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Ms. Meredith Williams
Acting Director
California Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814-2828

RE: 1,4-Dioxane in Personal Care and Cleaning Products

Dear Ms. Williams:

ISSA, the worldwide cleaning industry association, appreciates the opportunity to comment on the proposed regulation of 1,4-Dioxane in personal care and cleaning products by California's Department of Toxic Substances Control (DTSC) under the Safer Consumer Products program.

ISSA represents more than 9,300 distributor, manufacturer, manufacturer representative, building service contractor, in-house service provider, residential cleaning, and associated service members. Primarily we serve members in the industrial and institutional cleaning space, which often use different versions of cleaning products than those found on a retail store shelf.

1,4-Dioxane is not intentionally added and typically exists in trace amounts in all cleaning product categories as an unavoidable byproduct of the manufacturing process. 1,4-Dioxane is present in trace amounts as a contaminant as a result of the manufacturing process of ethoxylated and sulfated ingredients.

While more can and should be done to reduce the presence of 1,4-Dioxane in personal care and cleaning products, we do not believe DTSC should broadly regulate these products without additional scientific research and data. There is not enough science or data to support DTSC proposing an alternatives analysis threshold (AAT) of 1 ppm.

If DTSC decides to move forward, we suggest the department take into consideration the following concerns of our members when crafting the regulations:

1. The regulations should be based on the end-use amounts rather than the more concentrated form used in closed dilution systems that are used extensively by professionals in industrial and institutional facilities.
2. Any regulations should include a validated method of measuring threshold levels.
3. Any 1,4-Dioxane limit should be a reasonable threshold that can be measured reliably and doesn't compromise the efficacy of cleaning products.

First, with any rules, regulations, or limits on 1,4-Dioxane, we ask that you keep in mind that our members utilize highly concentrated institutional-use products. The reliance on concentrated products by the institutional markets results in environmental benefits because it reduces the need to transport water resulting in extensive energy savings and substantial reductions in emissions caused by transportation; and perhaps more importantly significantly reduces packaging waste. Institutional-use products generally contain higher levels of 1,4-Dioxane because of the concentrated nature of the products. Once they are transported and diluted by trained professionals to their end-use form the 1,4-Dioxane levels are similar to the consumer product equivalent found in retail stores. We urge you to base your regulations on the end use measurement to ensure these more concentrated cleaners are treated similarly so that the above stated environmental benefits can be preserved.

The California Air Resources Board (CARB) similarly took this into consideration when they imposed regulations on volatile organic compounds. According to the statute, “for consumer products for which the label, packaging, or accompanying literature specifically states that the product should be diluted with water or non-VOC solvent prior to use, the limits specified in subsection (a) shall apply to the product only after the minimum recommended dilution has taken place.” We urge DTSC to do the same with any proposed regulations of 1,4-Dioxane.

Second, limiting already-trace amounts of 1,4-Dioxane to levels as low as 1 ppm for instance would force cleaning product formulators to either skip ethoxylation by using formulations with non-ethoxylated surfactants or dilute the product to reach an allowable limit, which would interfere with the manufacturing of some critically important cleaning products that protect public health.

Moreover, revising product formulations to meet the proposed 1,4 dioxane limits may adversely impact product efficacy and present other long-term adverse and unintended consequences we don't yet know about that are just as bad or worse than the risks of current chemical formulations. If product quality and efficacy is impaired, institutions that depend on sanitation for their functionality, like hospitals, nursing homes, K-12 schools, and food-processing establishments, could see the safety and health of children, the elderly, and other vulnerable populations within them compromised.

Similarly, manufacturers cannot simply dilute the product to reach the allowable limit for 1,4 dioxane because it likewise would compromise product efficacy and functionality. Product formulations with high amounts of water present significant barriers to the manufacturing process in the case of certain cleaning products. For example, one of our members uses water-soluble film, so they cannot use ingredients with a high amount of water and low active ingredients. This would again imply that some in our industry would not be able to utilize more concentrated products or reap the environmental benefits of doing so.

Third, ISSA recommends that the 1,4-Dioxane limit is set to a measurable threshold in cleaning products. The 1 ppm proposal is predicated on a Practical Quantification Limit that has not been validated for these products yet. Until a validated method that can be repeated is set, there can be

no assurances that 1,4-Dioxane levels in these products are being measured accurately. Additionally, measuring at levels as low as 1ppm will be extremely expensive for our smaller and medium sized formulators.

As previously stated, we ask that the regulations be based on the end-use amount rather than the more concentrated form it comes in and that the 1,4-Dioxane threshold be set to a reasonable and measurable level.

Respectfully,

John Nothdurft
Director of Government Affairs
ISSA – The Worldwide Cleaning Industry Association