american cleaning institute®

February 12, 2024

Carmelle Sanders
NYS DEC - Division of Materials Management
625 Broadway, Albany, NY 12233-7253

Re: Comments on Proposed Subpart 352-1 1,4 Dioxane Limits for Household Cleansing, Personal Care, and Cosmetic Products

The American Cleaning Institute (ACI) – the association for detergent and cleaning product manufacturers – has a vested interest in policies regarding 1,4-Dioxane. ACI and its members have been engaging with the legislature and the New York Department of Environmental Conservation (Department) since Articles 35 and 37 of the Environmental Conservation Law (ECL) were amended in 2019. We have also been authoring peer-reviewed research regarding the measurement of 1,4-Dioxane in cleaning products, and supporting our industry's work to reduce the concentration of 1,4-Dioxane in cleaning products through product reformulation and the introduction of new manufacturing technologies. Our industry has made great strides to remain in compliance with the law and achieve the law's intent all while continuing to provide consumers with effective and safe cleaning products. We welcome the opportunity to provide comments on the proposed rule for Subpart 352-1.

Definition of "Household cleansing product"

The draft rule proposes a new definition for "household cleansing product" from what has already been published in statute under Environmental Conservation (ENV) law Chapter 43-B, Article 35. There is a meaningful difference depending on how this new definition is interpreted that will cause confusion and change how the Department and manufacturers have been determining what is in scope of this program as it has been implemented thus far. The rule adds "and other similar products that include an antimicrobial agent" in defining the products that are in scope. It is unclear if the intent of the addition of this language is to explicitly include antimicrobial cleaning products in the definition, or if based on the format of the sentence, to limit the scope of the definition to only those products that include antimicrobial agents in addition to surfactants and the specified uses. Furthermore, both the statute and rule explicitly exclude "drugs" and "pesticides" from the definition of cleaning products – complicating how the reference to antimicrobials is to be interpreted. For instance, hand soaps with antimicrobial properties are regulated by the U.S. Food and Drug Administration as an over-the-counter (OTC), non-prescription drug. These products must comply with an OTC Monograph which outlines the conditions of use for the active ingredient (e.g., an antimicrobial) in the product. In addition, the definition explicitly excludes pesticides from the definition of "cleansing product" and under New York law disinfectants and sanitizers are included in the definition of pesticide. In both instances, the proposed new definition will expand the restriction to product categories that are expressly excluded by the legislative language of the law. It is not our understanding that these changes to the definition were intended to significantly modify the range of products that would be identified as cleaning products, but they may. Therefore, we ask that the definition of "household cleansing product" remain the same as that which is already in statute.

Definition of "Manufacturer"

In any regulatory regime it is important that a responsible entity be identified for compliance purposes. ACI understands that manufacturers will bear the responsibility of ensuring that the products they sell to consumers are compliant with the law. This rule recognizes that an intricate supply chain may exist for a product where it is possible for various entities to reasonably be considered the manufacturer for legal purposes. The definition drafted in the rule adequately identifies the multitude of entities that may exist in bringing a product to market. However, without including a hierarchical element to the definition, the definition would inadvertently consider each entity the responsible party at the same time without clarifying which party would in fact bear the responsibility. Therefore, we suggest that the five entities listed in the definition of "manufacturer" be structured in a way that if party one (1) cannot be identified then party (2) be the responsible entity, so on and so forth. Doing so would still direct responsibility to upstream manufacturers first, but would establish a systematic method for identifying the next responsible entity if necessary and avoid confusion with compliance.

Formula Variation Concerns

The rule requires manufacturers to conduct compliance evaluation through the documentation of raw material suppliers, assessing the sum of concentrations from each raw material, and/or analytical testing. In Subpart 352-1.5 the rule adds that "if a manufacturer is aware or anticipates that variation may exist between formulations…which may affect the concentration of 1,4-dioxane in the product, such that it would alter compliance with applicable thresholds…the manufacturer must conduct the product's compliance evaluation action for the formulation that the manufacturer expects to result in the highest 1,4-dioxane concentration and which may be distributed, sold or offered for sale in the State." We support the intent of this language. However, we are concerned that in the event that the concentration of 1,4-Dioxane in a finished product changes *after* the product has been packaged and distributed in a manner *unanticipated* or for a reason unbeknownst to the manufacturer, a manufacturer could be charged with non-compliance. Further, if a product is tested by another entity that is not the manufacturer and finds different results, this language could likewise lead to lawsuits and litigation despite a manufacturer's own documentation illustrating otherwise. Therefore, it is important that 1) safeguards are in place that allow a manufacturer to demonstrate compliance, 2) factors that may affect the concentration of 1,4-Dioxane are understood (by both manufacturers and regulators), and 3) a process be in place that allows a manufacturer to demonstrate their documentation represents to the best of their knowledge that their evaluation was conducted on the formulation with the highest concentration of 1,4-Dioxane.

Accommodating Concentrated Products or Bulk Purchases

Concentrated and refill concentrate products contain less water in the formula, yielding environmental benefits. Some concentrated and refill concentrate products are sold in solid form with no water in the formula, yielding even more environmental benefits. As a result, the concentrations of ingredients as well as by-products in the formula are higher versus ready-to-use products. However, the amount of ingredients/chemicals that are used during product application on a single dose basis is still similar to ready-to-use products. This means the amount of chemicals that goes down the drain and eventually enters the environment is also similar.

The revisions to ECL 35 and 37 set a uniform limit for 1,4-Dioxane across all product forms which penalizes concentrated and refill concentrate products, and may prompt manufacturers to dilute such products with water as the easiest way to comply. However, this approach does not meet the spirit and intent of this statute because there is no reduction in the overall amount of

1,4-Dioxane entering the environment since users will consume higher volumes of the diluted products to achieve desired results.

Reforming concentrated detergents to lower 1,4-Dioxane levels is particularly challenging. Due to very low water content, concentrates can only use a narrow range of ingredients that can be solubilized under such conditions. For the same reason, concentrated products must rely on the alcohol ethoxysulfate (AES)-based surfactant system. AES is a surfactant associated with 1,4-Dioxane as a byproduct. The rule should include allowance for manufacturers to use a dilution calculation to demonstrate compliance in a finished product for concentrated products. The current guidance references a calculation for application of a waiver with a restrictive testing requirement but does not carry over that guidance to compliance with the final thresholds. If manufacturers lose the ability to market concentrated products to consumers due to the inequity in application of the standard, many may move away from these products with the unintended consequence of losing the environmental benefits gained from concentrated products (e.g., less water usage, less packaging, less energy consumption, etc.). More information about the impact of this law on concentrated products is attached.

California's volatile organic compound regulations recognize the benefits of concentrated consumer products. For refill applications, the Department should include language adapted from California Code of Regulations Title 17 § 94509 (b) to read "For consumer products for which the label, packaging, or accompanying literature specifically states that the product should be diluted with water prior to use, the limits shall apply to the product only after the minimum recommended dilution has taken place."

Method Performance Criteria

ACI staff and interested parties have committed significant resources to conduct peer-reviewed research relating to methodologies to measure 1,4-Dioxane at such miniscule concentrations like those that are referenced in this law. Much of this research was conducted in light of New York's law to assist the cleaning product manufacturers that sell across state lines, and to inform interested stakeholders about the state of the science. Two research articles that we believe are important to reference are "Precise measurement of 1,4-dioxane concentration in cleaning products: A review of the current state-of-the-art" (Hayes et al, 2022) and "A novel protocol for quantitative determination of 1,4-dioxane in finished cleaning products" (Palumbo et al, 2023). These two pieces together assess the methodologies used to quantify 1,4-Dioxane in surface and drinking water (and extends that assessment to commercially available products), and assess a novel approach to measuring 1,4-Dioxane in cleaning products specifically.

Based on the research referenced above, and what has been proposed in the rule, we have identified some areas for refinement.

- **Compliance Analysis Selection**: Subpart 352-1.5 (a)(2) should be amended to read as follows to conform with language in the rule that one or more of the following analyses are permitted. "A reasonable assessment by the manufacturer of the sum of the concentrations of 1,4-dioxane contributed by each raw material in the finished product formulation; ~~and~~ or…"

- **Method Performance Criteria**: Subpart 352-1.6 (a)(2) indicates that an isotope dilution method *must* be used, which implies spectrometer-based methodology. Gas chromatography–mass spectrometry is critical for third party labs which are not able to

complete true method validations for all products they may work with. Manufacturers and others in the cleaning product supply chain do not necessarily use mass spectrometry-based methods for regular, ongoing commercial process control strategies. For example, one technique that is used is flame ionization detection which has been shown to enable adequate selectivity and sensitivity across ethoxylated raw materials. While isotope dilution is the best practice for gas chromatography mass spectrometry-based methodologies (especially on unknown formulations), it is not necessary for high quality raw material measurements. This language is problematic due to the point the rule makes that "a manufacturer may utilize any analytical method to assess compliance," and as evidenced by research conducted by Hayes et al (2022), other analytical methods are available. For instance, this research found that bromofluorobenzene and tetrahydrofuran can be used as less expensive substances for internal standards and 1,4-Dioxane-d_8 does not always need to be used. Therefore, the rule should allow for manufacturers to demonstrate process control strategies which rely on method validation for each specific material that brings trace 1,4-Dioxane potential.

- **Calibration Concentration Curve**: Subpart 352-1.6 (a)(4)(iii) should be amended to read "The initial calibration must utilize at least ~~five~~ four non-zero calibration concentrations. For process control strategies, a wide calibration range may not be necessary, and a 4-point calibration curve is sufficient.

- **Calibration Verification:** Subpart 252-1.6 (a)(4)(iii)('a") and ('b') outline the acceptance criteria for initial equipment calibration and continuing calibration verification. It is common for criteria for these two processes to be the same, however, the rule proposes different accepted ranges from the true value. We propose matching the initial calibration verification with the continuing calibration verification with the following amendment in ('a'): "An initial calibration verification standard solution, with a concentration at or near the mid-point of the calibration curve, must be analyzed immediately following the initial calibration and be within ~~30~~ 20 percent of its true value."

- **Extraction Recovery:** Subpart 352-1.6 (a)(5) outlines quality control procedures that demonstrate extraction recovery between 70 and 130 percent of the expected analyte concentrations. There is a desire to tighten this range to avoid discrepancies between manufacturers and labs doing enforcement testing. Our own research demonstrates a range of 90-110 percent is achievable. Further discussion is needed, and consideration should be given to different ranges for extraction recovery percentages for spiking at either the limit of detection or the limit of quantitation level; therefore, the rule should clarify the spiking level.

As scientific technologies advance, and if new test methods, techniques and standards are developed, we ask that the Guidelines referenced here continue to adhere to sound, reliable and peer-reviewed procedures.

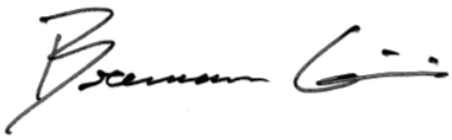
Compliance Timeline

The rule rightly requires that manufacturers conduct compliance evaluations and retain records of such evaluations. Further, the rule requires that this documentation be submitted to the Department upon request within 15 days. We respectfully ask that the timeframe for a

manufacturer to respond be extended to a more reasonable 30 days to ensure that complete documentation can be collected and submitted.

We would like to reiterate that a foundation in science is at the core of ACI's activities and engagement. Our members will continue to pursue the advancement of safe and beneficial cleaning products for the communities we serve. We hope the Department will take time to contemplate ACI input on this proposed rule and notify us if clarification is needed. ACI looks forward to providing necessary input regarding the performance of our products to achieve desired policy goals.

Sincerely,



Brennan Georgianni
Senior Director, State Government Affairs
BGeorgianni@cleaninginstitute.org

The Shifting Effects Of The New 1,4-Dioxane Law

Concentrated/Compacted Product,
10 ppm 1,4-Dioxane
(20% Surfactant)

25 ml Needed for Cleaning Task

50 mg of 1,4-Dioxane

1X Product,
5 ppm 1,4-Dioxane
(10% Surfactant)

100 ml Needed for Cleaning Task

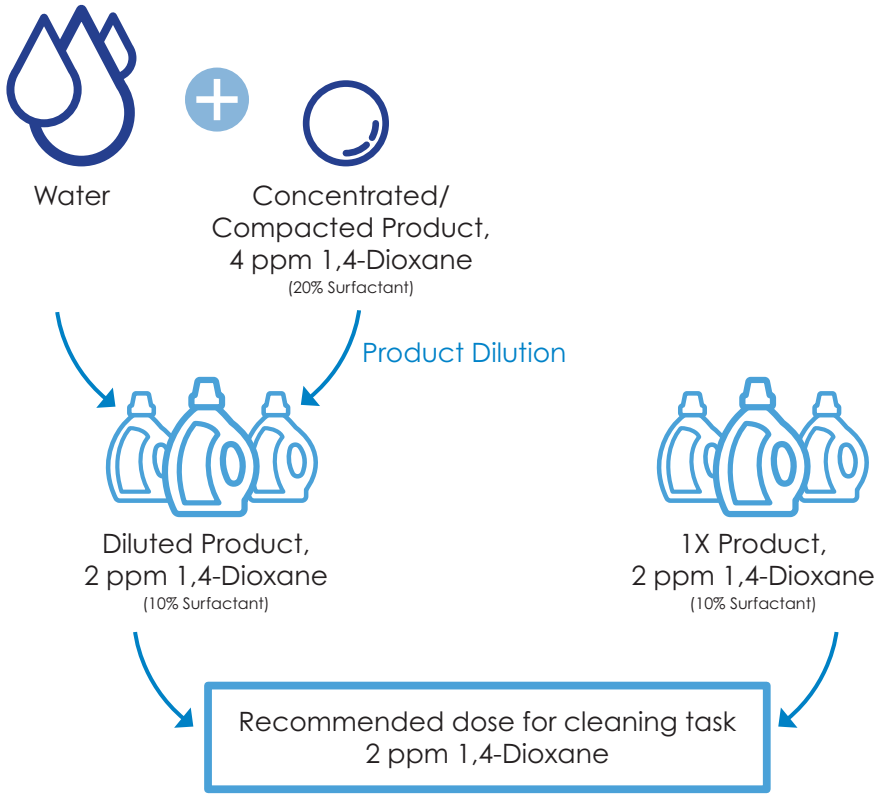
50 mg of 1,4-Dioxane

Same level of 1,4-Dioxane because more 1X product is needed for the same cleaning task.

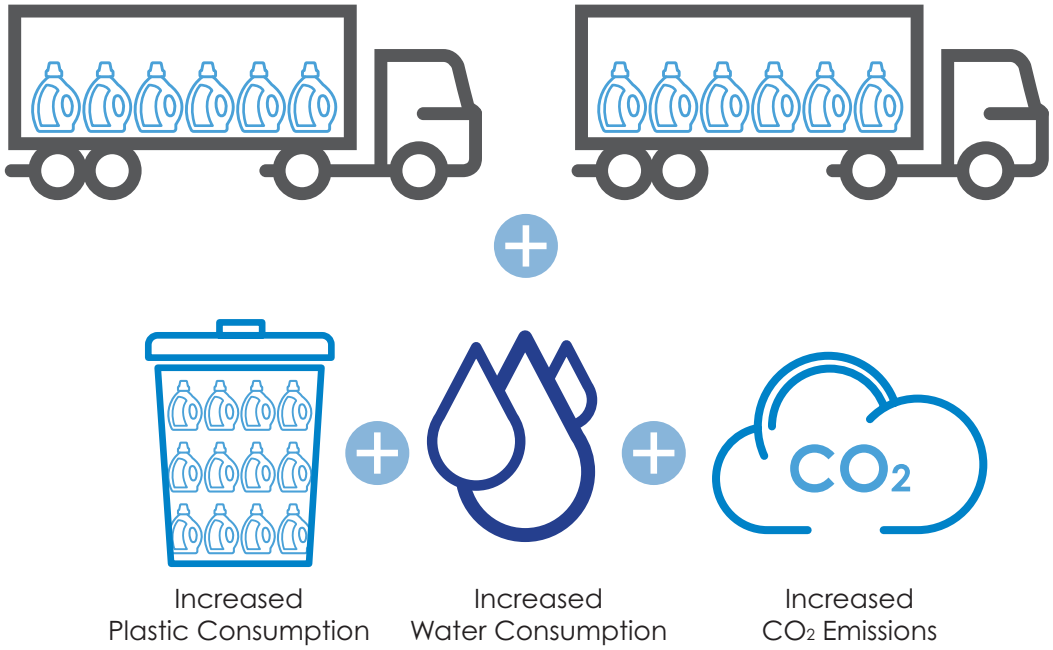
american cleaning institute®
www.cleaninginstitute.org

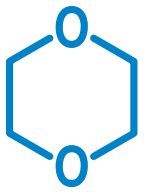
The Shifting Effects Of The New 1,4-Dioxane Law

POTENTIAL 2022 SHIFT FOR THE MANUFACTURER



POTENTIAL EFFECT ON OUR ENVIRONMENT





1,4-Dioxane

Some manufacturers may choose to (or need to) dilute their products to bring them into compliance of 1,4-Dioxane byproduct. In addition, this introduces the possible consequences displayed in the above graphic.

american cleaning institute®
www.cleaninginstitute.org