EMERGING CONTAMINANT SPOTLIGHT: ORTHO-PHTHALATES

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US Policy and Regulatory Alert

By: Dawn M. Lamparello

1,2-Benzenedicarboxylic acid esters, colloquially known as ortho-phthalates or simply phthalates, are a class of synthetic chemicals that were historically used in numerous industrial applications and in consumer products ranging from building and construction materials to cosmetics and food packaging. Despite significant reductions in phthalate usage in many applications over the past several decades—including in food packaging and cosmetics—the pace of scientific and legal developments surrounding phthalates has not slowed. In fact, several significant developments implicating phthalates within the past several months, as highlighted herein, may result in a renewed interest in phthalate regulation and the potential for litigation.

EPA RISK EVALUATIONS AND ASSESSMENTS UNDER TSCA

Among numerous significant developments pertaining to phthalates include the US Environmental Protection Agency (EPA) releasing final or draft risk evaluations steadily throughout 2025 under the Toxic Substances Control Act (TSCA) for seven phthalates: di-isodecyl phthalate (DIDP), di-isononyl phthalate (DINP), dicyclohexyl phthalate (DCHP), dibutyl phthalate (DBP), di-2-ethylhexyl phthalate (also referred to as di-ethylhexyl phthalate or DEHP), di-isobutyl phthalate (DIBP), and butyl benzyl phthalate (BBP). Specifically, in January, EPA announced the availability of its final risk evaluation for DINP and DIDP, which it had conducted in response to EPA receiving its first ever manufacturer requests for risk evaluations in May 2019.[1] EPA then released a series of draft risk evaluations over the course of several months for the five other phthalate chemicals pursuant to the terms of a Consent Decree the EPA entered into and that was signed by the US District Court for the District of Columbia on 22 November 2024, which resolved a majority of claims brought against EPA in *Community In-Power and Development Association, Inc. et al v. EPA*, No. 1:23-cv-02715-DLF. The EPA published the draft risk evaluation for DCHP in January,[2] the draft for DBP and DEHP in June,[3] and the draft for BBP and DIBP in August.[4] All of the comment periods have closed for these draft risk evaluations except for BBP and DIBP, which close on 6 October 2025.

As documented in the risk evaluations, EPA found that existing uses of certain phthalates presented unreasonable risks of injury to workers, consumers, the general population, or the environment. In circumstances in which a chemical is found to present unreasonable risk to health or the environment, as has been the case for certain phthalates, the chemical(s) will move to risk management action under the TSCA section 6(a) for the relevant conditions. Accordingly, further regulation of the seven implicated substances should be anticipated.

In addition to the above-mentioned risk evaluations, EPA also released a draft carcinogenicity assessment and an addendum (that included revised draft technical support documents) to the draft cumulative risk assessments for six of the seven phthalates: DEHP, DCHP, DBP, BBP, DIBP, and DINP. EPA concluded in the risk evaluations,

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carcinogenicity assessments, and cumulative risk assessments that none of the investigated substances were direct genotoxicants or mutagens and that DIDP, DINP, and DEHP are *not likely to be carcinogenic to humans*. Additionally, although no chronic toxicity or cancer bioassays were available for DIBP and DCHP, EPA concluded that there are not significant remaining scientific uncertainties in the qualitative and quantitative risk characterization for either of these substances. However, EPA preliminarily concluded that there is *suggestive evidence of carcinogenic potentia*l for BBP and DBP.

STATE LEGISLATION CONTROLLING PHTHALATE USE IN FOOD PACKAGING

State legislative efforts intended to reduce exposure to phthalates in food packaging is already underway and further developments in this arena are imminent. In January 2025, the Minnesota Senate introduced Senate File 188/House File 44, and in February 2025, the California Assembly Bill 1148 (known as California's Safer Food Packaging Act of 2025) was introduced to the State Assembly. The Minnesota bill would require food manufacturers and brand owners to test for and report the presence (or absence) of phthalates in packaged food products; it would also mandate that food manufacturers or brand owners that sell or distribute packaged food products in the state make testing results of all packaged food products publicly available by posting the results on a publicly accessible website. California's Assembly Bill 1148 would prohibit the manufacture, distribution, sale, or offer for sale in the state of any food packaging containing intentionally added phthalates above a limit to be specified, which expands on California's already passed Assembly Bill 1200 that banned phthalates in disposable food service ware. This proposed legislation follows similar and already enacted legislation controlling phthalates in food packaging in Maine (Me. Legis. L.D. 1433, 129th Legis. 2019), Vermont (18 V.S.A. § 1672, although it will be repealed effective 1 January 2026), and Minnesota (Minnesota Statutes § 34A.01, as amended by SF 188 / HF 44, effective July 2026).

PHTHALATES IN THE PRESS

Phthalates are also making headlines in the popular press and social media with many outlets publicizing the conclusions of a scientific journal article that attributed over 300,000 global deaths to DEHP in the year 2018 alone.[5] Authors of the study attempted to correlate cardiovascular mortality data and regional DEHP exposures to estimate burden, hazard ratios, excess deaths, and years of life lost allegedly due to DEHP exposures.

CONCLUSION

With these recent developments foreshadowing the potential for additional legislation, regulation, and litigation, industries that historically have used or continue to utilize phthalates should evaluate the significance of these developments on emerging business risks. Our Emerging Contaminants team is uniquely positioned to assist in matters relating to the evolving legal and regulatory landscape surrounding phthalates given our collective experience in such areas as chemistry and manufacturing, government agency administration and policy development, regulatory compliance, and litigation defense.

FOOTNOTES

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[1] 90 Fed. Reg. 638 (Jan. 6, 2025); 90 Fed. Reg. 3828 (Jan. 15, 2025); see also generally 15 U.S.C. § 2605(b)(4)(c)(ii).

[2] 90 Fed. Reg. 1125 (Jan. 7, 2025).

[3] 90 Fed. Reg. 23931 (Jun. 5, 2025).

[4] 90 Fed. Reg. 37855 (Aug. 6, 2025).

[5] Hyman, S., *et al.* (2025) “Phthalate exposure from plastics and cardiovascular disease: global estimates of attributable mortality and years life list” *eBioMedicine* 2025, Volume 117, 105730

KEY CONTACTS



DAWN M. LAMPARELLO
PARTNER

NEWARK
+1.973.848.4148
DAWN.LAMPARELLO@KLGATES.COM

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