September 20, 2021

Martin Brand
Deputy Commissioner
New York Department of Environmental Conservation
Division of Remediation and Materials Management
625 Broadway
Albany, NY 12233-7252

Re: Comments on NYDEC Program Policy DMM-2, Guidelines for Waiver Process per ECL 35-0105(6) and ECL 37-0117(7)

Dear Mr. Brand:

I write on behalf of The American Cleaning Institute® (ACI)[1], the Personal Care Products Council (PCPC)[2], Consumer Healthcare Products Association (CHPA)[3], Consumer Brands Association (CBA)[4], Household & Commercial Products Association (HCPA)[5], and American Chemistry Council (ACC)[6] regarding the New York State Department of Environmental Conservation's (NYDEC) implementation of the Environmental Conservation Law (ECL) Articles 35 and 37 that established maximum concentrations of 1,4-dioxane in household cleansing, personal care and cosmetic products and included provisions to allow a manufacturer to apply for a one-year waiver from compliance, up to two times under Program Policy DMM-2. These comments are in response to the recently released Guidelines for Waiver Process, which sets forth the process for manufacturers to submit a waiver request and clarifies the proof DEC will require to grant a waiver.

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[1]ACI represents the $60 billion U.S. cleaning product supply chain. ACI members include the manufacturers and formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and chemical distributors. ACI serves the growth and innovation of the U.S. cleaning products industry by advancing the health and quality of life of people and protecting our planet. ACI achieves this through a continuous commitment to sound science and being a credible voice for the cleaning products industry.

[2]Based in Washington, D.C., PCPC is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States. As the makers of a diverse range of products that millions of consumers rely on every day, from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance, member companies are global leaders committed to product safety, quality, and innovation.

[3]The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org.

[4]The Consumer Brands Association (Consumer Brands) champions the industry whose products Americans depend on every day, representing more than 1,700 iconic brands. From household and personal care products to food and beverage products, the consumer packaged goods industry plays a vital role in powering the U.S. economy, contributing $2 trillion to the U.S. GDP and supporting more than 20 million American jobs.

[5]The Household & Commercial Products Association (HCPA) is the premier trade association representing companies that manufacture and sell $180 billion annually of trusted and familiar products used for cleaning, protecting, maintaining, and disinfecting homes and commercial environments. HCPA member companies employ 200,000 people in the U.S. whose work helps consumers and workers to create cleaner, healthier, and more productive lives. Our mission is to protect, promote, and enhance the household and commercial products industry and the consumers and workers who use our members' products. Products represented by HCPA are divided into seven product divisions: Aerosol, Air Care, Antimicrobial, Cleaning, Floor Care, Industrial & Automotive, and Pest Management products.

[6] The American Chemistry Council (ACC) is a national trade association representing chemicals and plastics manufacturers in the United States, including member companies in New York State. Our members are committed to the safety of their products and to the protection of the public health. Over 96% of all manufactured goods are directly touched by the business of chemistry, making this industry an essential part of every facet of our nation's economy. Over 38,000 people are employed by the chemistry industry in New York State.

General Provisions

- The Department should explain the standards and criteria that it intends to apply to brick codes to make product category determinations.

Definitions

- The absence of a clear definition that distinguishes between manufacturers, distributors and retailers creates ambiguity. As written, the Program Policy places liability on manufacturers who sold product which, at the time of sale to a distributor, was in full compliance with the ECL. The Program Policy should address this situation by indicating that a sale by a manufacturer ends the chain of liability. See below our comment regarding sell through provisions. It is important for the department to recognize that manufacturers generally are not "owners" of the products after it leaves the facility of origin and enters the distribution chain.

Products in Scope

In Appendix A of the Program Policy, NYDEC listed several OTC drug products as "cosmetics", including sun protectant products (sunscreens), antiperspirants, and acne treatments. However, OTC drugs are neither 'cosmetics' nor 'personal care products'–indeed, they are classified and regulated separately as **drugs** by the U.S. Food and Drug Administration. They are decidedly out of scope from this law.

Unlike cosmetics or personal care products, OTC drug products are subject to federal monographs, which are developed and published in the Federal Register. Monographs are like recipe books that companies must follow, and formulated OTC drug products must comply with these very detailed monographs, which address ingredients, concentrations, formulations, and even labeling, before they can be marketed in the U.S.

The underlying law only covers (1) household cleansing products (2) personal care products, and (3) cosmetic products. Drugs are *not* within scope, and OTC drug products are *drugs*. As such, the policy should be amended to reflect this reality.

Waiver Operation and Requirements

- Our members are still operating under pandemic conditions. Therefore, we urge the Department to provide timely certainty via the waiver process so as to avoid significant disruptions in the availability of cleaning products for New York consumers. Given the long lead time for the manufacturing and distribution of covered products, the relatively short duration of the waivers and the Department's assurance, announced in Subsection V.E, that it "will take no longer than six months to" act on a waiver application. We recommend that in the event a manufacturer who does not receive written notice that its waiver request has been rejected within six months should be entitled to rely on an approval by default.

- Similarly, the Department is urged to grant waivers based upon a certification that there are no alternatives or replacement ingredients readily available in the marketplace that would be related to or result in less than trace amounts of 1,4 dioxane, where such alternatives are equal or better in product performance, including performance across the full life cycle of the ingredient and consumer product, compared to the present formulation of the identified household cleansing product. This degree of certainty could mitigate significant disruptions within the broad retail supply chain. Distributors,

resellers, and especially retailers–which play a paramount role in supplying communities with products, require a firm timetable. Ambiguity will only lead to imbalances in the supply chain, which we believe is not the intent of the policy.

- The first sentence of Section V.B should provide that manufacturers who submit timely waiver requests containing the required justification will qualify for a waiver; conversely, the Program Policy should not use the phrase "may obtain a waiver" to imply that granting waivers is discretionary. These waivers are provided for in the ECL and the Department's role in granting waiver is ministerial. Accordingly, the opening sentence of this Section should be revised as follows: "This document details the process by which the Department shall grant manufacturers ~~may obtain a~~ waivers ~~of the requirements of~~ as provided for by ECL 35-0105(4), 37-0117(3), or 37-0117(4)."

- The option to submit product-based concentrations of 1,4-dioxane includes the requirement that manufacturers "must be able to produce documentation of the applicable maximum 1,4-dioxane trace concentration" including test results "if requested" is different than what the comment response summary suggests when stating "this Program Policy does not require manufacturers to test the products for which they are seeking a waiver." If the department is requiring testing it should be clear within the policy.

- Under Subsection D.1.a, the Program Policy should establish what testing criteria/methods are acceptable to the Department. The aforementioned trades provided extensive and detailed comments on the Department's draft "Method Performance Criteria (MPC)."

- A significant number of products are sold in concentrated form and manufacturers will need to rely upon the intended dosing and dilution instructions provided to consumers to demonstrate compliance with the ECL. The Program Policy should confirm that the calculation of concentration of 1,4-dioxane is based on the "as used" concentration.

- The final portion of Subsection D.1.b should be amended as follows: "and an attestation that no other ingredients in the product ~~would~~ are known to contain 1,4-dioxane."

- Many of our members are working closely with suppliers to achieve compliance with the ECL. The Department should allow safety data sheets and other technical specifications to serve as the 'certifications' from suppliers permitted by Section D.1.b.

- Appendix D and E do not define what constitutes an acceptable explanation about efforts to reduce concentrations of 1,4-dioxane in products. Without this explanation, the Program Policy fails to provide manufacturers and Department staff critical information. Further, there are no definitive criteria set forth for the Agency to reject a waiver. These issues should be addressed by the Agency.

- Subsection V.F states that to renew a waiver a manufacturer must "include the original information." Such duplication is unnecessary. It should be sufficient for a waiver renewal to reference the prior application/approval and certify that the justification remains unchanged.

- Appendix D was not an active link in the version of the draft made available to us.

Sell Through Provisions

The Department has adequate authority to provide guidance on the reasonable treatment of current available-for purchase 'store shelf' product caught between implementation periods. Because Department elected not to include a 'sell through' provision in Subsection V.G (to ensure that compliant products with less than allowed trace amounts manufactured before a specified waiver expiration date remain in compliance even if sold to consumers after the expiration of the waiver), and considering the ambiguities in the definition of manufacturer, it is incumbent upon the Department to clearly provide that a manufacturer only 'distributes, sells, offers or exposes products for sale in this state' upon its initial transfer to a reseller or distributor. See also our comment regarding the two-part test for 'manufacturer.'

Thank you for your attention to our comments and we look forward to further engagement on this matter. Please contact: Arielle Brown (ACI) abrown@cleaninginstitute.org; Michael Gruber (CBA) mgruber@consumerbrandsassociation.org; or Michelle Kopa (HCPA) mkopa@thehcpa.org; Tom Myers (PCPC) myerst@personalcarecouncil.org if you have questions.