, this confusion in the use of terminology makes it difficult to apply the guidance to situations not explicitly addressed.

"causes an adverse effect" to the first step (Hazard Identification) of its uniformly-followed four-step risk assessment process. *Risk Assmt. in the Fed. Govt*. at 21; National Research Council, *Science and Judgment in Risk Assessment* 4 (1994) ("*Hazard identification* involves the determination of whether exposure to an agent can cause an increased incidence of an adverse health effect, such as cancer or birth defects, and characterization of the nature and strength of the evidence of causation.") (emphasis in original); *see* U.S. EPA, The History of Risk at EPA, http://www.epa.gov/ncea/risk/history.htm ("EPA has integrated the principles from this groundbreaking report [by the National Research Council] into its practices to this day.") (last visited on Feb. 4, 2015). Only after the adverse effect causation question is answered in the Hazard Identification step does the risk assessment process move into an evaluation of the potency or dose-response relationship of a chemical (Step 2 - Dose Response Assessment), an analysis of the extent and duration of exposure to humans or the environment (Step 3 - Exposure Assessment), and finally estimation of risk (Step 4 - Risk Characterization). *Risk Assmt. in the Fed. Govt.* at 21; *see* U.S. EPA, Human Health Risk Assessment, http://www.epa.gov/risk_assessment/health-risk.htm (explaining how EPA has implemented the NAS' four-step risk assessment process) (last visited on Feb. 4, 2015).[39]

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[39] An excellent, concise summary of the NAS's four-step process has been provided by the Society of Toxicology, a professional organization for toxicologists:

> Risk assessment involves four components: **Hazard identification** – an evaluation of the adverse health effects the agent is capable of causing. Examples might include the capacity of an agent to cause liver or nervous system damage or to cause cancer. **Dose-response assessment** – a determination of how much of an agent is required to cause a toxic effect, and prediction of exposure levels at which risk is likely to be negligible or nonexistent. **Exposure assessment** – a determination of how much of an agent people might be exposed to under various conditions such as use of a drug or a consumer product, environmental exposure at a hazardous waste site. **Risk characterization** – an integration of the pertinent information from the preceding steps to characterize the risks to the exposed population—e.g., what is the likelihood that there will be an increase in cancer in a population exposed to a particular contaminant in

(continued...)

Importantly, as outlined above in the four-step risk assessment process, the term "adverse effect" is *not* synonymous with the terms "dose response relationship" or "risk." "A dose-response relationship," EPA has explained, "describes how the likelihood and severity of *adverse health effects* (the responses) are related to the amount and condition of exposure to an agent (the dose provided)." U.S. EPA, Human Health Risk Assessment: Step 2 - Dose-Response Assessment, http://www.epa.gov/risk_assessment/dose-response.htm (last visited Feb. 4, 2015) (emphasis added). In other words, the dose-response relationship examines the potency of a chemical to cause an adverse effect at various exposure levels. "Risk" is defined by EPA as "[t]he probability of *adverse effects* resulting from exposure to an environmental agent." IRIS Glossary (emphasis added); *see also Risk Assmt. in the Federal Govt.* at 20 (describing risk as "the incidence of a health effect under various conditions of human exposure"). Thus, an adverse effect is the toxicological insult a chemical may cause, whereas a chemical's dose-response relationship is a measure of its potency to cause adverse effects and risk is the probability that such adverse effects will result under measured or estimated exposure levels.

Applying this framework to the case at hand shows both that the Mundt study did address a well-established adverse effect and that the ALJ and EPA-OCE have strayed far from the commonly-accepted meaning of the term "adverse effect." The Mundt study assessed whether occupational exposure to hexavalent chromium is associated with lung cancer. Lung cancer is an "adverse effect" as that term is used both generally in EPA risk assessment practice and specifically under the TSCA section 8(e) guidance documents. Lung cancer meets the IRIS definition of a "pathological lesion that affects the function of the whole organism" and in the words of the *1991 Reporting Guide* it is a "serious adverse health effect." Further, it is "well-established" that exposure to

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[39](...continued)
drinking water?

http://www.toxicology.org/AI/NEWS/news-riskassess.asp# (last visited February 6, 2015).

hexavalent chromium causes the adverse effect of lung cancer. More than a half-century of epidemiology studies,[40] EPA's classification of hexavalent chromium as a "known carcinogen" in 1984,[41] and the testimony of all the expert witnesses in this proceeding confirm that hexavalent chromium causes lung cancer.[42] Thus, the Mundt study potentially qualified for the Corroborative Information Reporting Exemption because it satisfies the gatekeeper criterion of addressing a "well-established adverse effect."

The ALJ erred by treating "the dose-response relationship between hexavalent chromium and cancer in [modernized] plants" as an adverse effect addressed by the Mundt study. Init. Dec. at 72. A dose-response relationship is not an adverse effect (i.e., a biochemical change, functional impairment, or pathological lesion that affects the function of the whole organism). Rather, the dose-response relationship describes the potency of a chemical to cause an adverse effect. To interpret a chemical's dose-response relationship as an "adverse effect" is a complete misreading of that term, as exemplified by EPA's own risk assessment documents and the National Research Council's paradigmatic risk assessment process.[43]

EPA-OCE makes a similar mistake in arguing that the "adverse effect" addressed in the Mundt study is "the adverse effect of lung cancer

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[40] Occupational Exposure to Hexavalent Chromium, 71 Fed. Reg. 10,100, 10,111–24 (Feb. 28, 2006) (collecting epidemiological studies dated between 1948 and 2005 documenting hexavalent chromium's lung cancer effect).

[41] Environmental Criteria & Assessment Office, U.S. EPA, EPA-600/8-83-014 F, *Health Assessment Document for Chromium* 7-107 (Aug. 1984).

[42] Hearing Tr. at 139:21–140:7 (testimony of Dr. Glinda Cooper), 477:12– 8 (testimony of Dr. Richard Clapp), 518:22–519:5 (testimony of Dr. Frank Speizer), 742:13–18 (testimony of Dr. Kenneth Mundt), 1034:4– (testimony of Dr. Herman Gibb).

[43] In fact, EPA-OCE concedes in its post-hearing brief that this case concerns the "dose-response assessment" step in the NAS' four-step risk assessment process, not the first step of identifying whether a chemical causes a hazard (adverse effect). EPA's Init. Post-Hrg. Br. at 16 n.3.

from hexavalent chromium exposure in modernized chromium production plants." EPA's Resp. Br. at 34. An adverse effect is a pathological lesion or functional impairment such as cancer or birth defect, not a conclusion about the probability that adverse effects such as cancer or birth defects will result from a specific exposure scenario involving a chemical known to have such toxicological properties. The latter is a conclusion about *risk*, not *adverse effects*. EPA-OCE unintentionally admits as much in discussing the "adverse effect" that the Mundt and other similar studies were designed to examine:

> The purpose of these post-change studies was to determine whether the change-over from the old and outmoded high-lime processes to modern low-lime or no-lime processes had lessened *the risk of lung cancer mortality* from occupational exposure to hexavalent chromium to chromate workers.

Id. at 32–33 (emphasis added); *accord* EPA's Post-Oral Arg. Br. at 1, 4 ("Respondent's exhaustive $500,000 study told the Agency for the first time that *lung cancer mortality risk* persists under exclusively modernized plant conditions despite industry efforts to reduce risk.") (emphasis added). Notably, EPA chose in its guidance documents to define the Corroborative Information Reporting Exemption in terms of information pertaining to "adverse effects," and not in terms of the section 8(e) statutory term of "risk of injury." Thus, this argument, similar to the ALJ's finding, deviates from the plain language in the guidance documents.

c. *The Mundt Study Is Corroborative of Hexavalent Chromium's Lung Cancer Effect*

Because the Mundt study addresses hexavalent chromium's well-established adverse cancer effect, it can qualify for the Corroborative Information Reporting Exemption if the information in the study is corroborative of that effect. On its face, the Mundt study appears to be corroborative information under this exemption. It confirms the association between hexavalent chromium and lung cancer and, in so

doing, it corroborates that the cumulative "dose" that causes cancer is not lower than previously documented. At the hearing before the ALJ, EPA-OCE attempted to show that despite the higher cumulative dose finding in the Mundt study as compared to the Gibb study, the information in the Mundt study was actually not corroborative because it involved a lower intensity of exposure than the exposure examined in the Gibb study. In its briefs filed with the Board, EPA-OCE also argues that the Mundt study is not corroborative because it reduces uncertainty about the dose-response relationship between hexavalent chromium and lung cancer. To resolve the "corroborative" issue, we first analyze what the guidance documents reveal about that term. Second, we consider the evidence EPA-OCE proffered at the hearing before the ALJ in some detail. What transpired at the hearing is instructive as much for what EPA-OCE could not prove as for what it did.

i. Corroboration Under the Guidance Documents

The guidance documents' explanations of the Corroborative Information Reporting Exemption give content to the term "corroborative" in two separate ways. First, the guidance documents supply several different examples of "terms" or factors bearing on whether information may corroborate an adverse effect. According to the guidance documents, the manner of testing – what strain, species, and route of exposure is used – may corroborate a chemical's adverse effect. Further, corroborative information may be supplied by the nature of test results the information provides: the examples given are "severity," "time to onset," and "dose."[44] Second, the guidance documents explain

[44] These factors are commonly cited as relevant to the adverse effect causality determination in the Hazard Identification step of the risk assessment process. The NAS has emphasized the importance of using different animal species and strains in testing and establishment of a dose-response relationship in the Hazard Identification analysis as to cancer. *Risk Assmt in the Fed. Gov't* at 22 ("Consistently positive results in the two sexes and in several strains and species and higher incidences at higher doses constitute the best evidence of carcinogenicity."). Multiple EPA guidance documents stress that the other listed corroborating factors, testing (continued...)

what type of results from these potentially corroborative considerations or factors, are, in fact, non-corroborative. The consistent theme in all of the guidance documents is that information on the listed factors are non-corroborative (and thus reportable to EPA) when they show the effects of a chemical are of "a more serious degree or different kind" than previously perceived. *1993 Proposed Policy Clarification*, 58 Fed. Reg. at 37,739. Information is deemed of "a more serious degree" if it shows more severe effects, a shortened time to onset of effects, effects at lower doses (i.e. greater potency), or effects in a different species or strain of test animal or by a different route of exposure. *Id.* The converse is also true. Information would be corroborative if it shows that effects are less severe, they occur only at higher doses, or they occur in a species or strain of test animal, or by a route of exposure, that has been previously documented. *See* Hearing Tr. at 43:21–44:8 (testimony of Toni Krasnic).

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[44](...continued)
by multiple routes of exposure and severity and time to onset of the effect, are relevant to adverse effect determinations. *See, e.g.*, U.S. EPA, *Guidelines for Carcinogen Risk Assessment* 2-14, 2-22, 2-23, 2-38, 2-39 (Mar. 2005) *available at* http://www.epa.gov/raf/publications/pdfs/CANCER GUIDELINES_FINAL_3-25-05.PDF; U.S. EPA, *Guidelines for Neurotoxicity Risk Assessment* 11–12, 53–56 (Apr. 1998) *available at* http://www.epa.gov/raf/publications/pdfs/NEUROTOX.PDF. However, a complicating factor here is that one of the corroborative "terms" mentioned – dose – has equal or greater relevance to step two in the risk assessment process, Dose-Response Assessment, than to the Hazard Identification step. Significantly, the guidance documents describe the corroborating factor of "dose" in a way that focuses on what dose levels at which adverse effects are seen, the main feature of the dose-response assessment, rather than the mere fact of a dose-response relationship, which is how dose is used to confirm the causation of an adverse effect. *See 1991 Reporting Guide* at 8 (emphasizing that information on dose is not corroborative if shows effects at lower levels). Thus, there is an inherent contradiction in the Corroborative Information Reporting Exemption as drafted. It specifies that it applies to corroborating information on adverse effects but then defines corroborating information, in part, as including information that pertains to a different aspect of risk assessment than determining whether a chemical causes an adverse effect. Given this mixed message, we conclude that, although the guidance documents intended the listed corroborative factors only to be examples, the guidance documents do not provide a clear signal as to what other factors might bear on the corroboration of a well-established adverse effect. This is particularly true as to corroborating factors that relate primarily to other aspects of risk assessment than the initial determination regarding adverse effect causation.

Although this seems a relatively clear explanation of what information EPA considers to be corroborative, it is a somewhat unusual use of the term "corroborate." In a scientific sense, the term corroborate means to confirm or "to provide evidence of the truth of, to make more certain." Webster's Dictionary at 512. But the Corroborative Information Reporting Exemption defines some information that under normal usage would seem confirmatory of the truth of a certain proposition to be, in fact, non-corroborative. The opposite is also true: the exemption, at times, defines information that is contradictory as corroborative. For example, if a rat study confirms the cancer effects seen in a mouse study, the rat study would be deemed under the exemption to be non-corroborative (different species); however, if a second mouse study fails to reproduce the most serious cancer effects (malignant tumors) seen in the earlier mouse study, and only showed less serious cancer effects (benign tumors), the second study would be deemed to be corroborative (effects are not more severe). Given this somewhat idiosyncratic meaning ascribed to the term "corroborate," we give little weight to the common definition of the term in judging what information EPA considers corroborative under the Corroborative Information Reporting Exemption in EPA's guidance documents.

ii. Evidence Presented at the ALJ Hearing on Whether the Mundt Study Is Corroborative of a Well-Established Adverse Effect

At the onset of the hearing before the ALJ, EPA-OCE briefly summarized its theory of the case. According to EPA-OCE, Elementis' liability turned on whether Elementis could prove its affirmative defense that EPA was "adequately informed" of the reportable information in the Mundt study. Hearing Tr. at 10:10–17. EPA-OCE explained that, as spelled out in its TSCA section 8(e) guidance documents, the Agency does not consider itself to be adequately informed of information that is non-corroborative of an adverse effect. *Id.* at 11:6–12. Further, EPA-OCE noted that "information is not corroborative where it newly identifies a serious health fact, a lower dose, or concentration than was previously known." *Id.* at 11:16–19. Turning to the matter at hand,

EPA-OCE argued that the evidence it planned to present would show that:

> although the cumulative exposure levels fall in a comparable range in both the [Mundt] and Gibb studies, they reflect fundamentally different exposure conditions; namely, workers in the [Mundt] study experienced lower concentration exposures over a longer duration, while workers in the Gibb study experience higher concentration exposures over a considerably shorter duration.

Id. at 13:16–14:4.

EPA-OCE's lead witness was Toni Krasnic of EPA's Office of Pollution Prevention and Toxics, who made the official Agency determination that Elementis had violated TSCA section 8(e) by not immediately submitting the Mundt study. *Id.* at 37:9–14, 40:22–41:3. Mr. Krasnic testified that he concluded that the Mundt study contained reportable information because the study showed "cancer effects" and "[a]s per our guidance in 1978, any instance of cancer is considered to be substantial risk information." *Id.* at 37:19–21. He further determined that the study was not "corroborative" under the terms of the Corroborative Information Reporting Exemption because it showed cancer effects at a lower dose. *Id.* at 37:22–38:18. His specific testimony on this point was:

> The [Mundt] study also showed the [cancer] effects of the lower dose. As per our '78 guidance, any study that shows effects at a lower dose is considered not to be corroborative. Therefore, this is a study that has substantial risk or [sic] information which wasn't corroborative of any other information and therefore should have been submitted to EPA.

Id. at 39:10–17. Not only did Mr. Krasnic testify that a study would not be considered corroborative if it showed cancer effects at lower levels

than previously known, but, on cross-examination, he admitted that the converse was true as well:

> Q. I'm asking you if [your technical experts] told you that there was a report that showed a substantial risk of lung cancer at a lower dose than the [Mundt] study, wouldn't you then conclude that this exception to reporting is applicable and the [Mundt] report did not have to be turned over?
>
> A. That would be correct but EPA would have to have possession and knowledge of the other study.

Id. at 43:21–44:8 (question from Mr. McAleese for Elementis).

EPA-OCE next presented the testimony of three scientists: one from within the Agency, Dr. Glinda Cooper, and two outside experts, Dr. Richard Clapp and Dr. Frank Speizer. Their testimony on whether the Mundt study showed effects at a lower dose, however, was much more nuanced than Mr. Krasnic's. Both the Gibb and Mundt studies measured hexavalent chromium exposure in terms of cumulative exposure over time, and the Gibb study showed a statistically significant cancer effect at a significantly lower cumulative dose than the Mundt study, about 20 times lower. Hearing Tr. at 1045:18–21 (testimony of Dr. Herman Gibb). Each of EPA-OCE's witnesses admitted as much on cross-examination. Hearing Tr. at 241:6–20 (testimony of Dr. Glinda Cooper), 459:11–14 (testimony of Dr. Richard Clapp), 1097:21–1098:4 (testimony of Dr. Frank Speizer). For example, Dr. Speizer was asked: "For a reader picking up the [Gibb and Mundt] studies and looking at what was reported, the Gibb report establishes an effect at a statistically significant level at a much lower dose level. Correct?" *Id.* at 1097:21–1098:3. Dr. Speizer admitted that this was true. *Id.* at 1098:4.

In an attempt to temper the force of this admission, the EPA-OCE witnesses contended that even though cumulative exposure levels

were higher in the Mundt study, the average daily hexavalent chromium levels to which workers were exposed was lower in the Mundt study compared to the Gibb study. They based this lower dose/lower intensity conclusion on two grounds. First, noting that the average duration of employment for the workers in the Gibb study was shorter than in the Mundt study, the EPA-OCE witnesses argued that given the relative cumulative exposure levels in the two studies, the workers in the Mundt study must have been exposed to lower levels of hexavalent chromium over a longer time frame because cumulative exposure *equals* the exposure level of hexavalent chromium *multiplied by* the duration of exposure. As Dr. Clapp explained, "[t]he average concentration [exposure] in the [Mundt] study must have been lower for the cumulative exposure to have been what it was, with longer duration of work." *Id*. at 468:8–11. Second, Dr. Cooper presented an exhibit, Exhibit 98 titled "Average Hexavalent Chromium Concentrations in Air: Gibb and Modern Four Plant Report Studies," which purported to show that exposure levels in the two German plants in the Mundt study were two to five times lower than the exposure level in the Baltimore plant studied by Dr. Gibb. (CX 98). On cross-examination, however, Dr. Cooper admitted that the Exhibit 98 did not take into account exposure levels over the full time of the Mundt study and that her estimate of exposure for the Baltimore plant was not based on the Gibb study but on a separate study that looked at a different time period than the Gibb study. Hearing Tr. at 214:19–21, 223:1–225:2.

Both Dr. Mundt and Dr. Gibb appeared as witnesses on behalf of Elementis.[45] Dr. Mundt and Dr. Gibb vigorously disputed the EPA-OCE witnesses' attempt to calculate average exposure levels from the cumulative exposure estimates in their studies. Dr. Mundt explained that "you can't refer to these exposures as average exposures, as everyone has a specific exposure, and that's why in each of these studies we took these, went through these painstakingly, to triangulate information, to get individual estimates of cumulative exposure for each and every individual." *Id.* at 637:19–638:3. Dr. Gibb was more blunt: "An average

[45] Dr. Gibb has left EPA and now works for a private consulting firm. Hearing Tr. at 1010:22–1011:5, 1018:18–20.

is * * * sort of a perversion, I think, of the data. I mean we have 72,000 measurements. I'm trying to capture everything, and an average would have been * * * an abuse of the information. * * * * [An average] doesn't capture what the exposure is to this cohort." *Id.* at 1038:22–1040:11. They also disputed the accuracy of EPA-OCE's Exhibit 98, which purported to show higher average exposure levels in the Baltimore plant studied by Dr. Gibb compared to the German plants studied by Dr. Mundt. Dr. Mundt estimated that if an average air concentration for the full time span of the German plants were studied, instead of just the later years, the value would be very similar to what Dr. Cooper projected for the Baltimore plant after it was updated in 1950. *Id.* at 897:15 – 904:11. Again, Dr. Gibb did not mince words:

> This figure up here is what I really object to though, is the Baltimore plant workers were exposed to average hexavalent chromium concentrations in the air two to five times higher than the concentrations in the German and U.S. plants in the [Mundt] report. * * * * [Y]ou can take measurements in one part of the facility. That doesn't mean that's what the workers were exposed to. You have to get, you know, down to what the workers were exposed to. So this depiction here, again, it is grossly misleading, you know. At best, it is disingenuous.

Id. at 1051:1–1052:9.

EPA-OCE did not challenge Dr. Mundt or Dr. Gibb on these assertions through cross-examination or by use of a rebuttal witness.[46] EPA-OCE did recall Dr. Speizer for rebuttal, but the thrust of his

[46] *See* Hearing Tr. at 910:14–924:10 (EPA-OCE only asked Dr. Mundt about: (1) his renumeration for his testimony; (2) the primary goal of his study; (3) whether his study showed that there was a threshold level for hexavalent chromium's lung cancer effect; and (4) what the effect was of bifurcating his study between the U.S. and German plants for publication); 1060:15 – 1061:17 (EPA-OCE essentially asked Dr. Gibb a single question: why did EPA fund his study if hexavalent chromium's lung cancer effect was so well-established?).

testimony shifted perceptibly from earlier. Instead of claiming that the Mundt study involved lower exposures over a longer period than the Gibb study, he now asserted only that the Mundt study contained additional information on exposure relevant to the dose-response relationship for hexavalent chromium's cancer effects. The critical exchange on rebuttal is as follows:

> Q. So, let me ask you, after hearing Dr. Mundt's testimony and Dr. Gibb's, let me ask you very directly, are you still of the opinion that the [Mundt study] contains new information about the risk of lung cancer mortality from hexavalent chromium occupational exposure?
>
> A. I think it contains certainly additional information. It helps reduce the uncertainty about what we hypothesize as the linear dose response curve. It probably also offers EPA additional information which they could use to construct their lower risk estimates.

Id. at 1093:15–1094:6 (question by Mr. Chalfant for EPA-OCE). A chemical causes a "linear response" curve if "the frequency or severity of biological response varies directly with the amount of dose." IRIS Glossary. Carcinogens are presumed by EPA to have a linear dose response curve even at very low doses unless data show otherwise. U.S. EPA, EPA/630/P-03/001F *Guidelines for Carcinogen Risk Assessment* ("*Carcinogen Risk Assessment*") 3-21(Mar. 2005) *available at* http://www.epa.gov/raf/publications/pdfs/CANCER_GUIDELINES_FINAL_3-25-05.PDF EPA; Hearing Tr. at 1070:5–9 (testimony of Dr. Herman Gibb). On the other hand, many other adverse effects are presumed to have a linear response to chemical exposure only above a threshold exposure level. Below that threshold, there would be no

deleterious effects expected.[47] EPA-OCE witnesses testified that the Mundt study "gives us another degree of information in this region [of the dose response curve examined in the Gibb study] which I think reduces the uncertainty [about the linearity of the dose-response relationship]." *Id.* at 1091:13–15 (testimony of Dr. Frank Speizer); *see id.* at 486:2–14 (testimony of Dr. Richard Clapp).

There were a number of issues, however, on which most or all of the scientific witnesses agreed. As noted earlier, all of the witnesses agreed that the association between hexavalent chromium and lung cancer was well-established. Two of the three EPA-OCE scientific witnesses agreed that Dr. Mundt's and Dr. Gibb's use of cumulative exposure was the "optimum," or at least an appropriate, exposure metric for occupational epidemiology studies. *Id.* at 304:2–6, 431:1–6 (testimony of Dr. Richard Clapp), 524:13–525:4 (testimony of Dr. Frank Speizer). Further, all concurred that statistically significant lung cancer effects were seen at a substantially lower level in the Gibb study compared to the Mundt study. *Id.* at 241:6–20 (testimony of Dr. Glinda Cooper); 459:11–14 (testimony of Dr. Richard Clapp); 1097:21–1098:4 (testimony of Dr. Frank Speizer); 908:3–909:16 (testimony of Dr. Kenneth Mundt); 1044:14–1045:21 (testimony of Dr. Herman Gibb). Finally, four of the five scientists agreed that the Mundt study provided "additional" information that would be "valuable" in assessing the carcinogenic risks posed by hexavalent chromium. *Id.* at 164:9–16, 204:6–205:4 (testimony of Dr. Glinda Cooper); 335:2–14 (testimony of Dr. Richard Clapp); 876:20–877:21 (testimony of Dr. Herman Mundt); 1091:8–21 (testimony of Dr. Frank Speizer). Only Dr. Gibb dissented on this point, concluding that the Mundt study is "corroborative of existing information but it adds nothing new." *Id.* at 1057:9–10.

Ultimately, the ALJ determined that EPA-OCE had failed to establish the facts underlying its lower dose/lower intensity theory. She

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[47] EPA risk assessment documents often refer to adverse effects that only occur above a threshold exposure level as nonlinear effects. *Carcinogen Risk Assessment* 1-11 n.3 ("[T]he term 'non-linear' refers to threshold models (which show no response over a range of low doses that include zero) * * *.").

held Exhibit 98 to be not "useful," due to "the serious doubts raised as to [its] accuracy and reliability." Init. Dec. at 45 n.17. *Importantly, she also dismissed EPA-OCE's argument that the exposure intensity level of the workers in the Mundt study was lower than in the Gibb study*. She concluded: "The testimony in support of this argument did not successfully quantify the difference in 'intensity' or concentration, or otherwise factually support the 'sense' that this was true." Init. Dec. at 67. EPA-OCE did not appeal this ruling.

At the end of the hearing, EPA-OCE's case-in-chief lay in tatters. EPA-OCE had not rebutted Elementis' argument that the Mundt study confirmed hexavalent chromium's lung cancer effect only at a substantially *higher* dose than in the Gibb study. EPA-OCE witnesses were forced to admit that "a reader" examining the Mundt and Gibb studies on the basis of "what was reported," would conclude that "the Gibb report establishes an effect at a statistically significant level at a much lower dose" than the Mundt study. *See, e.g*., Hearing Tr. at 1097:21–1098:4 (testimony of Dr. Frank Speizer). Further, EPA-OCE failed to substantiate its witnesses' contentions about low-intensity exposure, and the ALJ rejected EPA-OCE's Exhibit 98 that purported to show lower exposure levels in the German plants studied by Dr. Mundt compared to the exposure levels in the Baltimore plant Dr. Gibb studied.

Thus, EPA-OCE's entire case was left resting on testimony that the Mundt study contained "additional" information on exposure that decreased uncertainty regarding the dose-response relationship between hexavalent chromium and lung cancer. For the first time in this proceeding, EPA-OCE now argues to the Board that the presence of information in the Mundt study that reduces uncertainty about hexavalent chromium's dose-response relationship alone is enough to show that the study contained non-corroborative information. *See* EPA's Initial Post-Hearing Brief, at 37–44 (all three reasons given by EPA-OCE in its post-hearing brief to the ALJ for why the Mundt study contains non-corroborative information explicitly rely on the contention that the Mundt study involved low-intensity exposure compared to the Gibb study).

iii. *The Mundt Study Is Corroborative as Defined by EPA in its Guidance Documents*

We conclude that the information in the Mundt study is corroborative of the well-established adverse effect (lung cancer) caused by exposure to hexavalent chromium, as the term "corroborative" is defined by EPA's guidance documents. None of the information in the Mundt study showed that hexavalent chromium exposure results in a more severe effect than lung cancer or a shorter time to the onset of lung cancer than prior well-documented studies such as the Gibb study.[48] The Mundt study also was not conducted by a different route of exposure or in a different species or strain of animal than previous studies. Further, the Mundt study did not show lung cancer effects at lower doses than the Gibb study. To the contrary, the Mundt study only revealed statistically significant lung cancer effects at a substantially higher level than in the Gibb study. It is true that the Mundt study relies on different exposure data than the Gibb study; however, EPA-OCE was unable to prove that this different exposure information suggested, in any way, that hexavalent chromium caused lung cancer at a lower dose than previously established. In sum, the Mundt study is corroborative of hexavalent chromium's lung cancer effect as to each of the named corroborative factors (e.g., severity, species, dose, etc.), to the extent they are relevant; thus, the Mundt study does not "show adverse effects of a more serious degree or a different kind than already established." *1993 Proposed Policy Clarification*, 58 Fed. Reg. at 33,739.

The ALJ erred in ruling that the Mundt study was not corroborative of hexavalent chromium's lung cancer effect, as defined

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[48] Although EPA-OCE has not advocated that the Mundt study shows a shorter time to onset of lung cancer, Dr. Richard Clapp testified at the hearing that time to onset was "different" in the Mundt and Gibb study. Hearing Tr. at 481:6–18. Elementis responded that Dr. Clapp provided no reference or other support for such a conclusion, and, with good reason, given that neither study examined this issue. Elementis' Init. Post-Hrg. Br. at 29. The Mundt study includes as its only conclusion regarding time to onset that "[m]ortality from lung cancer showed no pattern with time since first exposure." *Collaborative Cohort Mortality Study* at 65 (CX 1 at 79). We conclude Elementis met its burden on this factor.

by EPA's guidance documents. She held that the Mundt study should have been reported because it contained exposure information that was not corroborative of the Gibb study as to dose and time to onset of cancer. Init. Dec. at 64. However, we can find nothing in her opinion to support such a conclusion. Her error stems, first, from a failure to attend carefully to the nature of corroborating information as defined in the EPA guidance, and second, from a failure to provide any explanation of how the exposure information she identified is non-corroborative of dose and time to onset of effect. Specifically, she never explains how this exposure information shows that effects occurred "at a significantly lower dose" or "within a significantly shorter time frame following exposure." *1993 Proposed Policy Clarification*, 58 Fed. Reg. at 37,739. These flaws are apparent as to each of the five examples of exposure information that she cites, as discussed below.

The first example of exposure information in the Mundt study that the ALJ cited as not corroborative is that the exposure information in the Mundt study better represented hexavalent chromium exposure levels in modernized chromium plants than the exposure information in the Gibb study. Init. Dec. at 64. The ALJ concluded that this difference in exposure data meant that the Mundt study presented "a more accurate assessment of risk to workers in a modern chromate plant environment." *Id.* Thus, the ALJ concluded that the Mundt study "present[s] distinct [information reasonably supportive of a conclusion of substantial risk] which cannot be claimed 'corroborative' of 'well-established' effects." *Id.* at 65. This analysis departs from the guidance in several ways. First, the test for corroboration under the guidance is not simply whether the new information is the same or different from the existing information supporting the adverse effect. Under the guidance, information can be different but still corroborative. For example, if the Mundt study had revealed a less serious form of lung cancer or a longer latency period before the onset of cancer, the Mundt study would have presented different information but information that is clearly corroborative under the terms of the guidance. Second, the fact that the Mundt study may have presented "more accurate" risk information does not make it non-corroborative. Under the guidance, information is only non-corroborative if it shows "adverse effects of a more serious degree or a

different kind." Finally, under the guidance, the relevant question is whether the information is corroborative of an adverse effect, not whether it is corroborative of risk. The term "risk" is a far broader term than "adverse effect." At no point did the ALJ offer any explanation of how exposure information that presents a "more accurate assessment of risk to workers" shows that hexavalent chromium causes lung cancer at a lower dose or at a shorter time to onset of lung cancer.

The ALJ committed a similar error with the second example of distinct exposure information she identified in the Mundt study – the Mundt study's exclusion of the type of short term workers included in the Gibb study. Init. Dec. at 65–68. The ALJ noted that the inclusion of short-term workers in the Gibb study raised questions about the conclusions reached in the Gibb study. Based on this, the ALJ concluded that the two studies "present different risk information on dose and time to onset of effect." *Id.* at 67. However, the ALJ did not explain why the different information in the Mundt study made it non-corroborative or how this difference in exposure information between the two studies even related to the corroborating factors of dose or time to onset, as those terms are used in the guidance. For example, the ALJ did not assert that the exclusion of short-term workers from the Mundt study resulted in finding of effects at lower levels or an earlier onset of lung cancer.[49]

The same errors appear as to the three other identified exposure items: information on hexavalent chromium levels in urine; information on how exposure data were collected; and more complete smoking data. The ALJ found that this information was "able to more accurately present a picture on dose" (urinary data), *id*. at 69; "contribute[] additional information" that "could potentially be very important to the

[49] Interestingly, Exponent, a consultant for the chromium industry, conducted a reanalysis of the Gibb study excluding the short-term workers, and submitted that reanalysis to OSHA. Occupational Exposure to Hexavalent Chromium, 71 Fed. Reg. 10,100, 10,118 (Feb. 28, 2006). OSHA found this reanalysis to be "useful" because "[i]t suggests that including cohort workers less than one year did not substantially alter the conclusions of [the Gibb study] with regard to the association between [hexavalent chromium] exposure and lung cancer mortality." *Id.* at 10,118.

field" (exposure data collection), *id.* at 70, and "more accurately accounted for * * * a potential confounding factor" (smoking history), *id.* However, the ALJ did not explain how this more accurate or additional information is non-corroborative of hexavalent chromium's lung cancer effect.

Like the ALJ, EPA-OCE adopts the position before the Board that the Mundt study is non-corroborative because it contains exposure information that is "new," "different," or "additional" compared to the exposure information in the Gibb study. EPA-OCE, however, attempts to supply the rationale missing from the ALJ's opinion as to how this exposure information is non-corroborative as to "dose." According to EPA-OCE, the new, different, or additional information does not corroborate dose because it "reduce[s] uncertainty about the hypothesis that the linear dose-response curve continues at lower exposure levels." EPA's Resp. Br. at 49. EPA-OCE relies on the testimony of Dr. Speizer for the proposition that adding information to reduce uncertainty is not corroboration in the field of epidemiology. EPA-OCE cites to Dr. Speizer's statement that: "It really is important that you actually have different investigators working in different populations. And that's not corroboration. That's adding information to the scientific base." Hearing Tr. at 552:16–20. In fact, Dr. Speizer holds a strikingly narrow interpretation of the term "corroboration," as the following disagreement between Dr. Speizer and EPA-OCE counsel reveals:

> Q. To the degree you have a series of studies that all point to that same conclusion, is it fair to say they corroborate one another, correct?
>
> A. They have made an association being interpreted as causal.
>
> Q. And in your mind that's not the same as corroborating the conclusion?
>
> A. Well, it isn't.

Id. at 553: 3–11 (questions by Mr. Chalfant for EPA-OCE).[50]

EPA-OCE's argument, however, fails because, under EPA guidance documents, non-corroborative information is not simply information that is new, different, or additional. Rather, these guidance documents repeatedly emphasize that non-corroborative information is information that "show[s] adverse effects of a more serious degree or a different kind," and as to non-corroborative dose information, that means information demonstrating that effects "occur at a significantly lower dose or concentration." *1993 Proposed Policy Clarification*, 58 Fed. Reg. at 37,739; *accord 1991 Reporting Guide* at 8. In a TSCA section 8(e) enforcement proceeding, the guidance documents' definition of the term "corroborate" controls, not the views of scientists about what the term means in general scientific usage. That is particularly true where, as here, EPA has used the term "corroborate" in its guidance documents in an idiosyncratic and somewhat counter-intuitive manner.

Importantly, EPA-OCE failed at the hearing before the ALJ to prove that the Mundt study showed cancer effects at a lower dose or lower intensity. EPA-OCE cannot reintroduce this claim by relying on testimony suggesting that the Mundt study "reduce[d] uncertainty about the hypothesis that the linear dose-response curve continues at lower exposure levels." EPA's Resp. Br. at 49. The "lower levels" about which the Mundt study reduced uncertainty were levels significantly higher than the level showing cancer effects in the Gibb study (or, at best, levels in the same range as the Gibb study). Reducing uncertainty about a dose-response relationship that is previously documented does

[50] If anything, Dr. Clapp took an even more narrow view of the term "corroboration." Dr. Clapp testified that "corroborate" means "replicate," Hearing Tr. at 463:16–19, and that an epidemiology study could never replicate findings from an earlier study unless those studies involve the same data sets – i.e., the same population over the same time period. *Id.* at 466:2–20.

not qualify as non-corroborative information under EPA's Corroborative Information Reporting Exemption.[51]

At times, EPA-OCE appears to argue that the ALJ-identified exposure information in the Mundt study is independently reportable as "new-found exposure data" apart from the support that information supplies for the study's cancer findings. *See id.* at 42 (the "new" exposure information in the Mundt study "directly addresses the Agency's definition of substantial risk in Agency guidance"); *id*. at 48 (the "new" exposure information in the Mundt study is reportable "when combined with the fact that lung cancer is an adverse effect of hexavalent chromium"). EPA-OCE is mistaken. EPA guidance documents have emphasized consistently that exposure data is only deemed reportable on its own merit if it shows exposure that is "extraordinary," Notification of Substantial Risk Under Section 8(e), 42 Fed. Reg. 45,362, 45,363 (Sept. 9, 1977), "widespread and previously unsuspected," *1978 Policy Statement*, 43 Fed. Reg. at 11,112; *1991 Reporting Guide* at 2; *2003 Policy Guidance*, 68 Fed. Reg. at 33,132, or "not only unknown, but considered unlikely based on previously available data,"[52] Frequent Questions: Sept. 2006 at A.27. There is

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[51] Further, EPA-OCE does not even address what the Mundt study itself concludes as to the shape of hexavalent chromium's dose-response curve. The Mundt study states that "[o]ur SMR [standard mortality ratio] results may suggest a threshold effect for chromium (VI)-induced lung carcinogenesis." *Collaborative Cohort Mortality Study* at 78 (CX 1 at 92). Thus, on its face, the Mundt study enhances understanding of the shape of hexavalent chromium's dose-response curve by raising questions as to whether EPA has been overly health-protective by assuming that the shape of the curve is linear at low doses (i.e., any exposure involves some risk). Again, this is the opposite of the sort of "dose" information that the guidance treats as non-corroborative.

[52] The centrality of the "previously unknown" criterion to the reportability of exposure information is confirmed by the process leading to the 2003 revision to the TSCA section 8(e) policy. In the 1993 proposal to revise the Policy Statement, EPA dropped the 1978 language that defined "environmental effects" as involving "[w]idespread and previously unsuspected distribution in the media," in favor of simply "widespread chemical contamination." *1993 Proposed Policy Clarification*, 58 Fed. Reg. at 37,741. A commenter challenged this change arguing that "for contamination to be reportable, it must be 'previously unsuspected' contamination." *2003 Policy Guidance*, (continued...)

nothing in the Mundt study suggesting that workers' exposure to hexavalent chromium is at levels "previously unsuspected" or "considered unlikely." To the contrary, EPA-OCE contended in the proceedings below, albeit unsuccessfully, that the Mundt study showed lower exposure levels than in prior studies.

As exemplified by the September 2006 interpretive statement, this is the opposite of when exposure reporting is required. In responding to a question as to whether new blood or urine exposure data should be reported, EPA wrote that such information should be reported if it "indicates a level of exposure previously unknown to the Administrator * * * * [But] [i]nformation that corroborates known exposure levels, such as those within the range of chemical blood levels and other biological monitoring data recording in the NHANES (National Health and Nutrition Examination Survey) data base, is not reportable." *Id.* at A.2.

Moreover, before this Board, EPA-OCE quotes EPA guidance out of context in claiming that the *1991 Reporting Guide's* call for the submission of "new-found exposure data" means that all new exposure-related data is reportable information. EPA's Post-Oral Arg. Br. at 3. The term "new-found exposure data" is used in the *1991 Reporting Guide* as a short-hand expression for data on "previously unknown and significant human and/or environmental exposure," as the following sentence shows:

> [T]he discovery of previously unknown and significant human and/or environmental exposure, when combined with knowledge that the subject chemical is already recognized or suspected as being capable of causing serious adverse health effects (e.g., cancer, birth defects, neurotoxicity) or serious environmental effects (e.g., non-trivial aquatic species toxicity), can provide a

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[52](...continued)
68 Fed. Reg. at 33,132. EPA agreed and re-inserted the "previously unsuspected" condition. *Id.* at 33,132.

> sufficient basis to report *the* new-found exposure data to EPA under Section 8(e) of TSCA.

1991 Reporting Guide at 2 (emphasis added). Thus, EPA-OCE's argument about the independent reportability of the exposure information identified by the ALJ is meritless.

Accordingly, the Board reverses the ALJ's finding of liability, as Elementis has established that, under the terms of EPA's guidance documents, it did not have a duty to report the Mundt study to EPA. Further, having reversed on liability, the Board also vacates the ALJ's penalty assessment.[53]

VI. *CONCLUSION*

The Board concludes that Elementis was not obligated to submit the Mundt study to EPA under TSCA section 8(e) in light of the Corroborative Information Reporting Exemption EPA provides in its guidance documents. We recognize that the evidence at the hearing suggested that the Mundt study supplies new and valuable information for use in the assessment of the lung cancer risk posed by hexavalent chromium. We also understand EPA-OCE's frustration with Elementis' behavior with respect to this study – i.e., publicly criticizing aspects of the Gibb study while possessing information from the Mundt study that might have undermined those criticisms and/or supported OSHA's rulemaking aimed at being more protective of human health. *See* EPA's

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[53] Given this disposition we have not reviewed the ALJ's penalty determination in depth. Nonetheless, we do note that we have questions regarding the appropriateness of the ALJ's use of a ten percent increase in the penalty amount to account for Elementis' "'attitude.'" Init. Dec. at 87–88. The ALJ made this extra adjustment based on what the ALJ described as Elementis' "efforts to subterfuge regulatory action" by OSHA. *Id.* at 87. However, in describing the factors to be considered in evaluating a person's attitude, EPA's TSCA penalty guidelines only mention factors related to a person's violation of EPA's regulations, not those of another agency. Guidelines for the Assessment of Civil Penalties under § 16 of the Toxic Substances Control Act, 45 Fed. Reg. 59,770, 59,773 (Sept. 10, 1980).

Resp. Br. at 40. Nonetheless, our decision is controlled, as it must be, by the language of the statute and EPA's long-standing interpretive guidance to the regulated community as to what the statutory requirements mean. Under EPA's guidance documents, otherwise reportable information is exempt from the TSCA section 8(e) reporting obligation if is "corroborative," which EPA has defined differently than the common meaning of the term – i.e., in EPA's guidance, information is corroborative if does not show that well-established adverse effect is "of a more serious degree or a different kind" than previously known. Information may very well be new, different, and valuable without showing an adverse effect to be substantially more serious.

The language of EPA's guidance documents thus is decisive in this case. As we have noted, we would have affirmed the ALJ's decision if we were limited to the plain language of TSCA section 8(e). EPA, however, has constrained the broad reach of the statute with its interpretation of what information EPA is "adequately informed of" in its guidance documents. EPA must honor the terms of its guidance while it remains extant. But nothing in this opinion suggests that the statute

compels the interpretation of the term "adequately informed" that EPA has chosen to provide in these guidance documents.[54]

So ordered.

[54] One alternative approach to the guidance's Corroborative Information Reporting Exemption could be to explicitly exclude epidemiological studies. As drafted, the guidance's Corroborative Information Reporting Exemption may function reasonably well for advising regulated parties on the reportability of animal studies. But the complexities of epidemiological data, and the testimony in this case explaining how epidemiological studies are used in an incremental fashion to establish scientific conclusions, may justify a quite different approach on reportability as to animal data and human epidemiological data. Another approach may be to exclude data from the Corroborative Information Reporting Exemption based on the adverse effect involved. For example, studies involving cancer can be particularly complex and controversial given the seriousness of the disease. Additionally, EPA's understanding of carcinogenesis continues to evolve. *See Carcinogen Risk Assessment* at 1-2, 1-7, 2-39, 2-49. Rather than struggle over devising criteria from distinguishing corroborative for non-corroborative cancer studies, it might be simpler for both EPA and industry to remove cancer studies from the Corroborative Information Reporting Exemption.

CERTIFICATE OF SERVICE

I certify that copies of the foregoing FINAL DECISION AND ORDER in the matter of Elementis Chromium, Inc., TSCA Appeal No. 13-03, were sent to the following persons in the manner indicated:

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Dated: MAR 13 2015

Annette Duncan
Secretary