

TOXIC AND HAZARDOUS SUBSTANCES LITIGATION

November 2019

IN THIS ISSUE

In New York's Executive Budget for Fiscal Year 2020, Governor Andrew Cuomo proposed a Prop 65-type scheme applicable to "consumer" and personal care products, for the purpose of providing consumers with information about chemicals contained in those products, including whether the ingredients were "chemicals of concern." While this has not yet become law, the proposed scheme presents an overbroad and ill-defined regulatory web and potential fodder for litigation.

Is an East Coast Version of Prop 65 in Our Future?

ABOUT THE AUTHOR



Paul V. Majkowski is a partner in Rivkin Radler LLP's Complex Torts and Product Liability group. His practice focuses on defending claims for personal injury and property damage purportedly arising out of alleged exposure to herbicides, pesticides, and other chemicals, in domestic and international venues. He can be reached at paul.majkowski@rivkin.com.

ABOUT THE COMMITTEE

Member participation is the focus and objective of the Toxic and Hazardous Substances Litigation Committee, whether through a monthly newsletter, committee Web page, e-mail inquiries and contacts regarding tactics, experts and the business of the committee, semi-annual committee meetings to discuss issues and business, Journal articles and other scholarship, our outreach program to welcome new members and members waiting to get involved, or networking and CLE presentations significant to the experienced trial lawyer defending toxic tort and related cases.

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Craig T. Liljestrand
Vice Chair of Newsletters
Hinshaw & Culbertson LLP
cliljestrand@hinshawlaw.com

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Earlier this year, New York Governor Andrew Cuomo included in his Executive Budget a proposed “Consumer Right to Know Act,” applicable to consumer and personal care products.¹ If enacted, this law would impose requirements on companies to disclose chemical ingredients and whether such chemicals have been identified as chemicals of concern -- in other words, an East Coast version of Prop 65.

In explaining the intent and purpose of the legislation, the Governor’s draft sets forth:

[C]onsumers in the state do not have ready access to information about the products they may use and the product ingredients they may be exposed to every day. . . . [M]ore must be done to give consumers real time access to product ingredient information so consumers can make informed decisions about which products to buy and use. . . . [C]onsumers should have the right to know if a product contains a carcinogen, mutagen or endocrine disruptors and other chemicals of concern [and] the state, as trustee of its natural resources should have the means to identify substances which may be discharged to the environment.”

With respect to personal care products especially, part of the impetus of the legislation is a lack of federal regulation. Finding that federal law “fails to adequately educate and protect consumers,” the New York law would “empower consumers with the information needed to make well-informed decisions regarding products that their families are exposed to daily,” by “requir[ing] the personal care product industry to more fully disclose the ingredients they use and, where applicable, identify ingredients that have been published as a chemical of concern on one or more lists identified by the commissioner [of health].”

As some consolation, unlike the California scheme, the initial proposal does not include a “bounty hunter” provision, relying only on departmental measures and civil penalties for enforcement.

Nevertheless, the enhanced labeling and disclosure requirements that would be imposed under such legislation places potentially significant burdens on companies. For example, in the personal care products section, required disclosures would include: (i) a list of each ingredient; (ii) “The nature and extent of investigations and research performed by or for the manufacturer concerning the effects on human health and the environment of such product or such ingredients”; and (ii)

¹ See FY 2020 New York State Executive Budget; Transportation, Economic Development and Environmental Conservation; Article VII Legislation; Part K (amending Environmental Conservation Law by adding

new Title 9, Consumer Product Disclosure, and Public Health Law, adding new Article 48-A, Regulation of Personal Care Products).

whether “an ingredient is published as a chemical of concern on one or more lists identified by the commissioner.”

For the category of “consumer products,” the labeling and disclosure requirements are left to the Department of Environmental Conservation, although such authority is similarly inclusive of regulations requiring labeling of ingredients containing “any carcinogen, mutagen, endocrine disruptor or other chemical of concern” and disclosure of “investigation and research” done by the manufacturer. Note that the definition of a “consumer product” falling with the legislation is extremely broad, including: (i) cleansing products; (ii) any product used or reasonably expected to be used by children; and (iii) a catch-all category encompassing any other product “that could, through normal use, expose the user to any carcinogen, mutagen, endocrine disruptor or other chemicals of concern.”

In addition to the immediate burdens of complying with new disclosure and labeling requirements, despite the lack of a bounty hunter provision, the identification by regulators of so-called “chemicals of concern” would likely be potential fodder for litigation as well, if not as traditional toxic tort actions, then as consumer class actions.

One of the troubling parts of this proposed regulatory scheme is the vague delineation of standards for whether a chemical falls inside or outside the scheme. Two aspects are worth highlighting: first, the reliance on lists of so-called chemicals of concern

developed by various agencies, and second, the broad catch-all definition of a regulated consumer product as anything that might “expose” the user “through normal use” to “any carcinogen, mutagen, endocrine disruptor or other chemicals of concern.”

On the first point, such reliance on “lists of chemical of concern” would seem to invite the sort of debate that has been generated, most recently in the glyphosate context, where the assessment of the International Agency for Research on Cancer (IARC) conflicts with the regulatory findings of the United States Environmental Protection Agency (EPA), Canadian Pest Management Regulatory Agency (PMRA) and European Food Safety Agency (EFSA) and others. On one hand, the IARC determination that glyphosate is “probably carcinogenic” is touted in support of such claims, and on the other hand, the findings of USEPA, EFSA and PMRA not assessing glyphosate to be a cancer risk is used to refute them.

Part of the contradiction in this particular debate arises from the differing nature of IARC’s and the regulators’ findings. The regulators consider “risk,” while IARC considers merely “hazard” in that IARC does not consider the likely human exposure or dose of the substance at issue.

Furthermore, as the Roundup MDL judge observed, the various reports are themselves only “secondary” sources of what the science shows.

The IARC and EPA reports analyze studies that were previously conducted on the carcinogenicity of glyphosate. The experts in this case will need to do the same thing—that is, they will need to analyze the studies themselves and offer opinions about what they show. The opinions of the IARC and EPA about what the studies show, while important, are secondary.²

While not explicitly articulated in the Roundup ruling, another issue with the “lists” on which the New York regulations would rely is that the processes under which the lists are developed are frequently criticized for lacking transparency.

On the second point, the definition of a consumer product that would trigger regulation, while seeming to acknowledge the need to consider exposure as part of whether a chemical poses a risk, also presents issues and overbroad results. Under the definition, a product would become subject to regulation if the user could be (1) exposed, (2) through normal use, to (3) *any* chemical of concern. This “test” poses several problems.

First, an inquiry of “exposure” alone is insufficient; rather, the necessary element is

whether the user was exposed “in a manner that can result in absorption into the body.”³

Second, that the presence of “any” carcinogen, etc. would render a product subject to regulation ignores the concept of a threshold or no observable effect level, which exposures would not be considered a toxic risk.⁴ The problem with ignoring a threshold level is exacerbated by ever increasingly sensitive detection technology, so that an “any” level standard would almost invariably be satisfied. Accordingly, the definition is overbroad.

Third, the notion of “normal use” is ambiguous and consideration of “normal use” would seem impractical. Too many variables that would complicate any attempt to consider evaluate “exposure”; how would a “normal use” element account for, for example, differences between a single use and repeated use, the use or failure to use safety precautions as directed, other ordinary circumstances of use, such as the effect of clothing as a barrier to dermal absorption?

While such factors that are recognized elements of a showing of legal causation are arguably not required for a regulatory standard, the New York standard strays too far away from such basic elements of toxicology to provide an appropriate

² *In re Roundup Prods. Liab. Litig.*, MDL No. 2741 (N.D. Cal. Mar. 13, 2017).

³ B. Goldstein and M.S. Henifen, “Reference Guide on Toxicology” in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 666 (Fed. Jud. Ctr. 3d ed. 2011).”

⁴ *Id.* at 669-70 (“If exposure to the substance is associated with the disease, is there a no observable effect, or threshold, level, and if so, was the individual exposed above the no observable effect level?”).

framework for analysis, leading to overbroad and burdensome regulation. In turn, the scheme would present foreseeable litigation opportunities for plaintiffs, as well as increased environmental regulation and litigation when a focus turns to how the wastes from such products and their chemicals of concern are being disposed.

The definition of such standards should be watched carefully during the legislative process, as well as in any administrative rule-making that follows if the legislation becomes law. Thereafter, application of such rules will inevitably engender disputes over interpretation of the “science.” Companies can expect to need to have processes in place to address the science and head off potential controversies. This proposal bears close watching.

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