

Environmental Appeals Board Issues Major Toxic Substances Control Act (TSCA) 8(e) Decision

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On March 13, EPA's Environmental Appeals Board's issued its long-awaited decision in the *Elementis* TSCA 8(e) case, reversing the ALJ's decision imposing a multi-million dollar penalty on Elementis. *In Re Elementis Chromium, Inc.*, TSCA Appeal No. 13-03 (March 13, 2015).

Section 8(e) of TSCA requires the "immediate" reporting of information which "reasonably supports the conclusion" that a chemical "presents a substantial risk of injury to health or the environment." In this case, an EPA ALJ levied a \$2,571,800 penalty against Elementis, alleging that an epidemiological study regarding hexavalent chromium completed in 2002 should have been reported to EPA under TSCA 8(e).

In perhaps the first reported decision that addresses the contours of TSCA 8(e) liability at such length, the EAB rejected Elementis' statute of limitations and statutory interpretation arguments, but found that the disputed study was not reportable based on EPA guidance providing that information is not reportable when EPA is "adequately informed" of the information. The key points are:

- The EAB rejected Elementis' statute of limitations argument, holding that the failure to submit TSCA 8(e) reports is a "continuing violation" and that the statute of limitations clock only begins to run when the disputed report is finally submitted.
 - In so doing, the EAB distinguished its own prior holdings that the failure to create annual PCB reports was not a continuing violation, and the Supreme Court's recent decision regarding the applicability of the "discovery rule" to SEC fraud cases. *Gabelli v. Sec. & Exch. Comm'n*, 586 U.S. ___, 133 S. Ct. 1216, 1221 (2013)
- The EAB rejected Elementis' argument that TSCA 8(e) only applied to a

single conclusory sentence in the disputed study, and not to the underlying data, methodological information, etc.

- In so doing, the EAB went through a lengthy analysis of what is meant by “information” that “reasonably supports a conclusion” that there is a substantial risk. The EAB noted that “information” is not limited to conclusions, and includes the underlying evidence, data, methodological information, etc. Such information reasonably support a conclusion if it “verifies, corroborates or substantiates” a substantial risk conclusion. According to the EAB, the term “reasonable” mandates a “degree of certainty,” and should not be speculative in nature. Commenting on the types of studies at issue in the case, the EAB observed that it can reasonably support a substantial risk conclusion if it is consistent with scientific principles for conducting such studies, is based on reliable data, and appropriate analytical and statistical tools are used to analyze the data. One cautions against taking the “degree of certainty” language too far, given that TSCA 8(e) requires the reporting of information that “reasonably supports” a conclusion, not just information that “demonstrates” or “proves” a conclusion.
- EAB nonetheless concluded that the study was not reportable because, pursuant to long-standing EPA guidance, the report corroborated a “well-established adverse effect” and therefore EPA was already “adequately informed.”
 - The EAB relied on EPA guidance stating that information was not corroborative when it newly identifies a serious toxic effect at a lower dose or confirms a serious effect that was only previously suspected. After a long discussion of what constitutes a “well-established adverse effect” and corroborative information, the EAB concluded that the disputed study reported a well-established effect regarding exposure to hexavalent chromium at higher doses than reported in previous studies. Therefore, though the study was reportable based on the statutory language, it was not when reviewed in the context of EPA guidance. Importantly, the EAB

rejected EPA's claim that the study was otherwise reportable as new exposure information, noting EPA guidance's is that new exposure information is reportable only if it is "previously unknown and significant human and/or environmental exposure," and that reporting on this basis is triggered if the exposure was not only unknown, but "considered unlikely based on previously available data" and was "previously unsuspected." The EAB concluded that the epidemiological information in the disputed study did not meet those criteria.

This is probably the most important TSCA 8(e) decision to ever come out of the EAB, and provides a level of detailed analysis never before provided in any TSCA 8(e) decision. So it bears close study by your TSCA 8(e) reporting team.

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